Optimising medicine information for patients in New Zealand

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Doctor of Philosophy

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Abstract

Background
Patients must receive sufficient information about their medicines to be able to take them safely, to make informed choices, and to understand the benefits of adherence. Providing written information alongside verbal communication is best-practice to ensure comprehension and aid recall. However, leaflet provision is not mandatory in New Zealand.

Automated provision of information in a digital format may support informing people about their medicines in practice. Internationally, digital tools have allowed self-reporting of chemotherapy side-effects (Patient Reported Outcomes) to provide medicines information and self-management advice. However, such systems are not yet available in New Zealand and it is not known how they would be received.

Aim
To investigate how patients are provided with information about their medicines in New Zealand practice and explore potential solutions to optimise quality and provision.

Methods
This study was conducted in four stages:

1. A description of patients’ views on what content should be included in medicine information leaflets and how they should be designed to improve usability and usefulness.

2. Surveys to examine a) pharmacists’ and general practitioners’ (GPs’) medication counselling practices, b) their opinions and use of written information, and c) patients’ opinions and experiences of receiving written medicine information.

3. Feasibility study to determine the viability of producing a medicines information tool (automatic leaflet-tailoring and prompting system) for GPs and pharmacists: a survey of vendors of prescribing and dispensing software in New Zealand.

4. Focus groups and interviews with former oncology/haematology patients to determine their opinions regarding the information provided about their medicines.
chemotherapy, and their views of the possible use of an online digital tool to report side-effects and receive information.

Main findings
1. Both summary and comprehensive medicine information leaflets should be readily available. Leaflet content requirements were identified, including names of the medicine, dose, benefits of treatment, and potential harms of therapy. The guidance provided by the New Zealand regulatory agency about how to design written medicine information does not align with patients’ stated needs.
2. Patients may not be receiving all the information they want or need to know about their medicines during verbal communication with GPs and pharmacists.
3. GPs and pharmacists do not routinely provide written medicines information leaflets. Facilitators to encourage provision included having summary and tailored leaflets available, more time with patients, and automatic computer prompts. GPs, pharmacists, and patients believe it is important that leaflets are given with new medicines.
4. At this time, it is not feasible to build an automatic leaflet-tailoring and prompting system within prescribing and dispensing management software used in New Zealand.
5. Oncology/haematology patients consider the way they are given information about their treatment could be improved. Many thought having a digital system available to report side-effects and receive information about management would be beneficial.

Conclusion
We need to improve the way we give people information about their medicines in New Zealand. Providing verbal and written information is not mandatory at present and may sometimes result in suboptimal practice. Patients and health professionals thought digital technology could be used to help provide medicines information. Furthermore, online digital tools utilising Patient Reported Outcomes might help patients better manage their medicines’ side-effects.
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<tbody>
<tr>
<td>API</td>
<td>Application Programming Interface</td>
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<tr>
<td>CMI</td>
<td>Consumer Medicines Information in the Australian and New Zealand context and Consumer Medication Information in the USA context.</td>
</tr>
<tr>
<td>DHB</td>
<td>District Health Board</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
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<tr>
<td>EMR</td>
<td>Electronic Medical Record</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>IT</td>
<td>Information Technology</td>
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<tr>
<td>NHI number</td>
<td>National Health Index number</td>
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<tr>
<td>NZ</td>
<td>New Zealand</td>
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<tr>
<td>NZF</td>
<td>New Zealand Formulary</td>
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<tr>
<td>NZULM</td>
<td>New Zealand’s Universal List of Medicines</td>
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<tr>
<td>OTC</td>
<td>Over-the-counter (medicines available to buy without a prescription)</td>
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<tr>
<td>PMS</td>
<td>Patient Management System</td>
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<td>PROs</td>
<td>Patient Reported Outcomes</td>
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<td>SDHB</td>
<td>Southern District Health Board</td>
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<td>UK</td>
<td>United Kingdom</td>
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<td>UKONS</td>
<td>United Kingdom Oncology Nursing Society</td>
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Publications during candidature

Peer reviewed paper


Young A, Tordoff J, Leitch S, Smith A. Do health professionals tell patients what they want to know about their medicines? Health Educ J. 2018;77(7):762-77.


Conference abstracts: poster presentations

Young A, Tordoff J, Leitch S, Smith A. Are patients receiving the information they want to know about their medicines? National Medicines Symposium, Canberra, Australia, May 2018.


Young A, Tordoff J, Smith A. What do patients' want? Time to innovate medicine information leaflets. World Congress on Integrated Care, Wellington, New Zealand, November 2016.

Conference abstracts: oral presentation


Young A. Patient-centred medicines information—a proposal for innovation. University of Otago School of Pharmacy research day, Dunedin, New Zealand, December 2016.
Publications included in this thesis

Publication entitled “‘What do patients want?’ Tailoring medicines information to meet patients’ needs. Res Social Adm Pharm. 2017;13(6):1186-90” was incorporated in chapter 2.

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Structure of thesis

This thesis has seven chapters. The first chapter is the introduction, which describes the primary health care setting in New Zealand, the requirements for patient-centred care, the benefits of providing written communication, and the potential difficulties and limitations for achieving optimal communication with patients in practice. It also briefly touches on how information for patients could be improved.

The second chapter is the narrative review outlining (i) what information patients want included in medicine information leaflets, (ii) how this information should be presented for optimal readability and understanding, and (iii) what legislative requirements are in place in New Zealand and internationally on how manufacturers should create this information. This chapter contains two published articles, one in section 2.3.1 (‘What patients’ want?’ Tailoring medicines information to patients’ needs) and one in section 2.4.1 (Regulatory agencies’ recommendations for medicine information leaflet: Are they in line with research findings?). These constitute the majority of this chapter.

The third chapter presents cross-sectional surveys of general practitioners and pharmacists working in New Zealand primary health care. This chapter describes, from self-reports, what verbal communication these health professionals have with their patients, compared with the patients’ desired information described in chapter 2. This chapter contains one published article in section 3.3.1 (Do health professionals tell patients what they want to know about their medicines?). This chapter also describes the limitations of relying on self-reports for determining participants’ practices.

The fourth chapter also presents cross-sectional surveys of general practitioners and pharmacists working in New Zealand primary health care, as well as one performed by patients. The focus of these surveys is (i) the delivery of medicines information leaflets to patients, (ii) health professionals’ and patients’ opinions of leaflets available, and (iii) the barriers and enablers to leaflet provision. This chapter contains three published articles, one in section 4.3.1 (Doctors and pharmacists provision and opinions of medicines information leaflets in New Zealand), one in section 4.4.1
(Patient-focused medicines information: General Practitioners’ and pharmacists’ views on websites and leaflets), and one in section 4.5.1 (General Practitioners’ medicine information leaflet provision: New Zealand patients’ views). These articles constitute the majority of this chapter.

The fifth chapter describes a feasibility study of building a tool within patient management systems in GP and pharmacy software to automatically create personalised medicines information leaflets and counselling points for health professionals to use at point-of-care. This chapter presents a Use Case (a description of individuals’ to be involved and actions required to complete a task) and an example of a personalised medicine information leaflet to describe how the software could work. These were presented to the six vendors of prescribing and dispensing software in New Zealand who were asked to complete a survey to determine the feasibility of building a tool. In the last part of this chapter, the outcome of the feasibility study is discussed.

The sixth chapter presents a qualitative study with focus groups and interviews with former oncology/haematology patients. This chapter describes (i) their opinions regarding the information provided about their chemotherapy medicines; and their views on (ii) receiving information about their treatment in a digital format and on (iii) the possible use of an online digital tool to report side-effects and receive management advice.

Finally, chapter 7 is the discussion and conclusion, which summarises the findings of the investigations in this thesis, strengths and limitations of the project, recommendations for current practice and recommendations for future research.

A pictorial overview of thesis structure can be seen in Figure 1 on the next page. An overview of objectives, research questions, and methods is described in Figure 2.
Figure 1: Structure of thesis
Figure 2: Overview of objectives, research questions, and methods
Chapter 1: Introduction

1.1 Background

1.1.1 The informed patient

Do patients need to be informed about their medicines?

Historically the answer was “no”. Healthcare professionals took an authoritarian approach where patients were generally expected to do as they were directed without being given information about their treatment.\(^1\) And until relatively recent times, medicines were commonly given to patients without printed information.\(^2\)

Today’s answer is “yes”. Fortunately, there has been a shift in decision making within healthcare systems in New Zealand and other developed countries\(^2,\,3\) with a drive toward patient-centred care and improved outcomes for patients. Approaches to this include patients and healthcare professionals sharing treatment decision-making and a focus on informed choice and patient empowerment.\(^1\) Adding fuel to this fire, is an increase in patient demand for information about their medicines and often a willingness to be involved in their own care.\(^2,\,4,\,5\) The gold-standard for decision-making in healthcare now is achieving concordance between a patient and their healthcare provider, meaning that a patient is involved in the decision that the treatment is the right option for them.\(^2,\,3\) We now acknowledge that the patient needs education about the medicine before it is dispensed and they take it home.

In line with this trend, the New Zealand Ministry of Health has outlined a Roadmap of actions in the 2016 New Zealand Health Strategy.\(^6\) The first theme on the roadmap is ‘people powered’ which encompasses the ideal of making services more people-centred with a focus on better knowing people’s health needs and experiences. One of the 5-year aims is to ensure “People have access to reliable, clear information, including online, to find out about the choices they can make and how they can take greater responsibility for their own health”. 
There is significant research about informing patients about their medicines. Literature reviews from the early 2000’s demonstrated that there is little information given to patients about their medicines in practice.\textsuperscript{7-9} Patients may also find it difficult to access their doctors to obtain sought-after information if they need to know more.\textsuperscript{2} So it is possible that patients are not receiving the essential information to facilitate safe and optimal medicine use. Health professionals need to engage patients in discussion about their medicines and ensure that they understand what is being communicated with them. Unfortunately, in practice many real and perceived barriers may prevent this occurring. Further discussion about informing patients about their medicines is in chapter 3.

### 1.1.2 The impact of poor health literacy

Health literacy is commonly described as peoples’ capability to acquire and understand information about their basic health and health-services needed to make suitable health decisions in regards to their care.\textsuperscript{10} Poor health literacy seriously affects the ability of individuals to be actively involved in decision-making about their health and treatment.\textsuperscript{11} People with poor health literacy tend to know less about their medicines and disease, have difficulty managing their own health, have poor adherence to their medicines, and have disproportionately higher rates of chronic illnesses, health care costs, and increased mortality.\textsuperscript{11-13} For example, the National Academy for an Aging Society in America estimates that low health literacy resulted in $73 billion (in 1998 healthcare dollars) in unnecessary healthcare costs.\textsuperscript{14}

Poor health literacy may disproportionately affect certain groups of people. The report \textit{Kōrero Mārama: Health Literacy and Māori} produced by the New Zealand Ministry of Health\textsuperscript{11} found that New Zealanders, particularly Māori, commonly suffer from poor health literacy. The review article by Sadowski\textsuperscript{15} also notes that older adults generally have poorer health literacy compared to the younger population. This is troubling as older age groups generally have increased healthcare needs and higher use of health services.\textsuperscript{11} Ensuring people with poor health literacy, particularly the groups at highest risk of poor literacy, are appropriately informed about their treatments is essential to improve their health outcomes and to decrease unnecessary healthcare costs. We
need to change focus in the way health professionals interact with people and make sure we are informing people about their medicine in an appropriate and culturally safe way.

### 1.1.3 Improving safety

Balanced and accurate medicine information for patients helps ensure that they take their medicines safely and will obtain as optimal benefit and outcome as possible. It is expected that all patients should at least know why a medicine is prescribed and how to take it. However, Jaye et al in a New Zealand study from 2001 showed that of 344 patients, only 87% knew the indication of their medicines and that the dose was only correctly recalled 83% of the time.\(^{16}\) And a 2004 survey of a sample of 616 patients in a community setting in Boston USA, showed that 13.5% of patients could not recall the indications of all their medicines.\(^{17}\) It is possible that patients who cannot identify the purpose or dose of their medicine, may also be unaware of other important aspects of their therapy such as signs of toxicity or allergy. In another New Zealand study, Brounéus et al\(^{18}\) found that 47% of medicine-users could not recollect information about the safety of their medicines. Nevertheless, 84% of these patients were convinced they could use their medicines safely. This leads us to question whether patients are making informed decisions about their medicines. How can they do so if they do not know the harms and benefits of the medicines they are taking?

Being able to recognise a reaction to a medicine can be crucial to prevent the escalation of an event. Hospitalisations and death have resulted from lack of comprehension on medicine use.\(^{19}\) In order to use a medicine safely, patients must at least know how to take the medicine, what could interact with that medicine, as well as the risk of side-effects and what action is necessary if they occur. This is particularly true for frail elderly patients who over-represent those admitted to hospital due to adverse events with their therapy.\(^{20}\) Hospitalisation due to adverse events results in an average of nine days of hospital admission,\(^{20}\) resulting in huge cost as well as possible physical and emotional trauma to the patient. In New Zealand there were 4373 reports of suspected adverse reactions to medicines in 2018, of which 1473 were for vaccines and 57 for complimentary or alternative therapies.\(^{21}\) Twenty percent of
these reactions were considered to be serious. The ability to recognise an adverse reaction to a medicine will help patients identify side-effects sooner, allowing for prompt discontinuation and medical treatment if required. In order to be fully concordant, it is necessary that patients know and understand the harms of their therapy.

1.1.4 Improving continuation of therapy

The report Adherence to long-term therapies: Evidence for action produced by the World Health Organisation in 2003, citing two reviews, states that ‘adherence to long-term therapy for chronic illnesses in developed countries averages 50% and in developing countries the rates are even lower’. This report also described the temporary effects of interventions that increase adherence, including leaflets and encouragement for use. These are only effective while the intervention is in place, and once it is removed, the benefits will decrease.

There are also varying levels to which information can be shared, digested, and used. Whilst at the very basic level patients must be informed about their medicines, that is to be told, taking the time to educate medicine users may result in more deeper understanding and willingness to continue therapy. Educating a person is a more time-consuming commitment, but may result in improved shared decision-making, removal of health literacy barriers, and actual improved knowledge of concepts about their treatment.

It has also been demonstrated that educating patients about their therapy and why they need to take it can improve patients’ overall satisfaction, desire to take their medicine, and their adherence to treatment. So is this education occurring in primary care? Many patients do not read accompanying written information supplied with repeat medicines when they collect them from a pharmacy so repeated discussions with patients about benefits and potential harms of treatment and the importance of adherence may be needed. This means an active conversation at every opportunity of repeat dispensing and prescribing. Further discussion about continued need for information on chronic therapy is discussed in chapter 3.
1.1.5 Some challenges faced in New Zealand’s primary health care setting

Costs involved

Primary healthcare in New Zealand is mostly funded from general taxation. This subsidises the cost of GP visits and prescription medicines to the patient.\textsuperscript{29, 30} The remaining cost is recuperated as fee-for-service payments from patients. Although these co-payments are a small charge compared to the full cost of treatment and service delivery, they can still drive inequity and result in an overextended health workforce.

Because GP practices are privately owned, the cost of a GP visit is variable. Adults earning a low income with a community services card can visit their GP for approximately NZ$19.\textsuperscript{31} However, for other patients who do not qualify for this additional subsidy, it is reported that visits can cost up to NZ$60 per consultation\textsuperscript{32} and this cost could impede accessibility of healthcare services.

Prescription charges for each medicine depend on the medicines’ funding status, the age of the patient, who prescribes the medicine, and whether the patient has a community services card\textsuperscript{30, 33} New Zealand’s Pharmaceutical Management Agency (PHARMAC) decides which prescription medicines the government will fund and the level of subsidy.\textsuperscript{34} For fully subsidised medicines the patient pays a co-payment of NZ$5 if prescribed by a GP (or NZ$15 if prescribed by a private specialist), or for partially subsidised medicine the charge is variable depending on the amount of subsidy provided.\textsuperscript{33} Although, there is some competition for customers between pharmacies, and some pharmacy businesses offer to supply medicines without the required co-payment. Furthermore, if a person, their partner, and dependent children together purchase over 20 prescriptions in one year from 1\textsuperscript{st} February, for the remainder of the year they do not have to pay the co-payment for prescriptions.\textsuperscript{33, 35} Nevertheless, some medicines are completely unsubsidised and require full payment for the medicine by the patient.
Time pressures

Quality face-to-face contact time with health professionals can be variable. Consultations with GPs are typically 15 minutes,\textsuperscript{36} which can result in significant time-pressure in complex circumstances e.g. if patients have multiple morbidity, language barriers, or cognitive impairment. Patients’ consultations with pharmacists about dispensed medicines are not funded, so, at busy periods their discussions may be short and lack the depth of information needed or not conducted at all. Pharmacists can receive additional funding for patient counselling if patients have long-term conditions,\textsuperscript{37} but this is mostly focused on patients’ medicine adherence rather than medicine knowledge. There is considerable information to tell patients in the short amount of contact time healthcare professionals have with them, let alone assess their understanding of what has been discussed. Although it is written into ethical standards that health providers must make people aware of the harms and benefits of treatment, it may not always be possible to reasonably do so in the current health model in New Zealand.

Communication issues

Adequately informing people about their medicines can be difficult. It would be challenging for a healthcare provider to inform every patient of all the required information about each medicine every time it is prescribed or dispensed. In addition to time pressures and lack of funding for services, other possible barriers include poor health literacy,\textsuperscript{12} lack of patient willingness to be counselled (a documented occurrence in pharmacies\textsuperscript{8}), and concern from health professionals that if they provide information on side-effects their patients will refuse their medication.\textsuperscript{2} Furthermore, patients are often not able to recall all of the information given in one brief interaction and much of the information that has been discussed will be forgotten.\textsuperscript{9,38,39} This can worsen if the patient’s ability to comprehend what is being explained to them is affected at the time e.g. if the patient is anxious or stressed,\textsuperscript{15} or the information was not well understood during consultation.\textsuperscript{12} Information overload can also be a problem.\textsuperscript{15}
The inability to remember or comprehend verbally provided information emphasises the importance of patients receiving easy-to-understand written medicine information that they can refer to at home, or ‘absorb over time’. However, it is not known whether suitable medicine information resources are commonly used at point-of-care in primary care in New Zealand.

1.2 Improving how information is given

Patients want to be given more information from their health provider. In New Zealand it is mandatory that people are provided with relevant and appropriate information by their prescriber and pharmacist dispensing the treatment. Yet compared to some other countries, the format of how the information is provided is not regulated. European union and UK legislation requires that every medicine is dispensed with a patient information leaflet (PIL), also known as a consumer medicine information leaflet (CMI), usually inside the medicine packaging. In the UK, it is believed that the medicine information leaflet provided with the dispensed medicine/s may be the only information a patient receives. This legislation ensures that, although verbal communication about medicines may be lacking, people are still receiving information about their medicine. In the USA, there are a large number of medicines where provision of information leaflets are mandatory if they are considered to have a significant safety risk.

In New Zealand and Australia there is no binding legislation on the provision of medicine information leaflets, and the ethical obligation to inform patients about their medicines does not demand the provision of medicine information leaflets. An Australian report identified that there is no widespread provision of CMI to patients and it is likely that New Zealand has the same variable provision practices. Therefore, it is likely that there are many occasions where patients are not given leaflets. Medsafe (the ‘New Zealand Medicines and Medical Devices Safety Authority’) recommends that medicine information leaflets are considered an adjunct to verbal counselling. The Medsafe website also lists the CMI for medicines where these are
available, but given that production of CMI is not currently a legal requirement, they are not available for all medicines. On the contrary, although Australia does not mandate the provision of leaflets, CMI have to be available for patients for all prescription and pharmacist-only medicines. Most CMI are made available on a central website to be downloaded and printed off as needed.

1.2.1 How medicines information leaflets support the informed patient and enhance safety

Patients’ value discussions with their healthcare professional about medicines they have been prescribed. However, a combined approach of both verbal and written information is favourable to increase patient understanding of their therapy. Ideally, medicine information leaflets should be given in conjunction with any verbal communication. As well as a source of information about their medicines, patients can use these leaflets as a tool to help manage their illness, aid the decision to continue or stop therapy, and to explain their treatment or condition to others. Medsafe states that information leaflets should be used to ‘assist consumers to distinguish between the symptoms of their illness and any possible side-effects induced by the medicine’.

As mentioned earlier, patients frequently feel they are not getting enough information from health professionals with some people being unaware of why they are taking a medicine or their treatment options. Some health professionals only discuss information that they think is important, rather than finding out what is important to their patient. Medicine information leaflets would ensure that all the information about a medicine is given to the patients. They may also give a patient confidence to raise concerns or queries with their healthcare provider where they would have felt unable to do so without a resource to justify their questions. Yet, there is evidence that medicine harms and side-effect information may be withheld by health professionals, even although this is often the most sought after information by patients. In these instances it is likely that medicine information leaflets could also be withheld.
1.2.2 Importance in an older population

Written sources of information are necessary to give older people important guidance about how to take their medicines, as well as possible harms with treatment. People over 60 years of age consume approximately 50% of all prescription medicines even although they represent only 12% to 18% of the population. Older patients are more susceptible to side-effects due to alterations in pharmacokinetics and pharmacodynamics of medicines, cognitive decline, and frailty, which may result in poorer outcomes to treatment. Although older people experience more health problems resulting in more chronic use of medicines, they often have poor knowledge of their medicines. In one study, over 40% of elderly patients did not know the dosing instructions of a medicine after visiting their doctor. Giving written medicine information is essential for older adults. Teaching strategies for older adults promote provision of written material to reinforce the major points of teaching. Thus to ensure adequate education about new concepts and difficult to understand harm versus benefit information, a leaflet about the information discussed should be provided to older adults at point-of-care.

1.2.3 The information leaflets available in New Zealand

In the US, leaflets have been required to accompany certain medicines since the 1960s. The FDA began evaluating leaflets in the US in the 1970s. In the 1990s, the FDA approved a law requiring provision of CMI to people receiving new medicines (stating that by 2006 at least 95% of people must receive leaflets with new medicines). Similarly, a European Union Directive in the 1990’s made it compulsory that manufacturer-produced leaflets accompany all dispensed medicines. At roughly the same time in Australia, new legislation required all new drugs to have patient information leaflets available—also written by the medicine manufacturer. Since becoming prevalent, research into optimal design of patient information materials has been ongoing. However, regardless of this continued research and recommendations, improvement is still needed.
Many organisations create medicine information leaflets for patients in New Zealand, although these all differ in content and style. The different leaflets available are discussed in further detail in chapter 2.

Medsafe encourages manufacturers and sponsors of medicines in New Zealand to make CMI leaflets available and publishes these on their website. These are sometimes included in boxes of dispensed medicines. However Medsafe does not review or approve the CMIs being created, instead they expect the sponsor of the medicine to self-assess the CMI they create against the requirements of the Medsafe Guideline and Template. Unlike the requirements for drug companies and sponsors from countries in the UK and European union, the use of the template is not mandatory when creating leaflets for patients.

The template recommended by Medsafe for the content of the leaflets (summarised in Table 1) is comprehensive, but may contain unnecessary and irrelevant information making leaflets needlessly lengthy. However, does the suggested content contain the medicine information that people most want to know about? The optimal content of medicine information leaflets is discussed further in chapter 2.

Table 1: Summary of the Medsafe guideline and template for preparing Consumer Medicine Information for New Zealand consumers

<table>
<thead>
<tr>
<th>Section title in leaflet</th>
<th>Summary of template suggestions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade name</td>
<td>• Trade name and the international nomenclature (generic) name</td>
</tr>
<tr>
<td></td>
<td>• Dose strength and form</td>
</tr>
<tr>
<td>What is in this leaflet</td>
<td>A small section of miscellaneous information, that does not inform the reader about what is in the leaflet, but states:</td>
</tr>
<tr>
<td></td>
<td>• To read the leaflet before taking medicine</td>
</tr>
<tr>
<td></td>
<td>• The leaflet does not include all the information (does not replace doctor or pharmacist)</td>
</tr>
<tr>
<td></td>
<td>• The doctor has considered the risks and benefits of the medicine</td>
</tr>
<tr>
<td></td>
<td>• To ask your doctor or pharmacist if any concerns</td>
</tr>
<tr>
<td>Section title in leaflet</td>
<td>Summary of template suggestions</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------</td>
</tr>
</tbody>
</table>
| What [Trade name] used for | • To keep the leaflet for future reference  
|                          | • Details of the New Zealand-approved therapeutic indications  
|                          | • Simple description of how the medicine works, the pharmacotherapeutic group, or type of drug action  
|                          | • Warning of habit-forming potential |
| Before you use [Trade name] | **When you must not use it**  
|                          | • List of instances when medicine should be avoided (contra-indications) |
|                          | **Before you start to use it**  
|                          | • List of precautions; if it can be used in pregnancy or breastfeeding |
|                          | **Taking other medicines**  
|                          | • Instructions to tell the doctor if taking other medicines including non-prescription medicines and complementary or alternative therapies  
|                          | • List of medicines (including non-prescription), complementary and alternative therapies, food, or alcohol that interact with the medicine |
| How to use [Trade name] | **How much to take**  
|                          | • Usual instructions on ‘proper’ use of the medicine  
|                          | • The dose  
|                          | • Method and route of administration |
|                          | **When to take it**  
|                          | • Frequency and time of administration; food considerations |
|                          | **How long to take it**  
<p>|                          | • Duration of treatment (including warning of withdrawal effects if necessary) |
|                          | <strong>If you forget to take it</strong> |</p>
<table>
<thead>
<tr>
<th>Section title in leaflet</th>
<th>Summary of template suggestions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Management strategy on what to do if missed a dose or more medicine is taken than prescribed; possible clinical consequences of missing a dose</td>
</tr>
<tr>
<td></td>
<td>• What to do if the medicine does not work, if applicable</td>
</tr>
<tr>
<td>While you are using [Trade name]</td>
<td><strong>Things you must do</strong></td>
</tr>
<tr>
<td></td>
<td>• Instructions to stop immediately and contact a doctor if pregnant, if applicable</td>
</tr>
<tr>
<td></td>
<td>• Instructions to inform doctor or pharmacist about the medicine before a new one is initiated</td>
</tr>
<tr>
<td></td>
<td>• Special warnings and monitoring requirements</td>
</tr>
<tr>
<td></td>
<td><strong>Things you must not do</strong></td>
</tr>
<tr>
<td></td>
<td>• Instructions to not give medicine to other people and warning to seek advice before stopping medicines that may cause withdrawal or side-effects</td>
</tr>
<tr>
<td></td>
<td><strong>Things to be careful of</strong></td>
</tr>
<tr>
<td></td>
<td>• Medicines effect on driving or operating machinery</td>
</tr>
<tr>
<td></td>
<td>• Other potential hazardous effects</td>
</tr>
<tr>
<td></td>
<td>• Alcohol avoidance if necessary</td>
</tr>
<tr>
<td></td>
<td>• Contact details of National Poisons Centre</td>
</tr>
<tr>
<td>In case of overdose</td>
<td><strong>Brief description of signs/symptoms of overdose if applicable</strong></td>
</tr>
<tr>
<td>Side Effects</td>
<td><strong>Instruction to inform doctor/pharmacist if feel unwell and to ask them questions</strong></td>
</tr>
<tr>
<td></td>
<td><strong>List side-effects that can occur and if urgent withdrawal and contacting the prescriber is required</strong></td>
</tr>
<tr>
<td></td>
<td><strong>List side-effects that are common, severe, or prolonged (only recognisable symptoms should be included)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Statement that other side-effects not listed may occur</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Statement to not to be alarmed by side-effects listed because they may not occur</strong></td>
</tr>
</tbody>
</table>
Despite having comprehensive suggestions for leaflet content, Medsafe has limited guidance on how to present the information for readability, and the little information given is also suggestive rather than mandatory. Without strict regulations, the medicine information leaflets available in New Zealand may have extremely variable designs and formats and thus variable readability and usefulness. In a New Zealand study of community-dwelling elderly people, 12% of participants had difficulty reading leaflets and 6% of participants had difficulty understanding them. However, there is also the risk that heavy legislative requirements for medicine information leaflets do not always correspond with expert opinion on user-friendly design resulting in sub-optimal leaflets being created. The templates used for leaflets in the European Union are often criticised. This demonstrates how important it is to get the style of the leaflet right, to ensure it is understandable to those who are going to be reading it. Any legislative requirements for document design must be strongly influenced by evidence for readability. How information leaflets should be styled for readability and usability is discussed further in chapter 2.
1.2.4 Providing leaflets at point-of-care

It is important that patients are made aware of leaflets when they are receiving their prescribed medicines. In a New Zealand study, 66% of patients reported that they like to use medicine information leaflets as a source of drug safety information. However, a UK study found that if leaflets are put in a bag with a person’s medicine and not discussed they may not be noticed and thrown away. Furthermore, as mentioned earlier, leaflet provision is not mandatory in New Zealand and so leaflets may not even be given to patients. A systematic review has shown that prescribers do not like leaflets and they do not encourage patients to read them. Furthermore, the reviewers found that some patients do not read leaflets because they trust and rely on their doctor to provide them with all the information they need and trust that they can recall the information given to them at time of consultation. In reality it is unlikely that people are provided with all of the harm versus benefit information about their medicine during a consultation with their doctor and even less likely they would be able to recall this information after the appointment. Furthermore, providing medicine information leaflets alone without discussing them with the patient does not improve adherence to treatment instructions. In Australia, Aslani et al recommended holding CMI consumer awareness campaigns which would alert patients to their availability, and formal incorporation of CMI into healthcare professional workflow practices e.g. highlighting relevant sections for the patient. This change in practice would help with providing leaflets to every patient as well as highlighting the availability and usefulness of leaflets to patients.

Many patients want leaflets to be used during discussions about medicines when they are prescribed. Using leaflets during initial treatment discussions with patients is optimal because (i) it will expose the availability and content of the information leaflets to patients and (ii) it will remind the health professional of important medicine points to cover during consultation. This approach could also give the patient the ability to ask further questions to improve understanding and willingness to take their medicines and assist informed decision making. Patients should also have an opportunity for discussion about their medicines when they are dispensed. However,
pharmacists may not be widely seen as sources of medicine information by the public. Studies show medication counselling practices can be variable. A 2009 review of studies from the UK, Australia, USA, Netherlands, Finland, and Canada by Puspitasari et al. found that pharmacist counselling rates ranged from 8–80% depending on the method used for data capture. Another more recent study conducted in 2014, investigating counselling practices in England using consumer self-reports (obtained as soon as they left the pharmacy), found that unsolicited counselling occurred with dispensing of 41.9% of new prescriptions and 25.5% of repeat prescriptions. Promotion of pharmacists’ skillset and knowledge by active counselling with medicine information leaflets would help further strengthen their place in primary care in patient’s minds and endorse their capabilities as a source of information.

The use of medicine information leaflets in primary care in New Zealand is further discussed in chapter 4.

1.2.5 Updating the way information is provided about medicines

So far, the usefulness of medicine information leaflets and verbal communication has been discussed, but there are limitations to the usefulness of these methods of communication. Apart from hesitancy from the health provider in giving leaflets to patients, some patients do not like reading them and can find them difficult to understand. Furthermore, leaflets can be very general and contain information that is not relevant to the person taking it, e.g. leaflets tend to contain pregnancy and breast-feeding advice which, obviously, is not relevant to male recipients. Some leaflets may contain numerous indications (see Figure 3), or conversely may contain only the most common indications in an effort to minimise information (see Figure 4).
What Apo-Propranolol is used for

The name of your medicine is Apo-Propranolol tablet. It contains the active ingredient Propranolol hydrochloride.

Apo-Propranolol is used to treat a number of conditions, most of which are related to the heart:
- Management of angina pectoris.
- Long term prophylaxis after recovery from acute myocardial infarction.
- Control of most forms of cardiac dysrhythmias.
- Control of essential and renal hypotension
- Prophylaxis of migraine.
- Control of anxiety and anxiety tachycardia
- Management of essential tremor.
- Adjunctive management of thyrotoxicosis and thyrotoxic crisis.
- Management of hypertrophic obstructive cardiomyopathy.
- Management of phaeochromocytoma (with an alpha-adrenoreceptor blocking medicine).

Your doctor may have prescribed Apo-Propranolol for another reason.

Figure 3: List of indications from propranolol manufacturer-produced Consumer Medicines Information (CMI) leaflet

PROPRANOLOL
pro-pran-oh-lool

What does it do?
Propranolol is used to treat some heart problems and high blood pressure. It is also sometimes used for other conditions such as migraines.

Figure 4: List of indications from propranolol leaflet produced by independent body

Full examples of these leaflets are available in Appendix 1.

1.2.6 Personalising information

It is obvious from Figure 3 that there is information included in manufacturer produced information leaflets that is not applicable to individual patients. However, is it more appropriate to simply not include this? Either option could lead to people questioning the relevance of the leaflet and undermine the integrity of the information given to them. For information to seem relevant to people it needs to be personalised, succinct, and contain what they want and need to know about a medicine to take it effectively. Unfortunately, there is no easy way to do this in
current practice. Yet, it may be possible to do this by utilising the personal information contained in digital health records. A software system could be used to extract relevant patient details and automatically personalise information for medicine counselling and information leaflets. Further discussion around the possibility of personalising information for patients is included in chapters 2, 4, and 5.

1.2.7 Digital information

In today’s technological society, some people might prefer an electronic source of medicines information. People are looking to the internet for health information and this could be seen as a suitable alternative to hard-copy leaflets. Furthermore, people expect to be given accurate and up-to-date information and this should be easier with a digital resource. Some people may prefer to access the internet to see the information about their medicine at a time that suits them rather than be given a printed leaflet that they have to then keep somewhere (and remember where it is kept) at home. Globally the use of digital applications (apps) has rocketed, and there has recently been development of an app (Mymeds) in New Zealand by the Ministry of Health that the public can download to access information leaflets about their medicines.

It is important to consider accessibility to technology when promoting the use of digital sources for information. Some groups may struggle to use the technology, may not be able to afford the technology, or have access to the internet. Governments and health providers should ensure equity in access to information by making it available in both hard-copy and digital formats.

Further discussion about providing digital information to patients is provided in chapter 4, 5, and 6.

1.2.8 Patient Reported Outcomes

Patient Reported Outcomes (PROs) are patients’ reports on their health, ability to function, and well-being. In clinical practice, PROs data can be used to aid diagnosis
or management of a condition. However, PROs are not routinely used in primary care to gather information about how a patient is taking their medicine, their experiences with their treatment, or to determine what people want or need to know about their medicines. Using a digital tool to gather information from people about what they need or want to know about their medicines would allow a personalised and relevant web-based information source, detailing exactly the information they desire. Furthermore, if it could gather information about side-effects they are experiencing with their therapy, specific details about the management of that side-effect could be given instantly; or they could be directed to seek immediate medical help if appropriate. Also if this is electronically linked to their National Health Index (NHI) number (a unique number allocated to healthcare users in New Zealand) the data could be automatically updated into their health record for: a) GP review and monitoring; and b) aggregation for population monitoring of drug safety. Using PROs for medicine information and safety could improve medicine management and adherence with treatment. The potential use of PROs in primary care in New Zealand are discussed in chapter 6.
1.3 Aims

The overall aim of this research is to investigate how patients are provided with information about their medicines in New Zealand practice and explore potential solutions to optimise quality and provision of medicines information for patients. Specific aims are presented in each chapter.

Prior to commencing, medicines were defined as either low-risk (common medicines dispensed in primary care with limited side-effect potential) or high-risk (medicines associated with serious side-effects that require frequent monitoring).

In order to achieve the aim, several areas for investigation were identified and the work was conducted in four stages:

1. A description of what information people want to know about their medicines (i.e. the content of information delivered to them) and what good-design principles to follow
2. A survey of current opinions and practice by New Zealand GPs, pharmacists, and patients about information provision for medicines in a community setting
3. A feasibility study for the implementation of tailored medicine information software
4. Interviews and focus group discussions to determine patients’ opinions on current provision of information about chemotherapy and ideas for improvement, and their perceptions of the possible use of Patient Reported Outcomes (PROs) for optimising information and medicine management.

To achieve these aims the following objectives were identified:

1. To determine, from a user’s perspective, the information that should be included in medicine information leaflets and how they should be designed to enable patients to easily find and comprehend information.
2. To examine pharmacists’ and general practitioners’ medication counselling practices and their opinions and use of written medicines information leaflets in their practice.

3. To examine patients’ opinions and experiences of receiving written medicine information.

4. Based on the findings from objectives 1 and 2, to determine the feasibility of creating a personalised medicines information tool (automatic leaflet-tailoring and prompting software) for GPs and pharmacists to promote the provision of verbal and written medicine information to patients.

5. To determine, from a user’s perspective, the effectiveness and usefulness of information provided about high-risk medicines (chemotherapy), and their perspectives on the possible use of digital platforms that could provide clinically appropriate information about chemotherapy medicines and allow integrated patient reporting and feedback on chemotherapy-related side-effects.

1.4 Hypotheses

It is hypothesised that:

1. Patient medication counselling performed by both general practitioners and pharmacists is of variable standard.

2. Written medicines information resources for patients are of differing quality, are under-utilised, and are sometimes given without adequate verbal counselling.

3. It is possible to digitally automate the creation and provision of personalised information about medicines at point-of-care.

4. The provision of information about high-risk medicines is of variable standard and the use of digital technology to provide patients with personalised and relevant medicine information might be well-received.
Chapter 2: Providing optimal information with medicines

2.1 Synopsis

This chapter examines the types of information patients want included in their medicine information leaflets and how this information should be presented to optimise understanding and ability to find information, and to increase people’s willingness to read it.

In a narrative review (published as a commentary) we identified a number of items that patients would like included in leaflets. These included names of the medicine, dose, benefits of treatment, and potential harms of therapy. Additionally, a clear set of content and design principles were identified that should be followed when leaflets are being created. Regulatory agencies’ leaflet design requirements were also examined. Countries differed in their regulations on whether leaflets must be provided. Countries where provision is mandatory tended to have more comprehensive guidance provided by regulators as to how leaflets must be written compared to New Zealand, where leaflets are not mandatory. However the findings in this chapter show there are still improvements that could be made to leaflets and that there is no one leaflet suitable for all patients, concluding that a personalised approach would be beneficial.

This chapter also examines whether informing patients about their medicines can be performed in a much smarter way. It explores the benefits of using digital technology to provide information about medicines and the use of Patient Reported Outcomes (PROs) to further enhance and personalise information for patients.

Chapter structure

This chapter has four distinct parts:
1. What patients want included in a medicines information leaflet and how they should be designed for optimal use. This section describes the clinical information a medicine information leaflet should include and briefly describes how leaflets should be designed for optimal communication with patients (manuscript 1).

2. How medicine information leaflets should be designed compared to regulatory agencies’ recommendations. This section expands on the information from the first section about how leaflets should be designed, and compares content and good-design principles with what is recommended by regulatory agencies in New Zealand and some other countries (manuscript 2).

3. Digital information about medicines, is there a need? This section explores the case for further development of digital information about medicines, and what benefit this would have for patients.

4. Patient Reported Outcomes (PROs). This section describes PROs in healthcare resulting from taking/using medicines and outlines their place in practice, discussing the benefits and pitfalls of their use and their potential to improve patient management.

2.2 Chapter aims

Patients need to be informed in a way that suits their needs for them to be able to take their medicines safely and as recommended. This chapter aims to provide an up-to-date commentary on what information about medicines should be provided to patients based on their requirements, how this information should be designed for optimal use, and possible issues with the provision of digital information.

Specific aim 1: To identify what information patients want included in medicine information leaflets for them to be adequately informed about their medicine and encouraged to take their medicines appropriately.
Specific aim 2: To define how medicine information for patients should be designed to enable patients to find what they need, understand it sufficiently, and improve their willingness to read it.

Specific aim 3: To determine the appropriateness, comprehensiveness, and consistency of countries’ published content principals and design requirements of medicine information for patients.

Specific aim 4: To outline the benefits for the provision of information about medicines in a digital format and the issues with unregulated availability of digital information for patients.

Specific aim 5: To discuss the advantages and disadvantages of Patient Reported Outcomes and outline how they could be used in practice.
2.3 What patients want included in medicines information leaflets and how they should be designed for optimal use

Published Manuscript Entitled ‘What do patients want?’ Tailoring medicines information to meet patients’ needs

The manuscript entitled “‘What do patients want?’ Tailoring medicines information to meet patients’ needs.” was published in the journal Res Social Adm Pharm 2017;13(6):1186-90.

The co-authors contributed to the manuscript as follows: Review and synthesis of the literature were performed by PhD candidate Amber Young, under the supervision of Dr Alesha Smith and Associate Professor June Tordoff. All the co-authors revised the content of the manuscript and approved the final version for publication. The PhD candidate Amber Young was the lead author in manuscript preparation and writing, and corresponding author.

The manuscript is presented as accepted for publication; however, the numbering of the pages, figures, and tables has been adjusted in accordance with the style of this thesis. All references from the manuscript can be found in the section ‘References’ at the end of the thesis.

The search strategy and inclusion/exclusion criteria for this narrative review are in Appendix 2. Only studies published from 2008 onwards were examined because prior to this large systematic reviews by Raynor et al., Aslani et al., and Shrank et al. investigated similar topics.2, 7, 26 The findings from Raynor et al’s review are discussed alongside the findings from this current work in section 2.4 of this chapter.
2.3.1 ‘What patients’ want?’ Tailoring medicines information to patients’ needs

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Abstract

Medicines information leaflets can equip patients to be in control of their own healthcare and support the safe and effective use of medicines. The design and content of leaflets influences patients’ willingness to read them, and poor examples can cause patient confusion and anxiety. Researchers examined the literature over the past 8 years to determine the content and design of medicine information leaflets that patients prefer in order to read, understand, and use them effectively. It was found that existing leaflets do not meet patients’ needs and appear ineffective. Leaflets lack the information patients seek and may contain non-essential material, affecting patients’ perception of, and willingness to read them. Additionally, the acceptable leaflet length varies between patients. Application of good-design principles improves readability, comprehension, and ability to locate information. Medicine information leaflets must meet patients’ needs and be well designed. Tailoring information leaflets to patient characteristics and requirements would enhance effectiveness. Passive provision of pre-printed leaflets is outdated, unvalued, and ineffective. Using automated computer systems for leaflet tailoring with the ability to further adapt patients’ information might be the best way forward.

Keywords medicine information, counselling, patient information leaflet, patient education, tailored information, information design
Introduction

Medicine information leaflets are essential

Patients’ expectations for information about their treatment and involvement in the decision making process has evolved remarkably within healthcare systems in developed countries in recent times.\(^{26}\)

Adherence to long-term therapy for chronic illnesses averages 50% (with even lower rates reported in developing countries), resulting in poorer health outcomes and escalating health costs.\(^{22}\) Patient education is a critical component of improving adherence to therapy and optimising medicine use.\(^{9,74}\) Because medicine information leaflets improve patient knowledge, satisfaction, and adherence to therapy,\(^{26}\) they should be provided with dispensed medicines. Adherence might also be affected by a patients’ engagement in their healthcare decision making process.\(^{22}\) Effective medicine information leaflets equip patients to be in control of their own healthcare\(^ {2}\) and empower patients’ participation in decision-making\(^ {3,19,40}\) thereby positively affecting their intention to adhere.

Mandatory manufacturer-produced leaflet provision with dispensed medicines applies in Europe,\(^ {40,48}\) although there is no such binding legislation in many other countries. However, ethical standards usually apply requiring patients to be fully informed and provided with relevant and appropriate information.\(^ {42,75}\) Medicine information leaflets for patients support these standards and promote safe and effective medicine use by reinforcing verbal information and improving patients’ understanding of their treatment.\(^ {9,74}\) Unfortunately, where there is no legal requirement to give out written medicines information, rates of leaflet provision may be as little as 30%.\(^ {26}\)

Medicines information leaflets need improving

Giving leaflets as an adjunct to counselling should improve outcomes, yet patients do not always find them useful and often throw them away.\(^ {4,9}\) Extensive research on medicine leaflets over the last few decades resulted in some improvement, however patients still do not value or consider them useful.\(^ {2,61}\) Patients are often dissatisfied
with the information they receive,\textsuperscript{2,9} perceiving leaflets to be poorly designed and complex.\textsuperscript{2} Furthermore current legislation, regulatory templates, and recommendations for patient leaflets support a ‘one size fits all’ approach where a single leaflet is expected to suit all patients taking a medicine. Leaflets need improving to satisfy individual patient needs.

Poorly written leaflets can increase confusion\textsuperscript{76} and are often written to a higher readability level than recommended for the general population.\textsuperscript{9,26,55,77} Patients who feel frightened and anxious after reading through the package insert may be less willing to continue with therapy and even stop their treatment.\textsuperscript{9} Poor readability is a major reason for older adults not using medicines information leaflets.\textsuperscript{15} Hence leaflets need to be written clearly, avoiding uncertainty and confusion for patients, and must include a balanced assessment of risks and benefits. Conversely patients’ confidence may be undermined by over-simplified leaflets that they perceive as dull, patronizing, or lacking in authority.\textsuperscript{9}

Providing well-written and useful medicines information leaflets and encouraging their use will improve their impact, and support safe and effective use of medicines. For this to be achieved, good-design principles should be followed and the patients’ requirements must be understood.

This commentary provides an up-to-date review determining ‘what patients want’ regarding leaflet design and content i.e. for conveying information attractively and increasing its use; and for encouraging patients to take their medicines. Nineteen studies were reviewed from multiple countries, three focused on content, seven on design and nine on both content and design of the leaflet.
What should an information leaflet contain?

Focusing on content, studies explored the inclusion of different components. They found that people want leaflets tailored to their condition or disease, age, and gender, as well as explanations of how the medicine works, and a general benefits statement. However, concerns were raised that a benefit statement might create unrealistic treatment expectations. The same study also found that people had difficulty interpreting the Number Needed to Treat (NNT) so this should not be included. In another study, incorporating information presented prominently at the beginning of a leaflet that summarises key safety messages about a drug did not help users find or understand information but was well liked by patients. Another theme across the papers was that participants felt that current leaflets contain too much information, so actions to reduce the length would be desirable.

Key findings

- Many medicines information leaflets do not meet patients’ needs and will not be used
- Medicine information leaflets should contain information on the medicine’s benefits
- Information should be tailored, at least to disease or condition
- Side effect information is often lengthy, confusing, and frightening to patients. This should be simplified, and the leaflet should state the action required if a side effect occurs
- Applications of good design and simplified language improve perceptions, comprehension, ability to locate information, and leaflet readability
- Preference of leaflet length is unclear – patients like one page formats in some studies, but in other studies they want more comprehensive information. Tailoring to requirements would be an advantage
What should the information leaflet look like?

Focusing on design, three studies evaluated new prototypes, comparing the usual style of leaflet against two novel formats; a ‘bubble’ format and a new styled prototype\textsuperscript{25} or American ‘OTC’ style prototype.\textsuperscript{81, 82} All three studies limited the information to one page, optimised design, and applied plain language principles to the new formats. The new designs improved comprehension,\textsuperscript{81} decreased the time required to find information,\textsuperscript{25} and were preferred by patients.\textsuperscript{25, 82} One study found that the new leaflets did not improve the participants’ ability to apply the information to scenarios.\textsuperscript{81}

Five studies compared effects of optimisation against original leaflets\textsuperscript{26, 59, 83, 84} with one study focusing on shortening the leaflet\textsuperscript{84} and one focusing on differing font sizes.\textsuperscript{83} Two of the studies included were from the Investigating Consumer Medicines information (I-CMI) project by Aslani \textit{et al};\textsuperscript{26} the \textit{User testing: Evaluation of Alternative CMI Formats}, and \textit{The CMI Pharmacy Trial}. All used multiple optimisation techniques to improve leaflet design and readability. Some techniques were used in more than one study e.g. removal of repetition, jargon, or difficult words, and simplification of sentences. Optimal leaflet design increased the likelihood that patients would read and keep it for later use\textsuperscript{26} and improved ability to locate information.\textsuperscript{26, 59, 83, 84} Patient perceptions of the leaflet improved reducing the total number of words or ‘difficult’ words.\textsuperscript{84} Increasing medical terminology in a leaflet decreased participants’ confidence in using the medicine, made them feel less informed, and reduced comprehension.\textsuperscript{84} The ability to locate information was best with font sizes between nine and 12, any lower than nine and leaflets were less likely to be read.\textsuperscript{83} However optimising the leaflet (e.g., simplifying sentences and removing repetition and jargon) improved participants’ performance more than changing the size of the font. Two studies showed that comprehension was improved with the revised text,\textsuperscript{59, 83} however the \textit{User testing: Evaluation of Alternative CMI Formats} study\textsuperscript{26} found that patient comprehension did not improve following optimisation.

Lastly, removal of negations improves leaflet readability and patients’ comprehension (e.g., \textit{no}, \textit{not}, \textit{only}, \textit{hardly}, \textit{never}, and prefixes such as ‘\textit{un}’). Negations increased
perceived complexity which decreased the participants’ appreciation of the leaflets and intention to adhere. Furthermore, participants favoured additional optimisation of leaflets such as a clear table of contents, bold or italics used for important elements, improved comprehensibility, and the inclusion of more information (seen as more important than reducing information).

Content AND design?

Three of the studies found that current medicines information leaflets were not meeting patients’ needs and because of their current content and design, participants thought them alarming which might cause patients to discontinue their medicines. The Needs Analysis showed that failing to determine patients’ needs and preferences leads to creating information leaflets that will not be used.

Four studies evaluated the effects of leaflet optimisation. All used multiple optimisation techniques to improve leaflet design and readability, often by simplifying the format and removing jargon. Two of the studies used specific tools for optimisation, and compared the new leaflets against the original style. Optimisation improved readability and comprehension. Two studies evaluated specially created leaflets, although these were not directly compared to existing leaflets. These studies found that younger and more highly educated participants wanted more information about their medicines and that a simplified format ranked highly in regards to readability, and ability to locate information.

Two major trends for leaflet content were highlighted in this review. Firstly, patients want information tailored to their disease or condition and prefer no ‘unnecessary information’. Secondly, patients want to know how a medicine works for them and the benefits of taking the treatment; in particular, how and how much the medicine would assist them. Patients perceptions of leaflets and intention to take medicines will improve if leaflets include information on how quickly they will ‘feel better’ after taking the medicine, and a statement about the medicine’s benefits and how it will works. Furthermore for some patients, knowing the possible consequences of not taking their medicine increases their intention to comply/adhere.
Knowing the type of information patients want included in the leaflets ensures the information is i) more appropriate for their needs, ii) more likely to be used (particularly if less pertinent information is omitted), and is iii) more likely to help them take the medicines safely and effectively.

Innovation is necessary
A single one page document performs better for comprehension, ability to locate information, and in overall perception of leaflets.\textsuperscript{25, 81, 82, 84} Some patients want a short summary leaflet,\textsuperscript{2, 26, 78, 89} but others require more comprehensive information.\textsuperscript{2, 61, 79, 85, 88} At the very least two versions should be available; a summary leaflet should be given with all medicines with access to more comprehensive information if desired.\textsuperscript{26} But we could go even further and tailor leaflets for patients.

Tailoring is an important and overlooked requirement for medicines information leaflets. Tailored interventions are associated with higher patient satisfaction and increased intention to change poor health behaviour.\textsuperscript{12} People only want information relevant to them, yet the leaflets can contain a number of confusing and irrelevant indications, doses, contra-indications, precautions, and side-effects. A young female patient prescribed salmeterol for asthma will need very different information compared to an elderly male prescribed the same medicine for chronic obstructive pulmonary disease, yet the same leaflet would be given to each patient. There are examples of patients being prescribed antidepressants for neuropathic pain who, on reading the accompanying information leaflet, have refused to take their medicine because they think it has been prescribed inappropriately.\textsuperscript{92} Furthermore, regimen and dosage strength are deemed important by patients;\textsuperscript{26, 87} however, if a patient’s dose is different to that stated in the leaflet, a particular problem for a legitimate but off-label use of a medicine, then there might be a risk of confusion and error.

Adherence to chronic therapy can also be encouraged through tailored information leaflets. The majority of patients do not read medicine information leaflets if they have taken that medicine in the past.\textsuperscript{2, 25-28} This is understandable as patients could not be expected to read the same information month-by-month with each dispensing of their medicine. Moreover individuals at different stages of chronic disease will have
quite different information needs. Tailoring information for patients on chronic therapy would enable more appropriate information to be given to them with each medication review cycle, such as further advice on lifestyle and long-term possible side-effects (e.g. Cushing’s syndrome with corticosteroids), and should encourage continued compliance.

A computerised system could automatically tailor leaflets to patient characteristics and medical condition, providing the core elements in a short summarised easy-to-read and understand information leaflet. For patients requiring additional and more comprehensive information, the system could populate personalised leaflets, allowing healthcare practitioners and patients to choose what to include in the leaflet. This would allow optimal leaflet tailoring for all patients’ needs, and point-of-care use of the leaflet for patient counselling. The added benefit would be the patient’s engagement in the process, acknowledgement of leaflet importance, and increased willingness to read and use the information. Whilst there is considerable research on computerised tailored information for patients, this has not centred on medicines information but focused on pre-surgical education and preventative health measures e.g. dietary changes, smoking cessation, disease education, and safe sex practices. Interactive Health Communication Applications (IHCA’s) such as those used by health insurance companies and other healthcare providers, tailor information according to data provided by the user and deliver digital health information, guidance, and support. They contain large volumes of information, but present it in small sections allowing users to select the information they want. IHCA’s are not intended for providing medicine information leaflets as they are not designed for direct face-to-face contact with patients. However, the concept of a program allowing this functionality would suit tailored and relevant medicines information for patients and following consultation, patients’ could continue to stylise their own information throughout their therapeutic journey.

Having printable leaflets at point of care is also of benefit as patients prefer information presented in an A4 format, making it easy to print from the internet
or computer programs and, as the electronic information can be edited as necessary, it would ensure that the most up-to-date information will be given to patients.

**Practice implications**

Current medicine information leaflets are not considered helpful by many patients and are infrequently used. Because of the varying needs of patients, a ‘one-size-fits-all’ version of a leaflet available for each medicine is not appropriate. Tailoring of information providing core 1–2 page information leaflets based on the content requirements (Box 1) to be given out alongside counselling from a healthcare provider is preferred. The ability to use automated computer systems for this process might be a desirable step forward.

**Box 1 Recommendations for content of medicine information leaflets**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the medicine&lt;sup&gt;2, 7&lt;/sup&gt;</td>
<td>The name people are most familiar with (i.e. the brand of the dispensed drug) should also be included.</td>
</tr>
<tr>
<td>Tailored information&lt;sup&gt;7, 26, 61, 78&lt;/sup&gt;</td>
<td>Tailored information to indication a definite requirement. Age and gender are less important to patients but worth considering if possible.</td>
</tr>
</tbody>
</table>
| How a medicine works and the benefits of treatment<sup>2, 7, 26, 40, 61, 79, 87, 89, 91</sup> | Include:  
  - why it is important to treat the disease and what would happen without treatment  
  - whether the medicine is curative, preventative, or provides symptomatic relief  
  - how long treatment will be required for.                                                                 |
| Dose<sup>26, 87</sup>                               | This information should only be included if it can be tailored to the patients specific regimen – i.e. personalised<sup>89</sup>. |
| How to take the medicine<sup>2, 7, 26, 61, 89</sup>  | Also include what to do if a dose is missed.                                                                                             |
| **How long to take the medicine for**<sup>2, 7, 26</sup> | For certain medicines also include what would happen if stop medicines e.g. withdrawal symptoms from antiepileptic medicines, return of infection for antibiotics etc. |
| **How to monitor the treatment’s effectiveness**<sup>26</sup> | Include when to return to the doctor if no benefit seen – i.e. antibiotics should start to see benefit within days compared to antidepressants which takes weeks. |
| **Comprehensive list of risks** | Important to include the action required if side-effects are experienced. Duration of risk would be helpful to include.<sup>40</sup> Note design of side effect list is mentioned below. |
| **Numeric description of side effects**<sup>25, 26, 40, 59, 61, 81, 82, 89, 96</sup> | As well as describing numerically, e.g. as natural frequencies (e.g., three in 100 people), side-effects should be categorised by how likely they are to occur and how serious they are with details of what action is required if a side-effect is experienced. Boxes or tables should be utilised for clarity with side-effects requiring immediate cessation of therapy or medical treatment listed first. |
| **Long-term effects**<sup>2, 26</sup> | Where applicable e.g. corticosteroids, benzodiazepines (addictive). |
| **Monitoring requirements**<sup>61</sup> | Such as blood monitoring and usual frequency. |
| **Interactions**<sup>2, 26, 86</sup> | Focus should be on over-the-counter medicines and foodstuffs. |
| **Allergies and excipients**<sup>26</sup> | Evidence-based cross-reactivity should be included as well as excipients and any particular allergy concern |
### How to store a medicine\textsuperscript{26, 61, 89}
The general recommendation of keeping out of reach of children as well as specific requirements. Also should include how to dispose of medicines (e.g. fentanyl patches—ensure nobody can accidentally be exposed to remaining active ingredient).

### Lifestyle information and general health tips\textsuperscript{40, 88, 89}
Lifestyle information about medicine or disease effects including driving, drinking, sexual activity etc. General health tips cover how to best self-manage disease e.g. healthy diet and exercise in diabetes.

### Details for more information\textsuperscript{26, 40, 89}
Where to see more detailed information leaflets, patient organisations, helpline numbers, and website addresses.

### Comparative information for alternative drug therapies and treatment options including non-pharmacological and natural medicine\textsuperscript{2, 26}
This may be problematic as it could confuse some people and lead to anxiety in some cases. It would be necessary to tailor this information following discussion with patients and before treatment decisions are made to aid concordance. Information should be succinct and evidence-based only and may not be available for a number of medicines.

### Date\textsuperscript{61, 89}
Date of last update of leaflet.

## Conclusion
This review focused on the content and design of medicine information leaflets, two very different but equally important factors that affect patients’ ability to locate and comprehend medicines information, and their desire to use it. Generally, the findings are consistent with the conclusions of earlier systematic reviews\textsuperscript{2, 7, 26, 97} although there is now more impetus driving the need for personalisation and innovation in leaflet generation. This is especially so, given that many countries have recently developed policies moving toward more patient-centred care alongside empowering patients to be actively involved in health decision-making.
This paper describes the types of information and presentation that improve patients’ ability to use their medicines safely and effectively. Furthermore, the review of other papers described here can be used for guidance on content and presentation; be used to help produce safe and effective patient-centred medicine information leaflets; and act as a template against which to assess those currently available.

Conflicts of interest
None.

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This research was undertaken with the aid of a scholarship from the University of Otago, New Zealand.

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2.3.2 Limitations of commentary

This commentary was designed to give an overview, from recent studies, of what patients want included in the information provided to them about their medicines; and how this information should be designed for optimal use.

To undertake this narrative review, we carried out a search of published literature with a focus on patient information leaflets. The ‘design’ information was gathered from the results of the studies identified. Studies were only included if they included patient preferences or opinions, or provided data showing a design characteristic improved acceptability, comprehension, or usability of leaflets. We used the terminology ‘design’ when discussing concepts that covered both the design of the information (font style and size, use of bullets, line spacing, ways to emphasise text, and page layout etc.) as well some content-design principles (e.g. simplified language, tone, sentence length, phrasing, paragraph length, sequence of content (organisation), use of jargon, and repetition). Although this was done to separate the desired clinical information from how it should be written and presented, this may mean there is disparity between this study and other studies when describing design principles. Furthermore, literature that investigated the use of imagery and pictograms were not included. It is understood that pictures help convey complex information to certain patient groups, but for the purposes of this project, papers that focused on the use of pictures and pictograms were excluded. Absence of discussion around the use of pictures in leaflets is not intended to downplay effectiveness of this technique for conveying information.

The limitations of the studies included in this commentary may restrict the ability to generalise to the whole population. For example, none of the studies included children so conclusions can only be drawn for adults. Many studies in the commentary excluded participants who were not native speakers of the language of the country so it is not possible to generalise findings to those who do not speak the ‘leaflet’ language fluently. Some studies also excluded those with learning difficulties or who misused drugs, or were on the methadone programme. This may mean that findings
may not relate well to those who have impaired ability to understand complex information.

Overall there is a consistent bias of participant self-selection among the studies included and this resulted in many of the studies having uneven representation of women of higher education levels, and of particular age group. Three studies had purposeful sampling in adults over 50 years, one study had purposeful sampling of children between 13 and 19 years and in adults over 50. Another study had younger participants with mean ages ranging from 22.2 to 32.9 in the differing participant groups in the study. Most other studies had participants with a mean age over 45 years (often much higher).

Furthermore, many of the qualitative studies reviewed were of a limited sample size. Although this is characteristic of studies involving one-on-one interviews and focus groups, it means that the results may not necessarily be generalised to other population groups.

None of the studies focusing on content of information leaflets measured the literacy of participants and this variable may affect outcomes of participants. However, some of those with a focus on design did quantify literacy, although differing measures were used between each study; often education level was obtained as a proxy for literacy.

For the studies investigating optimisation by design, many leaflets were enhanced in multiple ways in addition to the specific concept under scrutiny. This may result in overestimation of benefits of the specific intervention being investigated or make it difficult to know what did and did not aid readability and understanding of leaflets.

Lastly, the included studies’ measured outcomes and methodological heterogeneity prevented direct comparisons to be made between them, thus a narrative of outcomes was conveyed.
2.4 How medicine information leaflets should be designed compared to regulatory agencies’ recommendations

Published Manuscript Entitled Regulatory agencies’ recommendations for medicine information leaflet: Are they in line with research findings?

The manuscript entitled “Regulatory agencies' recommendations for medicine information leaflets: Are they in line with research findings?” was published in the journal Res Social Adm Pharm 2018;14(2):196-202.

The co-authors contributed to the manuscript as follows: Review and synthesis of the literature were performed by PhD candidate Amber Young, under the supervision of Dr Alesha Smith and Associate Professor June Tordoff. All the co-authors revised the content of the manuscript and approved the final version for publication. The PhD candidate Amber Young was the lead author in manuscript preparation and writing, and corresponding author.

The manuscript is presented as accepted for publication; however, the numbering of the pages, figures, and tables has been adjusted in accordance with the style of this thesis. All references from the manuscript can be found in the section ‘References’ at the end of the thesis.
2.4.1 Regulatory agencies’ recommendations for medicine information leaflet: Are they in line with research findings?

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Abstract

The design of medicine information leaflets can determine whether a leaflet will be read or discarded by patients. It may also influence patients’ ability to understand the information about their medicines within the leaflet. Researchers compared regulatory agencies’ recommendations for medicine information leaflet design from New Zealand, the United Kingdom, the European Union, and the United States against recommended good-design principles to determine the appropriateness, comprehensiveness, and consistency of their recommendations. Recommendations for medicine information leaflets varied between the regulatory agencies. There were some inconsistencies between the recommendations and some gaps were identified. There was little guidance given to creators of medicine information leaflets in New Zealand compared to other countries, and this could lead to manufacturer-produced information leaflets of a poorer quality. Up-to-date and enforceable guidance for creators of medicine information leaflets should be provided in all countries to ensure they are of an appropriate standard.

Keywords medicine information, patient information leaflet, patient education, information design
Background

The provision of medicine information leaflets

Medicine information leaflets are expected to increase consumers’ knowledge of medicines, assist in distinguishing side-effects and recognising interactions, and improve consumers’ health management skills. In New Zealand there are ethical requirements that patients are fully informed about their prescribed medicines. However, in contrast to other countries (e.g. within Europe), there is no legal requirement for medicine information leaflets to be given, nor any binding official requirements for manufacturers to adhere to when creating leaflets. This has led to a system where there is no consistency in the provision of medicine leaflets at dispensing between pharmacies, or possibly between individual pharmacists within a pharmacy. One benefit of not having to legally provide the manufacturers information leaflet is that health professionals can choose which material to provide to patients. Some examples are those produced by independent providers such as Med+info (a subscriptive resource for pharmacists to print for patients), SafeRx (produced by the Waitemata District Health Board), Healthinfo (a Canterbury District Health Board initiative), Kidshealth (a joint initiative between the Paediatric Society of New Zealand and Starship Foundation), and Health Navigator New Zealand. This allows scope for incorporating patient preference.

Compulsory provision of medicine information leaflets is regarded as a positive step forward in patient education, yet there are some patient reservations around the trustworthiness of manufacturer provided information. Furthermore, even although there are guidelines in place for manufacturers to use when producing information leaflets they may still be substandard. In the USA, private vendors create medicine information leaflets (named consumer medication information (CMI)) which are expected to be given with the first dispensing of all medicines. These leaflets, however, are of variable quality. One important problem with this system is that some vendors include too much information in an attempt to ‘cover all the bases’ and prevent possible litigation. The outcome of this is that leaflets fail to meet their primary purpose in effectively educating patients.
with serious and significant public health concerns (decided by the FDA), or those containing oral contraceptives or estrogen, and some other prescription medicines (decided by FDA or manufacturer) have manufacturer-produced medication guides or patient package inserts. These are reviewed and approved by the FDA, although still fail to meet federal standards and patient requirements.  

Why leaflet design is so important

Medicine information leaflets can be a useful tool for educating patients about their medicine, allowing patients to use their medicines safely and improve adherence. This is of particular importance to patients with poor health literacy, who have reduced ability to obtain and comprehend basic health information and make informed and appropriate decisions about their health. These patients also tend to be the most vulnerable to illness and suffer worse health outcomes.

A recent review looked at how information leaflets should be designed to convey information effectively and accurately. The key findings were that a well-designed leaflet with simple language improve patient perceptions of the leaflet, and improve patients’ ability to find and comprehend the information in the leaflet. However, as pointed out in the review, many patients find leaflets are poorly designed, complex, too long, and difficult to read so this reduces patients’ willingness to read the leaflet. Perceived complexity, perhaps due to leaflet length or use of jargon, decreases patients’ appreciation of the leaflet and probably the likelihood of following the recommendations. Patients have even reported stopping their medicine if the information in the leaflet is unclear.

This article provides an up-to-date comparison of government regulatory agencies’ recommendations from New Zealand, the United Kingdom, the European Union, and the United States with recommended good-design principles to determine the appropriateness, comprehensiveness, and consistency of their recommendations.
Methods

The investigators used their own “20 good-design principles” (20-GDP; Table 2) identified in a literature review\textsuperscript{109} to compare the recommendations made by Raynor et al,\textsuperscript{2} and made by medicines regulatory agencies in the EU,\textsuperscript{110, 111} New Zealand,\textsuperscript{3} the UK,\textsuperscript{40, 112} and the USA.\textsuperscript{113, 114} The regulatory agencies in the EU, New Zealand, and the UK provide advice to manufacturers and the USA to creators of CMI leaflets. UK recommendations were evaluated separately (but guidance provided by the EU is also relevant to the UK). These countries were chosen because their guidance was available freely online and in English. See Figure 5 for method diagram.

**Figure 5: Comparison of design principles between literature reviews and regulatory agencies**

All good-design principles identified in the reviews and the medicines regulatory agencies websites were tabulated for identification of similarities, inconsistencies, and gaps in guidance (see Table 2).

Each resource was given a star rating for consistency with the identified “20 good-design principles” by one investigator, which was corroborated by two other researchers.
Results

The guidance published by medicines regulatory agencies varied considerably in quantity and alignment with the investigators “20 good-design principles” (20-GDP) derived from the literature (Table 2). Regulatory agencies guidance was published online from three (UK) to 20 (USA) years ago. However, the US guidance was updated in 2006. Some design aspects identified in our “20 good-design principles”, such as number of pages and minimising repetition was not included in any guidance from regulatory agencies. It is worth noting that in some instances, the regulatory agencies’ guidance went into greater detail than what was found in the 20-GDP. This included the type of paper to be used (not glossy, shiny, or too thin), specifics for line length of documents, and the spacing between lines.

Generally speaking, the findings of this review are in line with the recommendations made by Raynor et al (see Table 2), suggesting that conclusions drawn around good-design principles from the previous decade are still highly relevant. However, there are a few important new points that we discovered in our review, such as avoidance of repetition, type of paper to use (A4), and leaflet length. Minor inconsistencies were also uncovered such as optimal font style and size.
## Table 2: Summary of design principles for medicine information leaflets

<table>
<thead>
<tr>
<th>Design Principles</th>
<th>Other information sources</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Articles included in review, 2008-2015</strong></td>
<td>Raynor et al, 2007²</td>
</tr>
<tr>
<td><strong>Words and language</strong></td>
<td>Medsafe New Zealand 2013³</td>
</tr>
<tr>
<td>User-friendly language. No medical terminology or semi-technical expressions (unless necessary and fully explained).</td>
<td>abUK, 2005 and 2014¹¹²</td>
</tr>
<tr>
<td>No acronyms or abbreviations.</td>
<td>European Commission, 2009¹¹⁰ and EMA, 2016¹¹¹</td>
</tr>
<tr>
<td>Write to appropriate reading level— year 6 (11 years of age).</td>
<td>aFDA USA, 1996¹¹³ and 2006¹¹⁴</td>
</tr>
<tr>
<td><strong>Tone, attitude, and meaning</strong></td>
<td><strong>Other information sources</strong></td>
</tr>
<tr>
<td>Instruct the patient not the healthcare professional, and conversational tone (‘you’ and not ‘the patient’).</td>
<td><strong>Other information sources</strong></td>
</tr>
<tr>
<td>Practical, straightforward, relaxed, and positive.</td>
<td><strong>Other information sources</strong></td>
</tr>
<tr>
<td>All statements must be correct, clear, and unambiguous.</td>
<td><strong>Other information sources</strong></td>
</tr>
<tr>
<td>Not discussed (but covered in European Commission, 2009¹¹⁰).</td>
<td><strong>Other information sources</strong></td>
</tr>
<tr>
<td>Do not repeat medicine name, instead say ‘your medicine’ or ‘this medicine’.</td>
<td><strong>Other information sources</strong></td>
</tr>
<tr>
<td>Use plain language and from the reader’s point of view.</td>
<td><strong>Other information sources</strong></td>
</tr>
</tbody>
</table>

Note: Stars indicate the level of agreement with the design principles.
<table>
<thead>
<tr>
<th>Design Principles</th>
<th>Other information sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Articles included in review, 109 2008-201525, 26, 59, 61, 78-90</td>
<td>Raynor et al, 20072</td>
</tr>
<tr>
<td></td>
<td>Medsafe New Zealand 20132</td>
</tr>
<tr>
<td></td>
<td>abMHRA UK, 200540 and 2014112</td>
</tr>
<tr>
<td></td>
<td>bEuropean Commission, 2009110 and EMA, 2016111</td>
</tr>
<tr>
<td></td>
<td>aFDA USA, 1996113</td>
</tr>
<tr>
<td>Tone, attitude, and meaning [continued]</td>
<td></td>
</tr>
<tr>
<td>Avoid being negative, patronizing, or emotive. Information should be direct,</td>
<td></td>
</tr>
<tr>
<td>positive, and unambiguous.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Voice and phrasing</td>
<td></td>
</tr>
<tr>
<td>Important to use active or imperative voice. Use affirmations, not negations</td>
<td></td>
</tr>
<tr>
<td>where possible and avoid non-quantifiable phrases.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>★★★</td>
</tr>
<tr>
<td></td>
<td>Active voice, and imperative voice for instructions.</td>
</tr>
<tr>
<td></td>
<td>Not discussed.</td>
</tr>
<tr>
<td></td>
<td>Not discussed (but covered in European Commission, 2009110).</td>
</tr>
<tr>
<td></td>
<td>Active, not passive style. Actions should be followed by reasoning.</td>
</tr>
<tr>
<td></td>
<td>Not discussed.</td>
</tr>
<tr>
<td>Sentence length</td>
<td></td>
</tr>
<tr>
<td>Short sentences.</td>
<td>★★★</td>
</tr>
<tr>
<td></td>
<td>Short sentences (15-20 words), preferably one type of information per sentence.</td>
</tr>
<tr>
<td></td>
<td>Not discussed.</td>
</tr>
<tr>
<td></td>
<td>Punctuation should be simple. Short sentences, no more than about 20 words.</td>
</tr>
<tr>
<td></td>
<td>Short sentences.</td>
</tr>
<tr>
<td></td>
<td>Not discussed.</td>
</tr>
</tbody>
</table>
### Design Principles

**Articles included in review,**¹⁻⁰ 2008-2015 ²⁻⁵, ²⁶, ⁵⁹, ⁶¹, ⁷⁸⁻⁹⁰

<table>
<thead>
<tr>
<th><strong>Font style</strong></th>
<th><strong>Other information sources</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sans serif style fonts preferable.</td>
<td>Raynor et al, 2007²</td>
</tr>
<tr>
<td>Avoid widespread use of capitals.</td>
<td>Medsafe New Zealand 2013³</td>
</tr>
<tr>
<td>All text horizontal.</td>
<td>abMHRA UK, 2005⁴⁻⁰ and 2014¹¹²</td>
</tr>
</tbody>
</table>

**Font style**

- Conventional familiar typeface. Serif or sans serif equivocal – some recommend serif for headings and sans serif for body.
- Only use capitals in headings.
- Easy to read font. Serif typeface preferred for extensive text (PILs), sans serif fonts for signs.
- Avoid writing in capitals. All text horizontal.

**Other information sources**

- Easy to read font (letters and numbers distinguishable).
- Avoid widespread use of capitals (can be used for emphasis). Italics can be used for Latin terms.

- Do not use ornate typefaces and italics. Bolder type over a thin version. Opinions vary on using serif or sans serif font. Many experts recommend sans serif for headings and serif for text. Avoid widespread use of capitals.
- Ensure adequate space between letters, no more than -3 “kerning” (i.e. space between letters).
<table>
<thead>
<tr>
<th>Design Principles</th>
<th>Other information sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Articles included in review,2008-2015</td>
<td>Raynor et al, 2007(^2)</td>
</tr>
<tr>
<td>Font size</td>
<td>★★★</td>
</tr>
<tr>
<td>Font size 10–12 point.</td>
<td>Font size 12-14 point.</td>
</tr>
<tr>
<td>Colour and contrast</td>
<td>★★</td>
</tr>
<tr>
<td>Colour may be useful to emphasise important points or sections (not conclusive).</td>
<td>Use sparingly. Do not use red type. Black on white or yellow maximises readability.</td>
</tr>
<tr>
<td>Design Principles</td>
<td>Other information sources</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Articles included in review, 2008-2015</td>
<td>Raynor et al, 2007&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Line length and spacing</td>
<td>ab MHRA UK, 2005&lt;sup&gt;40&lt;/sup&gt; and 2014&lt;sup&gt;112&lt;/sup&gt;</td>
</tr>
<tr>
<td>Shorter lines preferable. Lines must be well-spaced.</td>
<td>★★★</td>
</tr>
<tr>
<td>Both long and short lines impair reading. Aim for 40-70 characters (8-12 words). Spaces between lines important.</td>
<td>Not discussed.</td>
</tr>
<tr>
<td>Paragraph length and spacing</td>
<td>★★★</td>
</tr>
<tr>
<td>Short paragraphs. Avoid listing information in a paragraph format. Adequate spacing between paragraphs.</td>
<td>Not discussed.</td>
</tr>
<tr>
<td>Justification</td>
<td>★★★</td>
</tr>
<tr>
<td>Left justification of text.</td>
<td>Not discussed.</td>
</tr>
</tbody>
</table>

- <sup>a</sup>FDA USA, 1996<sup>113</sup> and 2006<sup>114</sup>
- <sup>b</sup>Medsafe New Zealand 2013
- <sup>c</sup>European Commission, 2009
- <sup>d</sup>EHRA UK, 2005 and 2014

- Line length and spacing: Optimal line length is approximately 40 letters and leading (space between lines) at least 2.2 mm. Spacing between lines important—generally 1.5 times that between words (at least 3mm).

- Paragraph length and spacing: Short paragraphs. Have adequate spacing between paragraphs. Short paragraphs where possible with adequate space between paragraphs.

- Justification: Align text to the left. Do not use justified text.
<table>
<thead>
<tr>
<th>Design Principles</th>
<th>Other information sources</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Articles included in review</strong>&lt;sup&gt;109&lt;/sup&gt; 2008-2015&lt;sup&gt;25, 26, 59, 61, 78-90&lt;/sup&gt;</td>
<td>Raynor et al, 2007&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Organisation of content</strong></td>
<td>Logical sequence of information. Treatment benefit, how the medicine works, and directions before risk.</td>
</tr>
<tr>
<td><strong>White space</strong></td>
<td>Page should not be cluttered. Plenty of white space.</td>
</tr>
<tr>
<td><strong>Table of contents</strong></td>
<td>Numbered table of contents with associated numbered headings in longer leaflets.</td>
</tr>
<tr>
<td>Design Principles</td>
<td>Other information sources</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>Articles included in review, 2008-2015</td>
<td>Raynor et al, 2007² Medsafe New Zealand 2013³ abMHRA UK, 2005⁴ and 2014¹¹² bEuropean Commission, 2009¹¹⁰ and EMA, 2016¹¹¹ cFDA USA, 1996¹¹³ and 2006¹¹⁴</td>
</tr>
<tr>
<td><strong>Headings</strong></td>
<td></td>
</tr>
<tr>
<td>Clear headings and subheadings necessary and must stand out from rest of text. The heading 'before you take' is ambiguous (people do not understand what information will be listed underneath it).</td>
<td>Short and on a single line. Clear subheadings. Questions may not be useful. Section headings in reverse type stand out (though less legible). Not discussed. Headings important. Must be visually prominent: use of reversed text larger and bold font contrasting colour. Must accurately describe the contents of section and be concise. Subheadings useful. Should be consistently placed with consistent font. Lines to separate text. Bold or different colour. Consistent font and spacing above and below. Lines to separate text. Caution with multiple levels (warranted for complex information). Adhere to section headings as per legal requirements.</td>
</tr>
<tr>
<td><strong>Bullet points</strong></td>
<td></td>
</tr>
<tr>
<td>Use of bullet points for lists rather than long paragraphs.</td>
<td>Organise text into steps or points (instead of numbered lists as appropriate). Numbered lists useful for numbered headings or instructions. Not discussed. Use of bullet points for lists rather than long paragraphs (maximum five or six points). Use of bullet points for lists rather than long paragraphs (maximum five or six points). Bullets should be used where possible.</td>
</tr>
</tbody>
</table>

**Headings**

- Clear headings and subheadings necessary and must stand out from rest of text. The heading ‘before you take’ is ambiguous (people do not understand what information will be listed underneath it).

- Short and on a single line. Clear subheadings. Questions may not be useful. Section headings in reverse type stand out (though less legible).

- Not discussed.

- Headings important. Must be visually prominent: use of reversed text, larger and bold font, contrasting colour. Must accurately describe the contents of section and be concise. Subheadings useful. Should be consistently placed with consistent font. Lines to separate text.

- Bold or different colour. Consistent font and spacing above and below. Lines to separate text. Caution with multiple levels (warranted for complex information). Adhere to section headings as per legal requirements.

**Bullet points**

- Use of bullet points for lists rather than long paragraphs. Organise text into steps or points (instead of numbered lists as appropriate). Numbered lists useful for numbered headings or instructions.

- Not discussed.

- Use of bullet points for lists rather than long paragraphs (maximum five or six points). Use of bullet points for lists rather than long paragraphs (maximum five or six points). Bullets should be used where possible.
<table>
<thead>
<tr>
<th>Design Principles</th>
<th>Other information sources</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Articles included in review</strong>&lt;sup&gt;109&lt;/sup&gt; 2008-2015&lt;sup&gt;25&lt;/sup&gt;, 26, 59, 61, 78-90</td>
<td>Raynor et al, 2007&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Emphasising information</strong></td>
<td></td>
</tr>
<tr>
<td>Bold to highlight important text. Avoid over use as this reduces the emphasis.</td>
<td>***</td>
</tr>
<tr>
<td>Use bold. Only use capitals in headings.</td>
<td>Not discussed.</td>
</tr>
<tr>
<td><strong>Page layout and page break</strong></td>
<td></td>
</tr>
<tr>
<td>A4 page, portrait orientation, with 2 columns for information (3-column format makes lines too short). Sections should finish on the page.</td>
<td>***</td>
</tr>
<tr>
<td>Avoid sections being broken between columns or pages.</td>
<td>Not discussed.</td>
</tr>
<tr>
<td><strong>Repetition</strong></td>
<td></td>
</tr>
<tr>
<td>Avoid repetition. All information on one topic should be included in one section.</td>
<td>***</td>
</tr>
</tbody>
</table>
## Design Principles

<table>
<thead>
<tr>
<th>Design Principles</th>
<th>Other information sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Articles included in review, 2008-2015</td>
<td>Raynor et al, 2007&lt;sup&gt;2&lt;/sup&gt;, Medsafe New Zealand 2013&lt;sup&gt;3&lt;/sup&gt;, MHRA UK, 2005&lt;sup&gt;4&lt;/sup&gt;-2014&lt;sup&gt;112&lt;/sup&gt;, European Commission, 2009&lt;sup&gt;110&lt;/sup&gt; and EMA, 2016&lt;sup&gt;111&lt;/sup&gt;, FDA USA, 1996&lt;sup&gt;113&lt;/sup&gt; and 2006&lt;sup&gt;114&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

### Paper

<table>
<thead>
<tr>
<th>Paper A4 page</th>
<th>★★★</th>
<th>★★★</th>
<th>★★★</th>
<th>★★★</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not discussed.</td>
<td>Not discussed.</td>
<td>Avoid glossy, shiny paper, or paper that is too thin and allows show-through of text.</td>
<td>Avoid glossy, shiny paper, or paper that is too thin and allows show-through of text. Folding must not affect readability.</td>
<td>Material should be printed on uncoated paper.</td>
</tr>
</tbody>
</table>

### Number of pages

<table>
<thead>
<tr>
<th>Number of pages</th>
<th>★★★</th>
<th>★★★</th>
<th>★★★</th>
<th>★★★</th>
</tr>
</thead>
</table>

---

<sup>a</sup> The more recent publication is not a comprehensive list of design principles, but refers to the earlier publication as a resource to be adhered to when creating medicine information for patients. The information included in both documents has been merged for the purposes of this table.

<sup>b</sup> It is a legal requirement that manufacturers' medicine information leaflets also undergo consumer user-testing before they are approved for use.

- ★★★ Consistent with the 20 good-design principles (20-GDP) from the investigators review<sup>109</sup>
- ★★★ Somewhat consistent with the 20-GDP
- ★★★ Not consistent with the 20-GDP or not discussed in recommendations
Discussion and conclusion

Discussion

In this commentary, the investigators compared regulatory agencies' recommendations for medicine information leaflets for alignment with the design principles found in two sources. One source was the investigators' recent review, and the other recommendations made by Raynor et al in 2007. Each source had identified design principles that would facilitate leaflet use by patients, and maximise leaflet effectiveness. The recommendations examined were from agencies in the EU, New Zealand, the UK, and the USA (see Table 2).

We found that the design recommendations for medicine information leaflets varied between the regulatory agencies. Understandably, guidance published by the EU and the UK were very similar and those from the USA also contained many similarities to them both. However, there were some inconsistencies between the recommendations and the literature; and some gaps in guidance were identified. This may be because our literature review was completed many years after the guidance on the agencies' websites were written or updated. This suggests that there is a lag in uptake of new information about textual style and design that becomes available from research. In New Zealand, there is little regulatory guidance given to the creators of medicine information leaflets compared to other countries, and this could lead to manufacturer-produced information leaflets of a poorer quality. New Zealand needs stronger regulatory guidance on the use of good-design principles for the creators of medicine information leaflets. Furthermore, in all countries, leaflets could be updated in line with research findings more rapidly, and there could be greater international collaboration by agencies when developing guidance.

A leaflet's appearance at first glance might attract or deter patients from reading it. Legislation in many countries concerning what must be contained in leaflets has led to them being long and cumbersome which does not encourage patients to read them. In the USA, leaflets produced by different vendors for the same medicine may have more than 1000 word difference in length between them. The longer leaflets contain
all of the necessary information but because of the quantity presented, it is not read and retained. Involving patient groups when creating regulations or guidance, rather than the standard of ‘user-testing’ after the fact, would help agencies exclude the unimportant. This would make leaflets a more desirable length, and more patient-centred.

As well as emphasising the importance of the leaflet design, there should be more guidance on the final provision of the information. Patients prefer printed information presented in an A4 format, making it easy to print from the internet or computer programs, and beneficial to both healthcare practitioners and patients who want to access it. However, it is important to note that leaflets presented on thin paper folded multiple times and inserted in a pack with dispensed medicines may not seem important enough to read. Likewise a leaflet folded and put into a dispensed bag of medicines, without discussion from a pharmacist, may go unnoticed or seem unimportant. Perhaps as well as updating recommendations on the design of medicines information leaflets, guidance should be provided on how printed information leaflets should be presented and discussed with patients. Furthermore, there has been no guidance for healthcare professionals on how to provide electronic medicines information, despite improved patient-access and preference for digital information alongside increasing use of smart phones. There are also new patient-centred initiatives such as patient accessible electronic health records where patients can view their health information and contact their health care provider directly. Regulation of information provided to patients digitally is warranted; this should include when electronic medicines information should be provided and what that information should be.

Practice implications
Many countries have developed guidance on how to produce well-designed information leaflets about medicines but only a few have regulations that require the leaflets to be given to patients when medicines are supplied. Other countries, including New Zealand, have little or partially outdated information, and guidance requires a complete update. Also there has been no guidance for the provision of
medicines information electronically, which is surprising in a time where the use of smart phones and patient electronic health record access is commonplace. A change in practice is required to establish up-to-date and enforceable guidance for those creating medicine information leaflets so that leaflets are produced to an appropriate standard and in appropriate formats.

Conclusion
There has been considerable investigation in Australia, the USA, the UK, and other countries within the EU into the strengths and weaknesses of currently available medicine information leaflets, and what could be done to improve them. Recommendations from research and regulators are available yet these are not consistent or fully comprehensive. In some countries, these recommendations are not commonly incorporated into leaflet-writing practice, or the common templates used may not allow these principles to be followed. Medicines information for patients should be as direct and simple as possible—it is essential that instructions are clearly given so patients know when action is required, and what action should be taken. We have highlighted recommendations (20 good-design principles) for medicine information leaflet design based on our literature review findings. These can be used as a template for creating and assessing medicine information leaflets in use.

Conflicts of interest
None.

Role of the funding source
This research was undertaken with the aid of a scholarship from the University of Otago, New Zealand.

Acknowledgements
We thank the School of Pharmacy, University of Otago for supporting this work, and the University of Otago for the doctoral scholarship.
2.5 Digital information about medicines, is there a need?

Many health professionals are continuing to rely on verbal discussion or, sometimes more often, printed leaflets. The Medicines and Healthcare Products Regulatory Agency UK report in 2005\(^4\) stated that printed leaflets may be the only information many people receive about their medicines. Providing information about medicines digitally can allow even more information to be provided if necessary or desired by the patient, and can improve patient engagement compared to routine clinical appointments.\(^{115}\) Linking to more useful information such as instructional videos or further resources for reputable information about the disease or condition would also be useful for patients.

As discussed earlier, patients have improved access to digital and personal health information yet there is no guidance about providing information about medicines or evidence-based treatment this way. Furthermore, people are increasingly looking to the internet for health information.\(^7\) Unfortunately, online information can be of variable standard and sometimes dangerously inaccurate.\(^{116,117}\) Like other health information, information about medicines is already available in a digital format and is being consumed by patients. This suggests there should be more emphasis on the need for suitable digital information rather than the need for having information available in a digital format. The key need is for healthcare professionals to be able to direct patients towards accurate, reputable, and easy-to-read digital information.\(^{117}\) For this to occur it is essential that the desired information is available digitally and easily for health providers to access and disseminate.

2.5.1 Practicalities

Digital information would need to be usable at point-of-care and accessible to the patient once they have left a consultation. Having the information available electronically rather than pre-printed may be seen as a natural evolution in a technology-rich society. It is important that patients can access information at a time that suits them and that it is available in a format suited to their requirements. Some
health providers no longer provide disease and treatment information in paper format, but instead send patients a reputable weblink via an SMS (text message). However, these services may still require active health professional engagement for the patient to gain access to the content. This can be remedied by some automation of information provision following consultation.

Digital information can be easily edited and disseminated which allows updates about the medicine to be available to patients straight away—possibly even alerting them to safety updates in real time. Digital information can also improve patient usability e.g. using in-built dictionaries to explain complex medical terms, allowing a change in font size on a mobile phone, or utilising a read-back function for audio versions of the text on the web page.

Nevertheless, it is important that digital medicine information is easy to access and does not lead to accidental access of incorrect information (e.g. patient searching for information about dextromethorphan accidentally reading information about dexamethasone). There are ways around these issues with links or codes being provided directly to patients rather than them searching for the information themselves. Examples of this are patients receiving email or an SMS (text message) with a direct web link, or a code (e.g. QR, quick response code) on medicine packaging. These could be electronically and automatically provided by the prescribers or dispensers of medicines. Text-based initiatives provided to patients via SMS have been shown to improve health outcomes in many situations including weight-loss, but there is not much information as to whether they are beneficial for providing medicine information and improving patient knowledge. It is likely that SMS would require links to applications or websites in order to be of benefit.

2.5.2 Patient preference

As discussed earlier, the presentation of the information can affect patients’ opinions of the resource. Poorly presented leaflets can be ignored. Digital information that is easily accessible can improve perception of the resource and patients’ willingness to read it. There is also a risk that patients may think the content is not important if not specifically provided by their health professional.
provider in the future to point patients in the direction of reputable digital information to minimise this assumption.

The growth of information technology supports improved patient engagement in healthcare with information being accessible anywhere at any time. Disease-specific mobile applications help patients feel more in-control of their own healthcare.\textsuperscript{115} With the use of educational websites patients feel they have a better understanding of their condition, more satisfaction with doctor’s visits, and advocate wider use of patient education websites by other health professionals involved in their care. They are also likely to return to the website as needed in the future.\textsuperscript{120} Many patients would be happy to receive information about their medicines electronically, and it may allow them to quickly navigate and find the desired information without having to read the whole leaflet.\textsuperscript{119} However it may not be appropriate for all patients such as those less tech-savvy or some elderly patients who are not well practised at navigating digital information. In these patients there may be acceptance for electronic information, but they may also want to continue receiving printed information.\textsuperscript{119} User-friendly eHealth services must be in place along with simple to follow education programs to educate patients who lack the know-how of more digitally advanced patients. But in addition to this, the information available digitally must be “printer friendly” to ensure those without digital access still can read the information important to them if a health provider, family member, or friend is accessing the content on their behalf.

Finally, if patients have access to information in a digital format it will be possible for them to tailor the information to their own requirements. For example, automatic personalisation could occur during consultation, with the healthcare professional providing a tailored short summarised leaflet, web link, or email with a link to access further information if required. In many cases, patients might find the summarised leaflet sufficient for their needs.\textsuperscript{2, 78} Yet some might prefer to receive comprehensive information and want to read as much as they can about their medicines. These patients would find the link to additional information useful and reassuring.\textsuperscript{2, 79, 85} For example, patients could either read the most common side-effects in the tailored information provided by their health professional, or they could link to more detailed
information about medicine harms. They might decide to look at pregnancy and breast-feeding information if appropriate; or look at alternative treatments or lifestyle factors that could help manage their condition more effectively if they were motivated to do so. For this to be of value to patients, the interface must be well designed, and the system must be user-friendly.

2.6 Patient Reported Outcomes

2.6.1 What are Patient Reported Outcomes?

So far this chapter has discussed the passive flow of information from provider to patient or from resource to patient. This assessment does not allow viewpoints and direct involvement from individual patients about what information they should be receiving. Patient Reported Outcomes (PROs) are patients’ direct accounts about their treatment or health condition,121, 122 and enable representation and discussion about what is most important to them.73, 121

The information collected by PROs can be either disease-specific (e.g. diabetes), condition-specific, or generic. This information can be attained by a number of different methods such as targeted patient interviews, self-completed questionnaires, or even patient diaries.121 Information can also be collected digitally using web-based forms on smart devices.121 PROs can be used for an almost infinite number of purposes and collected in a multitude of different ways for different applications: they can be collected during inpatient stays, outpatient visits, or during ambulatory care; for acutely presenting patients, for chronic patients, or for acute presenting chronic patients; at time of consultation, or between visits. The quantity of PROs collected is also for debate i.e. they can be a single report or recurrent reports; some PROs are collected on a daily basis.72 Because of the variation in type of information that can be collected, the way it is collected and when it is collected, PROs can be designed for almost any purpose and tailored to specific requirements.
PROs can be used to collect information from patients to help generate tailored information to be provided to them. For example, patients taking medicines associated with high-risk of harm (e.g. oncology medicines) can report the side-effects they are experiencing and depending on the responses they provide. Actionable side-effect management advice could then be provided to them to suit their needs. Patients can report specific problems experienced through pre-determined questionnaires and their responses can generate self-management advice based on those responses (or other useful information). This is being investigated for oncology medicines, but could be extrapolated to other drugs where patients need symptoms reporting on a regular basis to prevent worsening toxicity e.g. breathlessness for methotrexate, skin complaints with lamotrigine and so forth. Information about the medicine and harms of treatment are the most likely things to be requested.

2.6.2 Benefits of Patient Reported Outcomes

Increasing the information available to health practitioners for use during a consultation by acquiring PROs could improve person-centred care by encouraging clinicians to focus on the patient’s concerns rather than patient’s disease. Most current healthcare models allow discussion about treatment benefits and side-effects. However, these may rely on clinician-led appointments to discuss patients’ concerns and can be short and unfocused. This process is also often impeded by cost and by both parties having limited time to adequately undertake true shared-decision making. PROs could facilitate communication between patients and their healthcare provider thus enabling shared-decision making and engaging patients in their own care. PROs allow the flow of information from patients back to health professionals, facilitating adequate, up-to-date, and focused information to be discussed and reviewed during consultation, possibly without increasing consultation time. Furthermore, the information gathered by PROs assists early detection of health problems requiring urgent medical intervention, allows the application of standardised disease-progression measures, and enables evaluation of treatment impact on patients’ lives.
There are many different tools available that allow documentation of PROs, assessing a multitude of different outcomes including symptoms of disease or side-effects from therapy, functional status, quality of life, and perceived well-being. For some methods, patients can report outcomes at any time in the comfort of their own home. This would be beneficial when early detection and management of certain clinical issues is essential, such as signs of early infection in patients having chemotherapy. Furthermore if PROs are collected using digital mediums such as smart devices, there is potential for that data to be directly inputted into patients’ Electronic Health Records (EHR) and thus automatically alerting clinicians if urgent intervention is required.

It is well understood that health professionals may only provide patients with the information that they feel is important and may withhold information that some patients want including that on side-effects and potential harms of treatment. This phenomenon may also occur when health practitioners are following up with chronic therapy and discussing treatment effects with their patients. It is also possible that some issues that may concern the patient could be forgotten and not discussed. The use of PROs would ensure that the problems patients find most important could be flagged to their health provider for discussion during consultation, particularly those that may be otherwise overlooked. Furthermore, some side-effects are unable to be easily quantified and the resulting impact on patients may only be known to the patients themselves, such as fatigue and emotional pressures when undergoing chemotherapy; PROs are useful in capturing data on how patients are coping with their treatment. If PROs were used this way, patients could be directed to where they could find more information or support to help overcome these issues, for example tailored information leaflets or websites for support groups. This information for the patient could be sent to them in a digital format e.g. via email, text message, or through their patient portal.

Collecting PROs would also allow effective documentation of patients’ improvement or deterioration over time. In doing so, this would benefit individual patients by enabling them to manage their disease or symptoms more effectively. There is also
benefit at a population level where collected data could be aggregated for further analysis to determine treatment outcomes for certain population groups and to assess treatment effectiveness or side-effects. This would also facilitate more effective and tailored patient education about expectations of treatment and the side-effects they may experience. The aggregated data could also help shape future treatment strategies for managing toxicities or disease progression.

2.6.3 Disadvantages of Patient Reported Outcomes

Collection of PROs must be appropriate for patients’ skills and be easy for patients to complete accurately. Some PROs might require a high degree of digital literacy or could be too time consuming for patients to complete. It could also become burdensome for health professionals to teach patients how to use tools to capture PROs.

There may also be disadvantages to health professionals depending on where PROs are collected. If collected in a clinic, private space to fill in a form may need to be made available. If collected by the patient at home there needs to be either IT management if digital applications are utilised or manual data entry if paper PRO forms are used. Either way there are costs involved. Other disadvantages health professionals may be faced with include intensified workload due to increased information received, difficulty and extra time required to learn the systems for collecting and interpreting PROs, and the difficulty with fitting PRO explanation and discussion into their usual workflow.

A poorly designed instrument may not capture appropriate data, may not be sensitive enough to capture data to monitor change over time, and may miss outcomes important to patients. Involving patients in the early stages of developing tools for collecting PROs is essential to ensure the tools are user-friendly, understandable to patients, and effective enough to capture the outcomes to be measured. There is also a risk that PROs could cause anxiety to patients by overemphasizing problems that might not have concerned them. Alternatively, patients may receive ‘high scores’ but intervention may not be necessary because the problem may not be distressing to the patient, or the ‘high score’ may be due to something other than
what the PRO tool is intended to identify. Patients may also be averse to completing PROs due to worry that it may impact on their relationship with their clinician.

2.6.4 Use of Patient Reported Outcomes in practice

Patients are often described as being in charge of their own care, yet their concerns may not be consistently addressed in practice. Modern healthcare aims to increase patients’ well-being and improve quality of life, yet PROs for use in practice are not standardised or regularly used. A review article by Greenhalgh outlines a variety of ways that PROs can be used in practice. In summary, PROs can be used:

- During patient-clinician consultations for screening (e.g. for depression), monitoring (e.g. toxicities, treatment outcomes), and promoting patient-centred care such as supporting shared-decision making.
- To facilitate communication within a multidisciplinary healthcare team.
- To monitor health outcomes at a population level.

Over time it is possible that PROs could be aggregated and fed back to patients to help shape their expectations for treatment side-effects and outcomes. However, the effectiveness of PROs for use in general practice has not yet been adequately demonstrated, partly due to the heterogeneous nature of the studies describing their use, the way they have been applied in practice, and the types of PROs investigated. For example there is clear evidence that the use of PROs for screening purposes promote the detection of problems patients’ experience (such as depression), although there is no evidence that this encourages treatment adjustment or improves patient outcomes.

Identifying specific conditions for outcome reporting may be more appropriate and allow for a more focused and actionable approach. There are a number of studies showing benefit of using PROs in those undergoing chemotherapy, and also evidence for improving outcomes in psychotherapy patients predicted to have a poor treatment response. This may be because there is a defined set of criteria relating to treatment-failure with psychotherapy or toxicity of chemotherapy and that the outcomes of toxicity reports with chemotherapy are defined and targeted.
Therefore it is essential that if used, the PROs are targeted and focused where clear benefit might be obtained. It may be that on further investigation and refinement, PROs could be routinely reviewed alongside other reported information such as laboratory results.\textsuperscript{72}

\section*{2.7 Chapter conclusion}

This chapter described patients’ key requirements for the design and content of their medicine information leaflets, and compared regulatory agencies leaflet content principle and design recommendations against patients’ needs. Furthermore, the chapter discussed the need to provide appropriate digital information, and outlined the benefits and disadvantages of utilising Patient Reported Outcomes (PROs) for improving patient outcomes and involvement in their healthcare.

Some patients want comprehensive medicines information and some only a short summary. Many patients wanted tailored information provided to them, with irrelevant information removed. Ideally, the information given needs to be personalised to individual requirements. The information also needs to be well designed and in language that is easy to understand. Many current medicine information leaflets available in New Zealand do not fully meet patient requirements and could be improved.

Patients may not receive all of the information they require during consultations, and may experience difficulty in recalling what has been discussed with them. This is why providing additional readable information is so important. Unfortunately because providing medicine information leaflets in New Zealand is not mandatory (unlike the European Union), information leaflets are not available for all medicines. Furthermore, even if available, patients may/may not be receiving any printed or digital information with their medicines. This needs to be addressed at a regulatory level.

Many countries, such as the UK and those in the European Union, give specific and comprehensive advice about how information leaflets need to be written. However,
some of this guidance is out-dated and does not follow the 20 good-design principles identified in the commentary (2.4.1). New Zealand has very limited advice on writing leaflets. Perhaps this is because providing medicine information leaflets is not mandatory, so comprehensive and directive advice is not considered necessary by Medsafe.

Providing medicines information to patients has historically been through verbal communication, or more recently through the provision of medicine information leaflets in some shape or form. The rise of the internet has allowed wider access to all sorts of information and misinformation. Healthcare providers must embrace the digital provision of information as many patients appreciate information in this format and the importance that they be directed to a reputable information source cannot be overemphasized. Further to this, digital access gives flexibility to patients with regards to the type and quantity of information they can access. Digital sources also allow for supplementary media (e.g. instructional videos) being incorporated on websites to enhance understanding and engagement.\textsuperscript{120}

Patient Reported Outcomes (PROs) can be utilised to provide even more specialised personalised information to patients. Using aggregated data from collected PROs could enable calculation of specific harm-related risks for groups of patients and aid education on expected treatment outcomes.\textsuperscript{134} This information could also help to predict toxicity issues expected with certain treatments e.g. when expected side-effects with chemotherapy regimens are likely to occur in the cycle. As well as facilitating more effective education of patients, this could help shape future treatment strategies for managing toxicities or disease progression.

Further investigation into healthcare providers’ opinions and use of medicine information leaflets and the verbal information they give to patients during consultation will be conducted using surveys in chapters 3 and 4.

Further investigation into the utilisation of digital technology and Patient Reported Outcomes for medicine management will be undertaken in chapters 5 and 6.
Chapter 3: Verbal communication with patients about medicines

3.1 Synopsis

The gold-standard of care is considered to be verbal discussion accompanied by written information. This would support what has been discussed and provides information for the patient to refer to later. This chapter builds on the previous chapters’ descriptions of what patients want to know about their medicines to see if they are given this information verbally. Because it is not mandatory for GPs and pharmacists to provide information in a written format, we wanted to find out if the medicine information patients want to know is discussed during consultation.

We determined from self-reports that GPs are more likely than pharmacists to talk to patients about their newly prescribed medicines (chapter 3). Less than half of the pharmacists reported that they discuss newly dispensed medicines all of the time. Similarly, GPs were more likely than pharmacists to report discussing most counselling points identified in chapter 2 all or most of the time. Although some counselling points are discussed all or most of the time by GPs or pharmacists, overall patients are not receiving all of the information they want following prescribing and dispensing of their medicines. Therefore, relying on verbal communication to relay all the necessary information to patients is not sufficient.
Chapter structure

This chapter has three parts:

1. **What information is given verbally to patients about their medicines?**
   
   Section 3.3 explores verbal communication with patients and examines what medicine information GPs and pharmacists are talking to patients about during consultations.

2. **Methods, further information.** Section 3.4 describes the methodology of the study in more detail, including the rationale of approaches used.

3. **Limitations, further information.** Section 3.5 describes the limitations around using self-reported data collection when describing participant behaviour. Further limitations of the studies are also described.

### 3.2 Chapter aims

GPs and pharmacists are legally and ethically required to appropriately inform patients about their medicines. This chapter aims to examine New Zealand GPs’ and pharmacists’ verbal communication with patients about their medicines, and to ascertain ways that provision of medicines information could be improved.

A secondary aim of this chapter is to review the limitations of self-reporting when participants are completing health questionnaires and acknowledge the impact this has on the generalisability of the findings of this study.
3.3 What information is given verbally to patients about their medicines?

Published Manuscript Entitled Do health professionals tell patients what they want to know about their medicines?

The manuscript entitled “Do health professionals tell patients what they want to know about their medicines?” was published in the Health Educ J.2018;77(7):762-77.

The co-authors contributed to the manuscript as follows: Survey creation, execution, analysis, and write-up was performed by PhD candidate Amber Young, under the supervision of Dr Alesha Smith and Associate Professor June Tordoff. Dr Sharon Leitch provided advice from a practicing general practitioner perspective. All the co-authors revised the content of the manuscript and approved the final version for publication. The PhD candidate Amber Young was the lead author in manuscript preparation and writing, and corresponding author.

The manuscript is presented as accepted for publication; however, the numbering of the pages, figures, and tables has been adjusted in accordance with the style of this thesis. All references from the manuscript can be found in the section ‘References’ at the end of the thesis. Further details of the methods used and limitations of this study are described in section 3.4 Methods, further information and section 3.5 Limitations, further information.
3.3.1 Do health professionals tell patients what they want to know about their medicines?

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Abstract

Background: Discussing medicines with patients is the responsibility of prescribers and pharmacists. However, it is not well known if patients are given the information they want or if information provision continues when medicines are taken long-term.

Objective: To determine how often general practitioners (GPs) and pharmacists provide verbal information to patients about their medicines, and compare the information given with what patients want to know.

Design: Cross-sectional surveys.

Setting: New Zealand primary health care.

Method: Two questionnaires were developed and sent to a sample of pharmacists and GPs and chi-squared analysis was carried out. Open responses were analysed qualitatively to detect further ideas.

Results: 119 pharmacists and 150 GPs responded. For new medicines, significantly more GPs than pharmacists reported giving verbal information all of the time. Significantly more GPs than pharmacists reported discussing most counselling points all or most of the time. Pharmacists were more likely than GPs to discuss counselling...
points only when requested to by patients. For repeat medicines, significantly more GPs than pharmacists were likely to consider counselling points very important.

**Conclusion**: Patients may not be receiving the information they want to know about their medicines, and there may be an overall lack of verbal communication about medicines with patients. Some information will only be discussed if the patient actively requests it; the likelihood of this increases with repeat medicines. The use of counselling aids and tools, such as a medicine information leaflet, could help healthcare providers provide patients with the information they need.

**Keywords** medicine information, counselling, patient education, medicines education, verbal information, communication

**Introduction**

Optimal use of medications relies on the appropriate choice of drug and patient adherence.\(^2\),\(^1\)\(^\text{8}\) Patient adherence can be diminished by poorly constructed and complicated verbal communication or lack of information.\(^1\)\(^\text{3}\),\(^1\)\(^\text{9}\) Discussing medicines with patients is not the sole responsibility of a single health profession. The prescriber and pharmacist have a duty of care to ensure patients at least know what to take and how to take it. Although pharmacists provide information when dispensing medicines,\(^1\)\(^\text{4}\) in one New Zealand study, General Practitioners (GPs) or hospital-based doctors were considered the primary source of medicine information by 71.5% of patients, but pharmacists by only 0.5%.\(^1\)\(^\text{6}\) Another later survey of 316 people 75 years and over found that 93% would ask their doctors about medicine-related worries, and 32% their pharmacist.\(^5\)\(^\text{6}\) This disinclination to discuss medicine-related queries with pharmacists has also been shown in Australia.\(^1\)\(^\text{6}\),\(^\text{2}\)\(^\text{6}\) However, pharmacist medication counselling is important to ensure patients get their desired information, and can also help reduce adverse events and improve patient satisfaction.\(^1\)\(^\text{4}\)\(^\text{1}\)

Guidelines describe the information patients need about their medicines.\(^4\)\(^\text{2}\),\(^6\)\(^\text{3}\) Many health professionals rely on verbal communication to relay this and do not provide written information such as a medicines information leaflet.\(^2\)\(^6\),\(^1\)\(^\text{4}\)\(^\text{0}\) Because of difficulty in recalling important information about medical treatment,\(^6\)\(^3\),\(^1\)\(^\text{3}\)\(^\text{9}\) reiteration of
information is important, particularly if health professionals are relying on verbal communication to inform patients adequately about their medicines. It is unclear whether patients are being informed when they are prescribed new medicine and when they are prescribed repeated medicines for chronic conditions. Patients on chronic therapy have high rates of nonadherence and misunderstanding about their therapy, yet studies show that people collecting repeat medicines from pharmacies are less likely to undergo counselling than those picking up acute medicines. It is unclear whether GPs or pharmacists in New Zealand consider ongoing medicine counselling for repeat medicines as important. However, ongoing discussion about medicines with patients is essential to encourage adherence and detect any issues with their treatment.

We know what patients want to know about their medicines. Some key information they require is: what the medicine is for, how it helps the condition, and how to take it, risks of taking the medicine (contra-indications, precautions, side-effects, interactions), and monitoring of treatment. Unfortunately, some may not get enough information from their GPs and pharmacists at the point-of-care. Many studies have assessed pharmacists’ medication counselling performance. In a 2009 review, the rates of pharmacist counselling for prescription medicines based on proportions of prescriptions in Finland, the UK, and USA ranged from 60% to 80%. This review found that counselling rates differed depending on the research method used and were higher for self-reports than observation. Overall, 51–100% of pharmacists claimed to provide verbal counselling. Alarmingly, the rate of counselling in some observational studies reviewed was as low as 8%. In a 2009 US study with trained shoppers presenting new prescriptions, only 43 people (43%) received verbal counselling, and of these, 16 instances were prompted by the “patient”. Similar low rates of counselling from community pharmacies in Pakistan were observed in a 2011 study where no counselling at all was given in 52.7% (n = 582) of the observed cases. Studies have also shown that observed discussions between GPs and patients about medicines may be inadequate. Observational studies in New Zealand indicate that counselling times for prescription medicines appear to be short.
there is limited information about what information they give to people collecting prescription medicines.

Furthermore, it is not well known what type of information patients are receiving at point-of-care in New Zealand compared to what patients want to know. The 2009 review\textsuperscript{63} found that, in international studies, information on directions for use, dose, name of medicine, and indications were most commonly given. Medicine warnings such as precautions, side-effects, interactions, contra-indications were less likely to be given. A more recent Swedish observational study from 2014 found that pharmacists spent little or no time counselling patients about medicines with half of discourses about medical/pharmaceutical issues taking 10 seconds or less.\textsuperscript{150} A later study from the Netherlands showed not all necessary counselling points are covered adequately in pharmacy consultations.\textsuperscript{151}

Whilst many of these studies determined if specific points about medicines were covered, there is limited information on what verbal information is given to patients in New Zealand and no studies examining if the information that patients want to know is provided. The aim of this study was to determine from self-reports (i) how often GPs and pharmacists in New Zealand provide verbal information to patients about their medicines; (ii) compare the information given with findings from the authors’ recent review about what patients want to know about their medicines;\textsuperscript{109} and iii) make comparisons between the practices of both professions.

Methods

Questionnaire

A questionnaire was developed (Appendix 3) based on previously validated questionnaires\textsuperscript{140} and the authors’ recent review investigating what details (or counselling points) patients’ want to know about their medicines.\textsuperscript{109} GPs and pharmacists were asked how often they gave verbal counselling about low-risk types of medicines (e.g. an asthma inhaler). Low-risk medicines (e.g. an asthma inhaler) were chosen because they are common in primary care and patients need adequate information to ensure appropriate and safe medicine-use. They were also asked how frequently they discussed specific counselling points about low-risk medicines and the
perceived importance of each point for repeat long-term medicines. This was to identify what counselling points were deemed important as a guide to see what may be discussed during a consultation with patients on chronic therapy. Mostly questions were designed for tick box selection of single responses and included the option of ‘other’ where applicable. Where participants were asked to identify frequencies, *most of the time* was defined as more than half of the time, and *some of the time* was defined as less than half of the time. Three community pharmacists and three GPs were consulted during development by reading over and testing the questionnaires. Minor changes were made following this and the survey was piloted on a total of 10 GPs and 10 pharmacists. The study was approved by University of Otago Human Ethics Committee (Reference number D16/298; Appendix 4).

**Recruitment**

A selection of GPs and pharmacists practising in New Zealand were invited to participate. Following a sample size calculation, it was estimated that 278 responses were required to detect a significant effect (\(\alpha = 0.05\) and 95% CI). To allow for low response rates\(^1\) 600 GPs were selected for inclusion from a list obtained from the primary care advisory organisation bpac\(^{nz}\).\(^2\) Pharmacies were selected using the randomising function in Excel. Four hundred community pharmacies were identified for inclusion from a list created through publicly available records and other sources including the Pharmacy Guild, the School of Pharmacy, and Medsafe (the New Zealand medicines regulatory agency). Pharmacists were asked to participate through the selected community pharmacies and it was expected that 600 pharmacists would be reached. Invited participants were informed that survey participation implied informed consent.

**Data collection**

Questionnaires with a participant information sheet were emailed to potential participants in October 2016. Reminder emails were sent after one and six weeks. SurveyMonkey\(^{\circledast}\) was used to collect data from emailed contacts. Questionnaires and participant information sheets with a reply-paid envelope were posted to those pharmacies who did not have email addresses and those who did not respond to
email. To capture more responses, pharmacist questionnaires were linked to the Young Pharmacist group Facebook page in mid-October 2016 and reposted one week later. All participants had the option to enter into the draw to win a $100 or $50 supermarket voucher as an incentive for participation. The survey was closed for analysis in January 2017. Demographic information was collected for each group including participant’s age, sex, and the location of their practice.

Analysis

The frequency of provision and the nature of verbal information given was analysed for new medicines, and also the perceived importance of the same information given to those taking long-term medicines. Quantitative data underwent descriptive statistical analysis using STATA 13.1. Responses from GPs’ and pharmacists’ were compared using post-hoc chi-squared (χ²(1)) analysis performed at the two-sided 0.05 level. Fisher’s Exact test was undertaken when more than 20% of expected values were below 5. For the provision of verbal information analysis, the Likert scale was simplified by combining ‘never’ and ‘never, this is the role of the pharmacists/doctor’. For the analysis of counselling points for new medicines, the groups ‘all’ and ‘most of the time’ were combined, as were ‘never, the patient does not need to know this’ and ‘never, this is the role of the pharmacists/doctor’. Missing data were reported as ‘no response’.

Open responses were analysed by thematic analysis using an iterative approach by AY to detect further ideas. Qualitative data themes were identified and discussed amongst the research team.

Results

Demographics

Responses from 119 pharmacists and 150 GPs were analysed and demographic characteristic are shown in Table 3. This gave a response rate of 19.8% for pharmacists and 25.0% for GPs. This included responses from 18 pharmacists through the Facebook page. Survey responses from 15 participants were removed from analysis because they had more than 20% missing data.
Table 3: Summary of participants

<table>
<thead>
<tr>
<th>Demographic</th>
<th>GP group</th>
<th>Pharmacist group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>58 (38.7%)</td>
<td>53 (44.5%)</td>
</tr>
<tr>
<td>Female</td>
<td>83 (55.3%)</td>
<td>61 (51.3%)</td>
</tr>
<tr>
<td>No response</td>
<td>9 (6.0%)</td>
<td>5 (4.2%)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>3 (2.0%)</td>
<td>27 (22.7%)</td>
</tr>
<tr>
<td>30-39</td>
<td>32 (21.3%)</td>
<td>34 (28.6%)</td>
</tr>
<tr>
<td>40-49</td>
<td>31 (20.7%)</td>
<td>18 (15.1%)</td>
</tr>
<tr>
<td>50-59</td>
<td>50 (33.3%)</td>
<td>25 (21.0%)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>25 (16.7%)</td>
<td>10 (8.4%)</td>
</tr>
<tr>
<td>No response</td>
<td>9 (6.0%)</td>
<td>5 (4.2%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major City</td>
<td>63 (42.0%)</td>
<td>59 (49.6%)</td>
</tr>
<tr>
<td>Provincial City</td>
<td>37 (24.7%)</td>
<td>30 (25.2%)</td>
</tr>
<tr>
<td>Provincial Town</td>
<td>28 (18.7%)</td>
<td>23 (19.3%)</td>
</tr>
<tr>
<td>Rural</td>
<td>13 (8.7%)</td>
<td>2 (1.7%)</td>
</tr>
<tr>
<td>No response</td>
<td>9 (6.0%)</td>
<td>5 (4.2%)</td>
</tr>
</tbody>
</table>

Compared to the national population of GPs, respondents tended to be of a younger age group but similar distribution for gender. Pharmacist respondents were similar.
ages, but less likely to be female than national representation.\textsuperscript{157} Geographical location was not analysed similarly in national surveys, so comparison was not possible.

Providing verbal information

For new medicines, significantly more GPs than pharmacists reported giving verbal information all of the time (75.3\% vs 43.7\% respectively, $\chi^2(1) 28.0$, $p<0.001$).

For repeat medicines for chronic conditions only 5.3\% GPs and 3.4\% pharmacists stated they would give verbal information all of the time (Figure 6). For both professions, significantly more would advise patients only on request about their repeat medicines compared to a new medicine (GPs 13.3\% vs 1.3\% ($\chi^2(1) 15.9$, $p<0.001$)); pharmacists 37.8\% vs 4.2\% ($\chi^2(1) 40.5$, $p<0.001$)).

\begin{figure}
\centering
\includegraphics[width=\textwidth]{Figure6.png}
\caption{Reported frequency for giving verbal information about new or repeated medicines}
\end{figure}
Counselling points for new medicines

GPs and pharmacists mostly agreed about how often they would discuss counselling points (Appendices 5 and 6), but their most common responses sometimes differed:

- The generic and brand names of the medicine: GPs some of the time (56.7%), pharmacists all or most of the time (48.7%)
- What to do if a dose is missed: GPs some of the time (54%), pharmacists only on patient request (52.9%)
- How to monitor the treatment’s effectiveness (including when to come back if necessary): GPs all or most of the time (87.3%), pharmacists some of the time (37.0%)
- Potential interactions: GPs all or most of the time (51.3%), pharmacists some of the time (43.2%)
- General health tips that would improve treatment outcomes: GPs all or most of the time (70.7%), pharmacists some of the time (58.0%)
- Storage and disposal of the medicine: GPs never (40.7%), pharmacists some of the time (44.5%)
- Information about alternative therapies and treatment options: GPs some of the time (40.0%), pharmacists only on patient request (58.0%)

All other counselling points were mostly discussed all or most of the time by both groups except ingredients in the medicine (e.g. lactose, sugar) and where patients can access further information about the medicine or condition were most likely to be discussed only on patient request.

In response to an open question, a small number of pharmacists claimed to discuss technical issues such as funding or supply issues, stat dispensing, or repeat status. A few in each profession indicated they would discuss the use of a medicine information leaflet or website with their patients.
Types of information given all or most of the time

Significantly more GPs than pharmacists reported giving most counselling points all or most of the time ($p<0.05$) (Table 4, and Appendices 5 and 6). More pharmacists than GPs reported counselling patients on some points (generic and brand name of the medicine and medicine storage and disposal) all or most of the time. No difference was seen between groups for how to take the medicine (administration instructions), missed doses, ingredients, and where patients can access further information about the medicine or condition.

Table 4: Counselling points reported to be used all or most of the time for new, low-risk medicines

<table>
<thead>
<tr>
<th>Counselling point</th>
<th>Doctor n=150</th>
<th>Pharmacist n=119</th>
<th>Chi-squared, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>What the medicine is for</td>
<td>149</td>
<td>93</td>
<td>$\chi^2(1)=33.0$, $p&lt;0.001$</td>
</tr>
<tr>
<td></td>
<td>99.3%</td>
<td>78.2%</td>
<td></td>
</tr>
<tr>
<td>How the medicine helps the condition</td>
<td>140</td>
<td>66</td>
<td>$\chi^2(1)=53.1$, $p&lt;0.001$</td>
</tr>
<tr>
<td></td>
<td>93.3%</td>
<td>55.5%</td>
<td></td>
</tr>
<tr>
<td>Contra-indications and precautions</td>
<td>100</td>
<td>50</td>
<td>$\chi^2(1)=16.3$, $p&lt;0.001$</td>
</tr>
<tr>
<td></td>
<td>66.7%</td>
<td>42.0%</td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: dose and length of treatment</td>
<td>143</td>
<td>96</td>
<td>$\chi^2(1)=14.4$, $p&lt;0.001$</td>
</tr>
<tr>
<td></td>
<td>95.3%</td>
<td>80.7%</td>
<td></td>
</tr>
<tr>
<td>How to monitor the treatment’s effectiveness (including when to come back if necessary)</td>
<td>131</td>
<td>29</td>
<td>$\chi^2(1)=109.1$, $p&lt;0.001$</td>
</tr>
<tr>
<td></td>
<td>87.3%</td>
<td>24.4%</td>
<td></td>
</tr>
<tr>
<td>Monitoring requirements of the drug (if applicable)</td>
<td>122</td>
<td>50</td>
<td>$\chi^2(1)=44.5$, $p&lt;0.001$</td>
</tr>
<tr>
<td></td>
<td>81.3%</td>
<td>42.0%</td>
<td></td>
</tr>
<tr>
<td>Potential interactions</td>
<td>77</td>
<td>43</td>
<td>$\chi^2(1)=5.9$, $p=0.015$</td>
</tr>
<tr>
<td></td>
<td>51.3%</td>
<td>36.4%</td>
<td></td>
</tr>
<tr>
<td>Side-effects and what to do if they are experienced</td>
<td>121</td>
<td>57</td>
<td>$\chi^2(1)=31.8$, $p&lt;0.001$</td>
</tr>
<tr>
<td></td>
<td>80.7%</td>
<td>47.9%</td>
<td></td>
</tr>
</tbody>
</table>
### Counselling point

<table>
<thead>
<tr>
<th></th>
<th>Doctor n=150</th>
<th>Pharmacist n=119</th>
<th>Chi-squared, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Significantly more GPs than pharmacists talk to patients about these points all or most of the time</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestyle information (e.g. drug effect on driving, drinking, sexual activity)</td>
<td>90</td>
<td>56</td>
<td>$\chi^2(1)=4.5$, p=0.03</td>
</tr>
<tr>
<td>No significant difference between GPs and pharmacists</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: administration instructions</td>
<td>105</td>
<td>92</td>
<td>$\chi^2(1)=2.5$, p=0.11</td>
</tr>
<tr>
<td>What to do if a dose is missed</td>
<td>26</td>
<td>18</td>
<td>$\chi^2(1)=0.2$, p=0.63</td>
</tr>
<tr>
<td>Ingredients in the medicine (e.g. lactose, sugar)</td>
<td>2</td>
<td>4</td>
<td>$\chi^2(1)=1.3$, p=0.26</td>
</tr>
<tr>
<td>Where patients can access further information about the medicine or condition</td>
<td>21</td>
<td>14</td>
<td>$\chi^2(1)=0.3$, p=0.59</td>
</tr>
</tbody>
</table>
Types of information given only on patient request

Overall pharmacists were more likely than GPs to discuss counselling points when requested to do so by patients. Significantly more pharmacists than GPs claimed to discuss the following points only on patient request:

- what the medicine is for (5.9% vs 0.7%, $\chi^2(1) 6.3$, p=0.012);
- how the medicine helps the condition (26.9% vs 0.7%, $\chi^2(1) 42.4$, p<0.001);
- contra-indications and precautions (21.8% vs 3.3%, $\chi^2(1) 22.3$, p<0.001);
- how to take the medicine: dose and length of treatment (3.4% vs 0%, $\chi^2 (1) 5.1$, p=0.024);
- what to do if a dose is missed (52.9% vs 24.7%, $\chi^2(1) 5.6$, p=0.018);
- how to monitor the treatment’s effectiveness (including when to come back if necessary) (31.1% vs 0%, p<0.001, Fisher’s exact test);
- monitoring requirements of the drug (if applicable) (25.2% vs 2.0%, $\chi^2(1) 33.2$, p<0.001);
- potential interactions (19.3% vs 2.7%, $\chi^2(1) 20.4$, p<0.001);
- side-effects and what to do if they are experienced (18.5% vs 0%, $\chi^2(1) 30.2$, p<0.001);
- lifestyle information (e.g. drug effect on driving, drinking, sexual activity) (7.6% vs 0%, $\chi^2(1) 11.7$, p=0.001);
- general health tips that would improve treatment outcomes (16.0% vs 2.7%, $\chi^2(1) 15.0$, p<0.001);
- ingredients in the medicine (e.g. lactose, sugar) (80.7% vs 47.3%, $\chi^2(1) 31.3$, p<0.001).

Other points did not have significant difference between professions although those more likely to be discussed by pharmacists only when requested were how to take the medicine: administration instructions, where patients can access further information.
about the medicine or condition, and information about alternative therapies and
treatment options. GPs were more likely to discuss storage and disposal of the
medicines and the generic and brand names of the medicine only when requested,
although no significant difference was found (see Appendices 5 and 6).

Types of information given never discussed
Significantly more GPs than pharmacists reported never counselling about:

- storage and disposal of the medicine (40.7% vs 2.5%, p<0.001, Fisher’s exact
test);
- ingredients in the medicine (e.g. lactose, sugar) (39.3% vs 7.6%, χ²(1) 35.5,
p<0.001);
- where patients can access further information about the medicine or condition
  (7.3% vs 0.8%, χ²(1) 6.6, p=0.01); and
- how to take the medicine: administration instructions (3.3% vs 0.0%, χ²(1) 4.04,
p=0.04).

Pharmacists reported never counselling significantly more than GPs about: how to
monitor the treatment’s effectiveness (including when to come back if necessary)
(7.6% vs 0.7%, χ²(1) 8.8, p=0.003) and monitoring requirements of the drug (if
applicable) (8.4% vs 1.3% respectively, χ²(1) 7.8, p=0.005). Fewer than 10% of
pharmacists stated they never counsel patients on any counselling point.

Comparisons of the medicine information patients want to know with the information
given by GPs and pharmacists can be seen in Table 5.
### Table 5: Comparison of the medicine information most patients want to know with the information given by GPs and pharmacists

<table>
<thead>
<tr>
<th>Counselling points that most patients want to know</th>
<th>GPs</th>
<th>Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>The generic and brand names of the medicine</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>What the medicine is for</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>How the medicine helps the condition</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>Contra-indications and precautions</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>How to take the medicine: dose and length of treatment</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>How to take the medicine: administration instructions</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>What to do if a dose is missed</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>How to monitor the treatment’s effectiveness (including when to come back if necessary)</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>Monitoring requirements of the drug (if applicable)</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>Potential interactions</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
<tr>
<td>Side-effects and what to do if they are experienced</td>
<td>⭐⭐⭐⭐</td>
<td>⭐⭐⭐⭐⭐</td>
</tr>
</tbody>
</table>
## Counselling points that most patients want to know

<table>
<thead>
<tr>
<th></th>
<th>GPs</th>
<th>Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifestyle information (e.g. drug effect on driving, drinking, sexual activity)</td>
<td>★★★★☆</td>
<td>★★★★★</td>
</tr>
<tr>
<td>General health tips that would improve treatment outcomes</td>
<td>★★★★☆</td>
<td>★★★★☆</td>
</tr>
<tr>
<td>Storage and disposal of the medicine</td>
<td>★★★★☆</td>
<td>★★★★☆</td>
</tr>
<tr>
<td>Ingredients in the medicine (e.g. lactose, sugar)</td>
<td>★★★★☆</td>
<td>★★★★☆</td>
</tr>
<tr>
<td>Where patients can access further information about the medicine or condition</td>
<td>★★★★☆</td>
<td>★★★★☆</td>
</tr>
<tr>
<td>Information about alternative therapies and treatment options</td>
<td>★★★★☆</td>
<td>★★★★☆</td>
</tr>
</tbody>
</table>

★★★★★ given *all or most of the time* by more than 75% of responders

★★★★☆ given *all or most of the time* by most, but less than 75%, of responders

★★★★★ given *all or most of the time* by most, but less than 50%, of responders

★★★★☆ given *some of the time* by most responders

★★★★★ given *never, or only on patient request* by most responders
Information for patients with repeat medicines

GPs and pharmacists were asked to evaluate the importance of each counselling point for users of long-term medicines. Overall, significantly more GPs than pharmacists were likely to consider most counselling points very important and pharmacists were more likely to consider counselling points not important (Table 6, Figure 7, and Figure 8). The three counselling points considered very important by most GPs were what the medicine is for, how to take the medicine: dose and length of treatment, and how to monitor the treatment effectiveness.

**Table 6: Counselling points viewed as very important for patients’ low-risk repeat medicines**

<table>
<thead>
<tr>
<th>Counselling point</th>
<th>GP n=150</th>
<th>pharmacist n=119</th>
<th>Chi-squared, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>What the medicine is for</td>
<td>114</td>
<td>53</td>
<td>χ²(1)=27.9, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>76.0%</td>
<td>44.5%</td>
<td></td>
</tr>
<tr>
<td>How the medicine helps the condition</td>
<td>95</td>
<td>41</td>
<td>χ²(1)=22.1, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>63.3%</td>
<td>34.5%</td>
<td></td>
</tr>
<tr>
<td>Contra-indications and precautions</td>
<td>76</td>
<td>29</td>
<td>χ²(1)=19.3, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>50.7%</td>
<td>24.4%</td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: dose and length of treatment</td>
<td>103</td>
<td>55</td>
<td>χ²(1)=13.8, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>68.7%</td>
<td>46.2%</td>
<td></td>
</tr>
<tr>
<td>How to monitor the treatment’s effectiveness (including when to come back if necessary)</td>
<td>99</td>
<td>23</td>
<td>χ²(1)=58.3, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>66.0%</td>
<td>19.3%</td>
<td></td>
</tr>
<tr>
<td>Monitoring requirements of the drug (if applicable)</td>
<td>93</td>
<td>38</td>
<td>χ²(1)=24.0, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>62.0%</td>
<td>31.9%</td>
<td></td>
</tr>
<tr>
<td>Potential interactions</td>
<td>68</td>
<td>33</td>
<td>χ²(1)=8.8, p=0.003</td>
</tr>
<tr>
<td></td>
<td>45.3%</td>
<td>27.7%</td>
<td></td>
</tr>
<tr>
<td>Side-effects and what to do if they are experienced</td>
<td>92</td>
<td>44</td>
<td>χ²(1)=15.8, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>61.3%</td>
<td>37.0%</td>
<td></td>
</tr>
<tr>
<td>Counselling point</td>
<td>GP n=150</td>
<td>pharmacist n=119</td>
<td>Chi-squared, p-value</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>----------</td>
<td>-----------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Significantly more GPs than pharmacists considered these points very important</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General health tips that would improve treatment outcomes</td>
<td>92</td>
<td>41</td>
<td>$\chi^2(1)=19.2$, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>61.3%</td>
<td>34.5%</td>
<td></td>
</tr>
<tr>
<td>Where patients can access further information about the medicine or condition</td>
<td>43</td>
<td>13</td>
<td>$\chi^2(1)=12.7$, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>28.7%</td>
<td>10.9%</td>
<td></td>
</tr>
<tr>
<td>Information about alternative therapies and treatment options</td>
<td>22</td>
<td>7</td>
<td>$\chi^2(1)=5.3$, p=0.02</td>
</tr>
<tr>
<td></td>
<td>14.7%</td>
<td>5.9%</td>
<td></td>
</tr>
<tr>
<td><strong>Significantly more pharmacists than GPs considered these points very important</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The generic and brand names of the medicine</td>
<td>20</td>
<td>33</td>
<td>$\chi^2(1)=8.7$, p=0.003</td>
</tr>
<tr>
<td></td>
<td>13.3%</td>
<td>27.7%</td>
<td></td>
</tr>
<tr>
<td><strong>No significant difference in views between GPs and pharmacists</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: administration instructions</td>
<td>72</td>
<td>49</td>
<td>$\chi^2(1)=1.2$, p=0.26</td>
</tr>
<tr>
<td></td>
<td>48.0%</td>
<td>41.2%</td>
<td></td>
</tr>
<tr>
<td>What to do if a dose is missed</td>
<td>25</td>
<td>19</td>
<td>$\chi^2(1)=0.0$, p=0.88</td>
</tr>
<tr>
<td></td>
<td>16.7%</td>
<td>16.0%</td>
<td></td>
</tr>
<tr>
<td>Lifestyle information (e.g. drug effect on driving, drinking, sexual activity)</td>
<td>88</td>
<td>57</td>
<td>$\chi^2(1)=3.1$, p=0.08</td>
</tr>
<tr>
<td></td>
<td>58.7%</td>
<td>47.9%</td>
<td></td>
</tr>
<tr>
<td>Storage and disposal of the medicine</td>
<td>22</td>
<td>28</td>
<td>$\chi^2(1)=3.4$, p=0.06</td>
</tr>
<tr>
<td></td>
<td>14.7%</td>
<td>23.5%</td>
<td></td>
</tr>
<tr>
<td>Ingredients in the medicine (e.g. lactose, sugar)</td>
<td>4</td>
<td>6</td>
<td>$\chi^2(1)=1.0$, p=0.31</td>
</tr>
<tr>
<td></td>
<td>2.7%</td>
<td>5.0%</td>
<td></td>
</tr>
</tbody>
</table>
**Figure 7: Counselling points considered very important for repeat medicines**

<table>
<thead>
<tr>
<th>Topic</th>
<th>GP</th>
<th>Pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine generic and brand names</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What the medicine is for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How the medicine helps the condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contra-indications and precautions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicine dose and length of treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicine administration instructions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What to do if a dose is missed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring efficacy (e.g. when to come back)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug monitoring requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential interactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side effects and what to do if they occur</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestyle effects (driving/drinking/sexual)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General health tips to improve outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicine storage and disposal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicine ingredients (e.g. lactose, sugar)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where to access further information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alternative therapies and treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 8: Counselling points considered not important for repeat medicines**
In response to an open question a small number of pharmacists indicated that patient counselling in the current session depended on what was covered in a previous session. Likewise, a few in each profession indicated the key points covered would depend on patient need or type of medicine being taken.

Discussion

This study suggests some patients in New Zealand may not be receiving adequate information about their newly prescribed medicines. Ongoing communication and education about medicines appears even less likely when they are prescribed for chronic conditions. Furthermore our previous review investigated what information patients want to know about their prescribed medicines and determined that specific information is often desired. For this study, we labelled the specific information as “counselling points” (Tables 5 and 6) and determined if GPs and pharmacists discuss these points with their patients. The present study indicates that patients are often not given the specific information they desire. Self-reports suggest New Zealand GPs discuss most counselling points more frequently than pharmacists; pharmacists are more likely to discuss the medicine formulation and administration. Many counselling points are discussed only if requested by the patient.

Significantly more GPs than pharmacists considered most counselling points very important for repeat medicines. Nevertheless, the results from this study suggests that counselling patients with repeat medicines is not regular practice for either profession.

Providing verbal information

The present study suggests GPs and pharmacists do not verbally inform patients about new medicines all of the time. Three quarters of GPs and less than half of the pharmacists reported doing this. This is in contrast to studies in Australia where pharmacists and consumers indicate information is given all of the time with new medicines. Though as discussed earlier the counselling rates varied hugely and was more positive in self-reports. Methods other than self-reports, including mystery shoppers and direct observations tend to have lower observed counselling rates.
Informing patients about their medicines before they start treatment is written into New Zealand health professional standards. The fact that many respondents indicated they do not orally communicate with patients all of the time highlights the difference between ideal practice and what can be achieved in the real world.

For repeat medicines, the majority of participants said they would only give information some of the time. However compared to new medicines, more GPs and pharmacists would rely on patients requesting the information rather than giving it spontaneously, possibly because of an expectation that patients will remember what has been told to them previously.

It is worth noting that GPs report more frequent verbal counselling than pharmacists for new and long-term medicines. This may be because (i) GPs have a one-to-one counselling opportunity, (ii) the professionals perceive their roles differently and (iii) pharmacists could lack information (e.g. medicines indication) required to counsel effectively. Nevertheless, there is an opportunity for pharmacists to take a more proactive role in informing patients about their medicines. However, community pharmacies in New Zealand may struggle to engage in thorough clinical counselling for every patient with every visit, and the stresses of fitting in all the required counselling into the available time is a concern facing both professions. This is also a problem facing pharmacists internationally where pharmacy income is based on number of items dispensed or sold rather than patient counselling. Furthermore, lack of time is of international concern in community pharmacy practice and is often identified as a barrier to provision of services.

Given the above, healthcare providers should be encouraged to provide patients with an appropriate information leaflet about medicines. This will help ‘fill in the gaps’ around counselling points that are unable to be covered at the time. This would also be beneficial for patients who are unwilling to receive counselling at point-of-care. This is of particular importance in countries like New Zealand and Australia where providing information leaflets to patients is not mandatory as it is in the UK. Less than a third of patients in Australia may receive leaflets.
Counselling points for new medicines

Most guidelines recommend that counselling about medicines should satisfy the needs of the patient.In the present study, only what the medicine is for, how the medicine helps the condition, and the dose and length of treatment are reportedly discussed all or most of the time by over 90% of GPs (see Appendix 6), which was much higher than reported by pharmacists. Furthermore, GPs appear to discuss other counselling points with patients more often than pharmacists. However, what happens in actual practice was not determined.

Patients often feel they are not getting all the information they want. The literature highlights the disparity between what health professionals consider patients should know, and what patients themselves want to know. Health professionals more frequently discuss how to take the medicine and how the medicine will help the condition to aid compliance and decision making.

In the present study, almost all GPs and over half of pharmacists reported discussing this with patients all or most of the time. In comparison, most patients are more likely to be concerned about the risks of the medicines (including side-effects, potential interactions, and precautions). Nevertheless, this information is sometimes intentionally withheld by prescribers. In this study, GPs and pharmacists were less likely to discuss these risks all of the time or most of the time compared to discussing the possible benefits. Consistent with other studies, both professions frequently commented that giving side-effect information would increase patients’ anxiety and reduce compliance. A recent Swedish study demonstrated that community pharmacists spend very little, if any, time discussing clinical medicine information.

In this study, only the medicine name, ingredients, administration, storage and disposal instructions were predominantly provided by pharmacists (see Appendix 5). This was consistent with the Swedish study where pharmacists only discussed ‘non-medical’ counselling points. In Australia, however, pharmacists reported frequently discussing a wide range of counselling points with prompting from a consumer medicine information leaflet. Possibly using counselling tools and medicine
information leaflets as prompts for discussion in practice could help improve the
information being provided to patients by pharmacists.

The counselling point General health tips that would improve treatment outcomes is
an important addendum to medicine counselling to optimise treatment outcomes.
Ideally this should be given with all prescriptions to optimise benefits. Over two-thirds
of GPs in this study reported providing this information, but only about a quarter of
pharmacists reported this. Counselling about lifestyle interventions (e.g. diet and
exercise) is essential, particularly for conditions linked to the growing obesity epidemic
where modifications can have huge benefits for patients’ morbidity.

Counselling points appeared to be discussed by both professions to varying degrees.
Many counselling points were frequently only discussed when requested by the
patient. This indicates patients would not receive the information because many
would not think to ask about these individual points. These findings emphasise the
need for other methods of educating patients, such as providing information leaflets
to patients for both new and repeat medicines, to ensure patients are receiving the
required information if it is not given verbally.

Information for patients with repeat medicines
In the present study, GPs viewed counselling points as very important more frequently
than pharmacists. However, most GPs claimed they only discussed repeat medicines
some of the time (i.e. less than half of the time). This suggests possible discrepancies
between aspirations and practice and it has been demonstrated that self-reports may
show more positive outcomes than observational studies.63

Less than half the pharmacists considered any particular counselling point very
important. It has often been demonstrated that after the first dispensing, patients are
less likely to be counselled about their medicines.63, 140 This may be due to time
constraints,139 patients not wanting further information,26, 140 or the incorrect
assumptions that patients remember what they have been told during initial
discussions.138 Of note, slightly more GPs considered the positives (what the medicine
is for and how it helps the condition) than the negatives (risks of the medicine) very important which is a common opinion of health professionals.²

Limitations
Selection bias may have arisen due to the nature of recruitment, with participants interested in patient education possibly more likely to respond. Further bias could have resulted from participants incorrectly reporting practices; this was potentially mitigated with anonymity in survey responses.

Busy health professionals may have low response rates to surveys.¹¹³ However, the response rate was lower than expected and although statistical differences between the groups were demonstrable, the results may lack substantive significance in practice.

Because of the above, the findings are only indicators of what may be occurring in practice. Further research is necessary before drawing conclusions about medicine counselling more widely in New Zealand practice. The questions in the survey did not quantify the information given so it was not possible to know the extent or quality of information given. It was also not determined if respondents used counselling aids during consultation, such as medicine information leaflets, so complete methods of patient education used could not be elucidated.

Conclusion
Results from this study indicate that patients in New Zealand are likely to receive some verbal information with new medicines all or most of the time from GPs or pharmacists. With chronic therapy, continuing medicine counselling is less likely. The question remains if this is sufficient for their needs in these situations. Furthermore, the information provided by health professional groups may differ. General practitioners report they are more likely than pharmacists to discuss many counselling points including the clinical information (purpose of the medicine, how it might help the patient’s condition). Pharmacists are more likely than GPs to advise on practical aspects (how to administer the medicine, medicine formulation). Some information may only be provided if requested by the patient. Neither profession appear to
consistently cover all of the counselling points that the literature suggests patients in general want to know for both new and repeat medicines. Adequate verbal counselling about medicines may be difficult to achieve in practice. The use of counselling aids and tools such as medicine information leaflets should be encouraged, when leaflet provision is not mandatory, to ensure patients have access to information they need.

3.4 Methods, further information for the GP and pharmacist studies

Two surveys were created for this project, one investigating verbal counselling practices (as discussed in chapter 3), and one investigating the use of, and opinions on, medicine information leaflets (discussed in chapter 4, sections 4.3 and 4.4). These surveys were sent to both GPs and pharmacists in New Zealand. In the interest of brevity, the additional methods described below relate to both of these surveys. Figure 2 (xxviii) shows how the research questions map to the research objectives of the thesis.

Rationale of methods chosen

Quantitative questions

A quantitative method was chosen to statistically analyse responses and compare findings to similar international research, as well as comparing practice between pharmacists and doctors. A survey with quantitative questions could also potentially obtain a larger sample of people than a qualitative study and be more able to assure generalisability of the findings.

Scales were used in parts of the surveys to gather quantitative data. Due to limits on individual cognitive processing and ability to recall, we used scales as estimation strategies, as is typical practice. We based our scales on similar studies; however, we thought if we used short scales (Yes/No/Do not know) we might miss some high

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quality data, so to allow for more discriminating data we had more options for response.

Qualitative questions
Where we felt that further strength and depth could be added to the research findings, we included some qualitative questions for analysis. These were included where we wanted information about participants’ perceptions and we wanted to understand the reality of practice, and participants to explain in their own words ‘why’ they acted as they did in practice.

Questionnaire validity
The questionnaires were developed based on previously validated questionnaires.\textsuperscript{140} Questions added were extensions of the concepts investigated in this larger Australian study.

In the present study, a research team consisting of academics, pharmacists and a GP were consulted and provided feedback on the validity of the questions. Face and content validity were determined from having the research team involved in questionnaire creation to ensure suitability and comprehensibility to target groups. The research team focused on these three concepts:\textsuperscript{163}

1. Content standards (will questions determine what we want to know?)
2. Cognitive standards (are questions able to be understood and responded to appropriately and consistently?)
3. Usability standards (can the survey instrument be easily completed as intended?).

The research team assessed whether the content of the questions is measuring the intended concepts and whether other aspects were missed and needed addressing, and whether the questions met the cognitive and usability standards (i.e. checked that questions were clear and unambiguous). Concurrent validity was assured by comparing responses to other validated surveys\textsuperscript{140} with many comparative results being obtained. Construct validity was considered by reviewing whether based on
relevant existing knowledge, and the questions included were relevant to measure what was intended by the research team.

Following the creation of the questionnaire and expert review, the questionnaires were pilot tested in a small subset of the intended population (20 GPs and pharmacists) using the same modes of data collection as proposed for the study. This was to assess readability and understanding. When piloted, we included three extra questions:

1. Did you have trouble understanding the questions?

2. How did you find the length of the survey?

3. Did you feel you could answer the questions truthfully?

Responses to the first question identified an error in the web-based survey program that needed amending, and a clarification needed around one question in the survey (we changed ‘on patient request’ to ‘only on patient request’ in the verbal counselling questionnaire). One respondent thought the survey too long, but others thought it was fine so no change was made to the length. All who contributed responded that they could answer truthfully.

The verbal counselling questionnaire was estimated to take 10 minutes to complete and the use of, and opinions on, medicine information leaflets survey was estimated to take 15 minutes to complete.

**Survey dissemination**

We determined the sample size needed for each group to be 278,\textsuperscript{152} based on the estimation that there are approximately 1000 GP practices and over 900 community pharmacies in New Zealand. We chose a 95% confidence interval with a significance level set at 0.05. ($\alpha = 0.05$ and 95% CI). To allow for low response rates,\textsuperscript{153} we aimed to recruit 600 GPs and 600 pharmacists for participation.

Email was chosen as the most appropriate method of reaching large numbers of health professionals as it is a rapid method of communicating. In addition, we could send a direct link to an electronic survey with easy-to-use software. We also had
access to email lists so we felt that this would be a convenient and suitable means of sending a survey. We wanted to be cautious with the reminders, to avoid annoying potential participants. Both groups are busy health professionals and are often contacted by universities to complete surveys. Therefore, we decided that we would send out the initial reminder after one week. This seemed appropriate for those who might have intended to complete the survey later, but lost it in their emails. We considered that another attempt at the six-week mark might perhaps capture those who had not wanted to complete it at the time but who were now more willing to do so. We thought that two reminders would be sufficient and further attempts might cause annoyance.

We mailed out a paper copy of the surveys to pharmacies without known email addresses. Additionally, it became apparent that we were not receiving the numbers of responses we were aiming for from pharmacy, so we posted paper copies on 18 November 2016 to encourage those who had not responded to the email request for participation. (This was two days after their second email reminder and just over six weeks after their original email). For the verbal counselling practice survey (chapter 3) we received 48 responses from pharmacists by post (out of a total 119) and for the use of, and opinions on medicine information leaflets survey (chapter 4) we received 51 responses from pharmacists by post (out of a total 126).

The pharmacist surveys were also posted on Facebook after low completion rates were identified in the pharmacist group. The Facebook page used was the “New Zealand Young pharmacists” group. This is a private group set up on Facebook for young practitioners in New Zealand. We decided that it could also provide useful data from pharmacists who are from a younger demographic than pharmacy owners, who may be the people with access to post and email and be more likely to receive the other surveys sent by post or email. However, the impact on responses was small. There were only 18 further respondents in the verbal counselling practice survey (chapter 3) and 16 respondents in the use of, and opinions on, medicine information leaflets survey (chapter 4).
3.5 Limitations, further information

The limitations in this section describe the limitations of the studies in chapter 3 and chapter 4 of this thesis.

General limitations of the studies

Questionnaire

Whilst validity was determined for the survey, there was no statistical investigation into the reliability of the instrument. This lack of statistical analysis on reliability is a limitation of this and other questionnaires used in this thesis.

Recruitment

The databases of GPs and pharmacies used to recruit from were substantial but not exhaustive for all GPs and pharmacies in New Zealand. We acknowledge that we may not have captured all the possible ones in New Zealand by using our list. The GP database included a large proportion of the GP workforce, however, it did not list every practising GP, and there were some who contacted us stating they no longer practised. Because we had originally contacted many more than required by the sample size calculation, we did not add any more to our email list for inclusion.

The limitations of using the pharmacy database was that the email or letter only went to the pharmacy, not individual pharmacists. Thus only one person might have responded out of a possible multiple number of pharmacists. We tried to counteract this with using the Facebook group and also by encouraging those participants in pharmacies to ask their colleagues to complete the survey and/or be willing to be sent the other survey investigating the other topic. The limitation of using the Facebook group for recruitment was that we could not estimate the sample size we were trying to recruit from. The group currently (as of 2021) has 1255 members but we could not adequately determine the number of users who saw the post. This affects the response rate; however, we had very few responses from Facebook (18 in the verbal counselling practices survey (out of a total 119) and 16 in the use of, and opinions on,
medicine information leaflets survey (out of a total 126)) and it can be considered the overall the impact from this group is minimal.

Furthermore, a two-pronged approach to survey dissemination, the print and posted and web-based survey, was utilised to recruit for the pharmacy group. Web-based surveys are less costly and were our intention, but we did not have email contact details for all pharmacies whereas the postal addresses were all publicly available. A mixed-mode strategy (mail and web-based survey delivery) may minimise non-response so that is a benefit of undertaking this strategy. However, there is a risk that different visual layouts for questions may produce different responses from participants and this phenomenon was not explored as differences between web-based responses and mailed responses were not evaluated.

Response rate and participants
The questionnaire investigating use of, and opinions on, medicine information leaflets took approximately 5 minutes longer to complete than the verbal counselling questionnaire and there were more participants who had more than 20% of responses missing (29 removed compared to 15). The questionnaire may have been too long for busy professionals to complete.

The low number of responses to both studies has an impact on the power of the findings. Therefore we cannot reject the null hypothesis to say there is a difference between the groups (all GPs compared to all community pharmacists). The low response rate also prevented us from performing more in-depth statistical analysis with the data. We can only say there was a difference between our groups of respondents, but this may not be able to be extrapolated to whole population of GPs and pharmacists. Whilst disappointing that we could not achieve our aim for recruitment we felt that the results do provide an estimate of what is happening in practice and we were still able to get valuable information from individual GPs and pharmacists about their opinions and experience.

The demographics of respondents in both surveys differed slightly to the population of GPs and pharmacists in New Zealand. Compared to the national population of GPs,
respondents tended to be of a younger age group.\textsuperscript{156} With regard to informing patients about medicines, younger GPs’ experiences, attitudes, and techniques may differ from those of older GPs. Arguably capturing their attitudes and opinions is very important as the younger ones are the future of general practice, which is a known aging workforce with a large population due to retire within the next 10 years.\textsuperscript{156} Therefore, weighted capturing of the younger groups opinions may be pertinent to understand what will be happening in the future. The pharmacist participants had a similar age distribution to the national cohort, but more males participated in the research compared to national cohort of male to female ratio.\textsuperscript{157} Despite this, there were still more female than male respondents in the pharmacy group for both surveys. It has been suggested that female pharmacist can have increased job satisfaction through increased interactions with patients compared to males.\textsuperscript{166} However, conclusions for this difference could not be drawn because comparison in responses between genders was not undertaken.

**Limitations of self-reports**

Bias in any form will impact the generalisability of findings in research. A common bias that may have resulted in the recruitment process of these studies is selection bias. Selection bias can result in people choosing to participate in a study because they have a strong opinion about the concept investigated. However, the responses displayed diverse opinions, with a wide variety of thoughts expressed. Because of the wide spectrum of data gathered it could be assumed that selection bias for or against a concept was not an issue in these investigations.

This section will briefly describe another such bias commonly introduced when using questionnaires to describe participant behaviour and the actions taken to minimise risk.

These studies utilised a questionnaire for GPs and pharmacists to complete, with a focus on how they inform patients about their medicines. A limitation of this method is the reliance on true-reporting from the participant. It has long been recognised that some participants feel a social desirability to report attitudes or activities that present them more favourably to the research team. Inaccuracy in self-reporting can arise
from intentionally responding incorrectly to questions, or through ‘self-deception’ where participants believe the incorrect information they are reporting to be true.\textsuperscript{167} 
\textsuperscript{168} This phenomenon is called social desirability bias (SDB) and has been concerning for those undertaking survey-based research for many decades.\textsuperscript{168,169}

There are several methods for estimating potential social desirability bias in surveys, varying in complexity and degree of validation.\textsuperscript{169} However, health care professionals response to surveys can be low\textsuperscript{153} and inclusion of a social desirability scale section of the questionnaire would have negatively impacted response rate due to question-overload. In view of this, the research team identified ways to minimise SDB within the questionnaire responses. These included using a questionnaire format, rather than an interview or focus group;\textsuperscript{167} ensuring that participant anonymity is upheld;\textsuperscript{168} and basing the surveys on previously validated questionnaires.\textsuperscript{140} Furthermore, when the questionnaires were piloted, we asked participants if they felt they could answer the questions truthfully and all of the pilot participants responded yes to this question. However, we acknowledge that the risk of SDB is high even if responses are anonymous when there is both patient and fellow health professional expectations about certain professional standards of care that participants should conform to.\textsuperscript{167} This was also potentially mitigated by having two differing questionnaires sent to different health professionals; one for verbal counselling and one investigating use of written communication for counselling (see chapter 4). This split was purposeful because although informing patients about medicines in New Zealand is mandatory, guidelines do not specify what format this must be in. Thus some practitioners may prefer verbal discussion and not provide information leaflets and others may prefer leaflets and be less inclined to provide patients with a full verbal description of their medicines. This split was successful because responses by participants did not display overly favourable results for either profession and proved that improvement in both practices is still required. In the future, when investigating the current delivery of health information practices, adopting a validated technique to determine the potential social desirability bias when respondents are participating in questionnaires would be useful.
3.5 Chapter conclusion

This chapter described what GPs’ and pharmacists’ discuss with their patients about their new and repeated medicines through self-reports. The study examined the frequency of provision of certain counselling points (i.e. those identified in chapter 2) and the perceived importance of these for patients being prescribed repeat medicines for chronic conditions.

In general, GPs reported they discuss patients’ medicines with them more often than pharmacists when they are prescribing new medicine. However, it is apparent that patients could be prescribed and dispensed a new medicine without receiving adequate verbal information from their GP or pharmacist. Some patients may not think to ask for specific information when talking to their GP or pharmacist at point-of-care, and so may miss useful information about their treatment or need to look elsewhere for information.

Both health professions reported they are more likely to only discuss repeat medicines with patients some of the time or if requested by the patient. This is an understandable finding since the information may have already been covered and some therapies may have been safely taken for a number of months or years. Knowing that patients struggle to remember what they have been told about their medicines and in some cases may have been given inadequate information in the first place it would seem prudent to continue to discuss the medicine with the patient as treatment continues—perhaps it could be incorporated in an annual medicine review.

The type of medicine investigated in this study was low-risk type of medicine (though no medicine is considered risk-free from causing harm) so it could be assumed that for high-risk medicines these health professions may have more stringent verbal counselling practices. In saying this, it is a requirement that all patients must be fully informed about their medicines, not just those receiving high-risk medicines.

The findings from this self-reporting survey leads to the unmistakeable conclusion that verbal communication cannot be relied upon in practice because it is not adequately accomplished by GPs or pharmacists for every patient given new medicines. Even
when verbal communication about medicines is undertaken at point-of-care, not all information that patients want to know is discussed with them. Although improving verbal communication with patients is important, it is an unrealistic goal to discuss every aspect of information about medicines at point-of-care. Patients must be provided with other forms of information such as medicine information leaflets or links to reputable websites to ensure they know about the medicines they are taking. We examine this further in chapters 4 and 6.

The limitations of this research include social desirability bias and the small number of participants. Although some measures were taken to minimise bias, a larger study is needed to make comprehensive and certain recommendations for a change in clinical practice.

Examination of New Zealand GPs and pharmacists opinions about medicine information leaflets, the delivery of leaflets to their patients, and discussion about ways in which provision of written information could be improved is reported in chapter 4.
Chapter 4: Leaflet provision in New Zealand

4.1 Synopsis

The previous chapter identified that patients are not receiving all of the medicine information they want to know via discussions with their GPs and pharmacists. Verbally discussing information with supplementary written communication is ideal. However, if verbal communication is not up to the appropriate standard, routine provision of an information leaflet should then be considered as a minimal requirement for ensuring patients are knowledgeable of their treatment benefit and potential harms. We wanted to determine if patients are receiving medicine information leaflets to fill the gaps in verbal communications from their GP or pharmacist.

This chapter analyses self-reports and opinions given in two studies. The first study involved GPs and pharmacists (sections 4.3 and 4.4), investigating their provision and opinions of medicines information leaflets. We ascertained from self-reports that GPs and pharmacists are not giving medicine information leaflets to their patients all of the time, however most GPs and pharmacists agreed that leaflets should be provided to patients when they are given a new medicine. There are many reasons that GPs and pharmacists liked and disliked the leaflets available to them, which could influence their provision. Having summary and/or tailored leaflets available, more time with patients, and automatic prompting in software at point-of-care could improve leaflet delivery.

The second study involved patients (section 4.5), investigating how they are provided with medicine information leaflets from their GPs and their opinions of these. We found that in the last six months most patients had not received a leaflet from their GP, although the majority of participants thought it was important, particularly with
newly prescribed medicines. Most patients who received leaflets liked them, and found them easy to read and understand.

These studies show that patient information leaflets about medicines are considered important by health professionals and their patients, however the provision of leaflets could be improved in practice.

Chapter structure

This chapter has three distinct parts:

1. **Provision of medicines information leaflets and how they are perceived by health professionals.** Section 4.3 describes the findings from a study investigating whether New Zealand general practitioners (GPs) or pharmacists give medicine information leaflets to their patients, where they source these leaflets from, how they provide leaflets to their patients, and what they like and dislike about the leaflets that are available. This section includes a published manuscript.

2. **Using websites for medicine information and improving provision of leaflets**
Section 4.4 expands on the information from the first section, investigating whether GPs and pharmacists recommend websites to patients to read about their medicines. It also investigates what GPs and pharmacists think would facilitate the provision of leaflets in their practice. This section includes a published manuscript.

3. **Patients’ opinions on medicines information leaflet provision and usefulness.**
Section 4.5 describes the findings from a study investigating, from a patient’s perspective, GPs’ provision of medicine information leaflets. It also determines if patients like the leaflets given to them, how they use them, and if they want leaflets to be provided by their GPs. This section includes a published manuscript.
4.2 Chapter aims

Providing patients with written information along with verbal communication optimises their ability to understand and recall information about their medicine. This chapter aims to examine New Zealand GPs’ and pharmacists’ opinions about medicine information leaflets, their delivery of leaflets to their patients, and determine ways in which provision of written information could be improved.

Specific aim 1: To examine self-reported provision of medicine information leaflets by New Zealand GPs and pharmacists.

Specific aim 2: To examine what GPs and pharmacists like and dislike about the leaflets currently used in practice, and to determine whether they support tailoring of information leaflets to patients’ needs.

Specific aim 3: To determine how often GPs and pharmacists recommend websites to patients to read information about their medicines.

Specific aim 4: To understand why GPs and pharmacists do not use medicine information leaflets and to explore factors that might improve written medicine information provision to patients.

Specific aim 5: To examine patients’ estimations of receiving leaflets from their GP and their opinions and uses of the leaflets that they have been given.
4.3 Provision of medicines information leaflets and how they are perceived by health professionals

Published Manuscript Entitled Doctors and pharmacists provision and opinions of medicines information leaflets in New Zealand

The manuscript entitled “Doctors and pharmacists provision and opinions of medicines information leaflets in New Zealand” was published in the Int J Clin Pharm 2018;40(3):676-85.

The co-authors contributed to the manuscript as follows: Survey creation, execution, analysis, and write-up was performed by PhD candidate Amber Young, under the supervision of Dr Alesha Smith and Associate Professor June Tordoff. Dr Sharon Leitch provided advice from a practicing general practitioner perspective. All the co-authors revised the content of the manuscript and approved the final version for publication. The PhD candidate Amber Young was the lead author in manuscript preparation and writing, and corresponding author.

The manuscript is presented as accepted for publication; however, the numbering of the pages, figures, and tables has been adjusted in accordance with the style of this thesis. All references from the manuscript can be found in the section ‘References’ at the end of the thesis. Further details of the methods used and limitations of this study are described in section 3.4 Methods, further information and section 3.5 Limitations, further information.
4.3.1 Doctors and pharmacists provision and opinions of medicines information leaflets in New Zealand.

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Abstract

**Background:** Providing verbal medicines information to patients may be insufficient. Medicine information leaflets could benefit provision, however New Zealand health professionals’ opinions or use of leaflets is unknown.

**Objective:** To examine self-reported provision and health professionals’ views about medicine information leaflets and to determine their support for tailoring patient leaflets.

**Setting:** A cross-sectional survey of general practitioners (GPs) and community pharmacists in New Zealand primary care.

**Method:** GPs and pharmacists completed validated questionnaires. Data was collected using SurveyMonkey® and where applicable, chi-squared analysis was carried out.

**Main outcome measures:** Frequency of leaflet provision, how leaflets are used in practice and why, likes and dislikes of available leaflets, and opinions on providing tailored information.

**Results:** 143 GPs and 126 pharmacists responded. For new medicines, significantly more pharmacists than GPs reported providing leaflets *all or most of the time*. For repeat medicines, leaflets were more likely to be given *only on request*. Leaflets were given to ensure patients are well-informed. Most GPs and pharmacists report discussing sections of leaflets with patients. The likes and dislikes of leaflets were mostly about design and content. Both professions support tailoring leaflets to meet individual’s requirements.

**Conclusions:** Provision of medicines information needs to be re-evaluated. Relying on verbal communication is inadequate and leaflet provision appears to be suboptimal. Making leaflets more patient-centred and accessible could improve health
professionals’ perceptions and use of them. Automated creation and provision of tailored summary leaflets would be beneficial. Further advantage could be gained by digital patient access.

**Keywords** medicine information; counselling; patient information leaflet; patient education; tailored information; New Zealand

**Impact Statements:**

- GPs and pharmacists should consider using medicine information leaflets regularly as a counselling tool.
- The provision of medicine information leaflets for repeat long-term medicines should be encouraged.
- Access to suitable medicine information leaflets needs to be improved for use at point-of-care.

**Introduction**

Patients receive variable amounts of verbal medicine information from health professionals\(^7\)–\(^9\),\(^63\) and leaflets may be a key source of medicine information.\(^40\) Recall of verbal information given at point-of-care is known to be low,\(^7\)–\(^9\),\(^26\),\(^28\) particularly if the patient is anxious.\(^15\) Providing verbal and written information helps ensure patients learn important issues about their medicines.\(^13\),\(^15\),\(^26\) Leaflets can reinforce information from a consultation,\(^3\)–\(^9\),\(^63\) allow involvement in treatment decisions,\(^2\)–\(^3\),\(^7\),\(^9\),\(^66\) and improve treatment adherence.\(^170\)–\(^172\) Using a leaflet during consultation/counselling can emphasise important issues, such as how to recognise side-effects and other risks of treatment.\(^3\),\(^143\) Leaflets are also useful resources for patients to refer to later.\(^2\)

In many countries, prescription medicines are legally required to be supplied with a medicine information leaflet.\(^110\),\(^112\) However, where this is not compulsory, as in New Zealand, leaflets may be given infrequently by GPs or pharmacists or only if requested,\(^26\),\(^173\) and leaflets for all medicines may not be available. Although leaflet
provision in New Zealand is not mandatory, ensuring patients are fully informed about their treatment is a legal and ethical obligation. A New Zealand survey in 2001 (n=344) found only 2.1% of patients reported a leaflet being their primary source of information about prescription medicines. In New Zealand there are numerous available medicine leaflets including the manufacturer provided information (known as Consumer Medicines Information (CMI) in New Zealand and Australia or internationally as Patient Information Leaflets (PILs)), as well as others written by various health bodies. Unfortunately, the regulatory guidance for those creating leaflets for New Zealand consumers is not as robust as countries where there is legislation surrounding this and leaflets may not be written according to good-design principles.

All-purpose information leaflets are often disliked by patients and healthcare providers and are not used (particularly manufacturers’ versions), because they are too lengthy, difficult to navigate, and contain complex terminology. When health professionals do not like leaflets, there is little likelihood they will encourage patients to read them, as has been described internationally. Improving health professionals’ views on information leaflets may change the way they give them to patients e.g. discuss them with their patients rather than not acknowledging their availability. Tailoring information to patients’ characteristics and needs might produce a more useful resource for patients and improve health professionals’ perceptions and provision of leaflets. However there is little research on this topic in New Zealand. Because patients’ perception and use of the information of leaflets can be influenced by their health professional, investigating health professional opinions of leaflets could improve their utilisation of them in New Zealand and internationally.

Aim

The aim of this study was to i) examine self-reported provision of medicine information leaflets by New Zealand General Practitioners (GPs) and pharmacists; ii) examine their views on available leaflets; and iii) determine whether they support tailoring information leaflets for patients.
Ethics approval
The study was approved by University of Otago Human Ethics Committee (D16/298; Appendix 4).

Methods

Survey development
Structured questionnaires were developed by the research team (AY), from previously validated questionnaires (Appendix 7). One questionnaire was written for GPs and one for community pharmacists with input from GPs and pharmacists for validity to New Zealand practice. The survey was piloted with 20 GPs and pharmacists in total and minimal changes made. For frequencies, most of the time was defined as more than half of the time, and some of the time defined as less than half of the time. Questions were asked about low-risk types of medicines (e.g. an asthma inhaler) because these are commonly given and, although low risk, still require adequate information provision to ensure appropriate use.

Health professionals indicating they use information leaflets with patients were entered in to a subgroup with additional questions to determine how and why they use medicine information leaflets, and what they like and do not like about the leaflets they use.

Data collection
Sample size calculations estimated 278 responses were required to detect significance at a level of p<0.05 with 95% confidence. A list of GPs was obtained from Best Practice Advocacy Centre New Zealand, and 600 were randomly selected and were invited to participate. A list of New Zealand pharmacies created from a variety of sources (including the Pharmacy Guild, School of Pharmacy, Medsafe and publicly available records), was used to select 400 pharmacies where 600 pharmacists were expected to be reached.

In October 2016, the questionnaires and a participation information sheet were sent via email to the selected participants using electronic survey software
SurveyMonkey®. A reminder email follow-up was sent to those who had not responded after one and six weeks. Pharmacies without a known email address were mailed a hard-copy survey and participation information sheet. Following low initial responses, a paper copy was sent in November 2016 to pharmacists who did not respond. Paper responses were manually entered into SurveyMonkey®. The questionnaires were also posted to the Young Pharmacist Facebook group in mid-October 2016, and reposted after one week.

Demographic information was collected for each group including age, sex, and location of practice.

Analysis
Quantitative data were evaluated with statistical software. GPs’ and pharmacists’ responses were compared with Chi-squared analysis using STATA 13.1. Significance was set at p=0.05. Responses with more than 20% missing data were removed from analysis.\(^{152}\)

Qualitative data themes were identified\(^{155}\) by AY where data were analysed by reading responses several times using an immersion–crystallization iterative approach. Thematic grouping was undertaken after coding of individual responses and was discussed amongst the research team before the final analysis. Opinions of pharmacists and GPs were similar and have been analysed together.

Results

Demographics
In total 143 GPs and 126 pharmacists responded (Table 7). This gave a response rate of 21.0% for pharmacists and 23.8% for GPs. Sixteen pharmacists responded through the Facebook page. Twenty-nine survey responses with more than 20% missing data were removed from analysis. GPs (n=75, 52.4%) and pharmacists (n=65, 51.6%) were mostly female and from major city practices (GPs n=62, 43.4%; pharmacists n=54, 42.9%). GPs were mostly 50-59 years-old (n=54, 37.8%) and pharmacists were mostly 20-29 (n=31, 24.6%) and 30-39 years-old (n=32, 25.4%).
Table 7: Summary of participants

<table>
<thead>
<tr>
<th>Demographic</th>
<th>GP group</th>
<th>Pharmacist group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>58 (40.6%)</td>
<td>54 (42.9%)</td>
</tr>
<tr>
<td>n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>75 (52.4%)</td>
<td>65 (51.6%)</td>
</tr>
<tr>
<td>No response</td>
<td>10 (7.0%)</td>
<td>7 (5.6%)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>3 (2.1%)</td>
<td>31 (24.6%)</td>
</tr>
<tr>
<td>n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>26 (18.2%)</td>
<td>32 (25.4%)</td>
</tr>
<tr>
<td>40-49</td>
<td>35 (24.5%)</td>
<td>18 (14.3%)</td>
</tr>
<tr>
<td>50-59</td>
<td>54 (37.8%)</td>
<td>23 (18.3%)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>15 (10.5%)</td>
<td>15 (11.9%)</td>
</tr>
<tr>
<td>No response</td>
<td>10 (7.0%)</td>
<td>7 (5.6%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major City (e.g. Auckland, Wellington, Christchurch)</td>
<td>62 (43.4%)</td>
<td>54 (42.9%)</td>
</tr>
<tr>
<td>Provincial City (urban area with a population over 30,000 people e.g. Hamilton, Dunedin, Nelson, New Plymouth, Napier, Gisborne)</td>
<td>37 (25.9%)</td>
<td>31 (24.6%)</td>
</tr>
<tr>
<td>Provincial Town (town with a population between 1,000 and 30,000 people e.g. Levin, Gore)</td>
<td>20 (14.0%)</td>
<td>27 (21.4%)</td>
</tr>
<tr>
<td>Rural (non-urban areas such as rural centres with population under 1,000 people)</td>
<td>14 (9.8%)</td>
<td>7 (5.6%)</td>
</tr>
<tr>
<td>No response</td>
<td>10 (7.0%)</td>
<td>7 (5.6%)</td>
</tr>
</tbody>
</table>

**Self-reported provision of medicine information leaflets**

For new medicines, most GPs (n=68, 47.6%) and pharmacists (n=51, 40.5%) reported giving leaflets *some of the time* (less than half the time). Significantly more pharmacists than GPs (n=16, 12.7% vs n=3, 2.1%, p=0.001) reported providing leaflets *all of the time* and *most of the time* (n=35, 27.8% vs n=16, 11.2%, p=0.001) (Figure 9 and Appendix 8).
Figure 9: How often General Practitioners (GPs, n=143) and pharmacists (n=126) provide patients with medicines information leaflets

For repeat medicines significantly more participants reported they never give a leaflet for a repeat medicine compared to a new medicine (GPs n=49, 34.3% vs n=28, 19.6% (p=0.001); pharmacists n=11, 8.7% vs n=0 (p=0.001)) or would give it only on request (GPs n=67, 46.9% vs n=28, 19.6% (p<0.001); pharmacists n=93, 73.8% vs n=24, 19.0% (p<0.001)) (Figure 8 and Appendix 8).

When medicine information leaflets should be provided
Significantly more pharmacists (n=89, 70.6%) than GPs (n=81, 56.6%) thought leaflets should be provided with new medicines (p=0.0018), (Figure 10). Significantly more GPs (n=51, 35.7%) than pharmacists (n=26, 20.6%) thought leaflets should be provided before medicines are prescribed so patients’ can review potential risks and benefits of therapy (p=0.007).
Figure 10: When General Practitioners (GPs, n=143) and pharmacists (n=126) would like patients to receive leaflets

How and why medicine information leaflets are provided
A subgroup indicated using leaflets (n=89 GPs and n=94 pharmacists) and reported how and why they used leaflets.

The majority of these GPs (n=73, 82.0%) and pharmacists (n=76, 80.9%) reported they discuss chosen leaflet sections with patients. See Appendix 8 for other ways leaflets are provided to patients.

GPs and pharmacists mostly agreed about why they provided leaflets (Table 8).
Table 8: Why General Practitioners (GPs) and pharmacists would provide medicine information leaflets

<table>
<thead>
<tr>
<th>Reason why a leaflet would be provided</th>
<th>GP n=89</th>
<th>Pharmacists n=94</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient requests a medicine information leaflet</td>
<td>31 21.7%</td>
<td>52 41.3%</td>
<td>p=0.005</td>
</tr>
<tr>
<td>I want the patient to make an informed choice about their medicine to aid adherence</td>
<td>64 44.8%</td>
<td>56 44.4%</td>
<td>p=0.079</td>
</tr>
<tr>
<td>I have a duty of care to inform the patient about their medicine</td>
<td>57 39.9%</td>
<td>67 53.2%</td>
<td>p=0.30</td>
</tr>
<tr>
<td>The patient has a right to information about their medicine</td>
<td>52 36.4%</td>
<td>59 46.8%</td>
<td>p=0.55</td>
</tr>
<tr>
<td>I want to check that I did not forget to provide any medicine information verbally</td>
<td>52 36.4%</td>
<td>46 36.5%</td>
<td>p=0.20</td>
</tr>
<tr>
<td>I want to reinforce the benefits of the medicine and how to take it</td>
<td>56 32.2%</td>
<td>55 43.7%</td>
<td>p=0.35</td>
</tr>
<tr>
<td>The patient had a bad experience with a medicine in the past</td>
<td>13 9.1%</td>
<td>15 11.9%</td>
<td>p=0.80</td>
</tr>
</tbody>
</table>

Likes and dislikes of leaflets

There were 239 free-text responses about leaflet preferences and 226 about leaflet dislikes (Appendix 9).

Qualitative analysis indicated five themes about leaflets: i) design; ii) content; iii) accessibility; iv) perceived quality; and v) usefulness and usability.

i) Leaflet design
More than half of responses were about design. The majority of participants preferred simple, clear, and easy-to-read and understand leaflets. Some thought patients might misinterpret complex leaflets.

Over a third preferred concise leaflets whereas under a tenth preferred comprehensive ones. Over a third also thought leaflets have too much information or unnecessary detail. Some preferences were “easy to understand. Short and clear format”, “Short, to the point, good language that don’t overwhelm”. Some dislikes were “Some have much too much information and are scary for the patient. Others are far too generic and don't contain any useful information”, “Often too much information and not individually tailored, Not always useful for those with limited literacy”.

Some liked leaflets with a consistent format, designed with the patient in mind. Three participants thought leaflets were poorly formatted, difficult to navigate, and not user-friendly. Participants favoured A4-format, large-print leaflets with photos or pictures and disliked those considered confusing or hard to understand (including difficult for those with low literacy).

ii) Leaflet content

A fifth of responses related to content. Many more participants disliked than liked leaflet side-effect profiles. Participants who liked the side-effect section favoured easy-to-read leaflets with a selection of side-effects listed and valued leaflets advising what to do if side-effects occurred. Those who disliked this section thought a plethora of side-effects might stop patients taking their medicine, particularly when no frequency of effects was listed.

Six participants liked the inclusion of directions for taking the medicine and indications or benefits were mentioned by three. Ten participants were concerned if information was missing e.g. medicine benefits, dose, directions for use, or storage information.

Several participants worried about the all-purpose nature of the leaflets, and over a quarter of negative comments were about leaflets containing incorrect indications, or not being tailored to patients’ needs.
iii) Leaflet accessibility

A tenth of responses commented on accessibility. Most preferred easy-to-access leaflets, perhaps from a patient management system. Five of those concerned with accessibility disliked printing leaflets and thought digital provision would be useful. Two GPs felt there were too many options available.

iv) Perceived quality

Quality was mentioned in less than a tenth of responses. A few participants favoured leaflets from a known reliable source, others prioritised them being accurate and up to date. A few believed manufacturer’s leaflets more reliable, whilst others disagreed. Two participants disliked seeing advertising within leaflets.

v) Usefulness and usability

Usefulness and usability was mentioned in over a tenth of responses. Many GPs and pharmacists thought leaflets useful, informative and beneficial for patients because they provided more information than could be covered during consultation. However, nine participants were concerned that leaflets cause anxiety for patients, or were sometimes irrelevant.

Half the responses describing leaflets as useful was because they reinforce verbal information and give patients information to read when it suits them. Leaflets could help educate patients, allowing informed choice and be a guide for discussion. Conversely, over a third who commented negatively felt they would need to explain the leaflet to patients, and would lack time for this.

Some commented that leaflets were not useful because they were only available in English. A few commented that leaflets rely on patients’ wanting to read them and find the desired information.

Support for tailoring leaflets

Overall, GPs and pharmacists had similar views on each leaflet option proposed (Table 9). However, more pharmacists (n=80, 63.5%) than GPs (n=71, 49.7%) thought a tailored leaflet would be most useful to patients (p=0.02). Most popular were the
summary leaflets with instructions to access more information. Of these options, significantly more GPs and pharmacists preferred the personalised/tailored compared to the general leaflet (n=56, 39.2% vs n=39, 27.3% GPs, p= 0.03; n=63, 50.0% vs n=22, 17.5% pharmacists, p<0.001). The least preferred option was the comprehensive leaflet (manufacturer’s CMI or PIL).

Table 9: Which type of medicine information leaflet General Practitioners (GPs) and pharmacists thought most useful to provide to patients

<table>
<thead>
<tr>
<th>Type of leaflet</th>
<th>GP n=143</th>
<th>Pharmacists n=126</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A comprehensive leaflet (e.g. manufacturer CMI) available online, printed, or in the medicine box</td>
<td>2 (1.4%)</td>
<td>1 (0.8%)</td>
<td>p=0.64</td>
</tr>
<tr>
<td>A personalised summary leaflet printed from prescribing or dispensing software tailored to the patient’s characteristics</td>
<td>15 (10.5%)</td>
<td>17 (13.5%)</td>
<td>p=0.45</td>
</tr>
<tr>
<td>A personalised summary leaflet printed from prescribing or dispensing software tailored to the patient’s characteristics, with instructions on how to access more comprehensive information if the patient wants it</td>
<td>56 (39.2%)</td>
<td>63 (50.0%)</td>
<td>p=0.07</td>
</tr>
<tr>
<td>A general summary leaflet printed from prescribing or dispensing software</td>
<td>10 (7.0%)</td>
<td>12 (9.5%)</td>
<td>p=0.45</td>
</tr>
<tr>
<td>A general summary leaflet printed from prescribing or dispensing software with instructions on how to access more comprehensive information if the patient wants it</td>
<td>39 (27.3%)</td>
<td>22 (17.5%)</td>
<td>p=0.055</td>
</tr>
<tr>
<td>None of the above</td>
<td>2 (1.4%)</td>
<td>0 (0.0%)</td>
<td>p=0.18</td>
</tr>
<tr>
<td>No response</td>
<td>19 (13.3%)</td>
<td>11 (8.7%)</td>
<td>p=0.24</td>
</tr>
</tbody>
</table>
Discussion

Providing verbal medicines information during consultations may be variable so a medicine information leaflet should accompany all dispensed medicines. The present study found that New Zealand pharmacists and GPs do not often provide such leaflets and prefer them to be given for new rather than repeat medicines. GPs and pharmacists give leaflets to reinforce treatment benefits and inform of side-effects, thereby enabling patient participation in decision-making. Both professions also acknowledged leaflets’ importance as a reference tool and additional information source for patients.

Participants preferred a well-designed leaflet, a clear description of side-effects, and information about what to do if a side-effect was experienced. Informing patients of treatment benefits and accessibility of the leaflet was also considered important.

Some leaflets were described as too long and difficult to understand. Ideally, patients should receive tailored information. In the present study GPs and pharmacists supported the provision of tailored medicine information leaflets.

Self-reported provision of medicine information leaflets

It is not compulsory in New Zealand to provide medicine information leaflets to patients and the present study found that leaflet provision is low. From self-reports, pharmacists appeared more likely to provide leaflets than GPs. Furthermore, the likelihood for patients on long-term therapy to receive leaflets was even smaller, so patients would probably need to request one (Figure 9). In one Australian study, pharmacists reportedly provide leaflets more frequently with 48% giving leaflets all of the time, and 43% giving them most of the time (12.7%, 27.8% respectively in New Zealand). Consistent with New Zealand findings, 13% of Australian doctors would never give a CMI with a new medicine, although more would provide a leaflet all or most of the time. Medicines information leaflet provision should be increased because verbal communication appears extremely variable. Solely relying on verbal interactions is not considered good practice. Internationally, medicine information leaflets are provided more often because they are compulsory.
with dispensed medicines. Ideally leaflets should also be given with every medicine in countries where provision is not mandatory.

In New Zealand and Australia, specific leaflet sections are discussed with patients in order to cover important issues and encourage leaflet use by patients. In Australia, GPs and pharmacists were more likely to rely on the patient to read the leaflets themselves and return with questions if needed. Earlier consumer studies in Australia and the UK have shown patients report receiving leaflets without additional instruction. However, in this current study and the most recent Australian study, few GPs and pharmacists would now give a leaflet without any advice, which is a positive step forward in information provision.

In Australia most GPs and pharmacists claim to provide leaflets on patient request. In New Zealand, most provide leaflets to educate and inform patients which is in accordance with regulatory agency recommendations and ethical standards. Leaflets are being used in practice to reinforce verbal communication, provide information that cannot be given during consultation, ensure salient points are covered, and for patients to refer to later.

Leaflets should be seen as a useful tool for consultations and should not be a burden to the healthcare provider. However, many participants in the present study reported not having the time required to explain leaflets sufficiently.

Likes and dislikes of leaflets

Information leaflets were often described as lengthy, complex, and confusing in this and other studies. Most participants preferred simple, clear, and easy-to-read and understand leaflets which is similar to international outcomes. Well-designed leaflets help patients find and comprehend information. Improvement in leaflet design and readability could encourage leaflet use.

Risks, particularly side-effects, were the most popular and contentious leaflet component mentioned in the present study. Consistent with GPs’ and pharmacists’ views, patients’ want clear information about side-effects, including understandable information about the frequency of occurrence and instructions on how to manage
This information is often not provided in available leaflets and can be presented in an alarming manner. Treatment benefits are also important to both professions in the present study and to patients. Reasons for leaflet disapproval such as containing irrelevant information, inappropriate length, and generic nature could be improved by tailoring leaflets to individual patient requirements.

Accessibility is an important issue for busy health professionals. Time pressure is of considerable concern and leaflets that are difficult to obtain will be easily dismissed or forgotten. Five GPs mentioned that they would prefer to not print leaflets, but instead provide them digitally. However sending patient’s medicine information digitally is not seamlessly integrated within patient management systems in New Zealand. However, with increasing uptake of patient portals in New Zealand (where patients access their health information online) and with further innovation within patient management systems, digital provision of medicine information could soon be the preferred option.

Support for tailoring leaflets
New Zealand GPs and pharmacists support the use of tailored leaflets. Of all options in the present study, a tailored summary leaflet was most preferred. Tailored summary leaflets could improve health professionals’ opinions of leaflets and possibly encourage them to actively discuss them with patients. There is potential for patient management systems in community practice to analyse patients’ Electronic Health Record in order to tailor leaflets to their gender, medical conditions, and age. However there is no system in place to enable the creation of individually-tailored medicine information leaflets.

Patients also want tailored and relevant information about medicines. All-purpose and inappropriate leaflets can appear unsuited and lower patients opinion of them. New Zealand GPs and pharmacists concur the CMI is the least preferred leaflet option, agreeing with other studies that they are too long, difficult to understand, too detailed, and not patient-centred. Despite this, CMIs may be the only medicine information resource that patients receive because they are often inside medicine packaging and freely available, even although there are different options available.
Whilst New Zealand regulations about provision and creation of leaflets differ from other countries, the present study’s findings are well in line with the international research focusing on the provision of leaflets and why health professionals do not like them. International research indicates leaflets across the globe are inadequate and that improving them will benefit patients. Furthermore, many countries provide the generic manufacturer-created information for patients which this study has shown is the least-preferred option by health professionals. This study discusses health professionals’ opinions of leaflets and their accessibility, and gives examples of where health professionals feel improvement is needed. Improving leaflets by incorporating health professionals’ opinions should improve their provision of leaflets where it is not mandatory, and encourage active use of them with patients in New Zealand and overseas. These improvements could be made to leaflets and their accessibility worldwide.

Future studies in this area should focus on the ability to create accurately tailored information to patients and its impact on patient knowledge and adherence as well as leaflet provision. This would be useful in international practice where generic information is still the mainstay of medicine information leaflet provision.

There are some limitations to this study. Participants with an interest in leaflets and patient education were more likely to respond, possibly resulting in selection bias. Alternatively, selection bias may occur from those with a strong dislike of available leaflets wanting to put their opinion forward. Furthermore, the study relied on reported practices, so participants may have given a socially desirable response to impress researchers. This was potentially mitigated by allowing anonymity. The survey had a lower-than-expected response rate which affects generalisability of the results, but analysis was considered appropriate as the sample was over 20% for each group, statistical differences between the groups were detectable, and surveys among health professionals may show low response rates. Generalisability to international practice is affected due to the nature of leaflet provision in New Zealand and Australia compared to other countries where provision is mandatory, but other aspects of this
study such as the likes and dislikes of leaflets and how leaflets are provided are relevant to international practice.

**Conclusion**

Most GPs and pharmacists give information leaflets to ensure patients are informed about their medicines. This is in line with professional obligations in New Zealand.\textsuperscript{41, 42} However, healthcare providers need to re-evaluate methods for providing medicine information. Provision of information leaflets in New Zealand appears to be suboptimal with most GPs and pharmacists only giving leaflets to patients less than half the time they prescribe or dispense a new medicine. Many do not give leaflets for repeat medicines. Opportunities to give verbal advice vary, so providing an appropriate easy-to-read medicines leaflet containing all the patient wants to know would help ensure their information needs are met. Understandably, when leaflets were provided, GPs and pharmacists mostly discussed particular sections of the leaflet with patients. This would highlight the importance of the leaflet with patients and draw attention to important information. Because it is not mandatory to provide leaflets to patients in New Zealand, health professionals’ opinions of them will affect whether they are used. Overall, GPs and pharmacists preferred well-designed, patient-centred, concise leaflets, containing useful information and written in a way that avoids patient anxiety. Many GPs and pharmacists struggled with leaflet accessibility in their busy practice so improving this would help improve perceptions and usability of them as resources.

Both GPs and pharmacists preferred the concept of summary leaflets, and of these the tailored versions were most popular. For healthcare professionals to give leaflets that are of real benefit, leaflets should be tailored to meet their patients’ needs. At a click of a button it should be possible to provide or even create an appropriate leaflet. Furthermore, it should be possible to create leaflets that could be sent in a digital format allowing patients improved access and interaction with information about their medicines.
**Funding**
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**Acknowledgements**
We gratefully acknowledge the GPs and pharmacists who participated in the study.

**Conflicts of interest**
The authors have no conflicts of interest to declare.
4.4 Using websites for medicine information and improving provision of leaflets

Published Manuscript Entitled Patient-focused medicines information: General Practitioners’ and pharmacists’ views on websites and leaflets

The manuscript entitled “Patient-focused medicines information: General Practitioners’ and pharmacists’ views on websites and leaflets” was published in the Health Educ J 2018;78(3):340-51.

The co-authors contributed to the manuscript as follows: Survey creation, execution, analysis, and write-up was performed by PhD candidate Amber Young, under the supervision of Dr Alesha Smith and Associate Professor June Tordoff. Dr Sharon Leitch provided advice from a practicing general practitioner perspective. All the co-authors revised the content of the manuscript and approved the final version for publication. The PhD candidate Amber Young was the lead author in manuscript preparation and writing, and was corresponding author.

The manuscript is presented as accepted for publication; however, the numbering of the pages, figures, and tables has been adjusted in accordance with the style of this thesis. All references from the manuscript can be found in the section ‘References’ at the end of the thesis. Further details of the methods used and limitations of this study are described in section 3.4 Methods, further information and section 3.5 Limitations, further information.
4.4.1 Patient-focused medicines information: General Practitioners’ and pharmacists’ views on websites and leaflets

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Abstract

Objectives: To determine how often general practitioners (GPs) and pharmacists recommend patients obtain information about their medicines via websites and to explore factors that might improve delivery of written information about medicines to patients.

Design: Cross-sectional surveys.

Setting: General practitioners and community pharmacists in New Zealand primary care.

Method: Questionnaires were developed and sent to a sample of pharmacists and GPs. Data was collected using SurveyMonkey\textsuperscript{®} and analysed to examine views on websites and leaflets for informing patients about medicines.

Results: In total, 143 GPs and 126 pharmacists responded. GPs and pharmacists did not routinely direct patients to medicine information websites. Most commonly, GPs did not provide medicine information leaflets due to time constraints and concerns about possibly confusing information. Both professions thought leaflets might cause patients to worry about side-effects. Pharmacists mainly withheld leaflets because the
medicine was taken previously, or because leaflet indications differed to prescribed use. A summary leaflet, if available, would be the preferred option for improving leaflet provision.

**Conclusion:** Providing digital medicine information is uncommon in New Zealand. Summarised, relevant information tailored to patient requirements might facilitate provision of medicines information at point-of-care.

**Keywords** medicine information; patient information leaflets; consumer information; patient education; tailored information; New Zealand

**Introduction**

Adequate verbal counselling about medicines may not fulfil patients’ needs and be difficult to achieve in practice. Providing medicines information leaflets in addition to verbal counselling could increase patients’ understanding of their medicines, however some health professionals do not value leaflets or recommend them to their patients. Furthermore, when leaflet provision is not mandatory, some providers may purposefully withhold leaflets due to concerns that leaflets are confusing or could reduce adherence. Although many health professionals do give leaflets with newly prescribed medicines, they typically do not provide leaflets with repeat medicines. Providing leaflets for repeat medicines benefits patients by continuing and reinforcing patient education, supporting and encouraging compliance and by enabling healthcare professionals to assess patient understanding which is maybe overlooked in practice. Ongoing provision could also remind patients’ that leaflets are a useful resource if problems with therapy occur. It has been shown that summary leaflets are preferred by health professionals for new medications, but it is unknown if a summary leaflet would encourage leaflet provision for repeat medicines.

There are few alternatives for the patients if they are not provided with leaflets. Patients increasingly seek information from the Internet because of the convenience, coverage and anonymity of digital information. This is not ideal when not provided by a health professional because many websites contain incorrect and
Health professionals can guide patients to reputable user-friendly information online, but it is not known whether this occurs in New Zealand. Furthermore, some patients may be reluctant to seek information from sources other than their health professional for fear that this could be inferred as undermining professional opinion. This anxiety would be abated if the health professional provides further reading resources for patients to peruse at their leisure.

Internationally, many countries have made the provision of information leaflets mandatory with dispensed medicines in recent years. In New Zealand and Australia there is no such legal requirement. Our previous research found that leaflets are infrequently given with prescription medicines (see section 4.4.1). This paper reports on further findings from that study by examining whether GPs and pharmacists recommend patients obtain medicines information from websites, and factors that might discourage or encourage medicines information leaflet provision when provision is not mandatory.

Aim of the study
The aims of the present study were to i) determine how often GPs and pharmacists recommend patients obtain information about their medicines via websites; and ii) explore factors that might improve delivery of written medicine information to patients.

Method
The present study examined findings from a larger project (see section 4.3.1) involving a survey of GPs and pharmacists in New Zealand on medicine counselling practices and medicines leaflet provision. Structured data collection instruments were developed from previously validated questionnaires that utilised a combination of multi-choice questions, Likert scales and open-ended responses. Two surveys were prepared: one for GPs and one for community pharmacists with input from GPs and pharmacists for validity. The surveys were piloted on 20 GPs and pharmacists requiring minimal changes. The following questions were asked: For medicines considered low-risk (e.g. an asthma inhaler), are GPs and pharmacists recommending
websites as a source of medicine information for their patients; if medicine information leaflets are used (as determined in the larger project findings174), what is the preferred source of leaflets; why would GPs and pharmacists not provide leaflets to their patients; what might help GPs and pharmacists provide leaflets; and for medicines that could be regarded as high-risk and low-risk1, how they think leaflets should be provided (see Appendix 10).

A sample size of 278 responses were required to detect significance (p<0.05 with 95% confidence).174 A sample of 600 GPs and 400 pharmacies (expecting to reach 600 community pharmacists) were selected for participation.174

Questionnaires and patient information sheets were distributed via SurveyMonkey® in October 2016, with reminders sent at one and six weeks for those who had not responded. Paper copies of the surveys were sent to pharmacies when email addresses were not obtained and to those who did not respond to the emailed survey. Mailed responses were manually entered into SurveyMonkey®. In mid-October 2016, the questionnaires were also posted to the NZ Young Pharmacist Facebook group.

Quantitative data were evaluated using STATA 13.1 to determine GPs and pharmacists views on websites and leaflets for informing patients about medicines. Comparisons were made between GP and pharmacists responses using Chi-squared analysis with significance set at p=0.05. If responses had more than 20% of data missing, they were removed from analysis.152

Ethics approval

The University of Otago Human Ethics Committee (D16/298; Appendix 4) gave its approval for the study.

1 This was to determine if the perceived risk of the medicine would alter how health professionals believe leaflets should be provided; high-risk medicines are those at particular risk of side-effects and low-risk are those usually considered low-risk of side-effects e.g. an asthma inhaler.
Results

Demographics

In total there were 269 responses (143 GPs and 126 pharmacists) giving a response rate of 21.0% for pharmacists and 23.8% for GPs. The majority of respondents were female (GPs n=75, 52.4%; pharmacists n=65, 51.6%) and most commonly resided in a major city (GPs n=62, 43.4%; pharmacists n=54, 42.9%). Most pharmacists were aged 20-29 years (n=31, 24.6%) or 30-39 years (n=32, 25.4%), and most GPs were aged 40-49 (n=35, 24.5%) or 50-59 years (n=54, 37.8%). Further demographic information is reported elsewhere (see section 4.3.1).

The use of websites to give medicines information

Significantly more GPs reported giving web addresses to patients some of the time (GPs n=67, 46.9% GPs vs pharmacists n=43, 34.1% (p=0.034)). Significantly more pharmacists reported giving web addresses only on patient request (pharmacists n=62, 49.2% vs GPs n=22, 15.4% (p<0.001)). No GP reported recommending a website all of the time and only 4.9% of GPs reported recommending a website most of the time. None of the pharmacists reported recommending a website all of the time or most of the time.

The top three websites from which GPs and pharmacists obtained leaflets were:

- Medsafe (New Zealand medicines regulatory agency) (20.6% pharmacists, 15.4% GPs)
- New Zealand Medicines Formulary (15.4% GPs, 12.7% pharmacists)
- the ‘Patient’ website (8.4% GPs, 7.1% pharmacists).

Reasons why medicine information leaflets are not being used

GPs and pharmacists had different reasons for not giving an information leaflet (see Appendix 11). However they had a level of agreement on the following reasons: the patient has difficulty with understanding or reading the medicine information leaflets (pharmacists n=65, 51.6% vs GPs n=70, 49.0%); the leaflet is too long to print off.
(pharmacists n=36, 28.6% vs GPs n=55, 38.5%); and the leaflet is not available in other languages (pharmacists n=53, 42.1% vs GPs n=49, 34.3%).

The top three reasons selected significantly more by pharmacists compared to GPs were the patient has taken the medicine previously (pharmacists n=81, 64.3% vs GPs n=54, 37.8% (p<0.001)); the medicine is being used for a purpose other than indicated (including ‘off-label’ use) (pharmacists n=73, 57.9% vs GPs n=27, 18.9% (p<0.001)); and I am concerned the patient will worry about the possible side-effects and not take the medicine (pharmacists n=70, 55.6% vs GPs n=62, 43.4% (p=0.046)). Around half of GPs and pharmacists would not provide leaflets because they believed patients are not interested in receiving medicine information leaflets (pharmacists n=68, 54.0% vs GPs n=60, 42.0% (p=0.049)).

The top three reasons selected significantly more by GPs than pharmacists were I do not always have time to spend discussing a medicine information leaflet with the patient (GPs n=32, 52.4% vs pharmacists n=75, 25.4% (p<0.001)); I do not think to use them when talking with patients (GPs n=6, 30.1% vs pharmacists n=43, 4.8% (p<0.001)); and it is the (other professions’) role (i.e. pharmacist or GP as appropriate) to provide medicine information leaflets (GPs n=32, 22.4% vs pharmacists n=0, 0% (p<0.001)).

In free-text responses, sixteen participants reiterated time limitations. Seventeen participants would not supply leaflets that they considered too difficult to understand and could be misinterpreted, leading to anxiety. Nine participants thought that the available leaflets were too long with unnecessary detail, a further eight would not supply leaflets because of concerns with the side-effect information listed. Thirteen participants would not use leaflets because they give the information verbally and seven participants acknowledged patients’ preference for digital or internet information. Nine GPs reiterated that they did not give them because patients did not want them and nine also stated they would not give them because the pharmacist supplies them. Other reasons for non-use were poor accessibility (e.g. not available through patient management systems); and leaflets were not considered useful (including leaflets were too generic and not personalised or relevant).
What might help GPs and pharmacists provide leaflets to patients

Most participants believed that having a summary leaflet (covering important points about a medicine) would encourage them to provide leaflets (GPs n=102, 71.3% and pharmacists n=81, 64.3%), as well as having more time to provide and explain leaflets (GPs n=67, 46.9% and pharmacists n=68, 54.0%).

Significantly more GPs than pharmacists thought that automatic prompting to provide leaflets and recording when leaflets are given in the Patient Management System would help (GPs n=75, 52.4% vs pharmacists n=49, 38.9% (p=0.026)); and significantly more pharmacists than GPs thought that reimbursement for providing leaflets would help (pharmacists n=71, 56.3% vs GPs n=26, 18.2% (p<0.001)). There was much agreement on other measures to enhance provision: personalized leaflets tailored to patients’ characteristics, disease, or condition (GPs n=61, 42.7% and pharmacists n=54, 42.9%); specific counselling appointments to discuss a patient’s medicines (GPs n=58, 40.6% and pharmacists n=52, 41.3%); having leaflets available in different languages (GPs n=56, 39.2% and pharmacists n=59, 46.8%); and more frequent requests from patients for information leaflets (GPs n=53, 37.1% and pharmacists n=59, 46.8%).

Six GPs in free-text responses thought they would be more inclined to provide leaflets if they were improved. Seven pharmacists discussed how payment would help with their provision of leaflets. A few participants suggested other ways of improving leaflet provision such as having leaflets available in all medicine packages as they are in other countries, employing a system to send leaflets digitally, and improving access to available leaflets.

When and how a personalised summary leaflet could be provided

Participants were asked if a personalised summary leaflet was available, which profession should provide these leaflets, and when for new (Figure 11) and repeated medicines for chronic conditions (Figure 12).

New medicines

For new low-risk medicines, significantly more GPs and pharmacists believed that pharmacists could provide personalised summary leaflets all of the time compared to
the numbers who believed GPs could provide them (GPs: believed pharmacists could provide them n=80, 55.9% vs GPs could provide them n=51, 35.7% (p=0.001); pharmacists: believed pharmacists could provide them n=80, 63.5% rather than GPs n=44, 34.9% (p<0.001)). For new high-risk medicines, significantly more pharmacists thought they could be the ones to provide these all of the time (pharmacists could give n=105, 83.3% vs GPs could give n=88, 69.8% p=0.008) whereas GPs believed the leaflets could be provided by either health professional (pharmacists could give n=108, 75.5% vs GPs could give n=107, 74.8%).
Repeat medicines

Overall, both professions thought leaflets were less essential for repeat medicines. For low-risk repeat medicines, very few participants thought summary leaflets could be given all of the time. However, for high-risk repeat medicines, more GPs (18.9%) than pharmacists (7.9%) thought leaflets could be given by GPs (p=0.009) (Figure 12). Similar proportions of professions thought neither GPs nor pharmacists could give summary leaflets for repeat low-risk medicines. For repeat high-risk medicines,
proportions of GPs and pharmacists were again similar, but smaller than those for low-risk medicines.

Most GPs (81.8% for low-risk medicines, 85.3% for high-risk medicines) and pharmacists (77.8% for low-risk medicines, 74.6% for high-risk medicines) agreed that leaflets could be given if patients asked for them for repeat medication.

**Discussion**

Informed and knowledgeable patients have improved satisfaction with their therapy, improved adherence, and greater management of their condition. The aim of this
study was to explore factors that might improve delivery of medicines information to patients in a country where written information provision is not mandatory.\textsuperscript{160} This research provides important background information that may help develop targeted initiatives to improve on current low levels of medicine information leaflet provision\textsuperscript{174} in New Zealand and other countries such as Australia that do not regulate provision of non-verbal information.

This study found that providing patients with web-based information is not a regular practice among New Zealand health professionals. It is known that leaflet provision in New Zealand may also be sub-optimal,\textsuperscript{174} possibly because health professionals are concerned about the economic implications of providing them: GPs state they do not have the time to discuss them with their patients, while pharmacists are concerned with funding for this service. Often it is also thought that patients do not want leaflets or that leaflets are not suited to patients’ needs. Many GPs and pharmacists were concerned that side-effect information would cause anxiety and affect medication adherence.

Having a short, well-written, personalised summary leaflet is likely to encourage GPs and pharmacists to use leaflets during consultation. However, these summaries must be readily accessible at point-of-care. Neither profession felt that summary leaflets should be given with repeat medicines all of the time, although GPs were more inclined to think they should be routinely provided to patients.

The use of websites to provide medicines information

Patients search for health information online,\textsuperscript{70} but the sources available are of variable readability and quality.\textsuperscript{116, 117} GPs and pharmacists using online resources tend to recommend government funded websites who publish leaflets (Medsafe, New Zealand Formulary, Canterbury District Health Board). However, it is not well known if health professionals also inform patients about how to find this information on their own or educate them about the risks of searching for health information online.

Web based applications can improve patient knowledge\textsuperscript{120} and user-friendly applications have been developed that link to the manufacturer’s information
enabling patients to find leaflets more easily (e.g. MedSearch\textsuperscript{179}). However these types of services are not yet available in New Zealand (at the time of publishing this article). Other digital initiatives such as text messaging patients with links to online information leaflets have been developed\textsuperscript{118} but are not widely used. Increasingly digital-savvy patients expect to be able to conduct their own research and read up about their medicines online. However, the current study showed that most pharmacists and GPs do not regularly provide links to websites for medicine information leaving many patients without knowledge about what sources would be best to access.

Reasons why medicine information leaflets are not being used

Our study showed that many GPs and pharmacists do not give leaflets to patients who have taken the medicine before. Other New Zealand and Australian studies show health professionals agree that leaflets should be provided when a patient is given a new medicine, but not necessarily for repeat medicines.\textsuperscript{26, 174} Ongoing discussion and reinforcement of treatment benefits may however improve adherence to chronic therapy, which is as little as 50% in developed countries.\textsuperscript{22} While patients may not read leaflets following repeat dispensing,\textsuperscript{25, 26, 28} some information may have been forgotten or changed, so continuing leaflet provision and discussion is still important.

\textit{Time constraints}

In the present study, GPs and pharmacists reported time constraints as obstacles to providing and discussing leaflets with patients. This appears a greater barrier in New Zealand than Australia, and greater for GPs than pharmacists (52.4\% New Zealand GPs vs 39.4\% Australian GPs; and 25.4\% New Zealand pharmacists vs 8.3\% Australian pharmacists).\textsuperscript{26} Given time constraints, it might be more efficient to provide leaflets to patients and encourage them to return with any concerns. For patients who prefer not to receive this information at the time of prescribing or dispensing this allows them to read the information in their own time. Time constraints are also a problem in countries where leaflet provision is mandatory because they limit health professionals’ ability to actively discuss leaflets with patients and encourage patients to read them at home.
Not wanted by patients

It was commonly reported in the present study that participants did not provide leaflets because they believed that patients did not want them. Believing patients do not want further information is a common misconception internationally.\(^2, 26\) In an Australian study, 88% of 607 patients stated they had never refused a leaflet about their medicine,\(^26\) suggesting although not perfect, leaflets are still of use.

Not fit for purpose?

Medsafe (the New Zealand medicines regulatory body) states that to make informed choices, consumers need to know the benefits and risks of medicines and feel able to compare these with information about other treatment options or ‘no treatment’.\(^46\) In this study, and in Australia,\(^26\) GPs and pharmacists felt that leaflets were unsuitable for patients because side-effect information could cause anxiety, reduce adherence, and undermine healthcare professional recommendations. In contrast, other studies found patients value being informed about side-effects\(^4, 180\) and that providing such information does not cause the issues mentioned.\(^26, 162, 171, 181\) Furthermore, informed patients are more likely to avoid interactions, cope better with predictable side-effects, and recognise possible reactions sooner\(^18\) and giving leaflets would help fulfil the requirements to fully inform patients.

Around half of GPs and pharmacists in the present study do not provide leaflets because they view them as difficult for patients to understand. This is a valid concern because confusing or unclear information can affect adherence.\(^86, 87\) Many participants felt leaflets were poorly written, unsuitable, and not patient-centred which is often how manufacturer provided information is described internationally.\(^2, 26\) There is still much work to be done to improve manufacturer provided information on a global scale in order for health professionals to find them suitable to use in practice. If leaflets were consistently presented in a clear format with understandable and patient-friendly terminology, health professionals would be more inclined to use them.
What might help GPs and pharmacists provide leaflets to patients

In New Zealand, GPs and pharmacists commonly prefer to provide patients with summary leaflets. Unfortunately summary leaflets may not be readily in use and in many countries the leaflets provided are produced by the manufacturer and are often lengthy. Perhaps to promote active provision of written information, health authorities should promote summary leaflets to be made available for patients.

As mentioned above, improving leaflet quality may increase their provision by GPs and pharmacists, particularly because there is little time to explain confusing poorly written information. Given stakeholder agreement, perhaps independent organisations outside of industry should take control of leaflet writing and provide easy-to-read leaflets.

Many GPs in the present study did not think to use leaflets when talking with patients and said they could not or did not know how to access them. More than half the GPs said that integrating leaflet provision into Patient Management Systems (PMS) would help them provide leaflets. Pharmacists did not have this problem, perhaps because automatic provision of leaflets is already integrated into dispensing software in many pharmacies. Although available in some GPs’ PMS, widespread availability is needed. Including an option to print an appropriate leaflet within the workflow would prompt GPs to consider using leaflets while providing easy and direct access to the leaflet.

When and how a personalised summary leaflet could be provided

Ideally, information should be personalised to the patient’s requirements, including the condition being treated (even if the medication is used ‘off-label’) and in their own language. Personalised summary leaflets were considered more important for new medicines than for repeat medicines. Whilst there was no definitive answer about who could provide personalised summary medicines leaflets for patients and when, overall GPs and pharmacists felt that both professions could be involved, particularly for high-risk medicines. Pharmacists appeared to be the preferred provider which is consistent with current practice, although many patients prefer to receive leaflets from their GP or from both their GP and pharmacist.

Providing personalised
Leaflets should be adopted with every prescribing or dispensing of medicine by enhancing Patient Management Systems to create and print leaflets automatically and streamlining the process with current practice.

Limitations
Participant recruitment could have resulted in selection bias with those being more interested in leaflet provision possibly more likely to respond. Furthermore, the study involved self-report rather than observation so results may differ from actual practice. The small sample size of the study could affect generalisability of results, however statistical difference between groups was demonstrable. Additionally, participants were not asked if they were familiar with all websites that leaflets can be obtained from, and so it could not be determined whether their recommended sources were their personal preferences or one of only a few resources known to themselves.

Conclusion
Based on the findings of this New Zealand study, there are three main reasons why leaflets are not being used in practice. Firstly, GPs and pharmacists are unwilling to give leaflets to patients if they think the leaflets are difficult for patients to understand. Secondly, many leaflets currently available are not considered fit-for-purpose, and there is concern that side-effect information may cause patient anxiety. Summarised, relevant information tailored to patient requirements might overcome some GPs’ and pharmacists’ reluctance to provide leaflets, and could benefit patients. Thirdly, funding limitations (i.e. limited funded time to provide and discuss leaflets or lack of reimbursement) also prevents leaflets being used at the point-of-care. Time is short for verbal discussion, but this should not be a barrier to leaflet delivery. Incorporating leaflet provision into usual practice workflow through patient management software would improve leaflet delivery.

Digital resources appear to be underutilised by GPs and pharmacists as a source of medicines information for patients. Informing patients about where to find accurate, reputable, and up-to-date digital information needs to be encouraged. Development and provision of appropriate medicines information leaflets or digital resources may
help improve patients’ decision-making about medicine use. They could also help patients avoid interactions, cope better with predictable side-effects, and recognise possible reactions sooner.

Moving forwards, New Zealand’s medicines regulatory agency should advocate mandatory leaflet or digital medicine information provision with patients’ medicines. This would be consistent with international practice, by providing consumers with high quality, accessible health information to facilitate greater patient engagement, reduce costs, improve the utilisation of appropriate treatment, and strengthen informed choice.\textsuperscript{175}

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\textit{Declaration of conflicting interests}

The authors declare that there is no conflict of interest.

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4.5 Patients’ opinions on medicines information leaflet provision and usefulness

Published Manuscript Entitled Patients’ views of general practitioners’ provision of medicines information leaflets


The co-authors contributed to the manuscript as follows: Survey creation was undertaken by Amber Young and Sebastian Moore under the supervision of Dr Alesha Smith and Associate Professor June Tordoff. Survey administration, analysis, and an internal report was undertaken by Sebastian Moore under the supervision of PhD candidate Amber Young, Dr Alesha Smith, and Associate Professor June Tordoff. All the co-authors revised the content of the manuscript and approved the final version for publication. The PhD candidate Amber Young was the lead author in manuscript preparation and writing, and corresponding author.

The manuscript is presented as accepted for publication; however, the numbering of the pages has been adjusted in accordance with the style of this thesis. All references from the manuscript can be found in the section ‘References’ at the end of the thesis. Further details of the methods used and limitations of this study are described in section 3.4 Methods, further information and section 3.5 Limitations, further information.
4.5.1 Patients’ views of general practitioners’ provision of medicines information leaflets

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Abstract

Introduction: Giving patients medicine information leaflets with oral information could help improve patient understanding about their medicines. Some health professionals believe patients do not want to receive leaflets or find them too difficult to understand so do not provide them.

Aim: To investigate Dunedin general practitioners’ (GPs) provision of medicine information leaflets from patients’ reports and to examine patients’ views about the leaflets provided.

Methods: Patients collecting prescriptions from community pharmacies in Dunedin, New Zealand, between December 2016 and February 2017 were asked to complete a survey. Responses were entered into SurveyMonkey and data were exported into Excel for analysis.

Results: Of the 151 survey respondents, over three-quarters (79%) did not receive a medicine information leaflet from their GP in the last 6 months, although most believed it important to receive one. Many participants felt that leaflets improved their knowledge and helped them take their medication correctly. Most participants liked the leaflets they received, although over half (60%) would like a short summary leaflet. Patients do not commonly search for more information than their GP provided.
Discussion: Some patients may not seek further information about their medicines other than during consultation. Although rarely given, most participants who received leaflets from their GP appreciated them. Most participants read and understood leaflets they were provided, although ready access to a one- to two-page summary leaflet may be preferable. Technology could enable GPs to easily provide leaflets to patients in their care.

Keywords medicine information leaflet; patient communication; patient education; general practitioner

What gap this fills

What is already known

In New Zealand, it is not mandatory to provide patients with written information about their medicines. Although patients should ideally be given written and oral information about their medicines, many health professionals believe patients do not want to receive medicine information leaflets.

What this research adds

Patients in Dunedin are not often provided with medicine information leaflets by their general practitioners, but do wish to receive them. Most patients read leaflets when they are provided and think that leaflets improve their medicine knowledge and help them take their medicines correctly.

Introduction

Patients require information about their medicines to ensure they are used safely and effectively. Patients have access to health information from a number of sources, although some patients prefer to receive drug safety information from their GP. However, discussions with patients about their medicines may be limited in practice and access to GPs for medicine information following an appointment may be difficult or costly. Furthermore, patients struggle to remember information that has been discussed at point-of-care and they may not understand orally communicated drug information. This is a common problem internationally, with
studies showing that patients often feel they are not adequately informed and may not even understand why a medicine is prescribed.\textsuperscript{2}

Ideally, oral information should be supported by a medicines information leaflet\textsuperscript{183} because they can increase patients’ understanding of their medicines.\textsuperscript{9} Provision of information leaflets is mandatory in many countries\textsuperscript{160} and usually the manufacturer-produced consumer medicine information leaflet is provided with dispensed medicines. In New Zealand, provision is not mandatory and leaflets in use are either those produced by a drug manufacturer or an independent organisation.\textsuperscript{160} In Australia, leaflet provision is also not mandatory and research shows that they are often forgotten or deliberately withheld.\textsuperscript{26, 173} Similarly, research in New Zealand identified that general practitioners (GPs) rarely provide patients with medicine information leaflets.\textsuperscript{174} The reasons that GPs may withhold leaflets include their perception that leaflets are too long or confusing and difficult for patients to understand, or their concern that patients will worry about possible side-effects and not take the medicine.\textsuperscript{184} However, it is not known if these concerns are reciprocated by their patients.

The aim of this study was to investigate Dunedin GPs’ provision of medicine information leaflets from patient reports, and to examine patient views on the leaflets provided.

**Methods**

A survey was developed based on previously validated questionnaires (for health professionals)\textsuperscript{174} and then pilot tested on 10 members of the public to ensure validity for this group. Minor changes for clarification were made (final questionnaire in Appendix 12). A sample size of 150-200 participants was intended, based on studies using similar sample sizes to investigate medicine information in primary care (ranging from 80 – 143 participants).\textsuperscript{174, 185, 186}

S. Moore administered the survey in community pharmacies in Dunedin, New Zealand between December 2016 and February 2017. Patients 18 years or older attending the
pharmacy with a prescription were invited to complete the survey. As an incentive, participants could enter a draw to win one of two NZ$50 supermarket vouchers.

All responses were entered into SurveyMonkey® by participants, or on behalf of participants by S. Moore. Data were extracted and analysed in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Basic descriptive analysis of data was undertaken. Sub analysis was performed on those who had received leaflets to investigate how it was provided to them, their preferences and opinions of the leaflets they were given, and whether they read the leaflet. Analysis on all groups was then undertaken to assess when they would like to receive leaflets, and how they prefer leaflets to be given (paper copy/digital version or full text/short summary). The University of Otago Ethics Committee approved the study (D17/007; Appendix 13).

Results

There were 151 respondents to the survey. Most were female (70%), spoke English as their first language (99%), and all eligible age groups were represented (Table 10). Highest qualifications gained was lower than that of the general population with over half only educated to secondary-school level (54%).

Table 10: Demographics of participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total n = 151 n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>105 (69.5)</td>
</tr>
<tr>
<td>Male</td>
<td>46 (30.5)</td>
</tr>
<tr>
<td>Highest completed qualification</td>
<td></td>
</tr>
<tr>
<td>No qualifications</td>
<td>7 (4.6)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>82 (54.3)</td>
</tr>
<tr>
<td>Postgraduate diploma</td>
<td>29 (19.2)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>18 (11.9)</td>
</tr>
<tr>
<td>Postgraduate degree</td>
<td>15 (9.9)</td>
</tr>
<tr>
<td>Characteristics</td>
<td>Total $n = 151$</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------</td>
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<tr>
<td></td>
<td>$n$ (%)</td>
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<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>18–19</td>
<td>7 (4.6)</td>
</tr>
<tr>
<td>20–29</td>
<td>16 (10.6)</td>
</tr>
<tr>
<td>30–39</td>
<td>20 (13.2)</td>
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<td>40–49</td>
<td>39 (25.8)</td>
</tr>
<tr>
<td>50–59</td>
<td>25 (16.6)</td>
</tr>
<tr>
<td>60–69</td>
<td>22 (14.6)</td>
</tr>
<tr>
<td>&gt;70</td>
<td>22 (14.6)</td>
</tr>
<tr>
<td><strong>First spoken language</strong></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>149 (98.7)</td>
</tr>
<tr>
<td>Bengali</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Chinese</td>
<td>1 (0.7)</td>
</tr>
</tbody>
</table>

Receiving medicine information leaflets

Most participants ($n=119$, 79%) had not received a medicine information leaflet from their GP in the last six months. Almost two-thirds ($n=93$, 62%) believed it was very important to receive a leaflet about new medicines. For repeat medicines, fewer participants ($n=33$, 22%) thought it was very important to receive a leaflet.

Of the respondents who had received a leaflet ($n=32$, 21%), over half had either discussed the leaflet with their GP or their GP had drawn attention to specific sections ($n=9$, 28% and $n=8$, 25% respectively). Most participants who received leaflets felt that it had improved their knowledge ($n=23$, 72%), and half ($n=16$, 50%) believed it had helped them take their medication correctly. One third ($n=11$, 34%) thought the leaflets encouraged them to take their medication as instructed.
Opinions on provided leaflets

Overall, 97% (n=31) liked the leaflet they received. Over half liked its appearance (n=19, 59%) and 75% (n=24,) believed it contained relevant and findable information. Most agreed they could read and understand it (n=23, 72%), but 9% (n=3) thought it was too long. Two-thirds of participants had read the full leaflet (n=21, 66%) and 10 (31%) had partially read it. Only one participant (3%) had not read the leaflet. Over half said they had not kept the leaflet (n=18, 56%) but 43% (n=14) had kept it.

When and how patients want information

Most participants (n=116, 77%) would like to receive a leaflet from their GP when prescribed a new medicine, while 5% (n=8) preferred not to be given one at all. Approximately half of participants wanted to receive a leaflet when new information becomes available (n=82, 54%), when the medicine is associated with serious side-effects (n=80, 53%), or when there is a change in the brand (n=72, 48%).

Most respondents (n=120, 80%) would prefer a paper leaflet to a digital alternative. Over half (n=90, 60%) preferred a one– to two-page summarised version of a leaflet (summary leaflet) rather than a comprehensive leaflet, or a summary leaflet with the option of receiving more information.

Participants mostly never sought further information (n=50, 33%), or sought more information less than half the time (n=47, 31%).

Discussion

Patients are usually given information orally, but written information should also be provided to ensure patients are fully informed, and to remind them of information and instructions for use.\textsuperscript{109} Most participants in this and other studies consider it important to receive medicine information leaflets from their GP.\textsuperscript{26} However, when providing leaflets with medicines is not a legal requirement (as is the case in New Zealand)\textsuperscript{160} they are often not given.\textsuperscript{173, 174}

In New Zealand, previous research has shown that GPs avoid providing leaflets because of concern that patients cannot understand them, patient’s previous
medicines, assumed patient indifference and belief that pharmacists provide leaflets. Yet almost all participants who had received a leaflet from their GP appreciated it and had no difficulty in understanding the information it contained. Some participants did have difficulty understanding the content, and other research indicates that manufacturer-produced leaflets may be poorly suited to patients’ requirements in style and readability. However, participants in this study with qualifications higher than secondary school were underrepresented, indicating that those with potentially lower literacy still appreciate leaflets being provided to them.

Previous New Zealand-based research found that GPs provided leaflets to inform patients, aid medicines adherence, prompt discussion, and to reinforce instructions and benefits of medicines. Most participants who received a leaflet in this study read it fully and agreed that leaflets improved their knowledge and helped them take their medicines correctly, showing this achieves their GPs’ intended purposes. Discussing leaflets could benefit those patients who have difficulty understanding them but time-pressures can affect information provision. System technological improvements might facilitate this process by alerts suggesting leaflet provision and automated leaflet printing within GP prescribing software. Further investigation is needed to establish whether automatic provision would alleviate time restraints at point-of-care.

There is evidence to suggest patients are increasingly searching for information digitally, but most participants in our study preferred a paper leaflet rather than a digital alternative. Perhaps further encouragement and support from healthcare providers about reputable web-based information would help patient engagement. Most participants preferred the idea of a one- two-page summary and health professionals prefer to provide summary leaflets so this format may be more suitable than lengthy manufacturer-produced leaflets. Actively providing summary leaflets to patients is not common practice. Action by governments and health professional bodies may be needed to ensure patients have access to tailored information leaflets that suit their needs.
Some patients may want more information about their medicines than GPs’ currently provide, yet two-thirds of participants in this study did not look for further medicines information from other sources. Patients may need encouragement to be proactive and ask for more information from their GPs.

Limitations
As this was a small study, there are limitations to what can be gleaned from the data. Results may not represent other patients in Dunedin or in other more ethnically and age-diverse parts of New Zealand. Most participants spoke English as their first language and understanding written communication may differ for people who did not originally speak English.

We did not collect information on the medicines patients were prescribed, so no conclusions can be drawn as to the types of medicines more likely to prompt leaflet provision, although earlier research indicates leaflets are more likely to be provided with higher-risk medicines. This study did not confirm the type of leaflets participants received, so differences between manufacturer-produced leaflets and leaflets from independent organisations were not explored.

There is a risk of recall bias with participants being asked to remember the previous 6-month period. Participants may also not remember exactly who provided them with leaflets, with the questionnaire being administered in a pharmacy. Attempts were made to mitigate this risk by orally explaining to participants that the focus was on GP provision of leaflets before they completed the questionnaire, as well as in the questionnaire. Some participants may have still been confused and inadvertently answered about pharmacist provision of leaflets.

So far, there is no consensus on who should provide information leaflets. Both pharmacists and GPs are required to ensure patients are fully informed about their medicines. Further research is required to determine who should provide what information, at what time, and in what format. This could contribute to clearer guidance for GPs and pharmacists.
Conclusion
Patients value having leaflets provided to them with new medicines, but this may not commonly occur in practice because it is not a mandatory requirement in New Zealand. Patients should be encouraged to ask and look for information about their medicines from reputable sources. Ensuring they receive leaflets along with oral discussion about their medicines could help them take their medicines safely and improve their knowledge. Further research is required to determine patient preferences of the different leaflets available and the perceptions of patients from a larger sample of the population.

Competing Interests
The authors declare that they have no competing interests.

Acknowledgements and funding
The authors would like to thank the participants who completed the survey and the community pharmacies that allowed data collection on their premises. This work was supported by the University of Otago School of Pharmacy summer studentship scholarship for S. Moore.

4.5.2 Methods, further information
Rationale of methods chosen
A quantitative method was chosen to statistically analyse responses and compare findings to similar international research. A survey instrument with quantitative questions would take less time to administer in a busy pharmacy and potentially obtain a larger sample of people than a qualitative study and be more able to assure generalisability of the findings.

Questionnaire validity
The questionnaires validity was determined using the same methods described in section 3.4 (i.e. same methods used for the GP and pharmacist surveys). Following this validity testing, the questionnaires were pilot tested in 10 members of the public
using the same modes of data collection as proposed for the study. This was to assess readability and understanding. Any necessary modifications were implemented after careful assessment by the research team. Minor changes to wording were required, e.g. ‘verbally’ changed to ‘discussed with you’, ‘monitor the treatment’s effectiveness’ to ‘tell if the medicine is working’.

The questionnaire was estimated to take eight minutes to complete.

Recruitment

The research team identified eight possible pharmacies, when considering location in Dunedin, New Zealand, their customer/population profile, and suitability of their premises for data collection and privacy. The first five of these pharmacies approached agreed to take part and the survey was administered in those locations.

People 18 years and older were approached in a pharmacy as they waited for their prescription. Participants were required to be able to read and understand English and currently taking a prescription medicine. Pharmacy staff invited patients who had submitted a prescription to be filled to speak to a researcher based in the pharmacy. The researcher would describe a survey he was carrying out and ask if the patient would like to complete this while waiting for their prescription to be filled. This ‘arm’s length’ approach was to ensure that patients who were potentially under 18 years old, distressed or vulnerable were not directly approached by the researcher.

Those who indicated that they were interested in participating were provided with a paper Patient Information Sheet (PIS) to read and could ask the researcher questions if needed. Completing the survey was regarded as implying consent.

The questionnaire was entered into SurveyMonkey (electronic survey software) and presented to the participant via a tablet computer. Participants could complete the survey themselves, or if they preferred, the researcher could ask them the questions and enter responses on their behalf. If they preferred electronic access to the PIS and survey, participants could have provided the researcher with their email address and we would email them the PIS and a survey link. Alternatively, we could have provided them with a hardcopy of the survey weblink to complete the survey in their own time.
Because recruitment was being undertaken by busy pharmacy staff, data on recruitment rate was not collected. Instead, we had a target participation rate of 150–200 participants and continued recruiting until this target was attained.

4.6 Chapter conclusion

This chapter described provision of medicine information leaflets to patients with new and repeat medicines, GPs’ and pharmacists’ opinions on leaflets available and their reasons why they would and would not provide leaflets. The use of websites and provision of personalised information was also discussed.

We ascertained from self-reports that GPs and pharmacists are not giving medicine information leaflets to their patients all of the time. Most GPs and pharmacists give their patients medicine information leaflets some of the time (i.e. less than half of the time). Additionally very few GPs or pharmacists provide leaflets with repeated medicines. Most GPs and pharmacists agreed that leaflets should be given with new medicines and that they provide leaflets because they believe patients should be fully informed about the medicines they are taking. Our study also revealed that GPs and pharmacists do not usually guide patients to websites for reputable and accurate information about their medicines. This is concerning because, in chapter 3 it was discussed that patients may not be adequately receiving enough verbally provided information to take their medicines safely. Furthermore, as mentioned previously, there are limitations to purely relying on verbal communication for reasons such as patients’ limited capacity for remembering and understanding information at time of consultation. This study added to the information provision picture in New Zealand primary care by showing that patients may also not be receiving printed or digital medicine information they need.

To try to understand why leaflets may or may not be given to patients, we asked what GPs and pharmacists liked and disliked about the leaflets currently used. The reasons that both groups liked and disliked leaflets were similar and fell into the same categories: i) leaflet design; ii) content of the leaflet; iii) accessibility of leaflets at
point-of-care; iv) perceived quality; and v) usefulness and usability. With positive and negative comments given in each category (see Section 4.3.1). Tailoring leaflets would improve the content, complexity, and usefulness of leaflets and the GPs and pharmacists in the study support the creation of tailored summary leaflets for their patients.

So why else are leaflets not being provided? There are many reasons given by GPs and pharmacists. More pharmacists avoided giving leaflets because the patient had taken the medicine before and the medicine was being used for an indication that was not on the leaflet. Alarmingly many from both groups responded that they do not want to worry the patient with information about side-effects because this could cause anxiety and reduce adherence to treatment. This has been disproven in the literature, with some consensus that if potential harms are well explained to patients it does not discourage them from taking their medicines.26,190 Furthermore, this also takes away patient informed choice, where the choice to take no medicine should also be left up to the patient if they feel the risk of harms outweigh the potential benefits of their treatment.2

Other reasons that leaflets are not provided or liked by GPs and pharmacists include the lack of time available to discuss them, difficulty in accessing them, forgetting their availability, and the perceived lack of appropriateness for patients. System changes and the use of technology to support health professionals at point-of-care could help address these challenges. Improving accessibility and instilling their provision in the usual work-flow of GPs and pharmacists would encourage their use simply by making it easier for them to print off. This would require a change in the software currently in use e.g. for the incorporation of a ‘print medicine information leaflet’ button to be simply clicked at the end of the prescribing and dispensing process. Additionally, improving the design and content of leaflets currently available would be beneficial to GPs, pharmacists, and patients, with all groups disliking the length and complexity of the manufacturer-written CMIs. Across the board, a summary one- to two-page leaflet is the most preferred option, possibly improved further with the ability to personalise the information to the patient requirements. The combination of improvements in the
software and the production of appropriate summary leaflets would both work together to improve the time necessary to print and discuss leaflets with patients, which is a large barrier for current provision.

Unfortunately this technology is not yet available in clinical practice and it is unknown if software vendors are able to incorporate this functionality into current prescribing and dispensing systems. Further investigation into the feasibility of creating a digital system to provide personalised summary medicine information leaflets to patients will be discussed in chapter 5.

GPs and pharmacists often thought that patients did not want leaflets and so would not provide them. However this is an unsubstantiated assumption, as the small study asking patients’ views (section 4.5.1) showed a positive response to leaflets when received, with most patients feeling that the additional information aided their understanding and their ability to take their medicines properly. Over three-quarters of patients prescribed a new medicine would like to receive leaflets from their GP and most patients who had received leaflets liked them and found them easy to read. Other reasons a leaflet may be desired was when new information arises, when a medicine is associated with serious side-effects, or when there is a change in the brand. However, similarly to health professionals’ views, less than a quarter thought it was important to be given leaflets with medicines that they had taken before (when no new information available).

This study also found that most patients had not received a leaflet recently from their GP and patients tended to not look for further information about their medicines. However, there is an international trend that more and more patients are looking to the internet to provide them with information about their health, including information about their medicine. Patients may need encouragement to seek further information about their medicines to increase engagement in their health management.

With patients not receiving enough verbal information about their medicines, it is possible they may begin to search for information on the internet. Whilst this could be beneficial to patients’ autonomy, it may be concerning due to the general lack of
know-how on critical analysis of web-content for accuracy. Health professionals have a role in providing accurate and useful information about medicines or, at the very least, guiding their patients to reputable websites for medicines information.
Chapter 5: Feasibility of creating personalised medicine information

5.1 Synopsis

Previous chapters have discussed the pitfalls of providing patients with medicines information in current practice including the type of material given, the way it is provided, and the opinions of health professionals on the information available to impart to patients. This chapter is an investigation into the possibility of providing personalised medicine leaflets and counselling points for GPs and pharmacists to use at point-of-care using software built into existing practice systems in New Zealand.

A Use Case and mock-up example of personalised information resources was created, and a feasibility study was undertaken. For the feasibility study, the Use Case and mock-up example were sent to vendors of GP prescribing systems and pharmacy dispensing systems along with a questionnaire to determine vendors’ requirements to build the system and their opinions of market worth and practicality of the project. Informal telephone and email correspondence was also undertaken with those who were willing to discuss their thoughts on the project further.

From vendors’ responses, we determined that it is not feasible to build this system within the current prescribing and dispensing management software used in New Zealand. The reasons for this include its: low perceived value by the vendors, potentially prohibitive costs, and possible lack of consistent use of patient coding by GPs. In addition, the pharmacy vendors’ thought that such a system might not work because pharmacists may not always be performing the role of prescription-data entry in the dispensary work flow and be unable to control leaflet and counselling-point production; this role is often performed by pharmacy technicians.
An alternative method is needed to provide patients with personalised and relevant medicine information. Use of Patient Reported Outcomes (PROs) might allow for personalisation and specific information provision.

Chapter structure

This chapter has two parts:

1. **A Use Case for providing personalised medicines information in primary care.**
   Section 5.3 outlines a Use Case and mock-up example of automated personalised medicine information for patients at point-of-care for primary care prescribing and dispensing systems.

2. **Feasibility study for providing personalised medicines information in primary care.** Section 5.4 uses the resources generated in the first section and undertakes a feasibility study on the viability of the proposed Use Case.

5.2 Chapter aims

There are a number of difficulties that health practitioners are faced with during a consultation. There is often little time for lengthy discussions about treatments and sometimes remembering to provide patients with in-depth information falls by the wayside when faced with the other tasks required for diagnosing, prescribing, and dispensing medicines. This chapter aims to describe and determine the feasibility of building software that would integrate into existing systems to automatically provide personalised information at point-of-care in New Zealand practice.

Specific aim 1: To create a Use Case and mock-up example for GP prescribing systems and pharmacy dispensing systems to provide personalised medicines information at point-of-care for health care professionals to use during consultation.

Specific aim 2: With the help of New Zealand’s vendors of prescribing and dispensing software, determine the feasibility of building a system to provide automatic personalised medicines information (i.e. the Use Case) for GPs and pharmacists to use at point-of-care.
5.3 A Use Case for providing personalised medicines information in primary care

5.3.1 Introduction

The findings in chapters 2, 3, and 4 indicate that there is room for improvements to be made in the way that information is provided to patients about their medicines. The narrative review in chapter 2 described what patients want to know about their medicines to support adherence and safe medicine-taking, and if presented in a written format, how this is best designed to attract their attention and encourage them to read it. Chapter 3 discussed the current prevalence and consistency of verbally imparting information about medicines to patients. Chapter 4 outlined the utilisation of medicines information leaflets in practice and GPs’ and pharmacists’ opinions on those currently available in New Zealand. Overall, these chapters painted a picture of inadequate and inconsistent information provision to patients with a strong need for a universal change in practice. Due to time and other constraints of health professionals in practice, we need to use technological advancements to facilitate change. One solution is for software to automatically provide counselling points and medicine information leaflets for GPs and pharmacists to discuss with patients at point-of-care.

With this solution in mind, preliminary discussions were undertaken with a vendor of GP prescribing systems in New Zealand about what would need to be provided to software developers. A Use Case was requested by the vendor in order to “clearly articulate [our] approach & outcome, thus allowing the feasibility to be revealed i.e. effort vs benefit”.

A Use Case is a standard requirement in the software development process and defines what steps are required to achieve the desired goal and who is involved in each stage of the process (see Table 11). A Use Case can be adapted for project requirements but will generally contain the same basic components.
<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
<th>Example from daily life</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>A brief description of the Use Case.</td>
<td>A customer decides to purchase a specific item from a shop and goes to the shop to make the purchase.</td>
</tr>
<tr>
<td><strong>Level</strong></td>
<td>Description of what level in the system the steps described in the Use Case occur. These are typically either user goal (achieves the desired goal for user), summary (broader context often with a set of user goal Use Cases; typically over hours, days, weeks, or longer), or sub function (isolated part of user goal moved into a separate Use Case).</td>
<td>User goal – a single person achieves their desired outcome by buying an item.</td>
</tr>
<tr>
<td><strong>Trigger</strong></td>
<td>The event that causes the Use Case to occur.</td>
<td>Customer requests to buy an item from a shop.</td>
</tr>
<tr>
<td><strong>Primary Actor</strong></td>
<td>The main individual whose goal is satisfied on completion of the Use Case.</td>
<td>The customer making the purchase.</td>
</tr>
<tr>
<td><strong>Additional/Supporting Actors</strong></td>
<td>Other individuals who are also involved in the Use case.</td>
<td>Salesperson.</td>
</tr>
<tr>
<td><strong>Stakeholders</strong></td>
<td>Those who are not directly involved in the Use Case, but have an interest in the outcome.</td>
<td>Business manager.</td>
</tr>
</tbody>
</table>

Sales reps and wholesale staff.
| **Preconditions** | The list of conditions that must be true for the Use Case to be able to run. | Customer has funds to purchase item.  
The shop sells the required item.  
Technology available to complete purchase.  
Business has capability to accept funds. |
|-------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| **Main Success Scenario** | The simplest steps required to result in accomplishing the goal.  
This should describe the actions and responses by the actors and system in the Use Case that ends with a successful completion of the process. | Customer requests an item for purchase. Salesperson finds and scans item and requests payment.  
Customer pays for item and takes it away. |
| **Extensions** | Alternative routes and exceptions to the main success scenario. These are numbered according to what step of the success scenario that this alternate path occurred. | Customer has insufficient funds in chosen payment method (e.g. in their bank account) and pays by alternative method (e.g. with cash).  
Business does not accept chosen payment method (e.g. credit card) and customer must pay another way (e.g. with cash). |
Desired item not in stock and needs to be ordered in to shop.

Customer returns goods and is refunded for the purchase.

<table>
<thead>
<tr>
<th>Post Conditions:</th>
<th>1. Successful outcome of the Use Case (primary actor’s goal is satisfied).</th>
<th>1. Customer successfully buys an item.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Success End</strong> Condition</td>
<td>2. The assurance provided to all actors and stakeholders that their interests will be protected regardless of the outcome of the Use Case.</td>
<td>2. The customer can change their mind at any time.</td>
</tr>
<tr>
<td><strong>2. Minimal Guarantees</strong></td>
<td>3. What the resulting outcome is if the Use Case fails.</td>
<td>Customer’s personal information is not collected unless for a specific purpose (e.g. for contact after ordering in item). The item remains in the shop if not paid for.</td>
</tr>
<tr>
<td><strong>3. Failure End Condition</strong></td>
<td></td>
<td>3. The customer leaves the shop without making a purchase.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Frequency</th>
<th>How often the Use Case is expected to occur (to determine capacity requirements).</th>
<th>Transactions occur in this shop 45 times per hour.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Special Requirements</th>
<th>Additional factors that could impact the Use Case e.g. performance, privacy, usability, accessibility.</th>
<th>Good customer service is provided.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Shop is in suitable location to visit.</td>
</tr>
</tbody>
</table>
Suitable payment methods are available.

Shop is well-stocked.

Shop must comply with the New Zealand Consumer Guarantees Act.

<table>
<thead>
<tr>
<th>Issues</th>
<th>Items to keep in stock.</th>
<th>Language requirements for area shop located.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any issues that require clarification or follow-up work required before development can begin.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Use Cases are often displayed as a diagram to allow visualisation of how actors interact with the system. Summary Use Case diagrams can include multiple user goal Use Cases to show higher-level relationships between them. In the diagram actors are included as figures and Use Cases as ellipses. Lines are drawn that indicate the relationships, or communications between actors and Use Cases. Extensions to the Main Success Scenario (i.e. alternative route) can also be included. An extension is drawn using a dashed arrow between the extension to the Main Success Scenario (e.g. in the example in Table 11, an extension is not having the item in stock so ordering it in for the customer).

The vendor also requested an example of personalised information to understand how a “personalised leaflet [will] differ to what is already available? which includes a generalised leaflet coupled with the medication label.” Therefore, to present the solution to vendors of prescribing and dispensing software in New Zealand and to understand its feasibility, a Use Case and a mock-up example of personalised information was created.
5.3.2 Methods

A Use Case template was found\textsuperscript{191} that was suitable for the purposes of presentation of the proposal to vendors of prescribing and dispensing systems used in New Zealand. The template was adapted slightly to fit the purposes of this particular project e.g. justification and expected benefits were included to describe to vendors why the proposal is a good idea and how it could benefit GPs and pharmacists. Two Use Cases, one for GP prescribing systems and one for pharmacy dispensing systems, were created. A summary Use Case diagram was also created to help show where the Use Case would sit in the prescriber- or pharmacist-patient encounter.

An example of a potential personalised counselling point pop-up box and medicine information leaflet were also created. The content of these were adapted using the New Zealand Formulary,\textsuperscript{176} the British National Formulary,\textsuperscript{193} the manufacturers Data Sheets available on the Medsafe website\textsuperscript{47} which are commonly used in New Zealand primary care, and Medicines for Children UK\textsuperscript{194} (a leaflet used in paediatrics internationally).

The Use Cases, the medicine counselling points and information leaflet were created by AY with input from project supervisors AS and JT, and from GP advisor Dr Sharon Leitch.

5.3.3 Results

Two Use Cases were created, one for GP prescribing systems and one for pharmacy dispensing systems, and these are presented in Appendices 14 and 15. Summary Use Case diagrams to visually model the functionality of the Use Case systems were created and are presented below. The examples created for the personalised counselling point pop-up box and medicine information leaflet are also presented below.
Summary Use Case diagrams for functionality of integrated personalised medicine information tool

Figure 13: Prescribing systems summary Use Case diagram
Figure 14: Dispensing systems summary Use Case diagram

Example of potential personalised information

Example of key practice points
An example created for display in prescribing or dispensing systems is presented on the next page, with some key features explained. The example is key practice points for a fictional 70-year-old female prescribed amitriptyline for neuropathic pain. Examples of information for omission include pregnancy and breast-feeding advice, contraception information, other indications and doses of amitriptyline, and child-specific side effects.
Figure 15: The prototype for key practice points to be presented in the Prescribing or dispensing system

From this window it would be possible to automatically create a personalised information leaflet, by selecting ‘Medicine leaflet’. This would then form a personalised medicine information leaflet in the software to be printed by the prescriber or dispenser. An example of a personalised information sheet for the same hypothetical patient is presented on the next page. This is adapted from Medicines For Children UK (Amitriptyline for neuropathic pain),\textsuperscript{195} bpa_cnz,\textsuperscript{196} and the NZF.\textsuperscript{176}
Amitriptyline

for neuropathic pain

This leaflet is about the use of amitriptyline for the treatment of neuropathic pain (pain caused by nerve damage).

Name of your medicine

Amitriptyline (sometimes known as amitriptyline hydrochloride)

Brands available include Arrow-Amitriptyline and Amirol

What you have been prescribed

10 mg tablets

What amitriptyline will do for you

Amitriptyline will help you to feel less pain. The pain may be described as having a burning, shooting or scalding sensation.

How to take your amitriptyline

1 tablet at night for 7 days. This may increase over time, see the label on your medicine for more information. Tablets should be swallowed with a glass of water, milk or juice.

Follow your prescriber’s instructions about how much to take.

Amitriptyline must be taken regularly every day and, depending on the cause of your neuropathic pain, may need to be continued indefinitely.

Do not change the dose without talking to your prescriber first. Stopping suddenly may make you feel unwell. You will usually reduce the dose in small steps over time.

When the medicine should start working

Pain caused by nerve damage can be difficult to treat. It may take many weeks for amitriptyline to work properly. Continue to take the medicine as you have been told to. If amitriptyline does not seem to be helping your pain after four weeks, contact your prescriber for advice.

If you miss a dose or are sick

- If you forget to take amitriptyline, you can take the missed dose as long as this is 12 hours before the next dose is due. However, if amitriptyline makes you feel sleepy, it is better to skip the missed dose and take the next dose when it is normally due.

- If you are sick (vomit) less than 30 minutes after having a dose of amitriptyline, take the same dose again. If you are sick more than 30 minutes after having a dose of amitriptyline, you do not need to take another dose. Have the next dose when it is normally due.

Do not take a double dose of amitriptyline.

Monitoring

Your doctor may do a heart test (ECG) before you start and while you are taking amitriptyline.

Possible side-effects

Side-effects to see your doctor about straight away

- Up to 1 in 10 people may have an irregular heart beat e.g. your heart may feel like it is racing or have a fluttery feeling in your chest.

- Up to 1 in 1,000 people may get symptoms of jaundice like yellowing of their eyes or skin, dark urine (wee) or light-coloured poo. This could be a sign that you liver has been affected.

- Up to 1 in 1,000 people may bruise or bleed easier, or have a persistent sore throat or fever. This could be a sign that your bone marrow is affected.

- Up to 1 in 10,000 people have problems with their eyesight (e.g. blurred or double vision).

Other side-effects you need to know about

- More than 1 in 10 people feel sleepy for a few hours after having a dose of amitriptyline. This is why you should take amitriptyline in the evening.
• More than 1 in 10 people get a dry mouth. Taking sips of water or chewing sugar-free gum between meals may help. There are preparations that may help to moisten your mouth including sprays or lozenges, talk to your pharmacist or dentist. Make sure you brush and floss your teeth at least twice daily to prevent tooth decay.

• More than 1 in 10 people, when first start taking amitriptyline, feel sweaty, feel sick (nausea), have constipation (difficulty doing a poo) or find it difficult to pass urine (do a wee). These symptoms should settle down after a week or so.

If you still have any of these symptoms after 2 weeks, or you are worried, contact your doctor.

There may, sometimes, be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor.

Taking other medicines with amitriptyline
You can take medicines that contain paracetamol or ibuprofen, unless your doctor has told you not to.

Amitriptyline should not be taken with some common drugs that you get on prescription.

Tell your doctor and pharmacist about any medicines you are taking before starting amitriptyline.

Some other common medicines you can buy yourself from a pharmacy or supermarket may be harmful when taken with amitriptyline. These include antihistamines (in anti-allergy, anti-nausea and cough/cold medicines), cough/cold medicines containing dextromethorphan, St John’s Wort, and recreational drugs (e.g. ecstasy).

Check with your doctor or pharmacist before taking any other medicines. This includes herbal or complementary medicines.

Storing your medicine
• Keep the medicine in a cupboard in the container it came in, away from heat and direct sunlight. It does not need to be kept in the fridge.
• Make sure that children cannot see or reach the medicine.
• All unwanted medicines should be returned to your pharmacy for disposal.

Lifestyle information
• Amitriptyline may make you dizzy or sleepy. If this happens, do not drive or use tools or machines. Limit alcohol intake because it can increase these effects.

• Up to 1 in 10 people experience a lower sex drive. If you are concerned about this, talk to your doctor.

General health tips for neuropathic pain
• It is important that you get enough sleep at night time. Avoid watching television or using electronic devices in the bedroom. Avoid stimulants or diuretics, including coffee, tea, and alcohol close to bed-time. For more information, see Tips to improve your sleeping habits, Health Navigator New Zealand, https://www.healthnavigator.org.nz/healthy-living/sleep/sleep-tips/.

• Exercise improves strength and balance and should be continued if possible. If your pain or medicine is stopping you from being able to exercise, talk to your doctor; an occupational therapist, physiotherapist or counsellor may be helpful.

Alternative therapies and treatment options
There are other treatment options available if amitriptyline does not work for you, such as nortriptyline or gabapentin. Other treatments can help neuropathic pain, such as acupuncture or transcutaneous electrical nerve stimulation (TENS). Your doctor will discuss different options with you.

Who to contact for more information
Your doctor, pharmacist or nurse will be able to give you more information about amitriptyline and about other treatments for neuropathic pain.

Further advice and information is available from:
• Health Navigator New Zealand, Nerve pain: https://www.healthnavigator.org.nz/health-a-z/n/nerve-pain/
• Arthritis New Zealand: www.arthritis.org.nz/information/treatment-management/living-a-healthy-life/
• The Pain Toolkit, pain self-management tools: www.paintoolkit.org/tools
• New Zealand Pain Society: www.nzps.org.nz

The information in this leaflet was created by XXXX.
Leaflet printed 29.11.17
5.3.4 Discussion

Upon creation of the Use Case and higher-level diagram it is clear that the processes involved are complicated and require many systems (Use Cases) working together to successfully provide patients with personalised information. From an academic perspective, the benefits of achieving the outcomes described in chapter 2 (narrative review) would likely outweigh the work required to achieve them. Furthermore, chapter 4 showed that health professionals generally approved of the idea of providing personalised summary leaflets to patients. Yet we must acknowledge there are already generalised medicine information leaflets available to patients and that those who develop and maintain dispensing and prescribing system software may/may not agree that the benefits of our proposed new system would outweigh the work and costs involved.

5.3.5 Conclusion

A Use Case is an important first step in software design and project management. It outlines the roles and requirements for the process and examines what would occur if the ideal scenario is not accomplished. A Use Case, a summary Use Case diagram and a mock-up example of personalised information were created to present to vendors of GP prescribing systems and pharmacy dispensing systems in New Zealand. This was the first step in determining the feasibility of building this application into software currently in use in New Zealand practice.
5.4 Feasibility study for providing personalised medicines information in primary care

5.4.1 Introduction

A Use Case was described in section 5.3, outlining the requirements for a system to be able to build personalised information for patients within prescribing or dispensing systems. Moving forward we need to determine if this can be built and at what cost. The best way to do this is to undertake a business feasibility study.

A feasibility study determines the viability of a project and identifies potential problems that could occur. The common determinants in a business feasibility study are in Table 12.

<table>
<thead>
<tr>
<th>Component</th>
<th>What this is for</th>
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<tbody>
<tr>
<td>Market Feasibility</td>
<td>To describe how the project fits in with the current market and what future market potential is anticipated.</td>
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<tr>
<td>Technical Feasibility</td>
<td>To outline what would be necessary to implement the project (e.g. staff and resources required).</td>
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<tr>
<td>Financial Feasibility</td>
<td>To know what the start-up costs of the project would be (i.e. how much investment is required).</td>
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<tr>
<td>Organisational Feasibility</td>
<td>To describe how the project will work within the current organisation and if it would be disruptive to current workflows.</td>
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<tr>
<td>Conclusions</td>
<td>To explain how the project would improve the current business and enable it to work towards company philosophy or goals.</td>
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Using the identified components of a business feasibility study, the aim of this section is to:

a) ask vendors their opinions about building personalised information for patients within prescribing or dispensing systems;
b) determine the feasibility of producing the software from the vendors’ perspective;
c) ask vendors their opinions about whether this project would benefit users of their systems.

5.4.2 Methods

Questionnaire

Two questionnaires were created, one each for vendors of prescribing and dispensing systems (see Appendices 16 and 17), using the components of information required for a business feasibility study to determine opinions and estimations on the market, technical, financial, and organisational feasibility of the project. This was to identify the feasibility of the project from a business perspective. We also wanted to know vendors’ opinions on the project so we added an additional section in our survey of ‘possible benefits to users’.

Questions were about business case elements that would directly enable completion of the business case criteria. Each question was mapped against one of the required points for the business case. The requirements of the business case were section headings for the survey: benefit to users, market feasibility, technical requirements, financial requirements, scheduling feasibility, and barriers. The questions were designed as a combination of tick box selection and as open responses for estimations of required costs and timeframes. Further qualitative data could be captured with room for further comment after the questions.

Face and content validity was assured by having the research team involved in review of the questionnaire and mapping this to the business case criteria identified. Concept validity was determined by the mapping of questions to the requirements for the
business case. Further peer review independent of the research team was also undertaken.

The study was approved by University of Otago Human Ethics Committee (reference number D18/285). See Appendix 18 for copy of approval letter.

**Recruitment**

A list of all current vendors of software for primary care in New Zealand practice was collated, using information from the internet and local knowledge from GPs and pharmacists. This practical approach was taken because there are few software vendors in use in the primary care setting in New Zealand and the research team have extensive contacts working in pharmacy and general practice. Six vendors were identified through internet searching and local knowledge, four for prescribing systems, and two for dispensing systems, see Table 13. Contact details were found through an internet search.

**Table 13: Current vendors of prescribing and dispensing systems in New Zealand**

<table>
<thead>
<tr>
<th>Type of system</th>
<th>Vendors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prescribing</strong></td>
<td></td>
</tr>
<tr>
<td>MedTech</td>
<td></td>
</tr>
<tr>
<td>Indici</td>
<td></td>
</tr>
<tr>
<td>MyPractice</td>
<td></td>
</tr>
<tr>
<td>Intrahealth</td>
<td></td>
</tr>
<tr>
<td><strong>Dispensing</strong></td>
<td></td>
</tr>
<tr>
<td>Toniq</td>
<td></td>
</tr>
<tr>
<td>RxOne</td>
<td></td>
</tr>
</tbody>
</table>

All identified vendors were invited to participate in the study via email and were sent the Use Case, the summary Use Case diagram, and the mock-up example of personalised medicine information to look over before answering the questionnaire. Invited participants were informed that survey participation implied informed consent.
Data collection

An introductory phone call was made to vendors in October 2018 with request for most appropriate email address, for which to send the correspondence, participant information sheets, and questionnaire. Data from emailed contacts was collected using SurveyMonkey®. A follow up email was sent in one month, and in another three months later. A further phone call follow up was made after five months of the original call, then the survey was closed for analysis in March 2019. Responses were grouped for discussion and interpretation. Documentation of conversations was also undertaken for those who had expressed reluctance to complete the questionnaire but were willing to informally participate via phone and email correspondence. Permission to record telephone conversations was not obtained. Instead, quotes from the telephone dialogue were transcribed during conversation and repeated back to the interviewee for confirmation and approval. This correspondence underwent thematic analysis (AY) using an iterative approach to examine other constructive feedback for the project and identify barriers in regards to feasibility. 

5.4.3 Results

Only two of the six vendors were willing to participate in the formal questionnaire. Two vendors, one for dispensing software and one for prescribing software, were willing to have informal discussions about the project, one via telephone and one by email correspondence to provide further comment around feasibility and their opinions.

Survey findings

Possible benefits to users

Both respondents felt there is some need for a tool providing personalised medicines information for patients. One respondent also commented, “Provided they are accompanied by counselling they would help to improve patient outcomes”. They also commented, “My concern would be that pharmacists are already very constrained by time – (so) would they use them?”. Both respondents agreed or strongly agreed that patients would like to be given personalised information as described in the Use Case.
Respondents thought that all (n=1) or most (n=1) health providers would use the tool if it was available. One respondent provided further comment, “Somewhere between some and most pharmacists would use the tool. If experience in Australia is anything to go by, encouraging pharmacists to go through the leaflet with the patient could be a problem”.

Both respondents’ current software allows users (healthcare professionals) to print medicines information leaflets for patients. The leaflets are currently available from standardised software/ information available in New Zealand, e.g. Med+Info and MIMS, and the New Zealand Formulary is to be integrated at some stage. They did not know if this functionality is used at point-of-care. One respondent commented that, “...89% of [users] have access to some form of paid patient information. 100% of [users] have access to the CMI, but generally speaking these are too long. We don’t know how many [users] actually use these on a regular basis. The integrations are able to prompt [them] to print these for patients receiving new medicines”. One respondent estimated that, “...over half of [users] (maybe 70-80% even) .... use either MIMS or Med+Info”.

Market Feasibility
Both respondents anticipated this project (the ability to produce personalised medicines information sheets) has future market potential. One respondent added the proviso, “if provided free of charge”. Neither respondent anticipated the addition of the medicine information tool would influence potential buyers of the software.

When asked if the software were to be either provided in the current package or available as a subscription, respondents answered, “It would depend on the funding model” and, “It depends on how much work we’re required to do and who pays for that - it could be a sub or a one-off fee”. Neither respondents thought the addition of the medicine information tool would increase sales of their product. One commented, “It would certainly be seen as beneficial but I don’t think it would increase our sales”. Nor did they think it would give them a market advantage over their competitors.
When asked about features of their system that set them apart from their competitors, vendor one mentioned a single unique feature and vendor two mentioned several unique features.

Technical requirements
Only one respondent answered the question about the additional materials or resources required to undertake this project (and expected number) and identified they would need additional servers (1), computer hardware and software (2), additional office space for employee(s) (2), and telephone with answering system (1). They further commented, “Content is the key. Who is creating the content and serving it up? Ideally [we] wouldn't be holding or serving up the content, just making the content available...”. The other respondent thought it too difficult to estimate technical requirements at this stage and commented, “It is difficult to estimate this without a full and exact specification of what we need to do. If we receive a file of MILs (Medicine information leaflets) specific for indications eg Amitriptyline for Neuropathic pain then we would find that easier to produce a personalised version...”.

The number of current or additional employees that would be required to undertake this project (not including the clinical information within leaflets) were identified in Table 14. Responses were similar and combined into ranges where they differed. All are one-off costs except ‘on-going support and maintenance’.

Table 14: Estimated employees and time of employment required

<table>
<thead>
<tr>
<th>Type of employee</th>
<th>Number of Full Time Equivalents (FTEs, 1 FTE = 40 hours/week)</th>
<th>Time employee to be dedicated to project (e.g. in weeks or months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Management</td>
<td>1</td>
<td>n/a</td>
</tr>
<tr>
<td>Project Management</td>
<td>1</td>
<td>2–4 weeks</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Type of employee</th>
<th>Number of Full Time Equivalents (FTEs, 1 FTE = 40 hours/week)</th>
<th>Time employee to be dedicated to project (e.g. in weeks or months)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Software Developer</strong></td>
<td>1-2</td>
<td>4–8 weeks</td>
</tr>
<tr>
<td><strong>Additional clinical support</strong></td>
<td>1</td>
<td>1–3 weeks</td>
</tr>
<tr>
<td><strong>Testing (Quality assurance)</strong></td>
<td>[Not specified]</td>
<td>2–4 weeks</td>
</tr>
<tr>
<td><strong>Deployment</strong></td>
<td>[Not specified]</td>
<td>1 week</td>
</tr>
<tr>
<td><strong>Setup support and on-going support and maintenance</strong></td>
<td>[Not specified]</td>
<td>on-going</td>
</tr>
</tbody>
</table>

One respondent further commented about these requirements that, “These are very rough estimates”.

When asked whether there are other technology requirements not previously mentioned, needed to undertake this project, one respondent commented, “Time and priorities. There are already many other projects we are undertaking”.

**Financial requirements**

Only one respondent was willing to estimate the total start-up cost of this project, and they roughly estimated it would cost NZ$100,000. Both respondents stated that external investment would be required for the project, and only one of the respondents stated that their company currently sets aside funding for new projects.

Only one respondent believed this project would provide financial return on investment.
Scheduling feasibility
Both respondents felt it would take 3–6 months to create the software for this project and one respondent thought it would be disruptive to their current work schedules.

Barriers
Aside from the time and cost, other barriers to this project identified were on-going maintenance and updating of clinical information and taking the focus off the current schedule of development.

One respondent could foresee concerns about data protection with the implementation of this project and commented that, “With the customisation, the printed information actually shows who is taking the medicine, whereas the current ones are generic and do not need to be securely destroyed”.

Final thoughts
Only one respondent thought that this project is one that would be worth pursuing. However, both respondents thought this project would help their company meet their philosophy or goal although the philosophy and/or goals identified by the respondents’ companies were, “Professionally satisfying, financially successful” and “To ensure the smooth running of [the business].....” and not clinically focused. In conclusion, one respondent commented, “It would be a ‘nice to have’ and if delivered to us in a format that can be consumed easily would be beneficial”.

Further comments made via telephone and email conversation
Two vendors were willing to provide informal feedback to the project. The feedback has been grouped into Positives, Negatives, and Other possible beneficial suggestions.

Positives
There were three positive feedback themes identified: i) digital, ii) cost, and iii) patient-centred.
i) The digital theme comprised of two ideas, one was that the option of a digital leaflet may be better for consumers. The other idea was that including leaflet prompting and printing functionality would require minimal work from the software vendor.

ii) With respect to cost, the project would reduce costs to the users of the software for not having to print a leaflet if a digital one was provided. Also one vendor commented that there is, “Definitely space for a better free alternative but need funding to make this happen”.

iii) The positive patient-centred theme included how beneficial personalisation of information would be, “Some drugs are used for multiple purposes and your approach allows just that condition to be presented on the leaflet removing unnecessary clutter. This could be easily highlighted by comparing an existing leaflet against a customised leaflet which will obviously [be] smaller in content because it is targeted to the individual”. A further benefit would be how information could be specific to that patient rather than for other family/whānau on the same medicines for which the information is not appropriate, “You should consider ALL data elements which are necessary for example PATIENT NAME, I would expect to be contained within the leaflet so it is identified as personalised for a specific patient rather than be shared among whānau [extended family] who are on the same medication and details may not be applicable to them. And in light of this a generic disclaimer may be prudent. Perhaps even NHI number & DoB for greater uniqueness”. The last identified patient-centred benefit would be to enable more comprehensive documentation in patients’ clinical records, “The patient’s current condition list could be displayed for selection or another condition searched and once selected also adds to the patients condition list automatically”.

Negatives
The overwhelming majority of the feedback was critical of the project and there were many negative themes identified. The themes identified were i) cost, ii) workload, iii) risk of clinical harm, and iv) privacy.
i) The cost theme was about prohibitive costs to the software vendor, “Not commercially viable by itself, need funding to create and maintain it”, and to the user of the software “Costs – not everyone would want to pay”.

ii) The workload theme also covered workload to the software vendors, “Would be considerable work customising it” and the health professionals having to use the system, “Having the [health professional] include or remove information would be tricky and they may not want to take the time”. Workload for health professionals was further emphasised with the comment, “This is just talking about the prescribing process, I would be shocked if a prescriber would create a customised leaflet for every consultation/medicine. And yes they may see four patients per hour but it may typically involve prescribing more than one medication per patient. Long term conditions such as diabetes may involve easily six medications/products. Is there any awareness of drugs that need targeting? If so this could allow volumes to be extrapolated”.

Workload issues could arise due to the dispensing processes in community pharmacies, particularly if the prompt would appear when using the dispensing software. This is because a pharmacy technician may be responsible for prescription entry in the dispensing software (and hence leaflet and counselling point production) and a pharmacist may not be involved in this process. This process would not work if technicians rather than pharmacists are performing that task, which is often the case, so clinical judgement of what to include in the leaflets could not be given. Expecting pharmacists to oversee this process could cause significant disruption and may be impossible in small, busy community pharmacies.

iii) Risk of clinical harm could occur in numerous ways:

1. Inaccurate or inappropriate information being included by prescribers or pharmacists. For example,

   a. if free-type is an option.

   “you must decide could the information in the leaflet be relevant to other HCP’s involved in the patient’s care including Emergency HCP’s. If there is
relevance, which you cannot judge if you allow [them] to enter free-text as they could say anything and in a worst case scenario the contents may contradict the medication Label instructions AND may explain why they have shown up in Emergency. Going to the extreme if a patient should die then naturally the coroner will also require this access to see if this information may have contributed”.

b. Or if the medicine has numerous uses.

“a SINGLE medication could treat multiple conditions, now more so as medications are being combined into one tablet for patient convenience”.

2. Important information being excluded.

“How to avoid not including important information. This is probably the largest risk, which I mentioned above, that must somehow be addressed. Obviously it could be clinically dangerous if important patient information was omitted”.

3. Information was confusing to patients.

“Be careful about the use of abbreviations such as OTC, ‘much’ of the population may not know what this means”.

4. Inconsistency with medicine labels.

“I am assuming the patient DOSE information may be auto-populated in the leaflet, if so it should be highlighted this information is unmodifiable in the leaflet as it must not differ to the medication label instructions. Reference to such an aspect highlights you have considered patient safety in regards to two separated pieces of information which MUST remain consistent”.

Furthermore, there was a feeling that including dose ranges could allow patients to alter their medicines without prescriber involvement.

“Knowing the patient’s age allows the presentation of typical dosage ranges, but these facts are maybe best left to the prescribers as it could allow patients to alter dosage”.

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5. Information being outdated. One vendor commented that. “Dosages/Strengths can of course change, so there would be some hesitancy to include this, as the leaflet could become outdated”.

iv) The theme of privacy was about how including identifiable patient information in the leaflets could be problematic.

“Sorry I cannot see value in including the Name on the leaflet apart from increasing the risk to privacy. Obviously the patient would know the information is for them, so what’s the point. But if someone else sees it, it reveals their condition which would impact privacy”.

Other possible beneficial suggestions

Despite the critical comments about the project, there were useful suggestions for further improvement and considerations that could be included. The themes identified were i) architecture/software and ii) leaflet content.

i) The architecture of the project could be remodelled completely and one vendor suggested that a different approach would be easier to maintain and roll out to multiple vendors. This was to have a central database of information that the vendors’ software can interact with to pull the required information out to provide leaflets. This centralised model would require the architecture to work with multiple systems.

“The other aspect which springs out is that potentially this solution would be best deployed via a centralised model rather than distributed across some or all [prescribing or dispensing] systems”.

“A centralised model, which publishes an API [Application Programming Interface] which allows receiving the necessary parameters (Age, condition, current dosage?, name?) to it and then outputs the ‘customised leaflet’ for either printing or emailing. Conceptually it could even allow patients to generate their own directly”.

Another software solution was the possibility for GPs and pharmacists to have ‘go to’ templates that they prefer to use with their patients. The thought was that this would make the system more appealing to users.
“If software can help a prescriber and help repeat processes then it becomes more attractive, hence reference to allow the prescriber to construct a personalised leaflet AND save it as a template for use for other patients and yes I realise this goes against a key principle but many patients will fit into the same category hence the advice should be consistent and not have to manually customise every time”.

The final architecture/software solution was about having a web-page framework to allow patients to search for appropriate information online or for somewhere for GPs and pharmacists to refer patients to.

“Historically Dr’s are always hesitant to listen to patients who have done searches as the information may not be accurate or trustworthy. In light of this there may be value to constructing a web-page framework which displays ‘trusted data sources’. Which could be considered a trusted source of information and avoids the commercially weighted ordered returns Google provides. Trouble is the means to endorse the data source is necessary and it would need to be maintained. If this did exist the means for a doctor to easily pass these links to a patient portal allowing the patient to access later if necessary”.

The other benefit of a web-based system is that it is easily updated.

“Web-based ‘content’ is a better model as it allows updates to be published immediately, without a system upgrade”.

ii) There were two suggestions for including additional information in leaflet content. These were a photo or picture of the medicine the patient is taking, and having the ability to have multi-lingual leaflets.

“One other obvious gap is support for multiple languages particularly as NZ’s ethnic diversity is expanding….While the Treaty of Waitangi encourages the continued use of Māori, there is no legal obligations for other languages however obviously there is a clinical need to ensure the patient fully understands relevant details…. From a user’s perspective it would be nice to easily translate any information or even auto translate based on a preferred language setting for the users who are online anyway”.
5.4.4 Discussion

It is widely recognised that people benefit from information that is tailored to their needs.\textsuperscript{78, 109, 199} The possibility of automating the tailoring of leaflet creation and counselling points was investigated in the light of the time constraints and other limitations on counselling methods found in practice, in earlier studies in this thesis.\textsuperscript{132, 174}

The aims of the feasibility study were to a) ask vendors their opinions about building personalised information for patients within prescribing or dispensing systems; b) determine the feasibility of producing the software from the vendors’ perspective; and c) ask vendors their opinions about whether this project would benefit users of their systems. The Use Case, summary Use Case diagram, mock-up example of tailoring information to patient characteristics and condition/disease, and a questionnaire were provided to vendors of prescribing and dispensing systems in New Zealand.

Feasibility of the project

The overall outcome of this study was that vendors considered that the project is not feasible to pursue. The reasons for this include large cost to the vendors, time required to complete the project, and the risk of hindering the development of vendors’ current projects in progress. Some patients may also have a negative response to receiving automated personalised information. In a UK-Australian study from 2013, researchers gave an example of a tailored leaflet to participants (people who take medicines) and found they had some similar reservations of being provided with tailored information, such as the feasibility and costs required to achieve it.\textsuperscript{78}

In the present study there was also little perceived value by the vendors, so it is unlikely this project would be successful. Additionally, it was thought that the ability to create personalised medicine information for counselling/providing leaflets would not influence potential buyers of the software. However, this could be because there are few vendors operating in New Zealand resulting in less competition for business.
Perhaps manual personalisation of information during consultation is still the best approach, particularly for certain groups who may have difficulties understanding the generic information provided. This is possible for certain medicines where there are numerous leaflets available. However, it may be necessary for different patient groups to be involved to help decide what should be included in the information they are receiving, e.g. those using inhalers may need more in-depth information about inhaler technique.

There are calls for more adaptable and flexible information provision to suit patient needs and this could be accomplished with digital information presented to people on a smart platform. This could also allow people to ‘self-tailor’ their information as they see fit, which may be preferred by some people. However, this will not be appropriate for every patient. Individuals’ requirements for mode of information delivery need to be considered.

Another constraint to ability to provide leaflets identified in this study was how health professionals use their current software. There is lack of consistent use of patient coding by GPs, and limited access to determine indications for medicines by pharmacists. Furthermore, there is the limited/lack of involvement of pharmacists in the prescription-data entry processing in the dispensary work flow (and hence in leaflet and counselling point production).

Vendors expressed concern about keeping the information up-to-date. This was understandable because a clear pathway for the ongoing updating of clinical content and the costs were unknown. Perhaps also deciding what information is to be included, how it should be written, and what is considered ‘tailorable’ would be a monumental and time-consuming task and would require significant clinician and patient involvement before completion. It may be more practical to start with a smaller group of medicines or medicines for specific conditions before attempting to create information for all medicines available in New Zealand.

The vendors mentioned a number of potential clinical harm with the project including the possible inclusion of inappropriate information in leaflets, the risk of missing out important information from the leaflets, and the risk of contradictory information.
being present between the medicine labels and the information leaflet. Similar reservations were described in the UK-Australian patient study where concerns about patient safety (e.g. wrong information given to the wrong patient) and the quality of information (e.g. robust processes of content creation) were raised. These issues would need resolution before further work could be undertaken.

The vendors thought the project might be more feasible if the architecture was changed to a central repository with coded information that could be pulled out by dispensing and prescribing systems rather than full integration within these systems. This would require less outlay from vendors and the possibility for multiple patient management systems being able to work with the central repository if an API was employed. However, there would still be some requirement for vendors to adapt their current systems to include the functionality to prompt GPs and pharmacists to use this resource and a change in clinical practice.

Strengths and limitations

This study was unique in that it was investigating the feasibility of a project (developing a medicine information tailoring tool) with vendors and their opinions on its worthwhileness. This is a strength of the study, as until now the practicality of automatically tailoring information within patient management software has not gained insight from the vendors of the software about the pros, cons, and barriers to its implementation.

All vendors prescribing and dispensing software in New Zealand primary care were contacted for their opinions about this project. However, only two vendor representatives completed the questionnaire, which may limit generalisability to all vendor software developers in New Zealand. Most did not respond to repeated requests for participation; however, those who responded and declined to participate indicated they were unwilling to complete the survey as they felt it was asking for commercially sensitive information. The nature of gathering data from these disparate methods (by email and telephone conversation) makes the data and themes identified not readily generalizable to the vendor group as a whole. Nevertheless, the discussions held with two vendors gave further insight into concerns and suggestions
for project improvement, and allowed more exploration of ideas than gained from questionnaire responses. Furthermore, because all participants thought that the proposal was not practicable at this time, it could be concluded that this project is not feasible in New Zealand at present.

Because of the small number of possible participants, statistical measurements on survey repeatability such as test-retest reliability were not possible. We invited a potential participant to read the questionnaire and assess for readability, however statistical analysis of users repeat responses was not possible.

Generalisability for an international audience may be further limited because provision of medical services can vary significantly between countries. Nevertheless, the findings from this study may be somewhat relatable to countries with similar primary care medicine provision services where information provision is either a mandatory and/or an ethical requirement.

5.4.5 Conclusion

Creating personalised medicine information leaflets from within prescribing and dispensing systems, as described in the Use Case, does not currently appear to be a feasible option for software vendors in New Zealand. Vendors highlighted the following barriers: time and cost; on-going maintenance; current developmental obligations; data protection; and practicality for end-users. Vendors’ suggestion that using a central model with an API for the different software systems to interact with might be a more appropriate method for providing information available for the different software in use in practice.

However, the research team acknowledges the clinical scope is too broad for implementation of such a system for all medicines. There are numerous risks to patient safety involved, notwithstanding the initial requirements for clinical adaptation and ongoing maintenance. To move forward in this area, it may be better to focus on certain conditions or groups of medicines. This system could then be scaled up to other groups as a rolling development plan (i.e. start small and then expand).
To narrow the scope from ‘all medicine information’, a focus on high-risk medicines, e.g. chemotherapy for cancer patients, might be best. An emerging idea with an emphasis on patient-centred care is the use of Patient Reported Outcomes (PROs) to generate side-effect management information. As well as adapting general information to individual requirements, using PROs to provide personalised information to patients about how to manage their side-effects in a digital platform might be an innovative and achievable prospect for New Zealand practice. The use of PROs to provide tailored side-effect management information is discussed further in section 5.5 and chapter 6.

5.5 Chapter conclusion

This chapter is an investigation into the possibility of automatically providing personalised medicine information within prescribing and dispensing systems currently in use in New Zealand. Previous chapters have discussed the information that patients want to be provided with and suggested ways that the delivery and content of leaflets can be improved. This chapter described the a) creation of a Use Case, a summary Use Case diagram, and mock-up example for prescribing and dispensing systems to provide personalised medicines information at point-of-care; and b) the feasibility of the proposed Use Case from a business perspective with the help of New Zealand’s vendors of prescribing and dispensing software.

A Use Case, a summary Use Case diagram and mock-up examples of personalised information were created as resources in order to effectively describe the proposal to vendors and explain how it is expected to work at point-of-care. These resources outlined a proposal that would provide GPs and pharmacists with personalised counselling points to be discussed with patients at the time of prescribing or dispensing, and also provide personalised information leaflets for printing off or digital delivery to patients. Unfortunately, the proposal was not deemed feasible by vendors of prescribing and dispensing systems for reasons such as prohibitive costs, time, resources, and potential clinical and privacy risks to patients. Furthermore, although
there was some potential benefit seen by vendors, there was little to gain and overall feedback was unenthusiastic.

It was decided that this project is not viable because of the outcomes of the feasibility study and the broad scope for medicine information required. It was therefore determined that a narrower focus should be undertaken. Specifically, high-risk groups of medicines should be a primary focus where patient education and adherence is particularly important. A priority area is side-effects for oncology medicines that, if not managed appropriately and in a timely manner, may result in serious consequences.

**An alternative option to investigate**

An emerging idea of using PROs to generate tailored side-effect management information might have the potential to benefit patients immensely, particularly those taking high-risk medicines such as chemotherapy (see chapter 6).

Nearly all patients taking chemotherapy medicines will experience negative outcomes such as side-effects (e.g. vomiting) during their treatment. If not appropriately managed, these side-effects can worsen, resulting in severe toxicity or fatality. On chemotherapy initiation, a large amount of information is communicated to cancer patients, with a strong focus on how to manage side-effects and when to seek further help. As mentioned in chapter 3, patients have difficulty remembering the information provided to them during consultation, particularly when they are anxious. Therefore, improving the method of informing cancer patients about their treatment could help improve patient safety, satisfaction, and potentially even outcomes.

The use of PROs to aid medicine management works well in cancer therapy, where there are detailed validated algorithms on side-effect management in New Zealand (personal communication with L Dagg, Associate Charge Nurse Manager Oncology/Haematology Outpatients (SDHB, March 2018)) and internationally. Currently in New Zealand, if patients receiving chemotherapy experience side-effects, they can contact a designated oncology nurse at the DHB’s oncology unit, or the oncology ward (L Dagg, pers. comm. March 2018). A paper-based triage algorithm is commonly used to guide their nurses’ recommendations, e.g. attend the hospital
urgently, undergo monitoring, or provide home-based self-care management. The paper-based triage algorithms in use can be easily adapted into a digital questionnaire for patients to use at home, with their responses being captured in the hospital patient management record. The questionnaire could also be provided on a digital platform that contains useful medicine information for patients (including how to take, what side-effects to expect, and what you must avoid while taking the medicines) to provide a complete information and medicine management interface.

This digital platform could help cancer patients manage their own health and provide them with additional information whenever they want to access it. Using digital platforms to collect Patient Reported Outcomes with medicines has been trialled in the UK, Europe, and Australia, although it is novel in New Zealand. Adapting systems under trial internationally with a focus on the New Zealand cultural environment including Māori and Pasifika health could be a sensible first step to providing truly personalised information to New Zealand patients. The next chapter will discuss the use of PROs for information provision in oncology/hematology. It will examine views of those who have undergone chemotherapy to investigate their information needs and determine if a web-based PROs tool might be well-received for use in secondary care in New Zealand.
Chapter 6: Patients’ opinions about the delivery of information about high-risk medicines and their perceptions on use of Patient Reported Outcomes (PROs) for personalising information in practice

6.1 Synopsis

Chapter 5 examined the feasibility of building a personalised medicine information leaflet system into the current prescribing and dispensing management software used in primary care. The investigation found predominantly negative views: little perceived value by the vendors, prohibitive costs, lack of consistent use of patient coding by GPs, and that the pharmacist is often not involved in the patient data entry process in the dispensing management software and so would not be prompted to raise counselling points or print leaflets.

In secondary care, where drugs associated with a higher risk of side-effects are prescribed (high-risk medicines), there may be an even greater need for adequate information to be provided. There is abundant patient information available in New Zealand about cancer treatments from a variety of sources such as the Cancer Society of New Zealand,\textsuperscript{202} the Breast Cancer Foundation NZ,\textsuperscript{203} Leukaemia & Blood Cancer New Zealand\textsuperscript{204} eviQ,\textsuperscript{205} as well as locally produced patient information.\textsuperscript{206} In meetings with S Pointer Oncology/Haematology MOSAIQ Specialist (Southern District Health Board (SDHB), December 2017) and L Dagg Associate Charge Nurse Manager Oncology/Haematology Outpatients (SDHB, March 2018) the processes for providing chemotherapy patients with information were discussed. At SDHB a designated nurse
is available via the telephone to answer side-effect related queries and recommend either self-management options or attendance at the hospital. However, this service may be underutilised if people are hesitant to telephone the hospital for advice. Furthermore, Pointer and Dagg clarified that the way information is provided and how side-effect management information is delivered to chemotherapy patients differs in other DHBs around the country. To investigate the delivery of information about high-risk medicines, focus group discussions and interviews with patients who had undergone chemotherapy were undertaken. This was to understand their experiences of receiving information about their chemotherapy medicines and to identify any need for improvement.

Another avenue investigated was patients’ perceptions of using a digital platform or web-based tool for personalised and relevant information about their medicines. This chapter further describes the possibility of using PROs in New Zealand practice for reporting side-effects into a web-based tool which can then be used to generate information about managing side-effects and provide other desired information to patients e.g. if, or when, further intervention is necessary.

Chapter structure
This chapter has three parts:

1. **Patients’ experiences with medicine information about their chemotherapy.**
   Section 6.3 examines patients’ views on how they received information about their chemotherapy medicines. It investigates how New Zealand patients who have undergone chemotherapy treatment feel about the way they receive information about their chemotherapy, and whether they think that this process works well or could be improved.

2. **Patients’ views on the use of PROs for generating personalised information with high-risk medicines.** Section 6.4 examines patients’ views about the possible use of a digital tool utilising PROs. It describes findings from the second part of the above study about a) whether chemotherapy patients would like to use a digital tool to receive medicines information about their chemotherapy
and b) their opinions about reporting adverse treatment outcomes through a digital tool that would generate advice about how to manage the side-effects they experience.

3. **Strengths and Limitations.** Section 6.5 discusses the strengths and limitations of this study.

Section 6.3 and 6.4 are two parts of a single study that cover two distinct research aims—see 6.2, below.

### 6.2 Chapter aims

Patients receiving high-risk medicines need to be well-informed of the potential harm of treatment. The deluge of information provided for some medicines, e.g. chemotherapy, could be daunting for patients to receive—particularly because it is given during a stressful and emotionally-charged time in peoples’ lives. For information to best meet patients’ needs, it should be personalised and specific for their requirements. This chapter aims to investigate patients’ perceptions of the adequacy of the information provided to them about their medicines and their views of the possible use of web-based PROs to optimise their use of high-risk medicines.

Specific aim 1: To explore the opinions of New Zealand patients who have undergone chemotherapy cancer treatment about the information provided to them.

Specific aim 2: To determine the views of New Zealand patients about how possible web-based PRO tools could be utilised in future practice to improve medicine-related outcomes, and patients’ ideas on how this platform could be used.
6.3 Patient experiences with medicine information about their chemotherapy

6.3.1 Introduction

In New Zealand, more than 20,000 patients are diagnosed with cancer each year. Receiving a diagnosis of cancer will cause people to experience anxiety and distress and, as discussed earlier, this may result in them having difficulty comprehending and remembering information they receive at this time. Furthermore, chemotherapy medicines can be complex and associated with multiple serious side-effects so the type and quantity of information people receive about their treatment may be overwhelming.

Provision of chemotherapy medicines in primary care is increasing in New Zealand. In 2014 over 52,000 people received their chemotherapy or immunosuppressing treatment in primary care. Because of the aforementioned complications with conveying necessary information to people receiving chemotherapy at the time they are originally prescribed these medicines, it is imperative they are provided with adequate counselling and written resources to refer back to.

Provision of information

In informal meetings with S Pointer, Oncology/Haematology MOSAIQ Specialist (SDHB, December 2017) and L Dagg, Associate Charge Nurse Manager Oncology/Haematology Outpatients (SDHB, March 2018) the provision of information about chemotherapy medicines in SDHB were discussed. In the SDHB, people who are about to undergo chemotherapy have an intensive one-on-one session with a nurse to discuss their chemotherapy medicines and are given printed information to take away. In informal discussions with A Jamieson, Clinical Pharmacist (BPharm, July 2020), a pharmacist who worked in oncology at Nelson Marlborough DHB, it was clarified that the type of information provided to people about their treatment can vary depending on what DHB they reside in, what type of cancer they have, and what treatment they are receiving. The resources used were also discussed in an informal meeting with A Jamieson (informal pers. comm. July 2020) and there are various sources available to
be provided to patients, including booklets created in individual DHBs\textsuperscript{206, 215} and written resources provided by regional cancer networks.\textsuperscript{216} The Australian eviQ patient information resources created by the Cancer Institute New South Wales\textsuperscript{205} are also widely used in New Zealand. The Australian NSW state government-funded eviQ web content is written by specialists and is also used in 170 other countries globally.\textsuperscript{217} These are well-regarded resources and are easily available at point-of-care (S Pointer, informal pers. comm. December 2017, L Dagg, informal pers. comm. March 2018, A Jamieson, informal pers. comm. July 2020). In New Zealand, national resources are also available for children who are receiving chemotherapy, and their families.\textsuperscript{218}

Many other reputable sources of information about cancer types and treatments are available for people diagnosed with cancer in New Zealand. These can be easily found through web searches and include those produced by the Cancer society of New Zealand,\textsuperscript{202} and more specific information according to cancer type produced by organisations such as Breast Cancer Foundation New Zealand,\textsuperscript{203} Leukaemia and blood cancer New Zealand,\textsuperscript{204} and Bowel Cancer New Zealand.\textsuperscript{219}

**Providing information about side-effects with chemotherapy medicines**

Side-effects of chemotherapy range from those that have less serious consequences, such as hair loss, to those that are potentially fatal such as febrile neutropenia and rash.\textsuperscript{210, 212} Furthermore, not all reactions are experienced to the same degree. Some side-effects, e.g. diarrhoea, may be minor for some patients and require only advice for home management, whereas other patients may experience the side-effect so severely they require hospitalisation. Although, it is possible to foresee side-effects that relate to the chemotherapy regimen and cancer type, the extent of severity of side-effects cannot always be predicted.\textsuperscript{210} If appropriately handled in the early stages some side-effects can be managed at home. However, if not managed early, some side-effects can worsen resulting in severe toxicity.\textsuperscript{125, 129}

The United Kingdom Oncology Nurse Society (UKONS) (http://www.ukons.org) has created an oncology/haematology triage tool with a traffic-light system risk-assessment algorithm containing management advice for common and serious
chemotherapy side-effects. The tool is used in many countries worldwide, and its use in New Zealand was discussed in the meeting with L Dagg (SDHB, March 2018); similar to use in the UK, it helps the oncology staff decide what advice to give, e.g. advise patient to attend the emergency department at the hospital urgently, to attend the oncology ward for a review at a scheduled time, or to provide home-based self-care management advice. The benefit of using this tool is that it enables the provision of standardised and evidence-based advice to people suffering from side-effects associated with their chemotherapy.

In informal meetings with S Pointer (SDHB, December 2017) and L Dagg (SDHB, March 2018), the system of patients’ reporting side-effects to the hospital was discussed. In the SDHB, patients receiving chemotherapy are told they can contact a nurse at the DHB’s oncology unit if they experience side-effects via an exclusive phone line. During working hours this phone line is staffed by a dedicated oncology nurse and during out-of-hours the calls are answered by oncology ward nursing staff. The nurses use the UKONS triage algorithm to determine the action required. This system, with a dedicated oncology nurse for side-effect management, has been shown to reduce cost due to reduced admissions for toxicity management and reduce patient presentation at emergency departments. However its use is not widespread in New Zealand and DHBs around the country have differing approaches to monitoring and advising those requiring side-effect management.

Aims of this research

It is not clear whether the current practices of providing information about chemotherapy medicines are optimal for patients. The aims of this study are to explore the views of people who have had chemotherapy about (i) how they were given the information about their chemotherapy, (ii) whether they understood this and could act on the information given, and (iii) whether they think this could be improved.

This study was approved by the University of Otago Human Ethics Committee (reference number H19/144). The study protocol is in Appendix 19. The ethics approval and response to Māori consultation of the project are in Appendix 20.
6.3.2 Method

Participation

Plans for Participation
We planned to hold focus groups sessions with 6–8 people in each group. In order to participate, people needed to meet the following selection criteria:

- Be 18 years of age and over
- Have previously had chemotherapy and are in remission
- Can read and speak English.

Those who were under 18 years of age, currently using chemotherapy medicines, or cannot read or speak English were excluded from participating.

The first focus group would be a group from the general population from the Dunedin area. The second would be Māori participants from the Dunedin area. The third would be Māori participants from a rural part of North Island, New Zealand. The fourth would be a general population group from a more rural/remote location (to be recruited in Southland).

Food/kai would be provided during the focus group sessions. Upon completion of the survey, participants would receive a $20 supermarket voucher.

Participation in the study
Our original intention was to only hold focus groups and not to have interviews. The benefit of focus groups is that conversation can be encouraged, and more ideas can arise than in a one on one interview.²²¹, ²²² Involving a diverse population to discuss concepts should lead to an enrichment of responses. If people have a different mindset on the concept it will allow discussion from all angles giving more detailed discussion on each topic.²²², ²²³ Furthermore, focus groups may give more confidence to individuals to give their honest opinion if supported by others in the group. There is also the possibility of conflict and this can promote more opinions to come into light.²²¹, ²²²
In early February 2020 we were advised that there might be recruitment difficulties in some localities/population groups (e.g. rural areas, Māori), so we extended our study protocol to allow face-to-face or online interviews of individuals who met the recruitment criteria. Recruitment, focus group meetings, and interviews began soon after this.

Interviews may have some benefits over focus groups. They may allow more time for individuals to speak and individuals may speak longer on average to express their opinion. An interview guide is used and interviewers do not need to act as a moderator to control some of the conversation (as may be necessary in a focus group). Interviews are useful in giving respondents opportunities to express their attitudes without personal embarrassment from several other individuals being present. Generally, interviews are easier to organise and it is easier to recruit hard to reach groups (e.g. Māori participants). Moreover, the interviewer can adjust their interviewing style to fit people’s needs and participants do not have to worry about group dynamics.

At 11:59 pm, 25 March 2020 New Zealand went into ‘lockdown’, prohibiting all but essential services and cancelling all unnecessary travel, events, and meetings/gatherings during the Coronavirus disease (COVID-19) pandemic. These restrictions meant we were unable to hold group or face-to-face meetings for the foreseeable future. The research team initially thought that meetings and interviews in a digital space might result in potential bias toward those who have high digital literacy (an area of focus for this study), so we suspended recruitment for further focus group meetings or interviews at that point.

On Monday 8th June, New Zealand moved to alert level one meaning that meetings with people outside of direct family were now allowed. However, it was uncertain how long this alert level would be in place due to differences in international abilities to control spread of infection. The University of Otago Human ethics committee therefore continued to advise against holding face-to-face interviews and recommended videoconference or telephone options for data collection. Early analysis of the general population data already collected demonstrated we were close
to data saturation from this particular group. Because of this, we decided to continue recruiting participants from this population in the Dunedin area to ensure that data saturation occurred, offering telephone or videoconference methods. This would strengthen the findings of this study for applicability to the Pākehā (non-Māori) New Zealand population. Because of continued inability to meet face-to-face with Māori to foster relationships for recruitment and participation in this study, the research team agreed it was not possible to sufficiently align with Kaupapa Māori research methods\textsuperscript{227, 228} for data capture and recruitment. Therefore, we decided to abandon attempts to recruit Māori at present. The implications of this are addressed in the study limitations.

Recruitment methods
Study participants were recruited through local organisations/support groups. For the first focus group undertaken in Dunedin (pre-COVID-19 lockdown) we used the Otago-Southland division of the Cancer Society, EXPINK\textsuperscript{TM} (the University of Otago Physical Education School’s exercise programme for women who have had breast cancer surgery), the Dunedin branch of the Leukaemia and Blood Cancer New Zealand, Breast Cancer Foundation, Bowel Cancer New Zealand, and Ripple. We asked the leaders of these organisations to advertise the project to their members/patients through posters and/or email (if appropriate). Members could contact the research team if they were interested in participating. They were provided with a participant information sheet either by direct handout, post, or by email (according to their preference). The participant information sheet has the contact details for the study team to allow participants to ask questions about the project before deciding whether to participate (see Appendix 21).

Consultation with Māori advisors was undertaken about recruitment for this study and for support with understanding Kaupapa Māori research theory. Through this consultation we were given valuable contacts to aid our recruitment process (however, we could not proceed because of the COVID-19 lockdown restriction mentioned previously).
Focus group and interview outline

The focus group meeting and individual interviews consisted of four parts: i) an individual questionnaire; ii) a discussion about items from the questionnaire; iii) an introduction to the online tool (capturing Patient Reported Outcomes (PROs)); and iv) questions seeking participants’ thoughts on the online tool for capturing PROs (see Appendix 19). Parts three and four are reported in section 6.4 of this chapter.

The informed consent form for participation and the recording of the focus group or interview was completed at the start of each session.

Questionnaire and discussion guide development

A questionnaire and focus group discussion guide were developed to understand people’s experiences with receiving information during chemotherapy and their typical use of digital technology and the internet (see Appendix 19). These were developed based on relevant literature, clinical experience, and US government guidance on digital usability questionnaire templates. The questionnaires validity was determined using the same methods described in section 3.4 (i.e. following extensive research team and expert oncology review). Expert oncology review led to adaptation of the questions: removing the question asking if people were ‘comfortable’ with the information and instead asking if they liked it and understood it; removing the questions based on what people did if they experienced a side effect and changing focus to the information they had and how they had received it; making questions more focused and mapped closer to objectives by removing unnecessary questions (e.g. do you live alone). Expert advice on questionnaire validity was also received from a Māori advisor and changes following consultation were applied across all the questionnaires to make them identical. Specific changes were minor: removing education level achievement as knowledge and health literacy not necessarily bound to academic merit and Māori students as a group spend less time in the education system than non-Māori (the focus was changed to digital literacy instead); asking participants about cultural appropriateness of information received; removing questions on gender; re-arrangement of focus group discussion.
Following this validity testing, the questionnaires were pilot tested in three former oncology patients. This was to assess readability and understanding. No necessary modifications were implemented after careful assessment by the research team.

The questionnaire was designed to gather data and enable participants to recall their experiences ready for further discussion in the focus group or interview.

Consultation with Māori advisors was undertaken regarding the content of the questionnaire and discussion guide. Following their review, adjustments were made to improve cultural appropriateness.

**Part one: Individual questionnaire**

The first part of the meeting/interview consisted of a questionnaire. The focus group participants were asked to complete the questionnaire on their own in the first 5–10 minutes of the meeting. The individuals interviewed separately were sent the questionnaire 2–5 days beforehand so it could be completed prior to their interview. The questionnaire responses were collected by the interviewer.

**Part two: Focus group discussion about items from questionnaire**

The second part of the meeting consisted of a group discussion of the questionnaire facilitated by Amber Young and Dr Alesha Smith. This involved a wider discussion of the topics covered in the questionnaire in part one.

In this part we discussed what the participants think might be good for improving the medicine information services for oncology patients.

- *a. How were they given the information about their treatment and the possible side-effects (e.g. verbal only, written, web addresses)?*
- *b. Could this process of receiving information have been easier?*
- *c. Do participants think the information and how it is given is appropriate for someone from their culture? E.g. Māori or other culture*
- *d. Do they feel this could be improved in any way?*

We also discussed

- *e. If the information helped them feel well-prepared for any possible side-effects?*
f. What they did if they experienced a side-effect and needed help


g. If they looked for information themselves from other sources?

Analysis of data
The data from the questionnaire were entered into Microsoft Excel and basic descriptive analysis was undertaken.

The focus group discussion and interviews were recorded and AY transcribed these verbatim. AY then double-checked the transcriptions against the recordings and read through them again multiple times. JT and AS read through the final transcriptions. AY carried out semantic inductive analysis of the transcriptions, i.e. she reviewed the explicit content of the data and allowed themes to conceptualise from the conversations of people’s experiences. AY organised themes into a framework matrix in Microsoft Excel. The thematic coding and framework were reviewed by AS and JT. The analysis of this study met Lincoln and Guba’s criteria for trustworthiness. Credibility (i.e. how well the context, participants, and methods examine the intended concept) was assured by implementation of an appropriate research and advisory team and by thorough review of transcripts and framework matrix by AS and JT. Furthermore, many quotes were used to show representation within the matrix. Dependability (i.e. reliability of data collection over time) was assured through an open dialogue within the research team and review of transcripts and framework over time. Transferability (i.e. extent that findings can be transferred to another group/setting) was assured by clearly describing the participants, data collection, and the full presentation of findings with numerous quotations to represent themes. Variability in participants leads to richer data gathering and different views being discovered.

6.3.3 Results

Eleven individuals participated in the study. Seven participated in the focus group meeting (five females F1, F2, F3, F4, F5 and two males M6, M7; the focus group discussion lasted for one hour) on 11th March 2020 and four others were interviewed individually in separate face-to-face interviews. Two interviews were performed on
20th March 2020 (F8; interview time 23 minutes and M9; interview time 15 minutes) before New Zealand went into alert level four (see section 6.3.3). Two further interviews occurred following lifting of restrictions, one on 24th June 2020 (F10; interview time 21 minutes) and 30th June 2020 (F11; interview time 21 minutes). Only one interview was performed in person (with M9), the others were performed via videoconference (with F8 because of personal preference, and with F10 and F11 because of ethical restrictions required by the university—see section 6.3.3). All lived in the Dunedin area. Most of the participants were in the age group 51–80 years (n=6, 55%), three (27%) were aged 21–40 years and two (18%) did not disclose their age.

The demographics of participants are in Table 15.

Table 15: Demographics of Dunedin Participants

<table>
<thead>
<tr>
<th>Participants (n)</th>
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</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
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<tr>
<td><strong>Age range (years)</strong></td>
</tr>
<tr>
<td>71–80</td>
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<tr>
<td>61–70</td>
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<tr>
<td>51–60</td>
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<td>41–50</td>
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<td>31–40</td>
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<td>21–30</td>
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<tr>
<td>Unknown</td>
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<tr>
<td><strong>Ethnic group</strong></td>
</tr>
<tr>
<td>New Zealand European</td>
</tr>
<tr>
<td>Other (not disclosed)</td>
</tr>
<tr>
<td><strong>Cancer type</strong></td>
</tr>
<tr>
<td>Leukaemia</td>
</tr>
</tbody>
</table>

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Saturation of ideas was considered to be achieved following the first interview on 20th March 2020, three further interviews were held to confirm saturation achieved within this group of participants from the Dunedin area. No further focus groups or interviews were possible in the timeframe because of the aforementioned COVID-19 meeting restrictions. Therefore, contacts in oncology organisations in rural areas, Northland, and local Māori contacts were not followed up for recruitment (see Strengths and limitations).

Data analysis is described in two parts, firstly the analysis of the individual questionnaire responses using simple descriptive grouping analysis. Secondly the thematic analysis of the interview and focus group content is described.

Part one: Individual questionnaire responses relating to information about chemotherapy

_Verbal information received_

Most participants thought that the verbal information they received was easy to understand (n=7, 64%) and just over half agreed the way it was given to them helped them to understand it (n=6, 55%). However, participants had mixed views on whether the amount of information provided was too much (n=5, 45%) or too little (n=6, 55%). There were also mixed views about the statement _I was told how to get more information if I wanted it_ (disagree n=2 (18%); neutral n=4 (36%); agree n=4 (36%).

One participant provided further comment that in some situations, copious information is not appropriate, “appearing in hospital with extreme sickness there isn’t much time to deliberate over what type of treatment you receive and why.” [M6]
Another felt they had reached their limit of information-saturation, “They gave me all the information that I could take in.” [M9]

One participant indicated that the amount of information received is inconsistent, “I’ve had 3 lots of chemo over 16 years and every time [it] was different.” [F1]

Another participant thought that the quantity of information on differing topics was inconsistent, “The information regarding side-effects was abundant but information regarding what chemo was and how it was delivered was lacking.” [F3]

One participant who felt the information was not given in a way they could understand it commented, “Information was all provided in written format and a lack of personal explanation noting that I was not in a fit state to take in all of the information. I sought information from family members.” [F10]

Similarly, another participant further commented, “I remember this part of the appointment was very stressful as I had a lot of information given to me at once and I struggled to absorb it all.” [F11]

**Written information to take away**

Eight of the participants (73%) confirmed that they were given useful information to take away with them about management of side-effects, and one participant was given information to take away but did not consider it useful. The other two participants responded that they were not given useful information to take away.

Just over half of participants (n=6, 55%) thought that the information was easy to understand. However, opinions differed about the quantity of take away information; four people (36%) strongly agreed and four (36%) disagreed that there was too much information given, one participant was neutral and two did not respond to this question. Most participants read the information at home (n=7, 64%) and found it useful to read at a later time (n=7, 64%). One participant (9%) who found the information difficult to understand commented, “[I] was handed lengthy pieces of paper which to someone with little to no medical experience wasn’t helpful.” [F5]

Another participant thought the information could be improved, “It would have been useful to have someone highlight the key pieces of information...I didn’t realise what
was going to be important until I was in the midst of it and by then my brain wasn’t that functional and I was quite distressed.” [F8]

All participants shared information with other people such as their partner or family, and two shared it with their community pharmacist. One participant, who shared it with their pharmacist needed help to understand the information, “My daughter even had to go to the local chemist to try to understand some of the information relating to the medication and the side-effects as it was not clear on the multiple pieces of paper that I had accumulated.” [F10]

Following the Information given

Most participants (n=6, 55%) followed the advice provided if they experienced a side-effect. Two participants stated that they only sometimes followed the advice and one participant stated they did not follow the advice (two participants did not respond to this question). The participant who did not follow the information given to them, contacted their family for help instead.

The reasons given for not always following the official advice were because some participants deliberately ignored their symptoms to avoid going to hospital, and similarly because they did not have the energy or resilience to deal with, “another medical person poking and prodding me.” [F8]

Other reasons for not following the information given to them were they could not remember the information, the information provided was not relevant to their symptoms, they found the information too difficult to understand, or they could not find the information they were looking for, “[I] can’t remember the information and what I did have was spread over [the] document.” [F10]

All but one of the participants indicated they felt prepared about what to do if they experienced a side-effect.

Part two: Qualitative analysis about chemotherapy medicine information

Data analysis of the focus group and interview discussions revealed four main themes, and 12 sub-themes:
1) Gathering and use of information, with subthemes of
   a. Avoiding the information provided
   b. Information as a future reference
   c. Importance of family involvement
   d. Communication with HCP

2) Problems identified
   a. General concerns about information received
   b. Problems with information about the side-effects that were experienced
   c. Communication difficulties and barriers identified
   d. Inability to process information

3) Other opportunities used to aid understanding
   a. Help from fellow patients/support groups
   b. Other sources of information

4) Improving information provision
   a. How information provision could be improved
   b. Personalised information needed

Theme one: Gathering and use of information
All participants received information at the beginning of their chemotherapy treatment, with large quantities provided as pamphlets or information sheets and sometimes links to websites were provided. In most cases verbal and written information was given.

“Everything was written down for me as well...I also had, ah, websites I could go to, um they said a lot of stuff verbally as well.” [F5]
“There was lots of good information um about the drugs for the stem cell transplant you know and I’ve got the whole range of these, these things [information leaflets].” [F1]

“So the way I got information was much like that, just sort of like, all in pamphlet form.” [F2]

Because of the large amount of information, not all of this could be covered during a conversation. One commented, “I think there was some bits they went um, they went through with me but often it was, yeah ‘here’s, here’s the information, take it away and read it at home’.” [F8]

Another one said, “They also talk to you a wee bit about it, but you know they can only give you so much information, you know.” [M9]

One participant also indicated that the verbal information provided by their health professional was a comfort to them, “They explain things to you, what was going to happen, when it was going to happen, um, what to expect and you know like that...a lot of information to give you, you know? And that which takes the scariness out of it. You know? So it’s very good.” [M9]

Not all participants received information about websites to visit. “They don’t, don’t really put you on to websites. They, it’s mainly books and then pamphlets and then information like that.” [M9]

“No, nothing like that, no.” [F10]

One participant indicated that while they did not remember the specifics of the information given to them, the side-effects they experienced with their treatment were not unexpected. “I don’t think I was really surprised about any of the side-effects I experienced while I was having chemo so that indicates to me that I knew. Like when I think back I don’t think that there was anything that really I was like ‘ooh I wasn’t expecting that’.” [F11]
a. Avoiding the information provided

Six of the participants indicated that they avoided reading information about their treatment. The reasons for this varied—some were not interested in knowing or avoided information as a strategy to carry on with normal daily life, willing to wait and see what would happen. One participant said, “I didn’t really want to know too much either. Just get on with it... Didn’t really get into that side of it too much. Just let it happen. Trust the doctors.” [M7]

Another participant agreed, “Didn’t want to know. Pretend it’s not there, you know?” [F2]

Additionally, one commented, “Not actually delving too deep into it, I sort of at that time didn’t really care, didn’t really want to know.” [M6]

One participant worried that if they knew the side-effects, they would start expecting them to occur. “Sometimes I think you don’t want to know... My kind of thought was, if I look at it and I know, I’m going to like expect it or be looking for it.” Or started to experience a nocebo effect from their treatment “I didn’t want to put it in my head, otherwise I’m going to end up with everything.” [F3]

Two participants indicated that they did not want to read the information because of the quantity that was provided or the way it was presented.

“I did a bit of reading on it, but then I was just kinda ... turned off, I just didn’t want to know. I was just like, you know, I’m just going to get through it the way that I have to. I don’t want to read anything ... anything else. So yeah. It was easier to just sort of you know, keep it simple.” [F5]

“She fidgeted with all the pamphlets, poking them into this...and it was just really incredibly painful watching her do it. I was just like ‘oh, I hate that folder, I don’t even want to look at it’.” [F11]

Two participants found the information available on the internet was concerning.

“I never went online ‘cause you know going online is just scary as f***. I did at the start and I scared the sh** out of myself and I’m like I ain’t doing that again.” [F5]
And one participant indicated that their spouse didn’t want them to find out information that may frighten them. “Well my daughter went on the computer, and my husband said ‘get outta here! We don’t want to know the stuff off the computer’.” [F4]

b. Information as a future reference

One of the ways that the information was used, was to be referred to later when they are experiencing a problem. “Yeah it’s a good reference. It’s good reference material to go back if you need to, you know, check on something.” [F3]

Some participants liked to have the information for their support people to use when a problem arose.

“My daughter went on the computer, and my husband said ‘get outta here! We don’t want to know the stuff off the computer’.” [F4]

“You’ve really got to be given the information at the beginning and then hopefully if things happen, someone else, you know, one of your support people, you know, may look at this.” [F1]

c. Importance of family involvement

Family or support people were perceived as vital information gatherers and seen as an essential part of visits with the oncology or haematology team.

“I think it’s something that pretty well everyone has said that it’s essential to take a support person with you.” [F1]

“They [her children] dug it [the information] all out and that’s where I got my help from. But in saying that, my heart bleeds for Joe Bloggs who doesn’t have that back up support.” [F10]

One reason for this was because of the difficulty remembering what is discussed during a consultation.

“My husband, especially this last time writing things down, um, and because you know the, you’re not going to remember everything that’s said to you.” [F4]
“Luckily I had, you know, our daughter with us and, and she you know, brought all this stuff home, and later on if I had something I was going back and checking it.” [F3]

Even although some people avoided information, it was often the support person who read and kept the information about treatment.

“They might have looked at them [information leaflets], but I didn’t.” [M6]

“But my partner, she researched it on the internet as well as reading all the pamphlets...yeah, I've just, let her, let my partner deal with them all.” [M7]

One participant’s mother had just been through cancer so could provide some helpful support and tips for navigating the system. “My mum had cancer right before me and she gave me this notebook and this went with me everywhere I went and whoever was there with me would write down the notes of the questions that I would ask.” [F11]

Two participants also revealed that their family members were often the driving force behind them reporting their side-effects to the nurses at the hospital.

“You don’t want to go into the hospital ‘cause you don’t want to, you know, stuff them. So, that’s when your partner comes in and she says ‘no you’re going to have to go to hospital’, and then they help you.” [M9]

“Waiting it out in bed and Mum’s like ‘have you got a temperature?’ and I’m ‘nah I don’t have a temperature’ and Mum’s like ‘I want to take your temperature, let me take your temperature’ ‘why do you need to take my temperature?’ and it’s like ‘your over the limit’.” [M6]

One participant used their children, rather than the hospital, for help with managing side-effects. This participant was in a fortunate position of having health professionals in the family and in some instances were better at recognising medicine effects and how to manage these than the specialist team involved in their care. “When I was taking myself off morphine...such bad diarrhoea, and the hospital thought I might have eaten something but my haematologist son said ‘no that’s what happens when you come off morphine...have you ever seen the movie Trainspotting?’” [F10]
This participant was only able to stop the morphine, which was no longer needed, because of family support. “He’d said to me ‘you need to get off morphine Mum’ and he and his wife, they were here, and they just gradually got me off it.” [F10]

Discontinuation of morphine was important to this participant because it allowed their life to resume normality, and they appreciated the support of their family as integral to this process. “I just don’t know, I just don’t know how I would have coped at sort of being able to get back to a normal life without my kids’ support.” [F10]

d. Communication with Healthcare Professionals

Participants often described their direct communication with the oncology and haematology team at the hospital as favourable. “Nurses in Dunedin, ah, they’re great, the cancer nurses...so empathetic and so, just gives you the information and fantastic.... I’ve got a good haematologist, she’s fantastic, and the nurses who were great.” [M9]

Their ability to communicate was also well-received.

“They are very easy to communicate with. Yeah very good.” [M9]

“I felt like they were explaining, I felt like all of the team that I saw were really good at explaining things at a very basic level”. [F11]

The specialist nurses who provide the information about treatment were also highly thought of. “Specialist nurses...were invaluable.” [F3]

One participant also described having positive communication with a cardiology specialist following a long-term side-effect associated with her doxorubicin. “...and I had um lovely attention from the um cardiologists who explained everything well, how he was going to balance, you know heart drugs and everything like that... so I felt the treatment was much more personal um and that I had enough information.” [F1]

Another, who attended a different hospital for a stem cell transplant, valued communications with the ward pharmacist. “It was the pharmacist who you know, explained your drugs. Went through why you were taking it, side-effects and all that. I
couldn’t believe it, and gave you little sheets of paper that were yours, specially made out for you.” [F10]

The ability to speedily contact a designated nurse at the hospital for information when a side-effect occurred was appreciated by many participants.

“You could send a text at any time or phone up and you knew talk to, to them and they’d pass a message on to one of the cardiologist or the, the, um doctor” and “they did give me a number for the hospital, for, um, up in the oncology ward for a nurse there and she was great.” [F1]

“So, you’re, you’re advised what to do and they’re very um, they’re very strong on saying ‘look, if you really need help, go in. Don’t, don’t hesitate’.” [M9]

“I was very happy to ring because they were really clear with that, keeping that communication line open...I felt like a VIP customer in a way, like I felt like they knew, they took an interest?...You get to know the nurses on a first name basis.” [F11]

“They were very good because they’ve got a green card that you get with an 0800 number that takes you straight to help. So I’ve got no complaints about that. That was really well done. That was done through the oncology day unit. Yes I knew exactly what to do, yeah and I felt very comfortable doing it.” [F10]

However, one participant thought it would have been improved if you had more of a connection with this contact before you had problems with your treatment. “It would have been really useful to have either been rung by her or been encouraged to ring her before I started treatment... just so I felt like there was a bit of a connection already...I was only ever going to ring her when I was at a point where I was going ‘I don’t know what to do now’.” [F8]

Two participants also stated that they did not know about the medicines they were receiving but were happy to put their full trust in the oncologists and haematologists.

“I didn’t get involved in, um, what the chemicals were they were putting in to me. I trust the people that were doing it and the effects they are having, because everyone’s different.” [M9]
“Got to trust the oncologist or haematologist and, um, you know, the specialist that they’re not deliberately giving you a poison you know...so I wouldn’t really read into the treatment that much.” [M6]

“It’s not as if you get options it’s just that nobody asks what you want and you have to trust the specialists that it’s the right drug, this is the right drug.” [M6]

Theme two: Problems identified

Most participants (n=10) described problems with the way they were provided with information, or how they had difficulty understanding what they had been told. Some examples were given where there was a lack of communication and strained relationships resulting from communication difficulties. Participants also described how the cancer diagnosis affected their ability to understand the information provided to them by their doctors.

a. General concerns about information received

One participant felt they did not receive adequate verbal communication about their chemotherapy, which had a negative impact on their perceptions of the service. “I wasn’t really spoken [to] about it. I am very sceptical about all this [information about] treatment and I have to tell you, um I’ve got very negative thoughts about it.” [F10]

The reason for lack of verbal discussion was thought to being put on a different ward due to lack of space on the oncology/haematology ward. “The ward that I should have been on was full and I was put into a ward with dementia patients. So I sort of feel, perhaps if I had been on the correct ward I may have had more interactions...they could have come in and explained it more.” [F10]

Other participants described being given copious written information and the quantity of leaflets or pamphlets provided was sometimes overwhelming.

“They can only give you a small amount of oral...and then they gave the pamphlets...and I got it home and I went bloody hell, you know? I just couldn’t believe it because the side-effects were huge and then you look at that, and it scared the sh** out of me”. [M9]
“It was information overload at that time, so I don’t think I actually looked up any of those things until maybe later on when I was thinking ‘oh do I have to, what should I check about that’ if I was wondering about something.” [F11]

There was also concern that with the quantity of information provided and the way that it was given could limit comprehension, cause anxiety, or prevent you from finding what you were searching for.

“The way that the information was given to me was incredibly stressful”. [F11]

“It is just quite overwhelming. It’s overwhelming and it, the more they give you can confuse you.” [M9]

“With one particular folder there was a lot of information in there and .... I remember it getting a bit mixed up and it took me quite a while, um, a couple of visits to the hospital to work out ‘oh actually I needed to read this piece of paper’.” [F8]

Two participants further described their anxiety in how side-effects in particular were communicated to them.

“When I got all of the information on the side-effects I really nearly, you know I, I just got blown away to put it nicely, you know. Because it’s scary.” [M9]

“She gave me all of this, all these handouts just to reiterate the key side-effects and everything I was going to experience. And um, it was just information overload, like it was really stressful.” [F11]

Another participant found it confusing the way the names of the regimens are provided, compared to the names of the drugs. For example “Doxorubicin hydrochloride” is also called “hydroxydaunorubicin”: “One thing about the drugs that would be helpful, um, is that so many of these drugs are known by about six different names and just sort of having a kind of list” going on to say “the doxorubicin, well you think in RCHOP there’s no D, you know...just sort of listing the things so that you know that the H refers to doxorubicin.” [F1]

One participant used a notebook to document information about their ongoing treatment from all the different people involved, because each health professional
was providing separate information and it was difficult to remember everything being
told to them.

“I had that book and I had to record everything in it because I saw that many people,
and I had that, like I had a lot of information that related to all of my treatment,
beyond just the chemo aspect.” [F11]

b. Problems with information about the side-effects that were experienced
Five participants commented that they experienced a rare side-effect, and four of
these struggled to get information about it from their specialists. One problem
identified by many participants was the paucity of information about the rarer side-
effects experienced. “It was good to a certain point and then it was kind of like the
information kind of stopped and it was almost like you know you kind of had to force it
out of them.” [F5]

Or they perceived the healthcare team did not know about it, as described by one
participant who was asked if they found it easy to get information about a side-effect
experienced; “Nup ‘cause they didn’t really know what the problem was.” [F2]

Another participant, who had experienced a rare side-effect, struggled with knowing
what side-effects to pay attention to in the information provided to them. “So then I
was thinking about how you pay attention to what’s written down here, you know all
these things are here so look at that, oh yeah, yep uncommon, and then rare...and I
thought, well I really didn’t have common...so I think probably at the time I didn’t take
much attention to what was rare.” [F1]

Some (n=4) struggled to get information about rarer side-effects when they were
experienced.

“I didn’t know what was going wrong every time. I knew something was wrong, but
nobody ever explained.” [F4]

“Every time I came up to them and I wanted more information and stuff where I said
‘I’m getting this side-effect is it normal?’ and they were just like ‘mhmhm mhmhm’
and I’m like, ‘is that it? Are you going to tell me anything else? Is it okay to have this
symptom?’.” [F5]
One participant believed that if information about less common side-effect was more comprehensive, it could have avoided a visit to the ED, “I ended up there [in ED] a couple of times, um which yeah, again, it was like, that could have been avoided with a bit better information.” [F8]

Although people were encouraged to report their side-effects, they did not feel supported when rarer side-effects occurred, “But they gave me a diary to write all my symptoms in, um, to keep an eye on them and stuff like that, and I brought it in and showed the doctors but they sort of didn’t give me any info about it, they were just like ‘oh yeah no that’s fine that’s okay’, hmm okay I guess I’ll just struggle on then.” [F5]

This left some participants feeling like they had been fobbed off.

“I knew something was wrong, but nobody ever explained.” [F4]

“One of the side-effects I had was a lot of pain and that was not covered at all in my, in the information I got given and in the various meetings I had with the oncologist and the nurse. I was quite gobsmacked. Especially when I did find out that pain is not an uncommon side-effect.” [F8]

“When I went to them and went ‘I had this weird breathing thing’...and they were like ‘oh well that’s not one of the side-effects...we don’t know...if it keeps bothering you, go to your GP’. The GP’s like ‘I don’t know what it is’.” [F5]

One participant also felt this lack of communication also occurred when they experienced severe side-effects. “The first time [I was admitted to ED] they just put me in to rest, they didn’t tell you anything, or what was going on with anything.” [F4]

c. Communication difficulties and barriers identified

Some participants (n=3) experienced communication difficulties with their specialists, and this led to problems with their ability to receive information. “I feel like the, the, information is given as if we were, you know, these rational beings, ah, which we’re not at the best of times, and we’re certainly not at that time.” [F8]

In one instance, a relationship breakdown with their specialist occurred from poor communication. “The doctor, she says to me ‘oh you had it in your stomach as well’ I
says ‘no I didn’t’ she said ‘yes you did’. Now I’d never been told and my husband had never been told that, that I’d actually had it in my stomach as well...Nobody ever told me that. You know so... and I, we, sort of argued with them.” [F4]

And in another instance, there was no communication about their treatment being initiated. “I can remember the day someone came in and they pulled my curtains and somebody came in, in PPE gear, and gave me a jab in the belly...they never told me what it was, I didn’t know what was happening. No idea. Nobody said ‘well this is the start of your chemotherapy’ nothing like that was mentioned.” [F10]

Another participant was still wondering about why procedures were undertaken. “Like I went and got the stem cell thing done and I didn’t know what I was going for, it was just this appointment ‘here, go and do this’, you know you’re not explained to you what you are going for... I still don’t know why. Why did I have that done?” [F4]

One participant admitted that they struggled to comprehend information because of a strained relationship with their specialist. “My interactions got quite complex... because of that, um, I was probably coming into some of those conversations...with less than, a less open mind than possibly I could have.” They then acknowledged, “I was probably maybe not as open to the information or as calm and, um ah, as I needed, as I could have been to collect the information, yeah.” [F8]

Three participants were getting treatment at more than one location and felt that the communication received from these differing locations was not consistent.

“It was like bouncing between everywhere...they were all trying to, like, work together and it didn’t really work.” [F2]

One also felt that some areas had different knowledge about side-effects. “But when I was talking to one of the ladies in Christchurch, she actually told me about symptoms that Dunedin didn’t know about on my chemo.” [F5]

One participant also felt that an attempt to empower them with decision-making left them feeling unsupported. “A lot of frustration around that, well ‘I’ve given you the information and you can make a decision’. Um, I, I remember saying quite a few times ‘well just let me hit the pause button while I go off and get my medical training and get
20 years of experience and then I’ll come back to you with that decision.’” They went on to say, “I did want to be given the options, that’s for sure, and I wanted to be able to talk through all of the options, but then I also wanted some clear recommendations from that.” [F8]

Some participants (n=3) also felt that it was the basic information that was lacking in what they were told. For example, a simple explanation of how the treatment works was not understood. “No one explained to me what chemo was. Like they would say ‘and you have six rounds’ – what the hell does that mean? And so that’s where I feel it was really lacking ‘cause I didn’t know what that meant. ‘Six rounds’, and you try to look it up online and it just talks about rounds, but it doesn’t tell you what that means.” [F3]

And one participant felt they didn’t receive adequate explanation about their type of cancer. “I mean, you know I hadn’t heard of the word myeloma before, I didn’t know until one of the kids explained that it was cancer of the plasma cells.” [F10]

Another participant agreed with the lack of information saying, “Just little things that they don’t... they know it all. But they don’t tell you. They don’t explain everything. The logical things they don’t explain to you, you know?” [F4]

One participant thought this could be because the staff are so used to the terminology, they forget that it may not be suitable for patients. “Certain people get into their lingo...They just expect you to know that. But you might not know that. It’s sort of because they are stuck in an environment, they say that all the time, so, with their different colleagues, so they know what that is. Sometimes the...things that they think are really simple... are the things that actually go over your head.” [M6]

Conversely, one participant wanted to be provided with more in-depth information. “It was actually a bit too basic, I wanted to know a little bit more so I always had questions.” [F11]

d. Inability to process information

Participants found that their understating of the information given to them was impeded by their psychological reaction to their diagnosis. “I don’t know how other
people reacted, but with me, when they sat down and was explaining and giving me all the stuff, I was still in the ‘holy sh** I have cancer’ so I didn’t hear any of it.” [F3]

Following this statement there was general agreement in the focus group, with others going on to say;

“I just feel like you hear that word cancer and you sort of, you lose it, yeah you do lose it.” [F4]

“I was like that too, you sort of, you put a wall up.” [M7]

One participant also struggled with understanding information because they were taking morphine for cancer-related pain, and this left them unable to comprehend all the information provided to them. “The myeloma had attacked my back and I was on morphine and there was no way I could take anything in.” [F10]

Another found that it was the chemotherapy that made them struggle to remember information. “Over that time the effect on my brain was quite significant so I would forget things” and “I was struggling to remember everything because of chemo.” [F11]

Theme three: Other opportunities used to aid understanding

Participants often searched for information from other sources to find what they were looking for. Many participants (n=6) found talking about side-effects with those who had been through treatment before very valuable for information gathering and for support.

a. Help from fellow patients/support groups

Participants agreed that communication with other people who had been through chemotherapy was invaluable for understanding treatment and side-effects. As mentioned above, many participants commented that the basic information about chemotherapy was not adequately conveyed to them, or they had difficulty comprehending the information because of the overwhelming diagnosis or medicines that affected their cognitive ability.

One participant described how not understanding left her anxious and unable to cope. “And it was me having a breakdown in the oncology department and some lovely lady
going ‘what are you scared of?’ and so she sat and you know, I was like ‘I don’t know what this means’ and she sat and explained ‘cause she was going through it and then it was like ‘oh, okay!’.” [F3] This participant described being in “hysterics” and went on to say, “It was another patient explaining it versus anybody else” that helped them through that moment.

Similarly, another participant felt receiving information from a former patient helped them cope with side-effects experienced. “There was a lot of side-effects I had that weren’t on the sheets, but the other girl had had as well, and she made me feel more normal than the doctors did when I had them. I was like ‘oh okay that’s normal, I can get over that’.” [F5]

Other participants felt it especially helpful to talk to people who had been through a similar experience and were now recovered.

“Women that were going through treatment as well as women who had been through and out the other side for quite a period...it was great to talk to them...when you’re in the midst of it, it’s all just overwhelming.” [F8]

“I joined an online support group and relied heavily on the people there who’d had the same treatment regime as me because...it was really helpful to be able to rely on those people who had recently been through it because they could remember really well.” [F11]

“I mean there’s not that many internet sources that talk about the specific treatment that you’re on. Whereas I knew I was on FEC-D and anyone who had that would understand that course of drugs and the side-effects and how they played out and the different timing.” [F11]

One participant described how they struggled to get adequate information about a side-effect they experienced from their specialist but found help through a former patient. “I actually ended up going to, um, somebody else that had been through what I had been through and she was the one that confirmed that’s what my side-effects were and that she had them too and stuff like that.” They went on to say, “So it was
easier to actually go to someone that had actually done it, than go to the doctors for information.” [F5]

This participant suggested that new patients should be put in touch with people who had been through similar treatment before. “I think it would be easier if they gave you information on people who had actually been through it as well. So, you’ve got info there from, like, people who probably have the same side-effects as you as well.” [F5]

Many participants (n=5) described how much they appreciated the information and support received from patient support groups they went to. “Actually, it’s great when you go to a group if you can mix with people...you get to talk to people with different types of leukaemia and, um, you get to know, yeah, learn a lot more about it. And it is also good you support each other. I think the group is fantastic.” [M9]

Participants continued to find them useful years after they have finished their treatment. “I still go to the blood and leukaemia meetings, and, I mean it’s been six or seven years, but they say keep coming, you know, because they can see it’s the survivors, you know, so we trot along every month or so in to it, you know, it’s quite good and I have learnt a lot.” [F4]

And that the ability to share information with other people is useful. “you know, ‘cause my muscles are sore you know, ‘my muscles, oh I have that too’ sharing, as you say, sharing information with other people is really cool.” [F4]

Participants appreciated the encouragement for communication that these groups provided. “They [the Breast Cancer Foundation] encourage everybody who has been diagnosed with it to get on there [the smart application] and you can talk to other people who have the same stage or is going through the same.” [F3]

One participant had a family member previously go through chemotherapy and used them as a source of information as this was perceived to be more relatable than other possible sources. “I’d had a family member who’d had been through chemo as well and she was really helpful with giving me tips so I would ask her questions and she would know, and I found that to be easier than kind of reading through the internet at the risk of finding something that didn’t relate to you.” [F11]
One participant also found that support groups were very useful for their support person. “And it [the support group] is also good for your support person. If ever your support person give a, gives a chance for them to talk, um and yeah, yeah it’s great, yes.” [M9]

b. Other sources of information

Six of the participants described how they obtained information from other sources. Many of these participants received information from a patient support group, two of whom received information from the Leukaemia and Blood Cancer New Zealand.

“I got the information from Leukaemia and Blood foundation, that booklet and um and then there was you know lots of other, other things.” [F1]

“I think it was all leukaemia and blood foundation also had their website that I could go to and stuff.” [F5]

Another participant valued the information and services provided by the Breast Cancer Foundation New Zealand. “Well I think that’s where the breast care service here is really good...they give you a heap of information, like, they gave me a journal and websites to go to and, you know, the app to go to, and just all this stuff.” [F3]

The ‘app’ is a smart application provided by the Breast Cancer Foundation New Zealand that patients can use to contact a dedicated nurse for information. “So breast cancer services was really good as far as all that, and they assign you a nurse and that nurse... if you have any questions, so that part’s good.” [F3]

The Breast Cancer Foundation New Zealand encourages all people with breast cancer to sign up, and as well as resources and a specialist nurse, it provides an avenue for contact with fellow patients. “They encourage everybody who has been diagnosed with it to get on there and you can talk to other people who have the same stage or is going through the same.” [F3]

Other participants went to look for information independently of official organisations or recommendations from their specialists via the local library. “I did go to the, um, library as well and get books and things like that.” [F8]
Or by browsing the internet. “On my phone, um, I’d quite often go into CML and look up information um, but I try and make sure I go into good sites you know? And I would go in and look up to see what side-effects there are and things like that.” [M9] The information found on the internet could then be used for understanding when consulting with their specialists. “It gives you an idea of what’s coming, when it comes and it, so when the doc, when the specialist talks to you, you’ve got an idea of what they are talking about. You know?” [M9]

One participant described how they wish they had thought of relying on their general practitioner (GP) for support and information and did not appreciate at the time the role they could have played in their treatment. “In hindsight...I should have made much better use of my GP in terms of an advocate and a sounding board...that that’s sort of what I learned out of that whole process, is that my GP is my best point of contact and my best advocate. And I’m very fortunate that I have a very good relationship with my GP.” [F8]

Theme four: Improving information provision
Some participants (n=4) had ideas about how information provision could be improved which would have helped them when they went through chemotherapy.

a. How information provision could be improved
Two participants felt that restructuring or reordering of the current information would be useful.

One said, “You can only take so much information in and sometimes it’s probably better to give you the main facts, condense it, you know, rather than give you tons. ‘Cause I find when you go in there you don’t actually remember everything.” [M9]

Another participant suggested improving the findability and discoverability of the information could be achieved by separating content into different sections. “It would have been great to sort of, I don’t, where they had another pocket, two pockets in the folder, and, and the stuff in this pocket is the really critical stuff, and here’s the more background stuff.” [F8]
Three participants discussed the use of digital technology and how this could improve the provision of information to chemotherapy patients either via websites or smart applications.

“I think it could be done online....especially when you are going to and from hospitals if you’re taking it, you know, stuff gets lost and if you’ve got a login then that just makes it a lot easier.” [F2]

“Having like an online resource library would have been a much better way of giving me that information. Instead of giving me 12 different printouts or photocopies with various different websites like a one-stop online shop would have really helped me. Because that would have also saved me from delving into Dr Google unnecessarily which I tried to avoid.” [F11]

“It could be done on, like, an app...it could list all the stuff that’s on paper and you could go in and type in side-effects and then see if it’s actually related to the drug you are taking.” [F2]

“So that [breast cancer society digital tools] would be something good to have for other types of cancer...something set up that was specific to the different types that people that have that can go on and ask questions of other people or have the information or look up side-effects.” [F3]

There was general agreement in the focus group discussion with these comments [participants F1, F2, F3, F4, F5, M6, M7].

b. Personalised information needed

Three participants mentioned that personalisation of information provided to them would help. Two participants described how everybody reacts to treatment and disease differently.

“Yeah ‘cause it’s, it’s gonna be, like, everybody’s body is going to react differently too.” [F3]
“There’s a huge amount [of side-effect information], yeah. And the thing is everyone’s different. And how it effects one person to another person ... it can affect other people differently so yeah.” [M9]

One of these participants went on to describe a conversation with their specialist about differences in peoples’ reactions to side-effects. “She’d go ‘you know, some people have, um, this much problems [holds hands wide apart] but it’s only this [holds up thumb and forefinger apart] other people have that [holds up thumb and forefinger apart] and it’s really this [holds hands wide apart]’.” [M9]

Two participants who had a preference for smart applications felt that these could be usefully personalised.

“The doctors could you know, load on what, exactly what chemo’s you’re on and then it could list all the stuff that’s on paper.” [F2]

“Stuff like that would be good if it was, you know, something set up that was specific to the different types [of chemotherapy].” [F3]

6.3.4 Discussion

This study explored the views of people who have had chemotherapy about the information they received about their treatment, and whether this could be improved. Overall, the majority of participants thought that the information could be improved. However, most participants knew what to do and who to contact if they needed help or information about their treatment. Some participants liked the information more than others, and some suggested ways to improve the information being given e.g. by reordering the information, providing the information in a digital format, and by tailoring the information to personal requirements.

Being provided with information

In order to attain maximum comprehension of information, the gold standard is to give patients both verbal and written medicine information, and this appears to be what happens for those who are starting on chemotherapy at SDHB. Chemotherapy uses high-risk medicines that can cause many serious side-effects.
The risk and types of side-effects vary between regimens, but most people having chemotherapy will likely experience some. However, most individuals are willing to accept the toxicity that comes with chemotherapy to extend their life expectancy. To mitigate potential harm and prevent hospitalisation and fatalities, people need to be well informed. Furthermore, adequate provision of information about oral anticancer therapies can improve patients’ quality of life, satisfaction with treatment, and concordance.

It has been shown that much of the verbal information provided to cancer patients will be forgotten following a consultation. Receiving a cancer diagnosis and the information about chemotherapy will cause anxiety and negatively affect people’s ability to understand and remember the important information needed. Most of the information provided by the oncology/haematology team in the present study was in written form, with some recommendations of reputable websites for further information. The quantity of information provided is large and although many participants in our study said they understood the information, their opinions differed about whether they were provided with too much or too little information. Some studies show people want to receive plenty of information, whilst others show patients prefer to receive little information, highlighting the importance of tailoring information to patient requirements.

Written information

Information about chemotherapy is complex and frightening and it is given to people at a vulnerable time of their lives. It is important that people feel they can understand the information being provided to them and act on it. In this study, just over half of the participants felt that the information given to them was easy to understand and the way it was provided aided their understanding. Yet, several participants believed its format and provision could still be improved. Furthermore, one participant, thought the terminology and language used in written information was difficult to understand. The use of a digital platform may improve comprehension, and could explain complex terminology and provide both in-depth and basic descriptions of complex terms.
Many participants did not find the information given them to take away ‘too much’, possibly because, as shown elsewhere,\textsuperscript{234, 236} they could read this at their leisure if they wanted to. Consistent with a Dutch hospital study of 208 cancer patients, some liked to receive an abundance of information because it made them feel reassured.\textsuperscript{238}

Conversely, some participants were alarmed and felt overwhelmed by the abundant information provided to them and deferred reading it. This has also been described in other studies with lower-risk community-prescribed medicines,\textsuperscript{4, 40, 48, 65, 66, 173} and smaller quantities of information. One participant found the information difficult to navigate and described being unable to find the information they needed amongst all that was given to them. This highlights a problem and suggests the information provided was not fit-for-purpose. Consistent with other studies, some participants would prefer to receive information that summarised the main points and pointed to further information if required, rather than a plethora of material.\textsuperscript{109}

The findings of this study reinforce the need to tailor information to patients’ requirements.\textsuperscript{109, 238} Therefore, the type of information and how it is given must be suitable for their personal requirements to encourage them to read it and enable them to find what they need to know in a timely manner.

Digital information

Earlier studies have shown that people having chemotherapy like to receive information about their medicines via the internet.\textsuperscript{236, 240} The present study found that participants would appreciate digital resources that contain the information provided by the hospital as an alternative source, with some commenting that they would like a special app provided. Some participants thought it would be easier to find information online, it might reduce the quantity of printed information given, and allow some tailoring of information e.g. to their own chemotherapy regimen. Other studies have shown that information about chemotherapy read on the internet is generally well-received.\textsuperscript{240} However, it is recommended that patients are directed to high-quality websites to prevent acquisition of inappropriate information.\textsuperscript{237, 240}
Information about side-effects

Having information available for later reference is vital for patients to access and find important information to help them through situations that may arise. Previous research demonstrates that people might not be receiving adequate information about chemotherapy side-effects.\textsuperscript{238, 239} In this study, two participants felt scared by what they found when they sought further information themselves. This could be prevented if information was vetted and presented by their specialist team with opportunity to discuss concerns.\textsuperscript{235} In the present study, all participants shared information they were given with their family or support people, even if they were unwilling to read the information themselves at the time, so even if the side-effect information taken home is not used by the patient themselves, it will still be an important tool for someone supporting and caring for the patient.

Research demonstrates that withholding information, deliberately or otherwise, from cancer patients will increase fear, anxiety, and confusion.\textsuperscript{235} It can also create future difficulties for the patients and the health professionals involved in their care, i.e. causing communication breakdown. This will negatively impact patient experiences.\textsuperscript{237} It is essential that the oncology/haematology team ascertain patient preferences rather than postulate what information patients want or need to know and that they deliver information, particularly upsetting information, appropriately.\textsuperscript{235} This would support open and frank discussions of difficult topics and ensure understanding.

Other information

Participants also expressed the desire for contextual types of information being available and that its absence resulted in anxiety. This has been demonstrated in other studies with cancer patients,\textsuperscript{236} and been described in palliative care.\textsuperscript{235} One participant needed information about the terminology (‘chemotherapy rounds’) and how the treatment would be given. Lacking this, they felt lost and extremely anxious. This example highlights patients’ different needs—it was not the risk of side-effects nor the diagnosis making it difficult for the patient to cope, but the lack of information about the medical procedure they were having to undergo. It is possible the individual was given this information, but was unable to recollect it later, as described
previously. Some participants postulated that the experts may forget that patients new to this setting are unfamiliar with the jargon used and be unaware that more explanation is necessary. Regardless of whether the information was given, it emphasises the point that ongoing access to information about treatment that a patient wants to know is important. Moreover, it highlights that digital sources might enable the organisation of information into ‘type’ i.e. description of the chemotherapy and how it is given, side-effects, monitoring required etc. This would make it easier for users to find what they need at a time that suits them. In addition, having a standardised platform of information that could be personalised should ensure there was no information missed.

However, individuals’ information needs may change during an illness,\textsuperscript{236} so there is a need for an adaptable system to accommodate different patient needs at different times.

**Seeking information**

Overall there was high praise given to the oncology/haematology teams at the hospital. The designated nurses at the hospital that answer queries on side-effects and management were described as a valuable resource and much trust was put in the hospital team. Yet some participants in the present study spoke about communication problems they experienced perhaps from a relationship breakdown due to earlier miscommunication; perceived withholding of information by the specialists; miscommunication between hospital teams; and a lack of support in decision making. A cancer diagnosis and its treatment is a stressful time in a person’s life and can make people react in different ways. Regardless of their ability to have a constructive relationship with their specialist team, patients need to be able to receive, understand, and act upon information given to them with their treatment. It is essential that they understand the benefits and potential harms of their treatment, personalised to their requirements and in the context of their life expectancy.\textsuperscript{237} Reluctance to contact healthcare professionals because of a relationship breakdown should not cause reputable and accurate information to become unavailable. Having
information accessible, without having to contact the team, may be crucial for those who feel unsupported or out of touch with their specialists.

The common side-effects for chemotherapy regimens are well documented and readily accessible, but there appears to be a need for those considered less common. Most patients want to receive as much information as possible from their doctor.\textsuperscript{235, 236} Yet many participants described being blindsided by the rare side-effects they experienced that they were not counselled about. They felt they were not provided with adequate information and were left unsupported. This made them look for other sources of information about these side-effects.

**Information from fellow cancer patients**

The perceived lack of support about management of ‘rarer’ side-effects was deeply felt by participants, with some resorting to finding out information themselves through others who had experienced the treatment before them. Earlier studies also show that some people prefer fellow or former patients as providers of information.\textsuperscript{241}

Having access to other people who have been through treatment before was described as invaluable. For some, discussing their treatment and concerns with former chemotherapy patients improved their understanding and ability to cope with the side-effects they experienced. It was thought that those who had previously experienced side-effects could provide more useful information than what they were receiving from their specialists about what measures to take to manage their symptoms. Particularly, reassurance that the side-effects being experienced were ‘normal’ was a comfort. Access to support groups was also useful for discussing treatment, being provided with useful information, and finding answers. An Italian study also demonstrated that a large proportion of patients preferred to receive information about their chemotherapy from other patients (32.5%) or use other patients as educational aids (27.8%).\textsuperscript{241} This is a viable option for many people in New Zealand with the large number or support groups available.\textsuperscript{203, 204, 219, 242, 243}
One participant felt that everyone who is receiving chemotherapy should be given a person to contact for support and to provide them with information. Furthermore, other studies have found patient appreciation of fellow/former cancer patients as a source of information.\textsuperscript{236, 241} There are several initiatives in New Zealand for connecting online with fellow patients for example via the Breast Cancer Foundation app and the Ripple app. The latter is for all patients with cancer and was borne from a cancer survivor’s desire to connect with people in a similar position who are able to share their experience, or to ask questions, as stated on their website ‘often questions not even a doctor could answer’.\textsuperscript{243} The recent development of these apps indicates a nation-wide need for connecting people. The Cancer Society of New Zealand also offers an information service and helpline\textsuperscript{242} and other cancer-specific societies have other platforms such as closed Facebook groups that allow communication with other people going through treatment. Unfortunately, determining if participants in this study accessed these services and apps, and their experiences of using them, did not occur, although some did mention that they had used them.

Seeking information online

Some participants in the present study searched for additional information on the internet, whereas others deliberately avoided it, or were discouraged from looking by support people or family members. Other studies have demonstrated aversion to information on the internet because it was ‘overwhelming’ and ‘too confronting’ about the course of disease.\textsuperscript{236} Yet, as described above, cancer patients are willing to receive information digitally. More needs to be done to direct patients to look for information on reputable websites to ensure people access accurate advice.\textsuperscript{240} This could prevent people becoming overly alarmed or misled by online misinformation.

Taking the necessary action

Two participants could not always remember what to do if they experienced a side-effect, and presumably they could not find the instructions previously given. It is essential that people who are experiencing side-effects with their chemotherapy know when and how to act in order to prevent worsening of their condition.\textsuperscript{125, 129} Most of our study participants claimed they followed the information provided to them when
they experienced a side-effect, whether it was self-management or a requirement to visit the hospital.

Similar to other studies, some participants avoided contacting the hospital immediately \(^{129,211}\) because they did not want to be a burden. Others avoided seeking help because they did not want to undergo testing and wait around in the hospital, or be admitted for a lengthy stay. Other studies have also shown that for some cancer patients, the time in hospital or time taken travelling there was the worst aspects of their illness, even more so than the side-effects experienced.\(^{237}\)

Further communication and education is required for people who actively avoid contacting the hospital. Perhaps there is room for improving community support for those who are wanting to stay home as they may put themselves at risk in their desire to remain out of hospital. Moreover, systems must be put in place to avoid people being unable to seek help because they do not know how. Standardised information about how to manage side-effects and when to seek help should be provided in a way that guarantees patients know where to find the information easily at a later time.

Using family and friends for support with side-effects
Cancer patients often use their family and friends as information sources and depend on them for help with recalling the information given during consultation.\(^{237,241}\) In the present study, some participants relied on their family or support people to access the information they needed about their chemotherapy side-effects. Some participants described their support person taking control and becoming responsible for contacting the hospital for help with side-effect management. This highlights the necessity for family or support people to know what to do when problems arise. Thus, it is essential that information given to people about how to manage side-effects can also be used by family or support people so they can know what to do if side-effects occur.

6.3.5 Conclusion
Undergoing chemotherapy can be an emotional and stressful time in a person’s life. Being provided with information to understand the side-effects and know what to look out for is vital as some side-effects can result in severe morbidity and mortality.
However, the quantity of information currently given to people can either put them off reading it or can result in feelings of anxiety. Information given to patients about their treatment needs to be provided in a way that suits them. Although some people in this study decided to not read all of the information given to them, most used it later as a reference source. Therefore, the information provided must be user-friendly and well organised in order for them to find the information they want, when they need it. Some people would like to be given a short summary of the information about their treatment with the option to delve deeper and find more content on a given topic if they desire it. There was also some preference for being given information digitally and this will be further discussed in section 6.4.

Because everyone has different needs in regards to the extent of information they want, how they react to their treatment, and their experience of side-effects, information needs to be provided in a personalised way. The current system may be limited in capacity to provide personalisation of information for each patient, but this could be supported through the use of digital technology.

The strengths and limitations of this investigations are discussed in section 6.5.
6.4 Patient views on the use of Patient Reported Outcomes (PROs) for generating personalised information in a digital tool for chemotherapy medicines

6.4.1 Introduction

As mentioned in section 6.3, it is imperative that side-effects experienced with chemotherapy are managed quickly and appropriately. Patients undergoing chemotherapy are able to contact health professionals for advice if they are experiencing problems with their treatment (S Pointer, informal pers. comm. December 2017 and L Dagg, informal pers. comm. March 2018). However, relying on patients to phone for side-effect management advice might have some disadvantages. Hesitancy in reporting may result in progression of symptom severity, requiring more intense clinician intervention (i.e. patients cannot manage the side-effects at home). Patients may also have difficulty understanding and remembering verbal information given to them, relying instead on friends and family for support. This means that side-effects are not always reported or proper advice not sought or understood, possibly resulting in sicker patients and more hospitalisations.

PROs for chemotherapy side-effect management

Chapter 2, section 2.6 of this thesis discussed the advantages and disadvantages of PROs and outlined how they could be used in practice. In this chapter, we are focusing on the possible use of PROs to report patients’ experiences with chemotherapy medicines.

There are a number of prototypes that have been developed internationally for web-based collection of PROs from chemotherapy patients, and those systems undergoing trials show positive results (e.g. improved management of side-effects) and patient approval. These studies use validated algorithms for collection of side-effect information, similar to the information collected using the UKONs tool, focusing on common side-effects experienced with chemotherapy medicines including...
constipation, cough, diarrhoea, dyspnoea, dysuria, fatigue, nausea, pain, neuropathy, and vomiting. These programs use web-based questionnaires for patients to self-report side-effects and to generate self-management advice to send back to patients or alerts in real time when they need to see the hospital staff.\textsuperscript{125, 126, 129}

Some prototypes allow hospital staff to view the patient-reported side-effects in the hospital record and send urgent email notifications when severe side-effects are reported to ensure proper management is initiated.\textsuperscript{126, 129} Others send email notifications or messages via pager-type systems to nursing staff responsible for symptom management.\textsuperscript{123, 128} One system from the UK was adapted for use across Europe and successfully implemented in five European countries.\textsuperscript{244}

There has been a range of studies internationally determining chemotherapy patients opinions on using these systems. In an Australian study\textsuperscript{124} 17 chemotherapy patients completed semi-structured interviews about their experiences of using the system. Qualitative analysis showed that the PRO system gave them reassurance, improved ability to discuss and manage side effects, and improved empowerment and health awareness. The system was perceived to be easy to use and have a positive impact on care. A study in the UK\textsuperscript{245} also used semi-structured interviews with chemotherapy patients (n=12) to determine their experiences of using their online side-effect reporting system. Similarly, this study found their system increased patient knowledge and confidence to manage their own symptoms, gave them reassurance, and reduced anxiety. A larger study in the UK\textsuperscript{128} had patients who had used their advanced symptom management system perform questionnaires (n=36) or semi-structured interviews (n=12). The overall response to the questionnaires was that people liked using the system and most (91%) felt it had helped them manage their symptoms. Similar to other studies, participants in the semi-structured interviews felt reassured that their symptoms were being reported to their healthcare team.

Some problems were identified with functionality of the systems such as trouble answering questions or sending their symptom questionnaires,\textsuperscript{128} trouble inputting data because of previous disability, and lack of confidence in using the full functionality of the system.\textsuperscript{124} Problems were identified with the content of the
systems, such as: side-effects being experienced by participants that were not included in the system (thus could not be reported);\textsuperscript{124, 245} advice provided was too generic; the scales to identify severity of side-effects were too limited (and hence inaccurate reporting was done);\textsuperscript{124} and inappropriate question framing in the system meaning that historical symptoms were reported.\textsuperscript{245}

Because of the nature of the questionnaires used for collecting PROs, and the similarities to tools in current use in New Zealand, it should be possible to adapt these digital systems to our national requirements. The use of web-based reporting systems in New Zealand could be beneficial for patients, and may help overcome problems experienced with current systems of managing side-effects with treatment. However, it is necessary to investigate whether there are cultural differences that would prevent easy adaptation for use in New Zealand, and whether New Zealand patients would be able to, or want to, use electronic devices to receive targeted information about the management of chemotherapy medicines.

**Aims of this research**

It is uncertain whether the web-based PRO systems set up in other countries would be well-received in New Zealand or if they would be appropriate for our population. The aim of this investigation is to find out whether former chemotherapy patients would like to use a web-based PRO tool to receive information about their medicines and help them manage the side-effects experienced with their treatment.

**6.4.2 Method**

The methods described in this part are a continuation of those outlined in section 6.3 of this chapter, specifically about part three and four of the focus group/interview outline. Participants, recruitment methods, and structure of the focus group session are also discussed in section 6.3.

**Focus group and interview outline**

The focus group meeting and interviews contained four parts: i) an individual questionnaire; ii) a discussion about items from questionnaire; iii) an introduction of the online tool (capturing Patient Reported Outcomes (PROs); and iv) participants’
thoughts on the online tool for capturing PROs (see Appendix 19). Parts one and two of this study protocol are covered in section 6.3 of this chapter.

Questionnaire and discussion guide development is discussed in section 6.3 of this chapter. Questions about what digital technology was used by participants were adapted from U.S. government guidance on digital usability questionnaire templates to measure digital media use.\textsuperscript{230-232}

Part three: Capturing Patient Reported Outcomes (PROs) using an online tool

In the third part of this study, participants were introduced to the concept of using an online tool to capture PROs and how this could electronically provide cancer patients with personalised medicine-management advice online. A brief summary of international studies was given. The participants were provided with the information on a separate standalone document (this information is also in Appendix 19).

Part four: Participants’ thoughts on the online tool for capturing Patient Reported Outcomes (PROs)

The fourth part was an open discussion about the possibility of using an online tool for capturing PROs to determine participants’ ideas about the use of this tool and participants’ thoughts about the advantages/disadvantages of using this for people undergoing chemotherapy.

The following discussion points were used:

a. \textit{Do you think this online tool that we discussed would be something you would be able to use or like to use?}

b. \textit{What would you like about using the tool for a side-effect you experience?}

c. \textit{Would you also like to use this to look for other information about your treatment?}

d. \textit{What concerns would you have about using the tool to report a side-effect or to receive information?}

e. \textit{What would be useful about using this tool?}

f. \textit{Would you prefer to use the tool or to telephone the hospital?}
Analysis of data

The data from the questionnaire (in Appendix 19) that related to the use of digital technology and the internet was entered into data management software and basic descriptive analysis was undertaken. The focus group session discussion and interviews were audio-recorded and then transcribed verbatim by AY. AY double-checked the transcriptions against the recordings and read through them again multiple times. JT and AS read through the final transcriptions. AY carried out semantic inductive analysis of the transcriptions and organised them into a thematic framework matrix in Microsoft Excel. Semantic inductive analysis of focus group discussions and interviews identified repetitive themes, illustrating patient attitudes and perceptions on use of an online tool for capturing PROs and for providing information about their treatment. Thematic coding and framework were reviewed by AS and JT.

6.4.3 Results

The same eleven participants completed this investigation as the one reported in 6.3. Their demographic characteristics and other results relating to data capture are described in section 6.3 of this chapter.

Part one: Individual questionnaire responses relating to use of digital technology

All participants indicated they use the internet on a computer and/or smart device often, or on a daily basis. All participants engage in a wide range of activities on these devices, see Table 16.
<table>
<thead>
<tr>
<th>Typical activity undertaken on smart device</th>
<th>Number of participants who undertake the activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buy or make a reservation for travel</td>
<td>7 (64%)</td>
</tr>
<tr>
<td>Email or instant messaging/chat</td>
<td>10 (91%)</td>
</tr>
<tr>
<td>Look up a recipe</td>
<td>10 (91%)</td>
</tr>
<tr>
<td>Look for health/medical info</td>
<td>8 (73%)</td>
</tr>
<tr>
<td>Look for info on a hobby or interest</td>
<td>8 (73%)</td>
</tr>
<tr>
<td>Read the news/weather/sports/blog</td>
<td>8 (73%)</td>
</tr>
<tr>
<td>Online banking or bill paying</td>
<td>9 (82%)</td>
</tr>
<tr>
<td>Shopping</td>
<td>8 (73%)</td>
</tr>
<tr>
<td>Web searches</td>
<td>9 (82%)</td>
</tr>
<tr>
<td>Playing games</td>
<td>4 (36%)</td>
</tr>
<tr>
<td>Watch videos</td>
<td>6 (55%)</td>
</tr>
</tbody>
</table>

When asked directly if they have accessed a website to locate health information in the last year, one (9%) participant never had, five (45%) participants had a couple of times, three (27%) participants had about once or twice a month, and one (9%) about once or twice a week. One participant did not respond to this question.
Part four: Qualitative analysis about personalised information in a digital tool for chemotherapy medicines

The analysis of the focus group and interview data revealed four main themes (and three sub-themes of theme one):

1) Prefer the proposed digital tool over the current system
   a. Prefer it because they dislike the current system
   b. Prefer it because it would be easier than current system
   c. Prefer it because it would help them manage and understand their side-effects

2) Inputting information and how it is used

3) Concerns about using the tool

4) Prefer to use both current system and a digital tool

Theme one: Prefer the proposed digital tool over the current system
Some participants (n=5, 45%) liked the idea of the digital tool to report side-effects because they did not like some aspects of the current processes involved in reporting side-effects and the information received. Many (n=6, 55%) also thought that the system would help them better manage their side-effects.

a. Prefer it because they dislike the current system
Three participants talked about how they did not like to phone the hospital. “Yeah, I hated ringing in.” [F5]

Their reasons varied with some not liking how it made them feel.

“Yeah you felt horrible. You felt stupid.” [F2]

“I just, just didn’t feel comfortable ringing in.” [F5]

One felt that ringing in gave them anxiety. “Cause it was always sort of like, I guess a little bit of anxiety ringing in and then them being like ‘ok you’re going to have to come in’ and then it makes it sound more serious than what it is.” [F5]
Another participant also felt anxious and even now they are affected by the feelings they experienced at the time. “There was a couple of times it was, just, I don’t, I can’t deal with any more poking and prodding. I can’t deal with being asked questions, the waiting, the whole environment, um it was, you know, I still get, I still get breathless when I go to the hospital.” [F8]

One participant felt uncomfortable because of being asked about symptoms they were not experiencing making them worry unnecessarily.

“I didn’t like some of the questions they asked me. I know they had a certain set of questions that they always had to ask you. So, it’s like, you know, ‘have you had shortness of breath? Blah blah blah blah blah’. But I felt that every time they asked me, I felt like I started thinking about it too much. Like that’s another symptom I could have. So, I didn’t like them asking me continuously. But I knew it was their job to go through a list on a piece of paper and say ‘have you had this? Do you feel like this? Have you had this?’ And sitting there going ‘no, no, no, no’ and then they’re like ‘ok so what’s your symptom?’ at the end of the bl**** list. And I’m just like ‘you know what? I have probably got all of that now, because I am a hypochondriac now’...I just felt really uncomfortable ringing in and talking to them about it.” [F5]

Two participants commented on the nurses’ expectations that they phone about every side-effect experienced and how this was not always practical. One participant was informed by the nurses, “‘you need to ring up every time you have a side-effect, you know, that you are worried about or need to talk about. You need to tell us every side-effect you’re getting so we can write it down and have it on your file’.” [F5]

If they did not ring straight away they felt they could be reprimanded. “I got told off when I rang up to talk to one of the nurses, she gave me an earful over the phone, um, because I didn’t ring up and tell her about [diarrhoea]...she pretty much told me off for not ringing in the day it happened.” [F5]
Another participant agreed but then said, “But then you’re calling for every little thing.” [F3]

One participant also admitted that their reluctance in phoning the hospital may have resulted in an escalation of their symptoms. “The couple of times I ended up in ED I knew I should have rung earlier in the day but it was just like ‘this is alright, this is alright, this is better than going and getting poked and prodded’.” [F8]

Whereas another described how they dealt with their symptoms themselves. “Sometimes I just didn’t [ring the hospital]...I just got through it.” [F5]

Similarly, other participants avoided ringing because they preferred to stay at home, “Because it was always ‘come to the hospital’.” [F3]

One participant had a long way to travel to the hospital and being told to attend sometimes resulted in an unnecessary journey. “It was a long way for us to come to the hospital, you know, and then you get there and they say ‘oh no, you have to go home again’.” [F4]

b. Prefer it because it would be easier than current system

Two participants thought an online reporting system would be easier to use than the current phone-in system, with one stating, “getting on to a computer is not quite as demanding.” [F8]

One reason was because of how unwell they felt at the time. “I know there were a couple of times I just felt so bad I couldn’t even pick up the phone. That was too hard.” [F8]

Another suggested it would make dealing with minor problems simpler. “I would rather it just be like ‘oh no that’s fine’. Just take an extra pill for it, you know or something like that. And it’s like ‘ok I can stay at home and relax’.” [F5]

Rather than spending time having a lengthy discussion with a nurse, “I would rather just go online and have something where I can just type it in and then it just tells me straight away...[if] I can manage it myself, I don’t need to go in and see anybody. Um,
rather than have to ring in and they’re like ‘oh yeah, that’s fine’ and I’m like ‘oh well that was a waste of time ringing’.” [F5]

Participants also thought it would make the decision to go to hospital simpler and more straightforward. “I think it would just be easier [than phoning] because you’re just like ‘oh it’s telling me to go, I had better go. I’d better jump in the drive’.” [F5]

One participant thought it would be simple because their computer is always in use. “[the online tool] would be your first port of call. You know, because I don’t really close my computer down much, so it’s there, readily available. I have used it when I want to know side-effects of new drugs that I go on. [F10]

c. Prefer it because it would help them manage and understand their side-effects

Six participants thought that an online tool would help them understand their side-effects better. For example, it could help to further understand side-effect frequencies. “If they had two boxes, like one’s common and one’s uncommon, so you could see [you] might not get it.” [F5]

Or help them remember their side-effects experienced with a previous round of treatment. “I think it would be useful if you could rationalise the side-effects you are experiencing over time as well...Every time I had a treatment, and I had six of them, I would have some consistent symptoms or side-effects, and then some things appeared over time...I would think ‘is this normal for me? or was I having that at the beginning?’ because I couldn’t remember, my brain was so foggy I couldn’t remember... knowing what your normal is.” [F11]

Or better understand what treatment they will need. “I could go into a site that’s legit and look at what’s happening and um find out what’s going on you know? From a reliable site, what the next lot of treatment would be.” [M9]

One thought it would be better because it would be easier to find the information they need. “Yes, yes it would be [easier to navigate than booklets]. I wasn’t very impressed with the booklets.” [F10]
Many participants (n=5) felt that having the online tool would help them make that decision about when to seek treatment.

“It would help me make that decision...is this something I need to be worried about...is this just normal? Is this the way I should be feeling? Or is this something I should be worried about? So, any tool I think that could help with that um understanding would be great.” [F8]

“Yeah probably just knowing whether or not you need to be concerned in relation to your own specific situation about something.” [F11]

Another participant said, “you always brush things off you know...But with this you’d, um, you’d be putting down ticking boxes and you’d be making someone else aware of what the problems are and then they can make a better decision...alert you and confirm um that there is a problem.” [M9]

This could have been particularly beneficial when they preferred to not contact the hospital. “…that would help, ah, would help make that decision ‘is this normal or is this something I need to be worried about? And if this is something I need to be worried about then either I need to get over this being too hard or I need to get my partner to call’.” [F8]

Similarly another participant wanted to use it to know if they should be worried about a side-effect experienced when they would usually have avoided contacting the hospital by phone. “If I had something like that, you’d kind of tick things and it would’ve yeah, yeah, it would have alerted me, which sounds silly doesn’t it.” [M9]

The system would also help their family or support person when they could see that someone needed help, but they refused to seek professional advice. “She can see things but she’s fighting me ‘cause I didn’t want to go into hospital and be a burden. So this would actually kind of just alert, even myself, or someone else.” [M9]

In addition, this would help their support person to determine when to seek help for symptoms, reducing the anxiety around whether to push them to contact the hospital. “It would have alerted it, you know? And it would have taken a lot of worry away from my partner.” [M9]
Two participants felt that having a system like this would help explain side-effects to their family, with both going on to describe how their family did not understand what they were experiencing.

“I wish my family knew what fatigue was. I just don’t think a lot of people know what it is. They just think you are being lazy or you’re tired. But they don’t actually realise.” [F5]

“I would say...‘would you get me some wood and put it on the fire’ and he said ‘get it yourself, don’t be so bl**** lazy’. I just couldn’t physically get up.” [F4]

Theme two: Inputting information and how it is used

There was some discussion about how the information would be recorded and used. Many (n=6) participants agreed that they preferred their responses to be logged in the hospital record.

“I’d rather it be logged into the system.” [F5]

“Yeah I think it’s a good thing. Yeah, I think they need to know what’s going on.” [F4]

“And if you’re not calling in, then how else would they know?” [F3]

Another participant thought it was essential to ensure dangerous side-effects could be picked up. “There might be something that I’m putting in there that they’re going ‘that’s a red flag that we need to be aware of’.” [F8]

She explained that responses from nurses telling them they do not need to visit the hospital would be comforting, “having that confidence and assurance that, um yeah, there is somebody checking that and whether that’s a return email saying ‘hey with, um, thanks for uploading that, we’ve had a look at it um, yeah, if you’re happy to follow whatever’s been suggested then that all looks good’.” [F8]

Furthermore, for those who would avoid contacting the hospital, having it automatically logged into the system without having to phone in was considered a good option. “I’d just write it in and at least they know it’s happening.” [F5]
Two participants in the focus group felt that they would want to use the tool for information finding, so would like the ability to go through different scenarios without these being logged into the system.

“If they had an option of where could like ‘opt in’ to have it on your log, and then ‘opt out’ if you didn’t want it on your log.” [F2]

“Then you could have a button that says like, say you are looking up some of the side-effects, just because you are looking them up and wanna know. But if you are actually having them and you want it recorded you hit a button and it records them on the side.” [F3]

There was general agreement among other focus group participants with this discussion [F1, F4, F5, M6, M7].

One participant suggested that a comment box for inputting free text would be useful, “You could have a comment box in, just saying, you know....I feel that my, I’ve got pins and needles in my body today or something.” [M6]

Theme three: Concerns about using the tool

Six participants raised specific concerns they had with having an online tool to report side-effects and receive information.

One participant stated, “I’d just ignore it” going on to say “I think I would be more likely just to ignore the tool ‘cause I’d always ignore it myself, if I get a temperature of 38[°C], I’d just be like ‘I’m staying home’.” [M6]

This participant would avoid contacting the hospital when they were experiencing side-effects with their treatment, so would also avoid reporting side-effects with an online reporting system. “If it was getting into the amber and the red I’d still be like, ‘I just want to stay at home’.” [M6]

They also felt the tool would not benefit them because they already knew what action was necessary when side-effects were experienced. “I already knew what I was supposed to do, take some antiemetic drugs, you know in case. Um, I don’t know if...it would help me too much.” [M6]
Another concern raised was that health professionals may be lulled into thinking someone was not having problems because they were not reporting problems via the tool. “They have a patient that’s sitting there and ‘don’t need to know that stuff…I’m not going to report my diarrhoea, I’m not going to report my vomiting to someone’, so then they might get complacent and think that that patient’s fine when they’re not.” [M6]

And that if specialists relied on the system, they might think they do not need to go over these side-effects during consultation. “They’re not asking, going to ask those questions anymore that they always do. Because they got the, they get the feeling well you’ve got the app, you’re already doing it yourself, so why should I ask you this again? Some people, some people wouldn’t go over.” [M6]

Conversely, they were concerned that constant use of the online tool could be irritating to healthcare staff being reported to. “But you might get some that might just turn off the doctors, that they find some patients that just constantly rambling. A doctor being like ‘oh for god sakes, she’s on again, what are they on about? Constantly writing down stuff and fretting over every single thing’.” [M6]

Two participants were concerned with what happens to the information once it has been inputted by a patient and wanted to make sure it was reaching the right people at the right time. “I just ah, thinking the confidence that that data goes somewhere and someone’s looking at it...having that confidence and assurance that, um yeah, there is somebody checking that.” [F8]

One concern was if the tool was using a system like email, and not alerting the health staff via direct means and in real-time then it could cause issues. “It’s not direct enough. No one replies to an email ever. So, this would be essentially an email tool to someone. And no one ever replies to an email. So, you’d send it and no one would reply to you really.” [M6]

Three participants raised concerns with access to the internet, “Depending on access to internet and stuff.” [M7]
And other access barriers, “You don’t have to go far out of the city and, um, online becomes an issue or, an, or far out of, um you know of anyone of socioeconomic um, where you are. Yeah, so a lot of people just don’t have access to online things.” [F8]

Two participants were concerned with peoples’ abilities to use the tool or to understand the terminology used.

“I’m kind of basic on a computer, I can email, I can find things on the internet, um but there’s people a bit older than me or even the same age as me, um, who can’t.” [M9]

“Interpretation of medical jargon could be difficult because everybody’s got a different understanding of what the scale of something means. Like plain English versus medical speak.” [F11]

Two participants raised the concern about security.

“It would be all um, safe wouldn’t it, yeah?” [M7]

“I understand from what you are saying that it would be totally secure?” [F10]

Theme four: Prefer to use both current system and a digital tool
All of the participants preferred to keep both systems if an online tool became available. One preferred paper for finding information, “I’m still of that generation who likes to look at paper. I need to have paper so that I can refer backwards and forwards and relook at things and, and sometimes, you know, if its online...stuff is great but sometimes you can’t find stuff again.” [F8]

Some (n=4) liked to have contact with people and would like this to continue.

“I like people contact you know..., I’d rather look somebody in the eye and talk to someone.” [M9]

“When you pick up the phone and you’ve got a human voice at the other end it can be quite reassuring. And you get an instant reply.” [F10]

And would not like this to be taken away (n=2).
“I would be nervous if I was told that the tool was the only option I had because then there are times when you do just need to talk to a person.” [F8]

“I still don’t think you can bypass that personal face-to-face talk with somebody. When you ask questions and you get answers, and you can discuss... But would hope that it [the online tool] would not take the place of regular interactions face-to-face, asking questions, discussion.” [F10]

Two participants could see the online tool as part of the whole process.

“But this could be um, maybe something before you um went into the hospital and took their time up, you know?” [M9]

“So yeah, the tool sounds good, I certainly wouldn’t rubbish it at all. And probably that might be a first, or a start.” [F10]

Two participants [F2, F5] specified (“yeah”) that they would like the paper information provided by the hospital also to be included in the tool.

6.4.4 Discussion

In the previous section (6.3), participants described how they appreciated contacting the nurses at the hospital when they had a problem with a side-effect. In this second half of the study, we investigated their preference for an alternative system—the possible use of an online tool for recording and advising on side-effects.

This study investigated the views of people who had undergone chemotherapy about whether they would like to use a web-based PRO tool to receive information about their medicines and help them manage side-effects experienced with their treatment.

All participants in this study frequently used the internet for various functions and so it could be assumed they were digitally literate and internet savvy. Ten participants used a device for emailing or chatting and so have experience with inputting varied information and most find health information on the internet too. The present study found that participants would like to use an online system for reporting side-effects and receiving information about their treatment.
Further support for receiving information digitally

Take away materials are necessary to ‘process’ information after appointments but large quantities of complex information may prevent people from reading it at a later time. Cancer patients like to receive information in a digital format and some participants in the present study expressed their desire for provision of digital information before this phase of the study was begun, as discussed in section 6.3.

Having information available in a digital tool may prevent the visual overload of the paperwork provided by obtaining all of the same information tidied away in an easy to follow package. It would also enable the supply of even more information if wanted, with links to reputable websites for additional reading without further overwhelming patients with more printed material.

Personalising information

Tailoring information to personal requirements could improve patient acceptance of written material. It has been demonstrated that information should be tailored to requirements for cancer patients because their information needs depend on the individual or where they are in the cancer-treatment cycle. Digital tools could enable provision of targeted information personalised for different regimens in order to outline the most common side-effects expected for that patient. These tools could also provide other information such as long-term effects depending at what stage of treatment the patients are at. Furthermore, with the ability to target information for specific requirements, a digital tool could provide more in-depth information about the less well-known side-effects that could occur that are frequently not discussed. This was important for participants in our study as many experienced rare side-effects and faced difficulty when asking for help from their specialist oncology/haematology team (see section 6.3). A digital tool would have the capacity to provide in-depth information on a wider range of effects experienced by patients, not just the commonly discussed ones, without needing to manually search through an overwhelming amount of paperwork.
Other benefits of receiving information digitally

Other reasons that participants supported digital provision of information were described in the investigation in 6.3. These included improved ability to find information when using it as a reference source and perhaps the ability to be put in contact with former chemotherapy patients to give personal support and information. Many people valued the ability to talk to others about the rarer side-effects they experienced. There are ways for current patients to talk to those who have been through treatment previously, but this may be limited and dependant on cancer type and services available to that patient. There is currently an opportunity to undertake this communication and support more extensively using technology that is already available, for example the Ripple app developed in New Zealand.243

Participants expressed frustration and sadness when describing their family’s reactions to side-effects they were experiencing. Improving information provision to cancer patients can help improve their family members understanding of the cancer and the treatment.246, 247 So having a digital tool available may support family members to have a better understanding of what the patient is experiencing. Participants agreed that the digital tool could help with explaining side-effects to their family and would be useful when needing to communicate with them.

Support for digitally reporting side-effects and receiving management advice

The current system at SDHB of having a designated nurse for side-effect management advice was generally well-regarded. However, many participants in the study also liked the idea of a digital tool to report side-effects and to receive information. There were many benefits identified by participants that could improve the way they receive information and how they feedback treatment side-effects to their oncology/haematology specialists.

Improving patient empowerment

Hesitancy in contacting the hospital may result in worsening of symptoms and is a limitation of current systems in New Zealand and internationally, where people may
‘put off’ contacting the hospital in a timely manner.\textsuperscript{129,211} Hesitancy in phoning the nurses was also demonstrated in this study. The reasons why people avoid seeking help previously included not wanting to burden the nurses, wanting to avoid having to go into the hospital, and one participant also found that ringing and talking to a nurse would worsen their anxiety. Unfortunately, avoiding seeking help for side-effects experienced can result in a worsening of symptoms\textsuperscript{125,129} and this was experienced by one participant in this study.

One driving factor in development of digital symptom reporting tools internationally was to allow the capturing of real-time information about side-effects experienced to improve patient outcomes and reduce costs.\textsuperscript{248} A digital tool with access to reputable information and ability to provide side-effect management advice would be beneficial because it would provide both the reporting requirements and the required information to be given to people undergoing chemotherapy, bypassing their hesitancy in contacting the hospital.

Participants were in agreement that being able to search for information independently and find out how to manage symptoms themselves would reduce feelings of anxiety, sense of burden, and apprehension. Furthermore, one participant thought it would help them view the side-effects they experienced over time, so they could see what they usually experience and what is new. This would be useful for those who struggle with impaired cognitive function during treatment and would provide an ongoing record of their ‘normal’ responses to refer to.

There was general agreement in this study that having a digital tool to supply information about symptom severity and requirements for hospital treatment would be useful in a variety of ways. It would take away the anxiety over knowing whether a side-effect was something they should be worried about and confirm when they need to go to the hospital. Particularly because many people preferred home-management and it was important for them and their support person to know if this was appropriate for the symptoms experienced. This would be particularly useful for those support people who have to persuade patients to contact the hospital and who often feel stressed and anxious about a patient’s wellbeing.
Improving practicality of receiving information

Besides personal feelings of preference, there were discussions around why being able to report symptoms digitally may be more practical. Participants thought the digital system sounded simpler and easier to use than phoning the hospital. In studies investigating peoples’ experiences in the UK, participants in that study felt the system was easy to use and approved of it. Some participants in the present study described that occasionally they felt too sick to actually go through the process of ringing the hospital and that in these situations, using a digital system would be easier. Furthermore, participants described feeling unwell so often it was not practical to phone a nurse for advice every time illness occurred. Inputting data into a digital tool would be quicker and more straightforward than discussing symptoms with staff which, as described above, could result in feelings of anxiety. However, it would only be easier for people who had sufficient computer literacy to use the system without difficulty. Similarly, the system in use would need to be created with a high degree of user satisfaction and have no room for user error. Studies in the UK using such tools have been shown to have a high level of user satisfaction, so this suggests it may be similar for the New Zealand population. Systems overseas have also undergone rigorous user testing with oncology/haematology specialists and consumers. Comprehensive testing with our population and specialists would be necessary for a system to be accepted for use in New Zealand.

A digital tool may also lessen unnecessary travel from more rural areas. One participant, who had a 45 minute drive to the hospital, was instructed to visit the hospital when they phoned for advice, only to be told to return home once they got there; this occurred on more than one occasion. A digital reporting tool may help prevent unnecessary travel for those who live on the outskirts of main centres or in rural locations and must travel large distances to see a health professional. However, it would not prevent those patients being instructed to visit a hospital if there was a need.
Inputting information and how it is used

Participants were generally happy for their side-effect information to be logged into the hospital system to alert the staff. However, participants would also like the ability to use the system to search for information without it resulting in alerts being created. They wanted to be able to go through the questionnaire algorithm just to find out what information is given and would like an option of doing this without their responses being logged. Therefore, when a system is created, it would suit patients to be able to search for information with the ability to log in for information/alert production separately if needed.

The preference for patients’ side-effects being logged in the system was interesting considering the discussion about not wanting to be a burden or not wanting to go into the hospital. Yet people overwhelmingly agreed that symptoms must be recorded in the hospital system to keep the oncology/haematology team informed about what side-effects were experienced at home. This indicates that although people may want to avoid visiting the hospital, they are keen to have their information made available to their oncology/haematology team and follow the recommendations given, even if those are saying to ‘go to the hospital’.

Furthermore, in a UK study, 128 participants using a similar electronic tool, wanted to make sure that someone was looking at the information they inputted. They wanted a quick response and assurance that if they followed the advice provided they (i) do not need to visit the hospital, or (ii) would only have to if the symptoms escalated. This suggests that providing feedback to patients is essential. Perhaps any new tool developed could incorporate a pop up message to inform patients when their information is logged in the system, and, if they input a serious or severe side-effect, a note confirming that a nurse will be reviewing the information shortly and to expect a phone call. This would allay concerns about information disappearing into an abyss never to be seen again.

Nevertheless, some participants raised concerns about inundating their healthcare team with too much information by logging every side-effect experienced. Perhaps this could be reduced by the specialist team advising their patients about what is
expected to be logged in the system before giving them access to the system, and reassuring patients that logging symptoms was necessary and required by the healthcare team.

Furthermore, one participant was concerned their worsening health might be missed if they chose not to report symptoms via the tool. Perhaps this could be addressed by adapting the format of consultation with patients to ensure that both the side-effects that were documented in the system and others not yet documented (for whatever reason) were acknowledged.

Concerns with using the system

Logging of information in the system would still depend on the patient, as would acting on advice. For example, one participant was adamant they would even ignore the advice of the tool and stay at home if it was recommended that they go to the hospital. They admitted they avoided phoning the hospital for advice, although they had a very high temperature and were at risk of febrile neutropenia. Knowing the consequences (being contacted by the oncology/haematology team for review) may prevent them from using the tool. Because of this, they may only use a digital reporting tool as an information source rather than a tool to log their symptoms in a hospital record.

Most of the population in New Zealand has access to the internet. However, some participants expressed concern about widespread internet access, particularly in more remote areas of the country. Official New Zealand data shows that internet access in rural areas is still poorer than that in urban areas, but is improving. Other concerns raised were poor digital literacy and risk of inequity. New Zealand continues to have some problems with inequity and literacy, so measures would need to be put in place to ensure any system used would not worsen inequity and health outcomes for those most at risk, and that adequate support is provided.

Almost all participants wanted to have the current system in place as well as having a digital tool. This would be necessary for those who do not have reliable internet access, a device, or adequate knowledge of how to use the system. Also, the
participants highlighted that they sometimes prefer to talk to a person rather than use a questionnaire. So, any digital system adopted would be in addition to those already existing. This may make it harder to persuade those controlling the budgets to invest in a digital tool if savings cannot be made elsewhere in the system. Therefore, a feasibility study would be needed to discover if the tool would improve outcomes and save money for the health system.

6.4.5 Conclusion

This small study found that a digital tool to report side-effects, which logs these into patients’ hospital record and provides side-effect management advice online, would likely be well-received by oncology and haematology patients in New Zealand. Overall, it could benefit people undergoing chemotherapy by helping them understand their treatment and improve side-effect reporting and management. The tool could be used alongside current systems e.g. a nurse-staffed telephone helpline. Further work is needed to understand the views of Māori and ethnic minority groups and in those who are less frequent users of digital technology to ensure whether a digital tool is appropriate for all oncology and haematology patients in New Zealand society.

Furthermore, if an international system is introduced into New Zealand it would require adaptation to New Zealand cultural and health system requirements, and extensive user testing groups of people with different health, digital, and cultural needs.
6.5 Strengths and limitations

There are a number of possible strengths and limitations to the investigations in 6.3 and 6.4. The strengths were that we had eleven participants who contributed well to their focus group or individual interview and who provided a rich source of data for analysis. Saturation of ideas was reached within the number recruited; no new themes arose in the last three interviews. Participants in the focus group contributed equally to the discussions and no individual appeared to dominate the discussion. It is acknowledged that the latter factor can sometimes be a limitation among focus groups. This study met Lincoln and Guba’s criteria for trustworthiness. Analysis ‘credibility’ was attained by the iterative approach to transcribing data and repetitive re-reading of transcriptions by AY. Coding and interpretation ‘dependability’ and ‘confirmability’ was achieved through review of framework by JT and AS. ‘Transferability’ was attained through inclusion of rich data and inclusion of context to the analysis and commentary of the article. A limitation of the survey instrument used was statistical reliability tests (e.g. test-retest reliability) were not undertaken. This was because the questionnaire was designed to gather some data, but largely to ‘set the scene’ for individuals and to open conversation. Because of difficulty recruiting previous chemotherapy patients, we did not allocate time to perform test-retest reliability and other methods for statistical analysis on questions. This may limit the generalisability and reliability of findings from the survey instrument.

Focus groups were the initial chosen method for gathering qualitative data. The limitations of using focus groups is that some people may over talk others and have a disproportionate contribution. Focus groups also tend to have lower average speaking time per person. This means that people may not be able to delve into a topic as deep as they could in an interview. Moderator bias may be hard to prevent, but we tried to mitigate this by using the same topic guide as we did with the interviews.

Another potential problem is that on sensitive topics, some people may be unwilling to share. However, in our focus group we recruited people who no longer had cancer (in remission) and were well-used to using support groups and discussing the personal effects of their treatment with others. We found people openly shared...
problems with understanding information and other issues readily, as well as praise for the teams that looked after them.

Focus groups may also be more difficult to organise – the logistics of getting everyone in one place can cause problems. It took a while to organise ours initially but some of the people who could not make the focus group could do a one-on-one interview at a later date.

Interviews were utilised because we were advised this may be necessary to gather data from hard-to-reach groups. The implications of using different methods to gather qualitative data are that different types of responses may have been collected, with different possible bias involved. The interviews may not have raised as many different points, but may have yielded more in-depth information to be gathered.

Furthermore, there are different limitations to performing interviews compared to focus groups. There is a lack of a positive influence from others in a group that would facilitate deeper discussions. There may also be a risk of social desirability bias in interviews as people may be more inclined to tell the interviewer what they think the interviewer wants to hear.

Because the research was being conducted by health professionals, there was risk of bias from participants providing ‘socially desirable responses’. There was also a possibility of selection bias. The manner of recruitment for these investigations may have resulted in this, as those who had negative opinions about how they received information about their treatment may have been more willing to participate. However, there were a range of views articulated, and some participants liked the current system and most expressed their desire for it to remain in place regardless of possible digital solutions. This indicates that both positive and negative views were obtained.

Due to the COVID-19 pandemic and the recruitment difficulties outlined earlier, the final number of participants and focus groups was lower than originally planned. This may have limited the number of themes that could be explored. Furthermore, the findings would not be generalisable to all populations in New Zealand as participants were only able to be recruited from one DHB. It is unknown if patients opinions at
other DHBs would follow similar themes or be very different. As the study only took place in one country, New Zealand, the findings may not be generalisable to other countries.

There was a lack of ethnic diversity amongst participants in this study. This was partly due to the national lockdown from the COVID-19 pandemic limiting recruitment to the Dunedin area, and to online or telephone interviews. There were no participants who identified as Māori nor participants from other ethnicities and this means that opinions of non-Pākehā ethnic groups were not explored. Therefore, conclusions about their views on information provision cannot be drawn from this study.

It is disappointing that we were unable to obtain the views of a more diverse population. Māori, in particular, experience many health and social inequities.\textsuperscript{251, 252} Initially we had planned to incorporate Māori world views and have true Māori-centred focus and outcomes from this research. To do this we had tried to align our recruitment and data collection with Kaupapa Māori research methodologies.\textsuperscript{228} As non-Māori researchers, we sought guidance from Māori advisors from the University of Otago. They advised that we perform one-on-one face-to-face interviews with Māori participants as we may have difficulty in recruiting Māori participants for focus group meetings. This aligns with principle of āta\textsuperscript{227} and forming of respectful relationships and we agreed with this approach to recruitment.

The qualitative nature of the study would not be adversely affected by this differing data-gathering format so, we amended our study protocol with agreement from the University of Otago Human Ethics committee to allow recruitment of participants for interviews. Unfortunately, we were unable to recruit Māori for interviews in the few weeks prior to the COVID-19 pandemic lockdown and the Human Ethics Committee advised to only conduct telephone or online interviews after 8\textsuperscript{th} June 2020. We had previously been advised we needed to develop relationships with the Māori community to engage participation in the project and the research team felt this could not be done to an acceptable standard without having face-to-face meetings. Because of this a real opportunity was missed for valuable insight into Māori perceptions of
information given to them about chemotherapy and their thoughts on the use of
digital technology for this service.

Further research is therefore necessary to find answers from Māori and other ethnic
groups being treated with chemotherapy in New Zealand to confirm their medicine
information needs are met and that inequities are minimised.

Because of these limitations, the findings are only early markers of New Zealand
patients’ opinions about the information provided to them about their chemotherapy
medicines. However, it does provide some answers and feedback for maintenance of
and improvement on the systems currently in place, and strong support from patients
to investigate improved solutions for providing information and advice on
management of their chemotherapy.

Another limitation of this study is that participants were digitally literate and
frequently used digital technology in their personal lives so may be more positive
towards digital solutions. Therefore, more investigation is required to capture
opinions on the use of digital tools in those who are not as savvy with digital
technology.

Furthermore, this study was seeking opinions about a concept rather than an actual
tool, and this may limit ideas about what perceptions would be if a digital tool was
implemented in practice. However, this was a useful starting point to gauge
preliminary feelings about the digital tool concept and glean early ideas for
optimisation for New Zealand patient requirements.
6.6 Chapter conclusion

This chapter described what people thought about the chemotherapy medicine information they received, how they received it, and their perceptions on the use of a digital tool for reporting side-effects and giving feedback on the management and control of symptoms.

The amount of information given to people about their chemotherapy and the management of their side-effects is overwhelming and can be difficult to digest. Information must be tailored to patients’ needs in ways that makes it easier for them to find and understand what they are looking for. This is not possible when most information is provided in the format of hard-copy pamphlets, information sheets, and booklets. At the very least the information needs to be standardised and organised into a suitable list with short summaries available for overviews of information.

Unprompted, participants in this study voiced their preference for having the information given to them in a digital format, with some people hoping this would enable more personalised and specific information for them.

People liked the option of having a digital tool to report side-effects, provide them with side-effect management advice, and to give them information about their treatment. Having a tool in place could promote earlier reporting of side-effects. It could also dispel concerns over whether a side-effect warranted a phone call by allowing information finding through a reputable and standardised platform. Concerns raised over the use of a digital tool are surmountable and could be worked through with rigorous co-design in early stages of adoption. However, the service provided at the Southern DHB where patients can ring a designated nurse if they are experiencing a problem is highly valued by participants and there was a preference for this support to be retained.

More work needs to be done before implementation of the described digital tools to gather opinions and requirements of Māori and ethnic minority groups, and of those who have limited access and experience with digital technology.
Chapter 7: Discussion and conclusions

7.1 Overview of the thesis

In New Zealand between 2018–2019 there were over 46,000,000 funded medicines dispensed.\textsuperscript{253} The sheer quantity of these begs the question: ‘Is adequate information being given with each instance of prescribing and dispensing of a medicine?’ It is possible that barriers experienced at the coalface (lack of provision of information, or access to it\textsuperscript{2, 7, 9, 254}) are preventing some patients from receiving the essential information required to use their medicines safely and optimally.

Adequately informing patients about medicines improves satisfaction with their treatment and can support adherence to therapy.\textsuperscript{7} It also supports safer and more effective medicine-taking and allows improved patient involvement in treatment decisions.

The overall aim of this research was to investigate how patients are given information about their medicines in New Zealand and explore potential solutions to optimise quality and provision of medicines information for patients.

To achieve the aim, several areas for investigation were identified and the work was conducted in four stages (listed below; see also Figure 2). Their findings are outlined in 7.2.

The four stages of this thesis:

- A description of what information people want to know about their medicines and what good-design principles to follow
- a survey of current opinions and practice by New Zealand GPs, pharmacists, and patients about information provision for low-risk medicines
- a feasibility study for the implementation of tailored medicine information software
• interviews and focus group discussions to determine patients’ opinions on current provision of information about chemotherapy and ideas for improvement, and their perceptions of the possible use of Patient Reported Outcomes (PROs) for optimising information and medicine management.

7.2 Summary and discussion of findings in the thesis

7.2.1 Findings of chapter 2

The findings of each part of the literature review in chapter 2 are outlined below:

What patients want included in medicine information leaflets and how they should be designed for optimal use

This section described the findings from a literature review about the information that patients would like to know about their medicines. A list of required points that need to be included in medicine information leaflets was developed (Box 1). Patients appreciated this information being included in the leaflets and found that it improved their perception of the material.

Importantly, we found that patients wished for information to be tailored to their disease and condition, and wanted unnecessary information to be removed. Additionally, patients valued knowing how their medicines work and the benefits of taking the treatment. This specific information about medicine benefits can improve perceptions of medicine information leaflets and patients’ intention to adhere to treatment.

Other information patients wanted to know included: possible drug/food interactions, how to take the medicine, and what to do if a dose is missed. As described in the literature, patients want information about the potential harms of their medicines, yet healthcare providers can be hesitant in providing this.

Furthermore, how printed information is designed and presented is important. Our review found that optimising the design of leaflets improved patients’ ability to read, find, and understand the information that has been given to them.
How medicine information leaflets should be designed compared to regulatory agencies’ recommendations

This section described how medicine information leaflets should be designed, outlining 20 good-design principles identified in the previous literature search. We compared these principles to guidance from an earlier systematic review, and to the recommendations for written or printed leaflets that are available online from regulatory agencies in New Zealand, the UK, the EU, and the USA.

Some regulatory authorities had very specific guidance about content and presentation. Some guidance did not follow the 20 good-design principles and missed certain features. New Zealand had very little guidance for manufacturers which is a concern. Furthermore, because it is not mandatory to provide leaflets in New Zealand at this time, some medicines do not have New Zealand-based information available.

For the complete picture of medicine information for patients, it is important to investigate how medicine information is currently being delivered. Printed information about medicines has been common practice for a number of decades, but digital information provision is a newer practice. The following section gives an overview of innovative concepts of medicine information delivery.

Digital information about medicines, is there a need?

Providing information about medicines to patients in a digital format could unlock many other opportunities such as information expansion and audio-visual accompaniment. However, to ensure accurate, good quality information there would need to be regulation of how digital information is provided. It is essential patients are pointed in the direction of reputable evidence-based information. Other systems of disease-based information provision have shown promise in patient engagement and enhancing their knowledge. Therefore, digitally providing medicine information could improve patient perceptions of the information. Although many people can access and use basic computer programs effectively, the information should be printable for those who cannot access web-based information or do not have the technical know-how.
Providing information digitally could allow patients to tailor information to their own needs. This is important as individuals’ requirements for information vary significantly. Those who desire more comprehensive information about the medicine would be able to find what they need, and at a time that is convenient for them.

**Patient reported outcomes**

Patient reported outcomes (PROs) enable patients to provide direct accounts of their health or treatment to health professionals and allows response to concerns that are of greatest importance to them. PROs could therefore be used to provide patients with information that helps them use their medicines safely. The type, amount, and timing of information collected is hugely variable, and PROs can be designed for a multitude of different purposes.

There are many benefits in using PROs including increasing the information available to health professionals for use during consultation, enabling shared-decision making, encouraging patients’ self-management of health, and improving documentation and observation of improvement or deterioration over time. Disadvantages of using PROs include increased burden on health professionals’ time and costs involved.

PROs are not regularly used in general practice because their effectiveness has not been well demonstrated in reviews.\(^{73, 122}\) However, their effectiveness has been established when they are used for the reporting of specialised issues such as toxicity with chemotherapy\(^{124, 135, 136, 255}\) or progress for psychotherapy patients who are predicted to be poor-responders to treatment.\(^{137}\)

**Main findings, chapter 2**

Both summary and comprehensive medicine information leaflets should be readily available. Leaflet content requirements were identified, and include names of the medicine, dose, benefits of treatment, and potential harms of therapy. The guidance provided by the New Zealand regulatory agency about how to design written consumer medicine information does not align with patients’ stated needs. Innovative solutions for providing optimal information about medicines and the management of
medicines include adopting digital solutions and facilitating standardised patient feedback with Patient Reported Outcomes.

7.2.2 Findings of chapter 3

What information is given verbally to patients about their medicines?

This section focused on how frequently GPs and community pharmacists provide verbal information about medicines. A cross-sectional survey\textsuperscript{132} examined their reports of (i) providing information in general, (ii) providing information on specific counselling points, and (iii) the importance of these counselling points for repeat medicines prescribed for chronic conditions. The specific counselling points were determined in the literature review as described in chapter 2.

(i) We found that only three quarters of GPs and fewer than half of pharmacists reported they provided patients with verbal information about new medicines \textit{all of the time}. Furthermore, very few of them gave verbalised information about repeated medicines \textit{all of the time}. This supports findings from other research that people may not be receiving enough information when they are prescribed new medicines.\textsuperscript{7-9, 63, 144, 145} Similar studies investigating counselling provision by pharmacist from self-reports claim 51–100\% pharmacists report to provide counselling to patients\textsuperscript{63} or that information is given all of the time.\textsuperscript{140} However, from self-reports in our study, only 43.7\% of pharmacists provide verbal counselling \textit{all of the time}. GPs reported they provide verbal counselling 75.3\% of the time, and this is supported in observational studies that some medication counselling is given most of the time.\textsuperscript{145, 148}(ii) For most of the specific counselling points (e.g. what the medicine is for, potential interactions), GPs were more likely than pharmacists to report that they discuss these with patients \textit{all of the time}. More than three quarters of respondents from either profession reported to discuss \textit{all or most of the time}: what the medicine is for, the dose and duration of treatment, how to administer the medicine, how to monitor treatment effectiveness and further monitoring requirements of the medicine, possible side-effects and what to do if they occurred, and how the medicine helps the condition. Furthermore, many points are not frequently discussed by either health professional
including: contra-indications and precautions, potential interactions, lifestyle information (e.g. drug effect on driving, drinking, sexual activity), and what to do if a dose is missed (see Table 5). This is similar to findings from an observational study in Sweden where pharmacists generally discussed ‘non-medical’ counselling points. However, in an Australian study examining pharmacists reported verbal discussions covered a variety of clinical topics, using the medicine information leaflet as a prompt. Our study shows there may be differences in practice between pharmacists in New Zealand and Australia. The GP responses from self-reports indicated that most clinical information was covered. However, observational studies show that little of this information may be covered during consultation, notably that side-effect information is often not provided or trivialised.

(iii) For most of the specific counselling points for repeat medicines GPs were more likely to report they were very important than pharmacists. It has been demonstrated that verbal counselling is not as likely to be undertaken for repeat medicines as it is with new medicines. The findings from this study shows that though counselling is less likely, many GPs still think it important that people are informed about most aspects of their medicine when they are receiving repeat medicines for chronic conditions.

Main findings, chapter 3

The findings of this chapter supported the first hypothesis Patient medication counselling performed by both general practitioners and pharmacists is of variable standard.

Some GPs and pharmacists will not be adequately discussing their medicines with their patients. Furthermore, when medicines are discussed, patients may not be receiving all the information they want or need to know.
7.2.3 Findings of chapter 4
Provision of medicine information leaflets and how they are perceived by health professionals

This section described reported provision of medicine information leaflets to patients by GPs and community pharmacists. A cross-sectional survey examined their (i) self-reported provision of medicine information leaflets, (ii) views on available leaflets, and (iii) support for tailoring information leaflets for patients.

(i) Very few pharmacists and GPs reported they provided leaflets to patients all of the time; slightly more from both groups reported that they gave leaflets more than half of the time. Pharmacists were more likely to report providing them, although only 27.8% would give them more than half the time and 12.7% would give them all of the time. Both groups were much less likely to give leaflets for repeat medicines for chronic conditions. This differs to findings in a 2014 Australian study where pharmacists reported providing CMI when dispensing a new medicine most (n = 150, 43%) or all (n = 168, 48%) of the time. In this same study, GPs reported they provide CMI most (n = 56, 31%) or all (n = 18, 10%) of the time with new medicines—this is more in line with findings from our study (where 2.1% reported the y provided leaflets all the time and 11.2% reported providing them most of the time), though the findings in Australia are more positive. The situation on provision of leaflets is similar in New Zealand and Australia, where CMI is available on an accessible website. However, findings in Australia exhibit better leaflet provision. This may be because there have been large campaigns to promote the practice of providing leaflets at point-of-care in Australia. A 2001 New Zealand survey similarly demonstrated that patients may not be using leaflets as information resources. In international studies patients report receiving leaflets without discussion from their GP or pharmacist. However, in our study we found that when leaflets are provided, GPs and pharmacists tend to discuss leaflets with patients before giving them to take away, which is an improved method of providing leaflets to patients.

(ii) Qualitative analysis identified five themes that GPs and pharmacists liked and/or disliked about leaflets: design, content, accessibility, perceived quality, and usefulness
and usability. Leaflet design was considered both problematic and valued. The content of leaflets was disliked because of a perceived risk that some content could cause anxiety for patients and discourage them from taking their medication. Again, GPs and pharmacists appreciated well-designed leaflet content that informs patients about the benefits of their treatment, how to take it, the potential risk of experiencing side-effects, and what to do if they occurred. Similar themes have been identified in other studies when investigating the likes and dislikes of leaflets.\(^4, 40, 48, 65, 66, 173\) However, our study also identified that leaflets must be easily accessible at point-of-care and a digital format may be well received by health professionals. Leaflets also need to be of good quality, and be useful as an aid for educating patients.

(iii) A summary leaflet is most preferred by GPs and pharmacists and there is some support for the tailoring of leaflet information to patient requirements.

Using websites for medicine information and improving provision of leaflets This section discusses whether GPs and community pharmacists recommend websites to their patients as a source of information about their medicines. It also describes ways GPs and community pharmacists think their provision of medicine information leaflets could be improved. A cross-sectional survey\(^{184}\) examined their (i) self-reported use of websites for providing medicines information to their patients and (ii) their thoughts on what deters or encourages medicine leaflet provision.

(i) Neither GPs nor pharmacists often recommend websites to their patients for medicines information. The Medsafe website, where the manufacturers’ CMI are located, is still the most commonly used website by survey participants, although GPs were just as likely to recommend the New Zealand Medicines Formulary which provides a summary one-page leaflet. Similar to an Australian study investigating provision of leaflets,\(^{173}\) CMI were most likely to be given from the central repository (in our study, from the Medsafe website). However, it is encouraging that the summary leaflets available (from the New Zealand Medicines Formulary website) are used by almost as many GPs and pharmacists as the manufacturer CMI. This indicates, that where summary leaflets are available, they are being used in practice.
(ii) GPs most commonly did not give leaflets to patients because they lacked the time to discuss the leaflet, or they thought the patient might have difficulty reading and understanding it. Time constraints appear to be a greater restriction in New Zealand compared to Australia, where GPs and pharmacists are less likely to identify this as a barrier. Pharmacists most commonly did not give leaflets because the patient has taken the medicine previously, or the medicine was being used for an unlisted indication. Both groups commonly did not give leaflets because of concerns that the patient will worry about side-effects and refuse their medicine, and they believed that patients do not want leaflets. However, internationally it has been shown that patients appreciate the leaflets they receive and although a common concern, knowledge of side-effects does not make people stop taking their medicines without consulting a health professional. Almost a quarter of GPs thought it was the pharmacist’s role to provide medicine information leaflets and so did not provide them. This differs from findings of an Australian study where over half of GPs reported they do not give leaflets because they think the pharmacist will give them. However, as mentioned previously, GPs in New Zealand are much less likely to provide leaflets to patients than pharmacists and improving provision of leaflets by both groups should be encouraged.

Most commonly, GPs and pharmacists thought leaflet provision might be encouraged by having: (i) a summary leaflet available for discussions; (ii) automatic prompts from the prescribing system; (iii) personalised leaflets for patients, and (iv) specific counselling appointments to discuss medicines with patients. Pharmacists also favoured reimbursement for provision of leaflets, increased requests for leaflets from patients, and having leaflets available in different languages.

Patients’ opinions on medicines information leaflet provision and usefulness

This section investigated patients’ experiences and thoughts about receiving medicines information leaflets. A cross-sectional survey examined (i) patient reports of Dunedin GPs’ provision of medicine information leaflets and (ii) patient views on the leaflets provided.
Most participants had not received leaflets from their GPs in the last six months. This finding differed significantly from an Australian study investigating consumers reception of leaflets for prescription medicines where 69% reported receiving a leaflet in the last six months. Almost half of consumers in the Australian study reported receiving leaflets every time they received a new medicine. The majority of patients in our study thought it was important to receive a leaflet for new medicines, but not for repeat medicines, which was in line with our earlier studies investigating perceptions of GPs and pharmacists. Most patients would like to receive a leaflet from their GP when prescribed a new medicine and over half also wanted one when new information is available, when the medicine has serious side-effects, or when there is a change in brand. In general a paper-based summary leaflet was the preferred option.

When they had been given a leaflet by a GP, most patients thought it improved their knowledge and helped them take their medicines. This may be because patients struggle to remember verbal information once they have left consultations. Almost all participants liked the leaflet they received, even though previous investigations of CMI show they may be poorly designed. Overall they thought the information in the leaflet was readable and easy to find and understand. Almost all participants read all or some of the leaflet, which differed to findings in an Australian study where only two thirds of participants reported reading the CMI. This may be because patients are less likely to be provided leaflets in New Zealand, and because they are appreciated, they are used. Other studies show that CMI readership may be dependent on participant demographics e.g. age and education level. However, the participants in our study had lower completed qualification levels than the general population and were from a variety of age groups, indicating that people from differing literacy levels and age groups still appreciate receiving printed information. Nearly half of the participants kept the leaflet for future use.
Main findings, chapter 4
The findings of this chapter supported the second hypothesis Written medicines information resources for patients are of differing quality, are under-utilised, and are sometimes given without adequate verbal counselling.

GPs and pharmacists do not routinely provide written medicines information leaflets or recommend web-based information sources. To support leaflet provision, they need to be well designed, easy to read and understand, and concise because of the limited time to discuss leaflets in practice.

Facilitators to encourage provision of written medicine information included having summary and tailored leaflets available, more time with patients, and automatic computer prompts. GPs, pharmacists, and patients believe it is important that leaflets are given with new medicines.

Patients’ value having written medicines information leaflets provided to them with new medicines.

7.2.4 Findings of chapter 5
A Use Case for providing personalised medicines information in primary care
This section described the first of two proposed digital solutions to help medicine information provision: the creation of an automated personalised-information builder working within current dispensing and prescribing systems in primary care. This would provide (i) counselling points for the GP or pharmacist to use at point-of-care, and (ii) personalised information for the patient to take away with them.

A Use Case with summary Use Case diagram and a mock-up example of a personalised information leaflet were created to describe the project and goals of the system to potential programmers, (see Figures 13 and 14, and Appendices 14 and 15).
Feasibility study for providing personalised medicines information in primary care

To determine the feasibility of the project we asked vendors of prescribing and dispensing systems in New Zealand to complete a questionnaire about the perceived market for the digital tool, technical requirements involved, financial outlay required, scheduling feasibility, and potential barriers. Further feedback on the project by telephone and email was also gathered.

Overall, the survey found that the project described in the Use Case is not considered a feasible one to pursue and an alternative method of providing patients with personalised information should be sought. Barriers to the project identified include cost, time, inability to update clinical content, and risk of being unable to complete other projects. Vendors did not think the project worthwhile, although they thought that users may find it beneficial if such a tool was built.

Main findings, chapter 5

The findings of this chapter did not support the third hypothesis It is possible to digitally automate the creation and provision of personalised information about medicines at point-of-care.

At this time, it is not feasible to build an automatic leaflet-tailoring and prompting system within prescribing and dispensing management software used in New Zealand.

7.2.5 Findings of chapter 6

Chapter 6 investigated the current practice of providing information to patients taking high-risk medicines (chemotherapy) and also described the second of the two proposed digital solutions to help medicine information provision: the use of PROs to provide specialised and specific information about how to manage chemotherapy-induced side-effects on a digital platform. The platform could also provide patients with medicines information appropriate for their specific illness any time it is needed.
Patient experiences with medicine information about their chemotherapy

This section described the views of people who have had chemotherapy about the medicine information they were provided with. This study covered (i) how they were given the information about their chemotherapy, (ii) whether they understood this information and could act on it, and (iii) whether they thought this information could be improved. This information was collected using a questionnaire and then a focus group discussion or interview.

From the questionnaire responses we found that participants agreed the information they received was easy to understand and the way it was provided facilitated their understanding. However, the quantity was sometimes inappropriate (too great). This is similar to findings in other studies that demonstrate that some people want to receive plenty of information,\textsuperscript{238} whilst others show patients prefer to receive little information.\textsuperscript{236} This is where tailoring of information to patient requirements or signposting the most relevant information is important. Furthermore, some participants found the information they took home was too complex, or they were too ill to understand it or to find the content they were looking for. The use of digital resources may improve comprehension,\textsuperscript{240} by explaining complex terminology and providing further descriptions of concepts if necessary. Furthermore, previous research of information provision with chemotherapy medicines has demonstrated that adequate provision of information can improve adherence, quality of life, and satisfaction with treatment.\textsuperscript{236, 238, 239} So investigating ways to improve information for chemotherapy patients is necessary. Importantly, participants in our study reported having a good understanding of what they were required to do if they experienced a side-effect.

Four main themes emerged from the thematic analysis: (i) gathering and use of information provided with treatment; (ii) problems identified; (iii) other opportunities to aid understanding; and (iv) improving information provision.

(i) Most participants received verbal and written medicine information when they started their treatment. As has been mentioned previously with low-risk medicines,
verbal information provided to cancer patients might be forgotten following a consultation,\textsuperscript{214, 236} so it is a positive finding that both forms of communication are commonly used. The written information was often used as a reference source for future use, which is common practice with chemotherapy medicine information.\textsuperscript{234, 236} Not all participants were told which websites to visit for more information; however, studies have shown that chemotherapy patients like to receive web-based information\textsuperscript{236, 240} and this practice should be more widely adopted in New Zealand. Six participants avoided reading the information given to them. However, as described in other studies,\textsuperscript{237, 241} information was often gathered and used by their support people or family members.

(ii) Some participants actively avoided phoning for help because they did not want to have to go to the hospital and would rather try to manage their symptoms themselves at home. One participant could not find the information they needed to know. Some considered the quantity of reading material provided was overwhelming and frightening. Yet, some believed information was missing e.g. some basic information (e.g. what are ‘chemotherapy rounds’?) and details about rare side-effects. Lack of information has been described in other studies and can result in inferior patient experiences.\textsuperscript{235, 236} Other identified barriers to understanding included: communication breakdown with specialists; lack of consistency of information between DHBs; and lack of mental capacity due to emotional turmoil or medication-induced cognitive impairment.

(iii) Many participants identified that former chemotherapy patients and support groups were useful sources of information. The preference to use former chemotherapy patients has been described previously\textsuperscript{236, 241} and using them as a sympathetic information source for current patients is common, but not widespread, practice. There is progress in New Zealand with the development of web applications to connect oncology and haematology patients together, but these are not yet in widespread use.

(iv) Solutions to improving information provision included better structuring of information to improve findability, as has been suggested in other studies\textsuperscript{109} and
utilising websites and smart applications to organise and provide information. Three participants would also value personalised information.

**Patient views on the use of Patient Reported Outcomes (PROs) for providing personalised information in a digital tool for chemotherapy medicines**

This section described the views of people from the previous survey about using a proposed online tool for capturing Patient Reported Outcomes (PROs) and receiving information about their treatment and side-effect management. Any perceived advantages/disadvantages of using this tool were also discussed. Information about general use of digital technology was gathered by a questionnaire, and then a focus group discussion or interview was used to gather opinions on the proposed PROs tool.

From responses we found that participants frequently accessed the internet, and nine of the 11 participants had looked for health information on the internet in the past year. This indicates that participants in our study are adept at using the internet as an information resource and would be well-suited to digital health solutions.

From the thematic analysis of the focus groups/interviews, four main themes emerged: (i) preference for the proposed digital tool over current system; (ii) inputting information and how it is used; (iii) concerns about using the tool; and (iv) preference to use both the current system and a digital tool.

(i) Some participants thought the digital tool could overcome barriers to using the current system such as anxiety in phoning the hospital, reluctance to ‘cause a fuss’, and being physically unable to talk on the phone. Participants would appreciate the perceived ease of use, ability to find more information and share with family/support people, and being able to determine if a side-effect was serious enough to warrant contacting the hospital. These uses described by participants in our study are similar to those currently being described in practice in the international trials.¹²⁸,²⁴⁵

(ii) Most participants felt it important that a digital tool would automatically log side-effects in their hospital record, as shown in studies of users of the systems,¹²⁸,²⁴⁵ but
participants in our study also wanted the ability to seek information without this being automatically reported.

(iii) Participants wanted assurance that logged information was reviewed by their specialist team and that any lack of access to internet or digital devices would not lead to inequities. Reassurance after using web-based reporting systems was demonstrated in studies internationally,\textsuperscript{124, 128, 245} However, these studies were undertaken with participants already using the system and equity and access was not discussed. One study in Australia investigating perceptions of people who had used the system identified issues that did not arise from our discussions, such as trouble inputting data and lack of confidence in using the full functionality of the system.\textsuperscript{124} This may be because our group all used the internet for various functions and may be more tech-savvy than participants in this trial. Assessment of access to the appropriate digital requirements (whether hardware or internet) for all potential users of new technology is essential before investigation into new digital services for cancer patients.

(iv) Although there was support for using a digital tool, almost all participants wanted the current system to be retained. Some people wanted both because they prefer to read paper documents. Some thought it easier to discuss more complex problems with a healthcare professional than trying to use the described PRO digital tool.

**Main findings, chapter 6**

The findings of this chapter supported the fourth hypothesis *The provision of information about high-risk medicines is of variable standard and the use of digital technology to provide patients with personalised and relevant medicine information might be well-received.*

Oncology/haematology patients consider the way they are given information about their treatment does not suit everybody and could be improved. Many thought having a digital system available to report side-effects and receive information would be beneficial and help support their side-effect management. Using digital technology to find information about treatment would also be appreciated.
7.3 Strengths and limitations

7.3.1 Strengths

There are a number of strengths in this thesis.

The investigations undertaken had a multidisciplinary approach and guidance and advice was received from many health professionals involved in patient care including GPs, hospital pharmacists, oncology/haematology nurses, and oncologists, as well as IT consultants and software developers, business advisors, and research study-leads in oncology projects involving digital tools in the UK. This required much planning, communication, and coordination. It was a worthwhile approach as the multidisciplinary collaboration resulted in more comprehensive and effective approaches to the investigations. We used different types of research (quantitative to answer ‘how’ and qualitative to answer ‘why’) with different stakeholders to seek information from different angles. This was to get the full picture of what is happening in practice. Using these approaches, with different methodologies and key stakeholders, we could determine their needs and opinions on medicine information available and how it is provided. By surveying providers of information, those who receive the information, those who can support provision of information (i.e. the vendors) and users of information in a specific area we could triangulate the outcomes to inform the optimal ways of providing medicine information.

The qualitative data collected from the open ended questions in the surveys with GPs and pharmacists provided detailed material on how information on medicines is provided to patients in current practice, reasons for providing/not providing this, and valuable insight into how this process could be improved in the future.

A range of views, both positive and negative, were expressed by participants. The survey and correspondence with IT vendors in particular provided context to their reasoning, and detailed explanations of why they believed the proposed system (tool for automated tailoring of medicine information for patients) would not work in the current software market. Furthermore, the responses mentioned barriers that had not
previously been considered by the research team. This was useful to prevent further research being pursued in this area when the industry would be unlikely to support it.

Further strengths were that the eleven participants of the focus group/interviews in chapter 6 were good contributors to their group/interviews and provided rich data. A range of views were expressed, saturation of ideas was achieved, and no individual dominated the focus group session.

Another particular strength of this thesis is that a number of peer-reviewed articles relating to the investigations were published where the candidate was the first and corresponding author. The process of writing, submission, peer review, and revisions led to clarifications and improvements in the manuscripts, and to more robust content for inclusion in the thesis.

7.3.2 Limitations and how they were mitigated

There were some difficulties with recruitment in each of the investigations undertaken, but steps were taken to mitigate them.

Health professionals are known to be difficult to recruit\textsuperscript{153, 257} and the first investigation (questionnaires sent to health professionals) had fewer responses than hoped for. An electronic survey was administered, being easier for participants to access and use. However, given the likely lower response rates to electronic surveys \textsuperscript{257-259}, paper copies were posted to pharmacies who did not initially respond. To further encourage participation, email reminders were sent to GPs and pharmacists, and a monetary incentive was offered (a ‘prize draw’).\textsuperscript{260, 261} Lower participation than hoped for and possible biases (selection bias, recall bias, and possible socially acceptable responses), may limit the generalisability of results. However, because the results were not overwhelmingly positive, it is reasonable to assume there is a need for improvement in medicine information provision to patients.

Furthermore, international generalisability may be somewhat limited because policies on leaflet provision differ (mandatory in some countries, but not New Zealand). However, because we investigated opinions and the use of leaflets in practice, some inferences can be made to international experience. Additionally, GPs and pharmacists
were not asked to describe their likes or dislikes of a particular type of leaflet, so their opinions of specific leaflets cannot be ascertained. We were asking their opinions of leaflets in general, although their opinions could change depending on what leaflet they were thinking of at the time. However, the majority of respondents would prefer to not use CMI so it can be assumed that most of the comments about what they do not like about leaflets pertained to the lengthy manufacturer-produced CMI.

In addition, recruitment of the general public (survey about leaflet provision by GPs) may have been impeded by it taking place in a University city (Dunedin), where there is the possibility of research fatigue amongst its population.\textsuperscript{260}

The survey of vendors of software for prescribing and dispensing systems had a small number of participants because there are only a few vendors (n=6) in the market in New Zealand (see chapter 5). Therefore, the results of chapter 5 may be of limited validity and generalisability. Nevertheless, it was felt that the data provided was extremely useful in demonstrating the feasibility of the project.

Recruiting for qualitative research can be especially time-consuming and challenging\textsuperscript{262}, and this was found for our qualitative study (interviews and a focus group of people who had experienced chemotherapy). Furthermore, our study was investigating a sensitive topic, involving experiences at a stressful time of peoples’ lives which could have also resulted in lower participation numbers.\textsuperscript{262} Conversely, participation may be encouraged when people believe their experiences are important to themselves and to society.\textsuperscript{262} To encourage recruitment of members of the public we built up relationships with support groups and clinical staff,\textsuperscript{260} used mediators and personal contacts,\textsuperscript{262} and provided a small monetary incentive for participants.\textsuperscript{260} Recruitment activity took place as the COVID-19 epidemic emerged in Asia and Europe. As described earlier (chapter 6), recruitment of subjects for this investigation was halted soon after by restrictions imposed by the New Zealand government and the University of Otago. These prevented travel and face-to-face meetings when COVID-19 infections emerged in New Zealand. Unfortunately, as a result we were unable to recruit Māori, Pasifika, or rurally-based participants.
Further bias may be present from participants who had a troubled relationship with their specialist team or a particularly negative experience during their treatment. This may make people more inclined to participate and/or be more vocal during focus group sessions. We found that there were some negative experiences shared with the group, but overall a range of views were expressed. Furthermore, as we were attempting to identify areas for improvement and investigate ways of improving information provision, a slightly negatively biased group would have provided useful data.

All of the participants in the qualitative study investigating a possible digital solution to information provision and medicine management had experience with using the internet and many regularly searched for health information online. This may limit the findings of this study to those who are digitally literate and who have regular access to computers. Further study is required to seek opinions from those who are not frequent users of the internet or have restricted, or no, internet access before recommendations can be made for the New Zealand population. This, along with research with other poorly represented population groups (Māori, Pasifika, and people in rural areas) would also need to be addressed before any new system is introduced or further work is undertaken. Yet, the findings indicate that some improvements can be made and there is a section of the population that would appreciate digital solutions.

A modified investigation

Chapter 6 of this thesis investigated the opinions of former chemotherapy patients about how they received information about their treatment and their views on a possible digital tool to help manage their side-effects. This was a modification of an investigation that we had hoped to conduct.

Our original intention was to develop the digital tool described in chapter 6 and undertake a feasibility study of the use of this tool in New Zealand, subject to successful grant applications. The history behind the postponing/abandoning of these plans is as follows:
Video conferences were held with two research leads on similar projects in the UK, Professor Galina Velikova at the University of Leeds, and Professor Roma Maguire, from the University of Strathclyde. Both Professors gave valuable advice and were supportive of our project.

Six grant applications totalling (NZ$842,376) were submitted to funders between 2018 and 2019 (see Appendix 22). Unfortunately, none were successful.

At this point it seemed appropriate to undertake the first phase in a feasibility study instead, which was to gauge the opinions of New Zealanders who had experienced chemotherapy previously. Therefore, the investigations that were described in chapter 6 were conducted.

The outcomes found from the focus group and interviews in chapter 6 provide some evidence of the need for/possible value of a digital tool in New Zealand and further work in this area is warranted.

### 7.4 Recommendations for practice

In this section I will describe recommendations for current practice based on the outcomes from all areas of investigation.

The provision of medicine information leaflets either printed or sent digitally should be made mandatory in New Zealand by the government. Furthermore, advice being provided to those creating medicine information for patients should be adapted to incorporate the 20 good-design and content principles for readability.

Whilst information leaflets cannot be automatically tailored, the information discussed and the way written information is provided (via printed leaflet or digitally) can be carefully chosen to meet a patient’s requirements. There are different patient information leaflets available for many medicines, ranging from short one-page summaries to longer manufacturer-produced consumer medicine information leaflets. Health professionals could direct patients to the type they think most appropriate for them. Some patients want more information for complex conditions in a digital format
and the amount of information they desire could be discussed with their GP or pharmacist.

If printed information is being provided, it should be actively discussed with patients and important points highlighted to ensure understanding. People who are taking medicines for chronic conditions tend to not be provided with repeated and/or updated information about their treatment, particularly where provision of leaflets with treatment is not mandatory. Ideally, GPs and pharmacists should briefly check with patients each time they are having a follow up appointment or collecting a repeat prescription about whether they want more information or a leaflet and if they have any questions or concerns with their treatment.

To help with the provision of leaflets, IT systems should be set up to remind GPs and pharmacists to provide them, e.g. pop-up alerts within the software. Additionally, more should be done to encourage patients to ask for information and the availability of leaflets should be actively promoted. This could be achieved by having links for health and medicine information on the general practice or pharmacy websites or within patient portals, and by displaying lists of sources of information in waiting areas. Patients should expect to be provided with written information to take away. Furthermore, efforts should be made to ensure patients are comfortable with the resources being used and that they are supported to ask questions if they wish. Moreover, GPs and pharmacists should familiarise themselves with the different types of leaflets available and how to access information efficiently to use at point-of-care.

Importantly in this digital era, software should enable easy and standardised coding for indications and patient characteristics to enable future technologies to automate tailoring of resources e.g. using SNOMED coding. Furthermore, giving pharmacists access to the indications that medicines are being prescribed for will help them provide specific and useful counselling for patients. Not all pharmacists currently have access to this level of information. Vendors of patient management systems need to engage with the sector to improve the ability to print or digitally send medicine information to patients within their current systems. This should be undertaken in a manner that suits their users.
Patients undergoing chemotherapy can sometimes be overwhelmed with the large amount of information provided to them. Printed information should be provided in a format that makes it easy to follow, and find, the information that is needed. Some suggested changes were that summary leaflets also be given, content of leaflets optimally arranged (with most important information is separated from the rest), and that all information also be available in digital formats. Many patients valued talking to others who had already been through the same treatment, and this information sharing should be actively encouraged as a useful way to receive information about side-effects of treatment.

7.5 Recommendations for further research

First and foremost the voices of Māori, Pasifika, and other ethnic minority groups, and those of rurally-located people were not heard in the investigations undertaken in this thesis. This needs to be remedied and further research is required to understand their medicine information needs and how they manage their side-effects. Often these groups are marginalised and experience inequity in the health system so it is essential that their views and experiences are gathered and accounted for.

Further investigation is also needed for people with differing levels of health literacy, and in those in whom English is not their first language, and the difficulties they face in understanding medicine information in New Zealand. This should lead to the production and assessment of leaflets in different languages in New Zealand.

Investigation into other avenues to automatically tailor information leaflets for patient requirements could be undertaken, e.g. in systems that sit outside of patient management software. At the least, pop-up alerts within patient management systems reminding prescribers and pharmacy staff to print/send medicine information leaflets could be assessed for suitability and use in practice.

Although the research team were unsuccessful in accessing funding to create and assess a digital tool for providing chemotherapy medicine and side-effect management information, the feasibility of such a system in New Zealand should still
be investigated. The evidence of patients’ needs/acceptability (already described in chapter 6), when published, could be used in further funding applications. Moreover, using PROs for managing the side-effects of other treatments and for general use in primary care, requires further consideration.

7.6 Conclusion

Health professionals endeavour to provide the best healthcare they can for their patients. Unfortunately, providing information about medicines may not be considered an essential aspect of the services they provide. Healthcare professionals face worsening pressures in primary care with increasingly complex patients living to older ages and with limited time to talk with them about their illness, their lifestyle, and their medicines; it is understandable that some things may be overlooked. Adding another layer to the complexity of providing information about medicines, the type and quantity of information that patients want varies depending on numerous factors including their age, how long they have had the illness, their health literacy, and the severity of the illness they are experiencing. Getting the right amount of information about medicines to every patient is difficult.

This thesis investigated: what information patients want to know about their medicines; how written information should be designed; what information is being provided in New Zealand practice; the feasibility of adapting New Zealand Patient Management Systems to automatically tailor medicine information to patient characteristics; experiences of patients’ who received chemotherapy information, and their views on using a digital tool to provide them with personalised medicine information and side-effect management advice. The individual investigations undertaken were investigating ways to improve medicine information provision from current practice perspectives, i.e. in community pharmacy, in general practice, and in specialist hospital environments. In all instances there were gaps in provision and room for improvement.

Fundamentally the information being given to a person must be understandable to them. At this time, it is not mandatory to provide written information in New Zealand,
but whether mandatory or not, it is best practice to provide verbal and written information. Ideally patients should receive information tailored to them in a way that suits them. However, this takes time and effort from the provider, and time is a precious and an ever decreasing commodity. Nevertheless, people may not be receiving sufficient verbal information about their medicines, and providing complex and incomprehensible information leaflets can negatively affect adherence and patient satisfaction. Efforts should be made to optimise written medicine information for patients; this could improve both healthcare professionals’ willingness to provide them and patient understanding.

Healthcare professionals should promote the use of appropriate online resources for medicine information with their patients. People are already using the internet to gain information about their illnesses and medicines and would benefit from healthcare providers pointing them to reputable websites. Furthermore, with the global rise of telehealth due to the COVID-19 epidemic and lessening of face-to-face consultations with healthcare professionals, digital resources may soon become a necessary requirement for informing patients adequately about their medicines.

Medicines that can have serious side-effects (e.g. chemotherapy) may be accompanied by a multitude of alarming, confusing, and anxiety-producing information. There are systems in place to provide people with copious information about chemotherapy treatment, but there is still a need to adapt this for individual requirements. Digital tools being used internationally might help New Zealand patients better understand and manage their medicines. These would be well-received as an adjunct to current systems.

Further research is necessary to investigate ways to automate the provision of optimal medicine information for patients, and the use of PROs for medicine-management in wider practice. Both concepts have the potential to improve medicine information provision and patient outcomes. However, research into medicine information needs of Māori, Pasifika, and other ethnic minority groups, as well as people living in rural locations, those with lower digital literacy, and those with a poor grasp of English should also be explored. Changes made will only be a success if they ensure the
medicine information requirements for all groups residing in Aotearoa New Zealand are understood.
References


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188. Dickinson D, Raynor DT. Ask the patients—they may want to know more than you think. BMJ. 2003;327(7419):861-861.


206. Medical Oncology Service. Treatment Booklet: Canterbury Regional Cancer and Haematology Service Christchurch, New Zealand: Canterbury District Health Board (CDHB); 2019.


Appendix 1. Examples of information leaflets in New Zealand

Manufacturer produced CMI available from Medsafe website

Apo-Propranolol
Propranolol hydrochloride
10mg and 40mg Tablets

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Propranolol.

This leaflet answers some common questions about Apo-Propranolol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Apo-Propranolol against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Propranolol is used for

The name of your medicine is Apo-Propranolol tablet. It contains the active ingredient Propranolol hydrochloride.

Apo-Propranolol is used to treat a number of conditions, most of which are related to the heart:
- Management of angina pectoris.
- Long term prophylaxis after recovery from acute myocardial infarction.
- Control of most forms of cardiac dysrhythmias.
- Control of essential and renal hypotension.
- Prophylaxis of migraine.
- Control of anxiety and anxiety tachycardia.
- Management of essential tremor.
- Adjunctive management of thyrotoxicosis and thyrotoxic crisis.
- Management of hypertrophic obstructive cardiomyopathy.
- Management of phaeochromocytoma (with an alpha-adrenoreceptor blocking medicine).

Your doctor may have prescribed Apo-Propranolol for another reason.
Ask your doctor if you have any questions about why Apo-Propranolol has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Apo-Propranolol dose should not be individually determined when administered to children.

---

**Before you use Apo-Propranolol**

**When you must not use it**

Do not use Apo-Propranolol if:

- You are hypersensitive to, or have had an allergic reaction to propranolol hydrochloride or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest, swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- Propranolol must not be used if there is a history of bronchospasm or bronchial asthma.

- Propranolol as with other beta-adrenoreceptor blocking medicines must not be used in patients with and of the following:
  - known hypersensitivity to the substance
  - second or third degree heart block
  - cardiogenic shock
  - uncontrolled heart failure
  - hypotension
  - severe peripheral arterial circulatory disturbances
  - untreated phaeochromocytoma
  - Prinzmetal's angina
  - bradycardia
  - sick sinus syndrome
  - metabolic acidosis
  - after prolonged fasting

- The expiry date (EXP) printed on the pack has passed.
If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

- The packaging is torn, shows signs of tampering or it does not look quite right.

If you are not sure whether you should start using Apo-Propranolol, talk to your doctor.

**Before you start to use it**

Tell your doctor if:

1. **You have allergies to:**
   - any other medicines
   - any other substances, such as foods, preservatives or dyes.

2. **You have or have had any medical conditions, especially the following:**
   - A history of cardiac failure
   - problems with your circulation
   - heart problems
   - low blood pressure
   - diabetes or low blood sugar
   - an overactive thyroid gland or thyrotoxicosis
   - slow heart rate
   - asthma or serious breathing problems
   - liver problems including cirrhosis
   - kidney problems

3. **You are currently pregnant or you plan to become pregnant.**
   Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. **You are currently breastfeeding or you plan to breast-feed.**
   Do not take this medicine whilst breast-feeding.
   Propranolol can pass into breast milk and may affect your baby. Breast-feeding is therefore not recommended.

5. **You are planning to have surgery or an anaesthetic.**

6. **You are currently receiving or are planning to receive dental treatment.**

If you have not told your doctor about any of the above, tell them before you start using Apo-Propranolol.

**Taking other medicines**
Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Propranolol.

Some medicines may interfere with Apo-Propranolol. These include:

- calcium channel blockers - medicines used to treat high blood pressure
- sodium channel blockers – medicine used to treat tachycardia
- adrenaline
- digoxin - a medicine used to treat heart failure
- medicines for migraine
- medicines for diabetes
- warfarin - a medicine that stops blood clots
- theophylline - a medicine used to treat asthma
- rifampicin - a medicine used to treat tuberculosis
- ibuprofen, indomethacin - medicines used to treat pain and inflammation
- cimetidine - a medicine used to treat ulcers
- chlorpromazine - a medicine used to treat psychotic illnesses
- thioridazine – a medicine used to treat schizophrenia and psychosis
- lignocaine – a medicine used to numb tissue in a specific area
- anaestheis agents – medicines used to enable painless medical procedures to be performed

These medicines may be affected by Apo-Propranolol, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interact with propranolol.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Propranolol.

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**How to use Apo-Propranolol.**

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet. The label should be carefully read.

*How much to take*

**Hypertension:**
A starting dose of 80mg twice a day may be increased at weekly intervals according to response. The usual dose range is 160-320mg per day. With concurrent diuretic or other anti-hypertensive drugs a further reduction of blood pressure is obtained.

**Angina, Anxiety, Migraine and Essential Tremor:**
A starting dose of 40mg two or three times daily may be increased by the same amount at weekly intervals according to patient response. An adequate response in anxiety, migraine and essential tremor is usually seen in the range 80-160mg/day and in angina in the range 120-240mg/day.

**Dysrhythmias, Anxiety Tachycardia, Hypertrophic Obstructive Cardiomyopathy and Thyrotoxicosis:**
A dosage range of 10-40mg three to four times a day usually achieves the required response.

**Post Myocardial Infarction:**
Treatment should start 5-21 days after myocardial infarction, with an initial dose of 40mg four times a day for 2-3 days. In order to improve compliance the total daily dose can thereafter be given as 80mg twice a day.

**Phaeochromocytoma:**
To be used only with an alpha-adrenoreceptor blocking medicine.

**Pre-operative:**
60mg daily for 3 days is recommended.

**Non-operative malignant cases:**
30mg daily.

**Elderly:**
Evidence concerning the relationship between the blood levels and age is conflicting. With regard to the elderly, the optimum dose should be individually determined according to clinical response.

**Paediatric population**
The dose should always be individually determined. The following doses are intended only as a guide.

**Dysrhythmias, Phaeochromocytoma and Thyrotoxicosis:**
0.25-0.5mg/kg three or four times daily as required.

**Migraine:**
Under age of 12: 20mg two or three times daily.
Over age of 12: The adult dose.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

**How to take it**
Swallow the tablet(s) with a glass of water.
When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Your doctor will advise you when you can stop taking Apo-Propranolol completely.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

While you are using Apo-Propranolol

Things you must do

Immediately stop taking Apo-Propranolol and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Propranolol.

Take your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Apo-Propranolol.

Always discuss with your doctor any problems or difficulties during or after taking Apo-Propranolol.
Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Propranolol to last weekends and holidays.

**Things you must not do**

Do not give Apo-Propranolol to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other condition unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Do not take any other medicine while you are taking Apo-Propranolol without first telling your doctor.

Do not take Apo-Propranolol for a longer time than your doctor has prescribed.

**Things to be careful of**

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Apo-Propranolol affects you.

Dizziness or fatigue may occasionally occur during treatment with propranolol, patients driving vehicles or operating machinery should exercise caution until they have determined their reaction to the drug.

Caution must be exercised when using anaesthetic agents with propranolol. It may be decided to discontinue therapy with this medicine before surgery, in which case a gradual withdrawal is recommended. If it is decided not to discontinue therapy before surgery, care should be taken when using anaesthetic agents with propranolol. The anaesthetist should be informed so the choice of anaesthetic agent can be decided. Anaesthetic agents causing myocardial depression are best avoided.

**In case of overdose**

**If you take too much (overdose)**

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Propranolol.
Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much propranolol, it may cause bradycardia, hypotension, bronchospasm or acute cardiac failure.

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**Side Effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Propranolol or if you have any questions or concerns.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Propranolol is generally well tolerated.

**Tell your doctor or if you notice any of the following:**

This list includes the most common side effects. Mostly, these are mild and transient:

- Nausea (feeling sick), vomiting
- Diarrhoea, stomach pain, flatulence
- Loss of appetite (including anorexia)
- Cold hands or feet
- Dizziness, tiredness
- Rash, flushing
- Hair loss
- Feeling tired, lethargic, lack of energy

**Tell your doctor immediately if you notice any of the following.**

These may be serious side effects. You may need medical attention.

- Disturbed sleep, vivid dreams or nightmares
- Conjunctivitis, dry eyes
- Visual disturbances
- Trouble passing urine
- Unexplained bruising
- Mood changes, confusion
- Sexual problems
- Loss of hearing
- Slow heart beats
If you or someone you know or care for experience any of the following, stop taking propranolol and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

- Extreme tiredness or breathlessness on mild exercise
- Wheezing, difficulty breathing or an asthma attack
- Fast heart beats (palpitations)

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

---

**After using Apo-Propranolol**

**Storage**

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Disposal**

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

---

**Product description**
**What it looks like**

Apo-Propranolol 10mg tablets: Orange coloured, round, biconvex tablets, embossed with "P" and "10" on either side of the breakline on one side and plain on the other side.

Apo-Propranolol 40mg tablets: Green coloured, round, biconvex tablets, embossed with "P" and "40" on either side of the breakline on one side and plain on the other side.

The score line is not intended for breaking the tablet.

Apo-Propranolol 10mg and 40mg tablets are available in bottles of 100 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

**Ingredients**

**Active ingredient:**

Each tablet contains 10mg or 40mg of propranolol hydrochloride as the active ingredient.

**Inactive ingredients:**

- Lactose monohydrate
- Corn starch
- Sodium starch glycolate
- Magnesium stearate
- Povidone

The 10mg tablets also contain the colourants:

- Sunset Yellow (CI15985)
- Quinoline Yellow (CI47005)

The 40mg tablets also contain the colourants:

- Sunset Yellow (CI15985)
- Quinoline Yellow (CI47005)
- Brilliant Blue (CI42090)

This medicine is gluten free.

This medicine contains lactose.

**Sponsor Details**
Apo-Propranolol is supplied in New Zealand by:

Apothex NZ Ltd
32 Hillside Road
Glenfield
Auckland
New Zealand
Phone: (09) 64 9444 2073

Date of Preparation

This leaflet was prepared on 17 June 2019.
PROPRANOLOL
pro-pran-oh-lol

What does it do?
Propranolol is used to treat some heart problems and high blood pressure. It is also sometimes used for other conditions such as migraines.

How should you take it?
Take propranolol regularly as directed with a glass of water. Swallow the slow release (LA) capsules whole. Measure the liquid carefully with an oral syringe or measuring spoon. You can take propranolol with or without food, but take it the same way each time.

What if you forget a dose?
Take the missed dose as soon as possible. If it is close to the time for your next dose, skip the missed dose and carry on as normal. Do not take two doses at the same time.

Can you take other medicines?
Some medicines available without a prescription may react with propranolol including:
- anti-inflammatories, such as diclofenac (e.g. Voltaren®), ibuprofen (e.g. Nurofen®), or aspirin (e.g. Disprin®, in doses used for pain relief). These can also be found in some cold and flu medicines (e.g. Nurofen Cold and Flu®).
- diphenhydramine (e.g. Unisom SleepGels®)

Tell your pharmacist or doctor about all medicines or treatments that you may be taking, including vitamins, herbal products or recreational drugs.

What side effects might you notice?

<table>
<thead>
<tr>
<th>Side Effects</th>
<th>Recommended action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fainting, lightheaded</td>
<td>Tell your doctor</td>
</tr>
<tr>
<td>Swollen feet or legs, short of breath</td>
<td></td>
</tr>
<tr>
<td>Low mood</td>
<td></td>
</tr>
<tr>
<td>Tiredness or weakness</td>
<td>Tell your doctor if troublesome</td>
</tr>
<tr>
<td>Trouble sleeping, strange dreams</td>
<td></td>
</tr>
<tr>
<td>Cold hands and feet, tingling or numbness</td>
<td></td>
</tr>
<tr>
<td>Changes in sexual function</td>
<td></td>
</tr>
<tr>
<td>Somach upset</td>
<td></td>
</tr>
<tr>
<td>Lightheaded or dizzy after standing up</td>
<td>Stand up slowly. If it continues, or is severe, tell your doctor</td>
</tr>
</tbody>
</table>

If you notice any other effects, discuss them with your doctor or pharmacist.

Other information:
- Tell your doctor if you have liver or circulation problems, asthma or diabetes.
- Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding.
- Do not stop taking propranolol without talking to your doctor first.
Appendix 2. Search strategy and inclusion/exclusion criteria of review

Search strategy of review

<table>
<thead>
<tr>
<th>Database</th>
<th>Coverage</th>
<th>Search string / terms and limits</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web of Science</td>
<td>1898</td>
<td>(patient* OR consumer* OR public OR &quot;member* of the public&quot; OR client* OR customer*) AND TOPIC: (advice OR guidance OR recommendation* OR direction* OR instruction*) AND TOPIC: (medic* OR drug* OR prescription* OR pharmaceutic*) AND TOPIC: (&quot;printed information&quot; OR pamphlet* OR leaflet* OR handout* OR webpage* OR website* OR app*) AND TOPIC: (&quot;patient information&quot;)</td>
<td>204 hits</td>
</tr>
<tr>
<td>Scopus</td>
<td>1823+</td>
<td>(patient* OR consumer* OR public OR &quot;member* of the public&quot; OR client* OR customer*) AND TOPIC: (advice OR guidance OR recommendation* OR direction* OR instruction*) AND TOPIC: (medic* OR drug* OR prescription* OR pharmaceutic*) AND TOPIC: (&quot;printed information&quot; OR pamphlet* OR leaflet* OR handout* OR webpage* OR website* OR app*) AND TOPIC: (&quot;patient information&quot;) (due to unmanageable number: LIMIT-TO article, research article, subject: medicine.)</td>
<td>627 hits</td>
</tr>
<tr>
<td>Ovid: Embase</td>
<td>1947 to 2015 July 20</td>
<td>(patient* OR consumer* OR public OR &quot;member* of the public&quot; OR client* OR customer*) AND TOPIC: (advice OR guidance OR recommendation* OR direction* OR instruction*) AND TOPIC: (medic* OR drug* OR prescription* OR pharmaceutic*) AND TOPIC: (&quot;printed information&quot; OR pamphlet* OR leaflet* OR handout* OR webpage* OR website* OR app*) AND TOPIC: (&quot;patient information&quot;)</td>
<td>1164 hits</td>
</tr>
<tr>
<td>Medline</td>
<td>1946 to Present with Daily Update</td>
<td>(patient* OR consumer* OR public OR &quot;member* of the public&quot; OR client* OR customer*) AND TOPIC: (advice OR guidance OR recommendation* OR direction* OR instruction*) AND TOPIC: (medic* OR drug* OR prescription* OR pharmaceutic*) AND TOPIC: (&quot;printed information&quot; OR pamphlet* OR leaflet* OR handout* OR webpage* OR website* OR app*) AND TOPIC: (&quot;patient information&quot;)</td>
<td></td>
</tr>
</tbody>
</table>

Total 1995

Selected articles from title and abstract (and after removal of duplicates) 207

Relevant articles from search 5

Relevant articles from reference lists of the above, and articles citing the above 12

Total relevant articles 17
### Inclusion and exclusion criteria of review

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies published in English with:</td>
<td>Studies:</td>
</tr>
<tr>
<td>• Participants using and/or previously used medicine information leaflets</td>
<td>• Published before 2008</td>
</tr>
<tr>
<td>• Optimisation/improvement of leaflets by design and/or content changes (some studies may not have an intervention or comparator e.g. interviews, focus groups)</td>
<td>• Not involving patients/consumers</td>
</tr>
<tr>
<td>• Outcomes of</td>
<td>• About the usefulness of using printed materials in counselling</td>
</tr>
<tr>
<td>o Information preferences</td>
<td>• Focusing on</td>
</tr>
<tr>
<td>o Improved adherence</td>
<td>• If patients’ received or read leaflets</td>
</tr>
<tr>
<td>o Increased ability to find and comprehend information</td>
<td>• If patients’ understand the current leaflets available</td>
</tr>
<tr>
<td>o Increased likelihood for leaflet to be read and used</td>
<td>• Description of side-effects</td>
</tr>
<tr>
<td>• Qualitative (seeking patients’ opinions, feelings, and experiences directly) or quantitative (assessing usability, readability, or comprehension through questionnaires or interviews) outcomes</td>
<td>• One aspect of medicine use or administration</td>
</tr>
<tr>
<td>• Assessing or discussing printed medicines information</td>
<td>• OTC medicines</td>
</tr>
<tr>
<td></td>
<td>• Evaluating the effect of languages in a leaflet</td>
</tr>
<tr>
<td></td>
<td>• About pictograms or information in booklet form</td>
</tr>
<tr>
<td></td>
<td>• Evaluating leaflet templates or tools used to assess written information</td>
</tr>
</tbody>
</table>
Appendix 3. Questionnaire sent to GPs and pharmacists, chapter 3.3.1

Survey questions for GPs

1. How often do you give the following to patients about medicines that are NOT considered high-risk (e.g. asthma inhaler)? *(Tick the appropriate box in each line)*

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>Only on patient request</th>
<th>Never</th>
<th>Never, this is the role of the pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbal information about their <em>newly prescribed</em> medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verbal information about <em>repeated</em> medicines for chronic conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This question is about the information you give to patients about medicines they have *never* taken before. Please consider what information you would routinely give to patients prescribed a medicine that is *not* considered high-risk (such as an asthma inhaler).
2. How often do you discuss the following with patients? *Tick the appropriate box in each line*  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>Only on patient request</th>
<th>Never, this is the role of the pharmacist</th>
<th>Never, the patient does not need to know this</th>
</tr>
</thead>
<tbody>
<tr>
<td>The generic and brand names of the medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What the medicine is for</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How the medicine helps the condition</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contraindications and precautions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: dose and length of treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: administration instructions</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>What to do if a dose is missed</td>
<td></td>
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<tr>
<td>How to monitor the treatment’s effectiveness</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(including when to come back if necessary)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring requirements of the drug (if applicable)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential interactions</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side-effects and what to do if they are experienced</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestyle information (e.g. drug effect on driving, drinking, sexual activity)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General health tips that would improve treatment outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage and disposal of the medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Ingredients in the medicine (e.g. lactose, sugar)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where patients can access further information about the</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
324

This question is about what information you give to patients about medicines they have taken before (i.e. for a chronic condition). Please consider what information you would routinely give to these patients prescribed a medicine that is not considered high-risk (such as an asthma inhaler).

3. Please rate each of the following for importance (Tick the appropriate box in each line)

<table>
<thead>
<tr>
<th>Information</th>
<th>Not important</th>
<th>Somewhat important</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>medicine or condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information about alternative therapies and treatment options</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What the medicine is for
How the medicine helps the condition
Contra-indications and precautions
How to take the medicine: dose and length of treatment
How to take the medicine: administration instructions
What to do if a dose is missed
How to monitor the treatment’s effectiveness (and when to come back if necessary)
Monitoring requirements of the drug (if applicable)
<table>
<thead>
<tr>
<th>Potential interactions</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Side-effects and what to do if they are experienced</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestyle information (e.g. drug effect on driving, drinking, sexual activity)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>General health tips that would improve treatment outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage and disposal of the medicine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingredients in the medicine (e.g. lactose, sugar)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where patients can access further information about the medicine or condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information about alternative therapies and treatment options</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Other (please specify)**

---

**Please provide the following demographic information**

**4. Sex**

- ☐ Male
- ☐ Female

**5. Age**

- ☐ 20-29
- ☐ 30-39
- ☐ 40-49
- ☐ 50-59
- ☐ >60
6. Please tell us which area this surgery is located in

- Major City (e.g. Auckland, Wellington, Christchurch)
- Provincial City (urban area with a population over 30,000 people e.g. Hamilton, Dunedin, Nelson, New Plymouth, Napier, Gisborne)
- Provincial Town (town with a population between 1,000 and 30,000 people e.g. Levin, Gore)
- Rural (non-urban areas such as rural centers with population under 1,000 people)
## Survey questions for pharmacists

1. **How often do you give the following to patients about medicines that are NOT considered high-risk (e.g. asthma inhaler)?** *(Tick the appropriate box in each line)*

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>Only on patient request</th>
<th>Never</th>
<th>Never, this is the role of the doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbal information about their <em>newly prescribed</em> medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verbal information about <em>repeated</em> medicines for chronic conditions</td>
<td></td>
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</tr>
</tbody>
</table>

This question is about the information you give to patients about medicines they have **never** taken before. Please consider what information you would routinely give to patients prescribed a medicine that is **not** considered high-risk (such as an asthma inhaler).

2. **How often do you discuss the following with patients?** *(Tick the appropriate box in each line)*

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>Only on patient request</th>
<th>Never</th>
<th>Never, this is the role of the doctor</th>
<th>Never, the patient does not need to know this</th>
</tr>
</thead>
<tbody>
<tr>
<td>The generic and brand names of the medicine</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What the medicine is for</td>
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<td></td>
</tr>
<tr>
<td>How the medicine helps the condition</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contraindications and precautions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: dose and length of treatment</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: administration instructions</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>What to do if a dose is missed</td>
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<tr>
<td>How to monitor the treatment’s effectiveness (including when to come back if necessary)</td>
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<td></td>
</tr>
<tr>
<td>Monitoring requirements of the drug (if applicable)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential interactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side-effects and what to do if they are experienced</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lifestyle information (e.g. drug effect on driving, drinking, sexual activity)

General health tips that would improve treatment outcomes

Storage and disposal of the medicine

Ingredients in the medicine (e.g. lactose, sugar)

Where patients can access further information about the medicine or condition

Information about alternative therapies and treatment options

Other (please specify)

This question is about what information you give to patients about medicines they have taken before (i.e. for a chronic condition). Please consider what information you would routinely give to these patients prescribed a medicine that is not considered high-risk (such as an asthma inhaler).
3. How important do you rate the following if discussing a medicine patients' have taken before?

<table>
<thead>
<tr>
<th></th>
<th>Not important</th>
<th>Somewhat important</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>The generic and brand names of the medicine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What the medicine is for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How the medicine helps the condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contra-indications and precautions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: dose and length of treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to take the medicine: administration instructions</td>
<td></td>
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<tr>
<td>What to do if a dose is missed</td>
<td></td>
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<tr>
<td>How to monitor the treatment’s effectiveness (including when to come back if necessary)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Monitoring requirements of the drug (if applicable)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential interactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side-effects and what to do if they are experienced</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestyle information (e.g. drug effect on driving, drinking, sexual activity)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General health tips that would improve treatment outcomes</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Storage and disposal of the medicine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingredients in the medicine (e.g. lactose, sugar)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where patients can access further information about the medicine or condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information about alternative therapies and treatment options</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other (please specify)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Please provide the following demographic information

4. Sex
   ○ Male
   ○ Female

5. Age
   ○ 20-29
   ○ 30-39
   ○ 40-49
   ○ 50-59
   ○ >60

6. Please tell us which area this surgery is located in
   ○ Major City (e.g. Auckland, Wellington, Christchurch)
   ○ Provincial City (urban area with a population over 30,000 people e.g. Hamilton, Dunedin, Nelson, New Plymouth, Napier, Gisborne)
   ○ Provincial Town (town with a population between 1,000 and 30,000 people e.g. Levin, Gore)
   ○ Rural (non-urban areas such as rural centers with population under 1,000 people)
Appendix 4. Ethical approval D16/298

Dear Dr Smith,

I am writing to confirm for you the status of your proposal entitled "Investigation of consultation practices and use of medicine information leaflets in New Zealand", which was originally received on August 25, 2016. The Human Ethics Committee's reference number for this proposal is D16/298.

The above application was Category B and had therefore been considered within the Department or School. The outcome was subsequently reviewed by the University of Otago Human Ethics Committee. The outcome of that consideration was that the proposal was approved.

Approval is for up to three years from the date of HOD approval. If this project has not been completed within three years of this date, re-approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

Yours sincerely,

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8256
Email: gary.witte@otago.ac.nz

13 September 2016
Tuesday, 06 September 2016.

Dr Alesha Smith,
School of Pharmacy,
DUNEDIN.

Tēnā koe Dr Alesha Smith,

Investigation of consultation practices and use of medicine information leaflets in New Zealand

The Ngāi Tahu Research Consultation Committee (the committee) met on Tuesday, 06 September 2016 to discuss your research proposal.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states “Ngāi Tahu acknowledges that the consultation process outlined in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago”. As such, this response is not “approval” or “mandate” for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGeachan:

“Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal.”

The Committee considers the research to be of importance to Māori health.

As this study involves human participants, the Committee strongly encourage that ethnicity data be collected as part of the research project as a right to express their self-identity. That is the questions on self-identified ethnicity and descent, these questions are contained in the latest census.

The Committee suggests dissemination of the research findings to Māori health organisations regarding this study.
We wish you every success in your research and the committee also requests a copy of the research findings.

This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 06 September 2016 to 6 March 2018.

Nāhaku noa, nā

Mark Brunton
Karwhakahaere Rangahau Māori
Research Manager Māori
Research Division
Te Whare Wānanga o Ōtāgo
P: +64 3 479 8738
Email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz
Appendix 5. Figure: Use of counselling points for new, low-risk medicines

- Medicine generic and brand names: GP
- What the medicine is for: GP
- How the medicine helps the condition: GP
- Contra-indications and precautions: GP
- Medicine dose and length of treatment: GP
- Medicine administration instructions: GP
- What to do if a dose is missed: GP
- Monitoring efficacy (e.g. when to come back): GP
- Drug monitoring requirements: GP
- Potential interactions: GP
- Side effects and what to do if they occur: GP
- Lifestyle effects (driving/drinking/sexual): GP
- General health tips to improve outcomes: GP
- Medicine storage and disposal: GP
- Medicine ingredients (e.g. lactose, sugar): GP
- Where to access further information: GP
- Alternative therapies and treatment: GP

Options:
- All/Most of the time
- Some of the time
- Never
- Only on patient request
## Appendix 6. Table: GPs and pharmacists use of counselling points for new, low-risk medicines

<p>|                                      | GPs          | Pharmacists |              |              |              |              |              |              |</p>
<table>
<thead>
<tr>
<th></th>
<th>All/most of the time</th>
<th>Some of the time</th>
<th>Never</th>
<th>Only on patient request</th>
<th>All/most of the time</th>
<th>Some of the time</th>
<th>Never</th>
<th>Only on patient request</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The generic and brand names of the medicine</strong></td>
<td>39 (26.0%)</td>
<td>85 (56.7%)</td>
<td>5 (3.3%)</td>
<td>21 (14.0%)</td>
<td>58 (48.7%)</td>
<td>47 (39.5%)</td>
<td>0 (0.0%)</td>
<td>14 (11.8%)</td>
</tr>
<tr>
<td><strong>What the medicine is for</strong></td>
<td>149 (99.3%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>1 (0.7%)</td>
<td>93 (78.2%)</td>
<td>18 (15.1%)</td>
<td>1 (0.8%)</td>
<td>7 (5.9%)</td>
</tr>
<tr>
<td><strong>How the medicine helps the condition</strong></td>
<td>140 (93.3%)</td>
<td>9 (6.0%)</td>
<td>0 (0.0%)</td>
<td>1 (0.7%)</td>
<td>66 (55.5%)</td>
<td>21 (17.6%)</td>
<td>0 (0.0%)</td>
<td>32 (26.9%)</td>
</tr>
<tr>
<td><strong>Contra-indications and precautions</strong></td>
<td>100 (66.7%)</td>
<td>43 (28.7%)</td>
<td>2 (1.3%)</td>
<td>5 (3.3%)</td>
<td>50 (42.0%)</td>
<td>43 (36.1%)</td>
<td>0 (0.0%)</td>
<td>26 (21.8%)</td>
</tr>
<tr>
<td><strong>How to take the medicine: dose and length of treatment</strong></td>
<td>143 (95.3%)</td>
<td>6 (4.0%)</td>
<td>1 (0.7%)</td>
<td>0 (0.0%)</td>
<td>96 (80.7%)</td>
<td>19 (16.0%)</td>
<td>0 (0.0%)</td>
<td>4 (3.4%)</td>
</tr>
<tr>
<td><strong>How to take the medicine: administration instructions</strong></td>
<td>105 (70.0%)</td>
<td>38 (25.3%)</td>
<td>5 (3.3%)</td>
<td>2 (1.3%)</td>
<td>92 (78.6%)</td>
<td>22 (18.8%)</td>
<td>0 (0.0%)</td>
<td>3 (2.6%)</td>
</tr>
<tr>
<td><strong>What to do if a dose is missed</strong></td>
<td>26 (17.3%)</td>
<td>81 (54.0%)</td>
<td>6 (4.0%)</td>
<td>37 (24.7%)</td>
<td>18 (15.1%)</td>
<td>36 (30.3%)</td>
<td>2 (1.7%)</td>
<td>63 (52.9%)</td>
</tr>
<tr>
<td><strong>How to monitor the treatment’s effectiveness (including when to come back if necessary)</strong></td>
<td>131 (87.3%)</td>
<td>18 (12.0%)</td>
<td>1 (0.7%)</td>
<td>0 (0.0%)</td>
<td>29 (24.4%)</td>
<td>44 (37.0%)</td>
<td>9 (7.6%)</td>
<td>37 (31.1%)</td>
</tr>
<tr>
<td>Section</td>
<td>Count</td>
<td>Yes (%)</td>
<td>No (%)</td>
<td>Total (%)</td>
<td>Yes (%)</td>
<td>No (%)</td>
<td>Total (%)</td>
<td>Yes (%)</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Monitoring requirements of the drug (if applicable)</td>
<td>122</td>
<td>81.3%</td>
<td>15.3%</td>
<td>3%</td>
<td>50</td>
<td>42.0%</td>
<td>24.4%</td>
<td>10</td>
</tr>
<tr>
<td>Potential interactions</td>
<td>77</td>
<td>51.3%</td>
<td>44.7%</td>
<td>2%</td>
<td>43</td>
<td>36.4%</td>
<td>43.2%</td>
<td>1</td>
</tr>
<tr>
<td>Side-effects and what to do if they are experienced</td>
<td>121</td>
<td>80.7%</td>
<td>18.7%</td>
<td>1%</td>
<td>57</td>
<td>47.9%</td>
<td>32.8%</td>
<td>1</td>
</tr>
<tr>
<td>Lifestyle information (e.g. drug effect on driving, drinking, sexual activity)</td>
<td>90</td>
<td>60.0%</td>
<td>39.3%</td>
<td>1%</td>
<td>56</td>
<td>47.1%</td>
<td>44.5%</td>
<td>1</td>
</tr>
<tr>
<td>General health tips that would improve treatment outcomes</td>
<td>106</td>
<td>70.7%</td>
<td>26.7%</td>
<td>0%</td>
<td>31</td>
<td>26.1%</td>
<td>58.0%</td>
<td>0</td>
</tr>
<tr>
<td>Storage and disposal of the medicine</td>
<td>7</td>
<td>4.7%</td>
<td>24.7%</td>
<td>40.7%</td>
<td>45</td>
<td>24.4%</td>
<td>44.5%</td>
<td>3</td>
</tr>
<tr>
<td>Ingredients in the medicine (e.g. lactose, sugar)</td>
<td>2</td>
<td>1.3%</td>
<td>12.0%</td>
<td>39.3%</td>
<td>71</td>
<td>4.4%</td>
<td>10%</td>
<td>9</td>
</tr>
<tr>
<td>Where patients can access further information about the medicine or condition</td>
<td>21</td>
<td>14.0%</td>
<td>30.7%</td>
<td>7.3%</td>
<td>72</td>
<td>11.8%</td>
<td>33.6%</td>
<td>1</td>
</tr>
<tr>
<td>Information about alternative therapies and treatment options</td>
<td>30</td>
<td>20.0%</td>
<td>60.0%</td>
<td>3.3%</td>
<td>55</td>
<td>10%</td>
<td>31%</td>
<td>9</td>
</tr>
</tbody>
</table>
Appendix 7. Questionnaire, chapter 4.3.1

1. How often do you give patients an information leaflet about their *newly prescribed medicines*?
   - All of the time
   - Most of the time
   - Some of the time
   - Only on patient request*
   - Never*

2. How often do you give patients an information leaflet about their *repeated medicines* for chronic conditions?
   - All of the time
   - Most of the time
   - Some of the time
   - Only on patient request*
   - Never*

*If you answered *only on patient request* or *never* for questions 1 AND 2, please go to question 7

3. How do you usually use a medicine information leaflet with your patients?
   - Provide a leaflet only with no verbal advice
   - Provide a leaflet only with no verbal advice
   - Provide a leaflet, ask the patient to read it and come back if they have any questions
   - Draw attention to specific sections of the leaflet with some verbal advice
   - Verbally discuss the sections of the leaflet that you feel are important
   - Discuss the entire leaflet
4. What are your reasons for providing a medicines information leaflet? *(you may select more than one option)*

- I want the patient to make an informed choice about their medicine to aid adherence
- I want to check that I did not forget to provide any medicine information verbally
- I want to reinforce the benefits of the medicine and how to take it
- I have a duty of care to inform the patient about their medicine
- The patient has a right to information about their medicine
- The patient requests a medicine information leaflet
- The patient had a bad experience with a medicine in the past
- Other (please specify)

5. What do you like about the medicine information leaflets you use?

6. What don’t you like about the medicine information leaflets you use?

7. When would you like the patient to receive a medicine information leaflet for their prescription medicine? *(you may select more than one option)*

- Before they are prescribed a medicine to think about the treatment options or risks and benefits
- When they are prescribed/dispensed a new medicine
- When they are prescribed/dispensed a repeat medicine
- Every 6-12 months for repeat medicines
- When they have a change in the brand of their medicine *(e.g. generic substitution)*
When new information about the medicine becomes available

When they are prescribed/dispensed a medicine that is associated with serious side-effects

When they ask for it

Other (please specify)

Medicine information for patients is currently available as comprehensive leaflets provided by the manufacturer, or as summarised leaflets provided by independent providers. Personalised summary leaflets could provide tailored information according to patients’ characteristics such as disease, age, and sex, and hence are more relevant and patient-centred.

8. Which one of the following types of medicine information leaflet do you think would be most useful to provide to patients?

- A comprehensive leaflet such as the manufacturer CMI, or similar available online, printed, or in the medicine box

- A personalised summary leaflet printed from prescribing or dispensing software tailored to the patient’s characteristics

- A personalised summary leaflet printed from prescribing or dispensing software tailored to the patient’s characteristics, with instructions on how to access more comprehensive information if the patient wants it

- A general summary leaflet printed from prescribing or dispensing software

- A general summary leaflet printed from prescribing or dispensing software with instructions on how to access more comprehensive information if the patient wants it

- None of the above

- Other

Please provide the following demographic information

9. Sex
10. Age

- Male
- Female

- 20-29
- 30-39
- 40-49
- 50-59
- >60

11. Please tell us which area your pharmacy/ GP practice is located in

- Major City (e.g. Auckland, Wellington, Christchurch)
- Provincial City (urban area with a population over 30,000 people e.g. Hamilton, Dunedin, Nelson, New Plymouth, Napier, Gisborne)
- Provincial Town (town with a population between 1,000 and 30,000 people e.g. Levin, Gore)
- Rural (non-urban areas such as rural centers with population under 1,000 people)
Appendix 8. Table: Self-reported provision of medicine information leaflets

<table>
<thead>
<tr>
<th>How often leaflets are provided</th>
<th>GP group (n=143)</th>
<th>Pharmacist group (n=126)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For new medicines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All/most of the time</td>
<td>19 (13.3%)</td>
<td>51 (40.5%)</td>
</tr>
<tr>
<td>Some of the time</td>
<td>68 (47.6%)</td>
<td>51 (40.5%)</td>
</tr>
<tr>
<td>Never</td>
<td>28 (19.6%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Only on patient request</td>
<td>28 (19.6%)</td>
<td>24 (19.0%)</td>
</tr>
<tr>
<td>No response</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>For repeat medicines for chronic conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All/most of the time</td>
<td>0 (0%)</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Some of the time</td>
<td>26 (18.2%)</td>
<td>20 (15.9%)</td>
</tr>
<tr>
<td>Never</td>
<td>49 (34.3%)</td>
<td>11 (8.7%)</td>
</tr>
<tr>
<td>Only on patient request</td>
<td>67 (46.9%)</td>
<td>93 (73.8%)</td>
</tr>
<tr>
<td>No response</td>
<td>1 (0.7%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>Ways leaflets are provided to patients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provided with no verbal advice</td>
<td>1 (1.1%)</td>
<td>5 (5.3%)</td>
</tr>
<tr>
<td>Provided and asked the patient to read it and come back if they have questions</td>
<td>10 (11.2%)</td>
<td>2 (2.1%)</td>
</tr>
<tr>
<td>Draw attention to specific sections with some verbal advice or discuss sections of the leaflet you feel are important</td>
<td>73 (82%)</td>
<td>76 (80.9%)</td>
</tr>
<tr>
<td>Discuss the entire leaflet</td>
<td>1 (1.1%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (4.5%)</td>
<td>11 (11.7%)</td>
</tr>
</tbody>
</table>
Appendix 9. Tables: Likes and dislikes of available leaflets

Likes of available leaflets

<table>
<thead>
<tr>
<th>Themes and subthemes</th>
<th>Number of GPs</th>
<th>Number of Pharmacists</th>
<th>Selected quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>48</td>
<td>83</td>
<td></td>
</tr>
<tr>
<td>A4</td>
<td>0</td>
<td>1</td>
<td>“A4 size info with simple language”</td>
</tr>
<tr>
<td>Big print</td>
<td>0</td>
<td>1</td>
<td>“Big print”</td>
</tr>
<tr>
<td>Photos/pictures</td>
<td>0</td>
<td>1</td>
<td>“I like the manufacturers pamphlets that have photos e.g. efudix as I feel it gives the patient a better idea of what to expect”</td>
</tr>
<tr>
<td>Designed for patient</td>
<td>1</td>
<td>5</td>
<td>“Specifically designed for pt”</td>
</tr>
<tr>
<td>Concise</td>
<td>11</td>
<td>22</td>
<td>“concise and in plain language”</td>
</tr>
<tr>
<td>Use of tables</td>
<td>0</td>
<td>1</td>
<td>“Contain tables for ease of reading”</td>
</tr>
<tr>
<td>Simple, clear, easy to read</td>
<td>24</td>
<td>46</td>
<td>“Clear, non-technical language”</td>
</tr>
<tr>
<td>and understand</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comprehensive</td>
<td>8</td>
<td>6</td>
<td>“comprehensive and easy to read”</td>
</tr>
<tr>
<td>Consistent (e.g. easy to find</td>
<td>4</td>
<td>0</td>
<td>“They follow a standard format so that when a medication is changed the patient can follow the new information sheet more easily”</td>
</tr>
<tr>
<td>Content</td>
<td>19</td>
<td>12</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----</td>
<td>----</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Side-effects (with/without including required action)</td>
<td>8</td>
<td>8</td>
<td>“only certain side-effects mentioned”</td>
</tr>
<tr>
<td>Directions</td>
<td>5</td>
<td>1</td>
<td>“clear info about how to take”</td>
</tr>
<tr>
<td>Missed dose</td>
<td>0</td>
<td>2</td>
<td>“what to do if miss doses”</td>
</tr>
<tr>
<td>Excipients</td>
<td>0</td>
<td>1</td>
<td>“tablet excipients”</td>
</tr>
<tr>
<td>Where to go for more information</td>
<td>1</td>
<td>0</td>
<td>“Clear language, concise information and directions where to go for further information”</td>
</tr>
<tr>
<td>Indications and benefits</td>
<td>3</td>
<td>0</td>
<td>“details of benefits and side-effects”</td>
</tr>
<tr>
<td>Mode of action</td>
<td>1</td>
<td>0</td>
<td>“They explain mode of action, address how best to take”</td>
</tr>
<tr>
<td>When to seek advice</td>
<td>1</td>
<td>0</td>
<td>“common side-effects and side-effects including when the patient ought to seek medical review”</td>
</tr>
<tr>
<td>Accessibility</td>
<td>13</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Easy to access and produce</td>
<td>13</td>
<td>11</td>
<td>“Convenience - link from dispensing software”</td>
</tr>
<tr>
<td>Usefulness and usability</td>
<td>18</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Feature</td>
<td>Score</td>
<td>Feedback</td>
<td></td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------</td>
<td>--------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Informative at patient level</td>
<td>4</td>
<td>“Informative at patient level”</td>
<td></td>
</tr>
<tr>
<td>Can provide more information</td>
<td>2</td>
<td>“Can provide more information about the medicine than can be provided (or</td>
<td></td>
</tr>
<tr>
<td>about the medicine</td>
<td></td>
<td>remembered by patient) in the short time available with current funding</td>
<td></td>
</tr>
<tr>
<td>that can be covered in consultation</td>
<td>4</td>
<td>structure, and gives them the opportunity to come back to me with further</td>
<td></td>
</tr>
<tr>
<td>further questions”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information is provided and the patient can go back to it”</td>
<td>5</td>
<td>“Information is provided and the patient can go back to it”</td>
<td></td>
</tr>
<tr>
<td>it reinforces what you have said and it gives the patient a reference in case they forget or get confused about information given verbally”</td>
<td>3</td>
<td>“Reinforces/compliments verbal discussion”</td>
<td></td>
</tr>
<tr>
<td>OTC awareness”</td>
<td>0</td>
<td>“OTC awareness”</td>
<td></td>
</tr>
<tr>
<td>Guide for discuss”</td>
<td>2</td>
<td>“Guide for discuss”</td>
<td></td>
</tr>
<tr>
<td>Save time, informed consent, thorough”</td>
<td>1</td>
<td>“Save time, informed consent, thorough”</td>
<td></td>
</tr>
<tr>
<td>Useful</td>
<td>1</td>
<td>“Useful”</td>
<td></td>
</tr>
<tr>
<td>Quality</td>
<td>8</td>
<td>“Direct from the manufacturer or medsafe, up to date information,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>comprehensive”</td>
<td></td>
</tr>
<tr>
<td>Up to date</td>
<td>0</td>
<td>“Up to date”</td>
<td></td>
</tr>
<tr>
<td>From manufacturer or Medsafe (New Zealand’s medicines regulatory authority)</td>
<td>2</td>
<td>1</td>
<td>“Direct from the manufacturer or medsafe”</td>
</tr>
<tr>
<td>From a reliable source</td>
<td>2</td>
<td>3</td>
<td>“trusted source (CDHB). Concise. Readable”</td>
</tr>
<tr>
<td>Accurate</td>
<td>3</td>
<td>0</td>
<td>“accurate easy to print off”</td>
</tr>
<tr>
<td>Not from drug company</td>
<td>1</td>
<td>0</td>
<td>“I am familiar with them, not from drug company so unbiased”</td>
</tr>
</tbody>
</table>

### Dislikes of available leaflets

<table>
<thead>
<tr>
<th>Themes and subthemes</th>
<th>Number of GPs</th>
<th>Number of Pharmacists</th>
<th>Some examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>65</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>No colour</td>
<td>0</td>
<td>1</td>
<td>“black and white, no colour”</td>
</tr>
<tr>
<td>Too long</td>
<td>13</td>
<td>14</td>
<td>“can be lengthy”</td>
</tr>
<tr>
<td>Can be misunderstood/misinterpreted</td>
<td>13</td>
<td>1</td>
<td>“Can be miss interpreted, if taken the wrong way can actually act as a barrier to compliance and/or lead the patient to make a misinformed choice leading to a negative health outcome”</td>
</tr>
<tr>
<td>Too much information or</td>
<td>23</td>
<td>14</td>
<td>“contain information the patient does not need”</td>
</tr>
<tr>
<td>Issue</td>
<td>Rating</td>
<td>Total</td>
<td>Notes</td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------</td>
<td>-------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Unnecessary detail</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confusing or hard to understand (including difficult for those with low literacy)</td>
<td>5</td>
<td>3</td>
<td>“they are wordy, confusing and not written easily for patient consumption”</td>
</tr>
<tr>
<td>Too technical</td>
<td>3</td>
<td>4</td>
<td>“may be too technical for the patient - verbal advice can overcome this”</td>
</tr>
<tr>
<td>Too simplistic</td>
<td>3</td>
<td>1</td>
<td>“My experience with patient info sheets is that they tend to be too simplistic, eg 'keep medicines safely away from children blah blah' or pages of irrelevant stuff”</td>
</tr>
<tr>
<td>No pictures</td>
<td>0</td>
<td>1</td>
<td>“Ones printed off TONIQ i feel are too wordy, no pictures, just text after text - makes it hard to read, not direct and to the point, not addressing main issues but are just covering manufacturers”</td>
</tr>
<tr>
<td>Small font</td>
<td>0</td>
<td>2</td>
<td>“sometimes too long and small that old patients cannot read”</td>
</tr>
<tr>
<td>Not easy to find information</td>
<td>0</td>
<td>1</td>
<td>“sometimes contain irrelevant information and it's hard to distinguish the main points”</td>
</tr>
<tr>
<td>Does not print pharmacy details</td>
<td>0</td>
<td>1</td>
<td>“Small writing. Not pre-printed with our details (considering the come via our dispensing programme)”</td>
</tr>
<tr>
<td>Badly written</td>
<td>3</td>
<td>1</td>
<td>“The content can be too generic and not practically helpful, or worded badly”</td>
</tr>
<tr>
<td>Content</td>
<td>27</td>
<td>36</td>
<td>Content</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----</td>
<td>----</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Bad format and not user friendly</td>
<td>2</td>
<td>0</td>
<td>“I don’t like the format, not very user friendly, they don’t seem to have different ones for different uses of the medications”</td>
</tr>
<tr>
<td>Adverse effect list</td>
<td>18</td>
<td>17</td>
<td>“side-effect list can scare patients”</td>
</tr>
<tr>
<td>No 'off-label' information or wrong indication</td>
<td>1</td>
<td>4</td>
<td>“drug use not always accurate e.g. tricyclics for depression yet almost always used for nerve pain. This may stop patients from taking medicines”</td>
</tr>
<tr>
<td>No dosing guide</td>
<td>0</td>
<td>1</td>
<td>“no doses guide so will sometimes use prescriber ones. Not all meds have leaflets”</td>
</tr>
<tr>
<td>No benefits of taking medicine</td>
<td>0</td>
<td>1</td>
<td>“no motivation for the patients regarding the benefits of the medicine None”</td>
</tr>
<tr>
<td>Too generic and not specific enough</td>
<td>1</td>
<td>6</td>
<td>“some are very generic and not specific”</td>
</tr>
<tr>
<td>Not personalised</td>
<td>5</td>
<td>1</td>
<td>“Not personalised and use medical English”</td>
</tr>
<tr>
<td>No storage information</td>
<td>0</td>
<td>1</td>
<td>“Sometimes a little more information regarding storage and use of the medicine would be helpful”</td>
</tr>
<tr>
<td>Inadequate directions on use</td>
<td>1</td>
<td>1</td>
<td>“special instructions e.g. cytotoxics, best time to take, not always more prominent”</td>
</tr>
<tr>
<td>Does not contain the desired information</td>
<td>0</td>
<td>4</td>
<td>“sometimes does not have all the information I would like to pass on”</td>
</tr>
<tr>
<td>Issue</td>
<td>Freq</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>Too many interactions</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Sometimes too much is written- such as</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>listing all potential side-effects or</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>interactions even if very remote</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>possibility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accessibility</td>
<td>15</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Not available or readily accessible</td>
<td>8</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>“Not all medicines have an information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>leaflet on medsafe website”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient sign up to program necessary</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>“Not enough of them or can be too</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>technical for patient. Don't like when</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>they ask patient to sign up to a program</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>to receive info as I believe this makes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>them less likely to use resource</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High cost</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>“The cost to subscribe to them!”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have to print off</td>
<td>5</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>“a lot of my patients don't have</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>computers or the internet, so have to</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>print things off”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Too many options</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>“Printing is time consuming, too many</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>leaflets available so hard to select and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>stay up to date”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usefulness and usability</td>
<td>10</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Only available in English</td>
<td>0</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>“Need more languages other than English</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>available”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not relevant</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>“Possibly lacks relevance”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---</td>
<td>----</td>
<td>--------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lacks patient perspectives</td>
<td></td>
<td></td>
<td>“they are made as &quot;one size fits all&quot; - information is usually only about treating a</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&quot;disease&quot; not treating illness or a persons experience of their disease - including</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>socioeconomic issues”</td>
</tr>
<tr>
<td>Cause anxiety</td>
<td>3</td>
<td>4</td>
<td>“may cause patient anxiety”</td>
</tr>
<tr>
<td>Relies on patients to find</td>
<td>1</td>
<td>0</td>
<td>“Puts the responsibility on the patient to access the info, which can be good and bad”</td>
</tr>
<tr>
<td>information or want to read it</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Require a lot of explanation</td>
<td>1</td>
<td>4</td>
<td>“some of them esp consumer info sheets show so much - it deters many patients and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>have to be used with quite lot of explanation”</td>
</tr>
<tr>
<td>Not enough time to print and use them</td>
<td>3</td>
<td>0</td>
<td>“Time issue”</td>
</tr>
<tr>
<td>Quality</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Sometimes out of date</td>
<td>0</td>
<td>1</td>
<td>“Sometimes the tablet/capsule description is out of date/incorrect but this gets fixed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>when we contact the company”</td>
</tr>
<tr>
<td>Contain advertising</td>
<td>1</td>
<td>1</td>
<td>“I dont hand out the ones I do not like for example advert focused ones”</td>
</tr>
<tr>
<td>Written by Manufacturer</td>
<td>3</td>
<td>1</td>
<td>“Often produced by the manufacturer of the medication”</td>
</tr>
<tr>
<td>Variable quality</td>
<td>0</td>
<td>1</td>
<td>“quality varies considerably. Not concise”</td>
</tr>
</tbody>
</table>
Appendix 10. Questionnaire, chapter 4.4.1

These first two questions are about the information you give to patients to read about medicines that are NOT considered high-risk (e.g. asthma inhaler). [NB. most of the time was defined as more than half of the time, and some of the time defined as less than half of the time.]

1. How often do you give patients an address for a website containing information about medicines?
   - All of the time
   - Most of the time
   - Some of the time
   - Only on patient request
   - Never

2. What is your preferred source for supplying medicine information leaflets to patients? (select the most commonly used option)
   - Medsafe website
   - Patient.info website
   - UpToDate website
   - Healthinfo website
   - New Zealand Formulary website
   - Other: 1. Website (please specify); or
   - 2. Computer program (please specify); or
   - 3. Loose leaflets (please specify); or
   - 4. Unmentioned source (please specify)

3. What are the main reasons you would not provide a medicine information leaflet to patients? (please select up to 5)
   - The patient receives all the information they need verbally
   - The patient should trust the doctor to prescribe a medicine that is suitable for them
   - The patient has taken the medicine previously
   - Patients are not interested in receiving medicine information leaflets
   - The medicine is for short term treatment (less than 2 weeks)
It is the role of the doctor/pharmacist to provide medicine information leaflets

I am concerned the patient will worry about the possible side-effects and not take the medicine

I do not believe the medicine information leaflet is useful to the patient

I do not think to use them when talking with patients

Other (please specify)

4. Do any of the following prevent you from providing a leaflet to patients? (you may select more than one option)

The leaflet is not available in other languages

The medicine is being used for a purpose other than indicated (including ‘off-label’ use)

The patient has difficulty with understanding or reading the medicine information leaflets

I do not always have time to spend discussing a medicine information leaflet with the patient

The leaflet is too long to print off

There is no available printer

There is no reimbursement for printing costs

It is not the policy of the pharmacy or pharmacist/individual GP or GP practice to provide information leaflets

Other (please specify)

5. What might help you or other pharmacists to provide leaflets to patients? (you may select more than one option)

More frequent requests from patients for information leaflets

More time to provide and explain information leaflets

Specific counselling appointments to discuss a patient’s medicines

A leaflet that gives a summary of the medicine, making it easier to cover salient points

Personalised leaflets tailored to patients’ disease or condition, and characteristics

Having leaflets available in different languages

Having a self-serve computer in the pharmacy/GP surgery for patients to print the medicine information they want

Reimbursement for provision of leaflets.
6. When do you think a personalised summary leaflet could be provided for medicines considered LOW risk (e.g. asthma inhaler)? (*Tick the appropriate box in each line*)

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Some of the time</th>
<th>None of the time</th>
<th>Not applicable, a summary leaflet is not suitable</th>
</tr>
</thead>
<tbody>
<tr>
<td>By the <strong>doctor</strong> at the time of prescribing a <em>new</em> medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By the <strong>doctor</strong> at the time of prescribing a <em>repeat</em> medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By the <strong>pharmacist</strong> on dispensing a <em>new</em> medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By the <strong>pharmacist</strong> on dispensing a <em>repeat</em> medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When patients ask for it</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Other (please specify)

**Note,** *Most of the time* is considered more than half of the time and *Some of the time* is considered less than half of the time.

7. When do you think a personalised summary leaflet could be provided for medicines considered HIGH risk? (*Tick the appropriate box in each line*)

353
<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Some of the time</th>
<th>None of the time</th>
<th>Not applicable, a summary leaflet is not suitable</th>
</tr>
</thead>
<tbody>
<tr>
<td>By the <strong>doctor</strong> at the time of prescribing a <em>new</em> medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By the <strong>doctor</strong> at the time of prescribing a <em>repeat</em> medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By the <strong>pharmacist</strong> on dispensing a <em>new</em> medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By the <strong>pharmacist</strong> on dispensing a <em>repeat</em> medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When patients ask for it</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

○ Other (please specify)

Note, *Most of the time* is considered more than half of the time and *Some of the time* is considered less than half of the time.

Please provide the following demographic information

8. Sex

○ Male

○ Female

9. Age
10. Please tell us which area your pharmacy/GP practice is located in

- Major City (e.g. Auckland, Wellington, Christchurch)
- Provincial City (urban area with a population over 30,000 people e.g. Hamilton, Dunedin, Nelson, New Plymouth, Napier, Gisborne)
- Provincial Town (town with a population between 1,000 and 30,000 people e.g. Levin, Gore)
- Rural (non-urban areas such as rural centers with population under 1,000 people)
### Appendix 11. Table: Why General Practitioners (GPs) and pharmacists do not provide medicine information leaflets

<table>
<thead>
<tr>
<th>Reason why a leaflet would not be provided</th>
<th>GP n=143</th>
<th>Pharmacists n=126</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reasons with similar response rates from GPs and pharmacists</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient has difficulty with understanding or reading the medicine information leaflets</td>
<td>70</td>
<td>65</td>
<td>p=0.666</td>
</tr>
<tr>
<td></td>
<td>49.0%</td>
<td>51.6%</td>
<td></td>
</tr>
<tr>
<td>The leaflet is not available in other languages</td>
<td>49</td>
<td>53</td>
<td>p=0.188</td>
</tr>
<tr>
<td></td>
<td>34.3%</td>
<td>42.1%</td>
<td></td>
</tr>
<tr>
<td>The leaflet is too long to print off</td>
<td>55</td>
<td>36</td>
<td>p=0.087</td>
</tr>
<tr>
<td></td>
<td>38.5%</td>
<td>28.6%</td>
<td></td>
</tr>
<tr>
<td>The patient receives all the information they need verbally</td>
<td>34</td>
<td>32</td>
<td>p=0.758</td>
</tr>
<tr>
<td></td>
<td>23.8%</td>
<td>25.4%</td>
<td></td>
</tr>
<tr>
<td>There is no available printer</td>
<td>4</td>
<td>5</td>
<td>p=0.594</td>
</tr>
<tr>
<td></td>
<td>2.8%</td>
<td>4.0%</td>
<td></td>
</tr>
<tr>
<td>The patient should trust the doctor to prescribe a medicine that is suitable for them</td>
<td>1</td>
<td>2</td>
<td>p=0.489</td>
</tr>
<tr>
<td></td>
<td>0.7%</td>
<td>1.6%</td>
<td></td>
</tr>
<tr>
<td><strong>Reasons more commonly selected by pharmacists (p&lt;0.05)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient has taken the medicine previously</td>
<td>54</td>
<td>81</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>37.8%</td>
<td>64.3%</td>
<td></td>
</tr>
<tr>
<td>The medicine is being used for a purpose other than indicated (including ‘off-label’ use)</td>
<td>27</td>
<td>73</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>18.9%</td>
<td>57.9%</td>
<td></td>
</tr>
<tr>
<td>I am concerned the patient will worry about the possible side-effects and not take the medicine</td>
<td>62</td>
<td>70</td>
<td>p=0.046</td>
</tr>
<tr>
<td></td>
<td>43.4%</td>
<td>55.6%</td>
<td></td>
</tr>
<tr>
<td>Patients are not interested in receiving medicine information leaflets</td>
<td>60</td>
<td>68</td>
<td>p=0.049</td>
</tr>
<tr>
<td></td>
<td>42.0%</td>
<td>54.0%</td>
<td></td>
</tr>
<tr>
<td>Reason</td>
<td>Count</td>
<td>Percentage</td>
<td>p-value</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------</td>
<td>-------</td>
<td>------------</td>
<td>---------</td>
</tr>
<tr>
<td>There is no reimbursement for printing costs</td>
<td>14</td>
<td>9.8%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>I do not believe the medicine information leaflet is useful to the patient</td>
<td>16</td>
<td>11.2%</td>
<td>0.022</td>
</tr>
<tr>
<td>Reasons more commonly selected by GPs (p&lt;0.05)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I do not always have time to spend discussing a medicine information leaflet with the patient</td>
<td>75</td>
<td>52.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>I do not think to use them when talking with patients</td>
<td>43</td>
<td>30.1%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>It is the role of the doctor/pharmacist to provide medicine information leaflets</td>
<td>32</td>
<td>22.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>The medicine is for short term treatment (less than 2 weeks)</td>
<td>23</td>
<td>16.1%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>It is not the policy of the pharmacy or pharmacist/practice or individual doctor to provide information leaflets</td>
<td>15</td>
<td>10.5%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Appendix 12. Questionnaire, chapter 4.5.1

1. Are you currently taking any prescription medicines?
   - Yes
   - No (thank you for your time, we have no more questions)

2. Have you received any information leaflets about your medicines from your doctor in the last 6 months?
   - Yes
   - No (go to question 11)

If there has been more than one information leaflet about your medicines given to you, please think about the most recent example when answering the following questions

3. How did they use this leaflet with you?
   - Provide a leaflet only, without talking to you about it
   - Provide a leaflet, ask you to read it and come back if you had any questions
   - Draw attention to specific sections of the leaflet and spoke to you about these sections
   - Talked about the sections of the leaflet that you felt were important (for example, possibly answering a question you may have had)
   - Discussed the entire leaflet
   - Other (please specify in box below)

4. Did you feel that this leaflet was helpful because: (you may select more than one option)
   - It improved your knowledge about your medicine
5. For the following question, we are wanting to know what you thought about the style of the leaflet

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you like how the leaflet looked (the leaflets design)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Could you find the information you were looking for?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you think the leaflet had relevant information in it?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Could you read and understand the information in the leaflet?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you think the leaflet was too long</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Overall, would you say you liked the leaflet?

- Yes
- No
- Don’t know

7. Did you read this leaflet?

- Yes I read the leaflet fully (go to question 10)
- Yes, I partially read or skim read the leaflet (go to question 10)
- No
8. Why did you not read the leaflet? (you may select more than one option)

- I didn’t need to, the doctor told me all I needed to know
- I have taken this medicine before
- I am only taking the medicine for a short time (less than 2 weeks)
- It was too difficult to read and understand
- The leaflet was too long
- I didn’t think it was important
- Other (please specify in box below)

9. Did you keep this leaflet?

- Yes
- No

10. How important is it for you to receive medicine information leaflets from your doctor about the following: (tick the appropriate option in each line)

|                      | Not important | Somewhat important | Very important |
|----------------------|---------------|--------------------|               |
| New medicines        |               |                    |               |
| Repeat long-term medicines |           |                    |               |

11. When would you like to receive a medicine information leaflet from your doctor? (you may select more than one option)

- Before you are prescribed a medicine - to get information about the benefits of the medicine and its possible side-effects before you decide to take it
- When you are prescribed a new medicine
When you are prescribed a repeat medicine

Every 6–12 months for repeat medicines

When there is a change in the brand of your medicine

When new information about the medicine becomes available

When you are prescribed a medicine that is associated with serious side-effects

I would prefer to receive the leaflet at the pharmacy

I’d prefer not to be given medicine leaflets

Other (please specify in box below)

12. How would you like to receive information about your medicines? (you may select more than one option)

A paper copy printed by doctor or pharmacist

A digital (printable) copy emailed to you

A digital (printable) copy in a patient portal (patient portals are online websites provided by GPs, where patients can access their health information and interact with their general practice)

A digital (printable) copy on a website

Other (please specify in the box below)

13. What would you prefer:

A short 1–2 page summary leaflet about your medicines
A short 1–2 page summary leaflet about your medicines, with the option to choose more information to be included in your leaflet

A comprehensive leaflet containing all the information about a medicine

14. How often do you seek additional information about your medicines, other than that given to you by your doctor or pharmacist?

- All of the time
- More than half of the time
- Half of the time
- Less than half of the time
- None of the time
- Not applicable

15. What is your gender

- Male
- Female

16. What is your highest level of formal education?

- No qualification
- Secondary school (high school)
- Postgraduate diploma (for example nursing or teaching diplomas, or advanced trade certificates)
- Bachelor’s degree
- Postgraduate degree

17. What age bracket are you?

- 18-19
- 20-29
18. Is English your first language?

- Yes
- No my first language is........................................
Appendix 13. Ethical approval D17/007

D17/007

Academic Services
Manager, Academic Committees, Mr Gary Witte
7 February 2017

Dr A Smith
School of Pharmacy

Dear Dr Smith,

I am writing to confirm for you the status of your proposal entitled "Investigation of consultation practices and use of medicine information leaflets in New Zealand", which was originally received on December 20, 2016. The Human Ethics Committee’s reference number for this proposal is D17/007.

The above application was Category B and had therefore been considered within the Department or School. The outcome was subsequently reviewed by the University of Otago Human Ethics Committee. The outcome of that consideration was that the proposal was approved.

Approval is for up to three years from the date of HOD approval. If this project has not been completed within three years of this date, re-approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

Yours sincerely,

[Signature]

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8258
Email: gary.witte@otago.ac.nz
Appendix 14. Use Case [1]: Using an integrated information tool in prescribing systems to create personalised medicines information for patients

1. Description
The prescriber decides to create patient-specific information about medicines for use at point-of-care. The medicine information tool uses the information about the patient held within the Patient Management System (PMS), and information about the medicine to present information to the prescriber that is personalised for their patient at the time of consultation. It will also provide an individualised medicines information leaflet for the patients to read and take away, and/or be sent to the patient’s portal for future reference.

2. Justification
Prescribers have little time to talk to patients about medicines, let alone seek out relevant medicine information. Easily accessed personalised information could help GPs fulfil their ethical obligations to ensure patients are fully informed about their medicines.

In a recent study\textsuperscript{174} we determined that more than:

- 70\% of GPs want their patient management system to display key counselling points about medicines automatically tailored to their patient for use during consultation.
- 50\% of GPs would like patients to receive a medicine information leaflet when they are prescribed a new medicine yet 30\% of GPs report they do not think to use them at point-of-care.
- 50\% of GPs think that prescribing software that prompts to provide and record the provision of the leaflet automatically, would help them in providing leaflets to patients.
- 50\% of GPs think the most beneficial leaflets would be a personalised summary leaflet tailored to patient requirements.
2.1. Information for patients

Patients do not always find leaflets useful and they often discard leaflets without reading them. Many studies over the last few decades have led to some improvement in medicine information for patients, however there is still much room for improvement; patients are often dissatisfied, considering leaflets to be poorly designed and difficult to understand. In a recent review article we determined the information that patients want included in their information leaflets:

**Box 1 Recommendations for content of medicine information leaflets**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the medicine</td>
<td>The name people are most familiar with (i.e. the brand of the dispensed drug) should also be included</td>
</tr>
<tr>
<td>Tailored information</td>
<td>Tailored information to indication a definite requirement. Age and gender are less important to patients but worth considering if possible</td>
</tr>
</tbody>
</table>
| How a medicine works and the benefits of treatment  | Include:  
- why it is important to treat the disease and what would happen without treatment  
- whether the medicine is curative, preventative, or provides symptomatic relief  
- how long treatment will be required for |
| Dose                                                | This information should only be included if it can be tailored to the patients specific regimen – i.e. personalised |
| How to take the medicine                           | Also include what to do if a dose is missed                                                                                             |
| How long to take the medicine for                   | For certain medicines also include what would happen if stopping medicines e.g. withdrawal symptoms from antiepileptic medicines, return of infection for antibiotics etc. |
| How to monitor the treatment's effectiveness        | Include when to return to the doctor if no benefit seen – i.e. antibiotics should start to show benefit within days compared to antidepressants which take weeks |
| Comprehensive list of risks                         | Important to include the action required if side-effects are experienced. Duration of risk would                                         |
| Numeric description of side-effects | As well as describing these numerically, e.g. as natural frequencies (e.g. three in 100 people), side-effects should be categorised by how likely they are to occur and how serious they are with details of what action is required if a side effect is experienced. Boxes or tables should be utilised for clarity with side-effects requiring immediate cessation of therapy or medical treatment listed first. |
| Long-term effects | Where applicable e.g. corticosteroids, benzodiazepines (addictive) |
| Monitoring requirements | Such as blood monitoring and usual frequency |
| Interactions | Focus should be on over-the-counter medicines and foodstuffs. |
| Allergies and excipients | Evidence-based cross-reactivity should be included as well as excipients and any particular allergy concern |
| How to store a medicine | The general recommendation of keeping out of reach of children as well as specific requirements. Also should include how to dispose of medicines (e.g. fentanyl patches—ensure nobody can accidentally be exposed to remaining active ingredient) |
| Lifestyle information and general health tips | Lifestyle information about medicine or disease effects including driving, drinking, sexual activity etc. General health tips cover how to best self-manage disease e.g. healthy diet and exercise in diabetes |
| Details for more information | Where to see more detailed information leaflets, patient organisations, helpline numbers, and website addresses |
| Comparative information for alternative drug therapies and treatment options including non-pharmacological and natural medicine | This may be problematic as it could confuse some people and lead to anxiety in some cases. It would be necessary to tailor this information following discussion with patients and before treatment decisions are made to aid |
concordance. Information should be succinct and evidence-based only and may not be available for a number of medicines

<table>
<thead>
<tr>
<th>Date</th>
<th>Date of last update of leaflet</th>
</tr>
</thead>
</table>


A new type of Medicine information leaflet

Much of the information listed above is either missing from current leaflets available (such as those available via New Zealand Formulary, Canterbury District Health Board, or some manufacturer produced information), or is written in such a way as to make leaflets too long and difficult to navigate and understand (e.g. some manufacturer produced information).

New information for patients will be created by the research team with review and input from practicing healthcare professionals. Information will be sourced from validated resources including the Medsafe approved Data Sheets and Consumer Medicine Information, New Zealand Formulary, and SafeRx. Our project will be a “proof of concept study” where we will develop and test one customisable leaflet for one condition. At a later date, we anticipate that we will work with collaborators to widen the number of medicines included.

2.2. Expected benefits

There will be written point-of-care information for GPs to use when speaking to patients in the form of key practice points particularly relevant for each patient. Patients would have a relevant personalised medicine information leaflet to take away, or a digital copy through their patient portal, for them to refer back to if needed.

The following benefits can be measured via user surveys:

- For prescribers
  - Improvement in prescriber-patient communications.
- Improved confidence in information communicated during consultation with support of information tool.
- Less time wasted searching for appropriate information to give to patient.

- For patients
  - The personalised nature of these leaflets will improve patients’ perceptions of the information leaflet and willingness to read it.
  - Increased patient knowledge about their medicines.
  - Improved intent to adhere to medicines.
  - Increased satisfaction with consultation.

3. Level
Summary (this Use Case occurs as part of a broader context of receiving information about medicines).

4. Trigger
The Prescriber writes a prescription for a medicine for the patient and the medicine information is automatically created.

5. Primary Actor
The Primary Actor is the prescriber who is discussing and prescribing a patient’s medicines.

6. Additional/Supporting Actors
Secondary Actors:

- Patients
- Research team creating medicine information for patients
7. Stakeholders

Stakeholders:

- Pharmacists/their staff dispensing the medicines
- Other health care professionals involved in care
- Patients’ carers (if applicable)

8. Preconditions

1. The prescriber must be logged into and have entered patient details into the Patient Management System correctly.

2. The patient must be prescribed a recognisable medicine in the database.

3. If the patient wants to receive information digitally, they must have access to the internet.

4. The patient must be able to read and understand English (other languages could be created too).

5. Information must be stored within the system to allow the information to be tailored to patients’:
   a. name
   b. gender
   c. age and date of birth
   d. indication medicine is being taken for [an option for including this is required]
   e. dose of the medicine and directions for taking it

6. The tool needs to be aligned with e-health standards already in place in New Zealand e.g. SNOMED CT and the NZULM, be user friendly, and be automated and editable.
9. Main Success Scenario

1. Prescriber and patient choose a medicine for treating condition.

2. Prescriber enters patient details and medicine details into PMS.

3. Using information from the electronic health record, the medicine information tool will auto populate key counselling points for the prescriber to use during a consultation.

4. The prescriber can then create a leaflet by clicking a button. Using information from the electronic health record, the medicine information tool will auto-populate a personalised information leaflet for the patient.

5. Prescriber discusses key counselling points and relevant sections of leaflet.

6. Prescriber gives the patient the leaflet to take away.

7. The system notes that information about medicine given to patient.

8. Patient leaves consultation with prescription and information.

10. Extensions

4. Alternative: Patient wants digital information:

   1. Prescriber sends digital leaflet to patient either via email, or sends to patient portal.

   2. Patient receives digital leaflet.

   3. Confirmation of receipt stored in PMS and the system notes that information about medicine given to patient.

   4. Patient leaves consultation with prescription.

4. Alternative: Prescriber wants to give more or less information to patient:

   1. Prescriber can review all stored information about the medicine and can cut and paste leaflet sections in a ‘drag and drop’ format allowing creation of updated information leaflet.

   2. If wanted, the prescriber can tick a box to indicate if these sections are to be included for all future leaflets for patients, or for all leaflets for this specific medicine.
3. Prescriber discusses key counselling points and relevant sections of leaflet.
4. Prescriber gives the patient the leaflet to take away or sends digitally as described above.
5. The system notes that information about medicine has been given to the patient.
6. Patient leaves consultation with prescription and information.

5. **Alternative:** Patient wants further information via their patient portal:
   1. Prescriber sends digital leaflet to patient via patient portal.
   2. Patient receives digital leaflet.
   3. Confirmation of receipt stored in PMS.
   4. Once patient opens digital leaflet, the leaflet icon will change to indicate it has been opened (e.g. as emails have a closed envelope for unread and an open envelope for read mail).
   5. Patient can review all stored information about the medicine and can cut and paste leaflet sections in a ‘drag and drop’ format allowing creation of own information to refer to.

3. **Exception:** Insufficient information in electronic health record:
   1. Prescriber includes required information in patient record via medicine information tool.
   2. The medicine information tool can then carry on usual processing.
   3. Personalised medicine information can be given.

3. **Exception:** Medicine indication not included in stored medicine information:
   1. Prescriber prompted to enter the indication. They can select from the patient’s current condition list or another condition searched and selected (this also adds to the patient’s condition list in the PMS automatically). There will be the option to include more than one indication for the medicine.
   2. The medicine information tool can then carry on usual processing.
   3. Personalised medicine information can be given.
5. Exception: Patient does not want information about medicines:
   1. Prescriber does not print leaflet.
   2. The system notes a leaflet not given.

6. Exception: digital information not sent/received:
   1. The system notes a leaflet not given due to system error.
   2. Prescriber has option to send again.

11. Post Conditions

11.1. Success End Condition
The PMS notes that medicine information has been given.
The patient receives relevant and instructive information about their medicines.
The prescriber is confident the required information has been passed on to patient in order for them to take their prescribed medicines safely and effectively.

11.2. Minimal Guarantees
The prescriber is able to prescribe and manage patient information as per usual workflow if medicine information tool not in place.

11.3. Failure End Condition
The prescriber will not have information about medicines at their fingertips, assisting effective and personalised consultation with patients and enabling fulfilment of ethical obligations for informing patients. Their patient will have not have the access to well-designed information (i.e. as a personalised summary medicine information ‘leaflet’).

12. Frequency
Prescribers will see patients and prescribe medicines approx. 4 times per hour. At this time it is unknown how many times a leaflet will be created. Once the test medicine has been confirmed, more accurate frequencies can be calculated.
13. Special Requirements

13.1 Performance
The prescriber should have the relevant medicines information within 1 second (maximum 3 seconds) of entering the PMS. Leaflets should also be created within 1 second (maximum 3 seconds) of pushing the button.

13.2 Privacy
Patient details will not be available for review to any third party not involved in direct patient care.

13.3 Unmodifiable information
13.3.1 Patient specific information
The patient information details included in the leaflet will be obtained directly from the PMS. These details will not be able to be changed unless they are updated within the PMS. The details include:

   a. patient name
   b. patient sex
   c. patient age and date of birth
   d. indication medicine is being taken for [an option for including this is required]
   e. dose of the medicine and directions for taking it.

13.3.2. Medicine specific information
The information contained in the system will be obtained via an information ‘pool’ and is dragged and dropped from a Source template. The information sections contained in the ‘pool’ are not modifiable. The only changes able to be made will be if the information sections are to be included in the information leaflet or not. The information will be created by the research team and owned and hosted by the University of Otago.
13.4. Usability / Accessibility
Prescribers and patients must be able to view page in English. Prescribers will need access to the internet; patients wanting digital information will also require internet access.

13.5. Other
Once the program has been developed the research team will provide medicine information on a group of medicines (e.g. those for gout or hypertension), for initial piloting and analysis. Researchers are flexible as to whether piloting will be undertaken in a small subset of practitioners or will have a national roll out.

The project/trial will be deployed and available for use by general practitioners. In order to determine the usability, usefulness, and effectiveness of the alerts the solution will need to:

1. Record each time consultation points have been produced.
2. Record the prescriber’s interaction with an alert (i.e. engagement with the program).
3. Record the creation of the medicine information leaflet.

14. Next Steps and future extensions

14.1. Next Steps
Next Steps:

- Finalise requirements with system developers
- Create medicine information for use in practice
- Decide on medicines and conditions to for pilot

14.2. Future extensions
Many enhancements can be made to the medicine information tool once initial development, user testing, and piloting have been completed. User feedback is essential before future extensions can be developed.
Examples of possible future extensions for consideration:

- Further tailoring to health literacy levels
- Translation into different languages
- Different information for new medicine-users compared to chronic medicine-users
Appendix 15. Use Case [2]: Using an integrated information tool in dispensing systems to create personalised medicines information for patients

1. Description
The pharmacist decides to create patient-specific information about medicines for use at point-of-care. The medicine information tool uses the information about the patient held within the dispensing system, and information about the medicine to present information to the pharmacist that is personalised for their patient at the time of consultation. It will also provide an *individualised* medicines information leaflet for the patients to read and take away, and/or be sent to the patient’s portal for future reference.

2. Justification
Pharmacists have little time to talk to patients about medicines, let alone seek out relevant medicine information. Easily accessed personalised information could help pharmacists fulfil their ethical obligations to ensure patients are fully informed about their medicines.

In a recent study \(^{174}\) we determined that more than:

- 60% of pharmacists want their dispensing system to display key counselling points about medicines automatically tailored to their patient for use during consultation.
- 70% of pharmacists would like patients to receive a medicine information leaflet when they are dispensed a new medicine.
- 40% of pharmacists think that dispensing software that prompts to provide, and record the provision of the leaflet automatically would help them in providing leaflets to patients.
- 60% of pharmacists think the most beneficial leaflets would be a personalised summary leaflet tailored to patient requirements.
2.1. Information for patients

Patients do not always find leaflets useful and they often discard leaflets without reading them. Many studies over the last few decades have led to some improvement in medicine information for patients, however there is still much room for improvement; patients are often dissatisfied, considering leaflets to be poorly designed and difficult to understand. In a recent review article\textsuperscript{109} we determined the information that patients want included in their information leaflets:

**Box 1 Recommendations for content of medicine information leaflets**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the medicine</td>
<td>The name people are most familiar with (i.e. the brand of the dispensed drug) should also be included</td>
</tr>
<tr>
<td>Tailored information</td>
<td>Tailored information to indication a definite requirement. Age and gender are less important to patients but worth considering if possible</td>
</tr>
<tr>
<td>How a medicine works and the benefits of treatment</td>
<td>Include: why it is important to treat the disease and what would happen without treatment, whether the medicine is curative, preventative, or provides symptomatic relief, how long treatment will be required for</td>
</tr>
<tr>
<td>Dose</td>
<td>This information should only be included if it can be tailored to the patients specific regimen – i.e. personalised</td>
</tr>
<tr>
<td>How to take the medicine</td>
<td>Also include what to do if a dose is missed</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>How long to take the medicine for</td>
<td>For certain medicines also include what would happen if stopping medicines e.g. withdrawal symptoms from antiepileptic medicines, return of infection for antibiotics etc.</td>
</tr>
<tr>
<td>How to monitor the treatment’s effectiveness</td>
<td>Include when to return to the doctor if no benefit seen – i.e. antibiotics should start to show benefit within days compared to antidepressants which take weeks</td>
</tr>
<tr>
<td>Comprehensive list of risks</td>
<td>Important to include the action required if side-effects are experienced. Duration of risk would be helpful to include. Note design of side effect list is mentioned below</td>
</tr>
<tr>
<td>Numeric description of side-effects</td>
<td>As well as describing these numerically, e.g. as natural frequencies (e.g. three in 100 people), side-effects should be categorised by how likely they are to occur and how serious they are with details of what action is required if a side effect is experienced. Boxes or tables should be utilised for clarity with side-effects requiring immediate cessation of therapy or medical treatment listed first.</td>
</tr>
<tr>
<td>Long-term effects</td>
<td>Where applicable e.g. corticosteroids, benzodiazepines (addictive)</td>
</tr>
<tr>
<td>Monitoring requirements</td>
<td>Such as blood monitoring and usual frequency</td>
</tr>
<tr>
<td>Interactions</td>
<td>Focus should be on over-the-counter medicines and foodstuffs.</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------------------------------</td>
</tr>
<tr>
<td>Allergies and excipients</td>
<td>Evidence-based cross-reactivity should be included as well as excipients and any particular allergy concern</td>
</tr>
<tr>
<td>How to store a medicine</td>
<td>The general recommendation of keeping out of reach of children as well as specific requirements. Also should include how to dispose of medicines (e.g. fentanyl patches—ensure nobody can accidentally be exposed to remaining active ingredient)</td>
</tr>
<tr>
<td>Lifestyle information and general health tips</td>
<td>Lifestyle information about medicine or disease effects including driving, drinking, sexual activity etc. General health tips cover how to best self-manage disease e.g. healthy diet and exercise in diabetes</td>
</tr>
<tr>
<td>Details for more information</td>
<td>Where to see more detailed information leaflets, patient organisations, helpline numbers, and website addresses</td>
</tr>
<tr>
<td>Comparative information for alternative drug therapies and treatment options including non-pharmacological and natural medicine</td>
<td>This may be problematic as it could confuse some people and lead to anxiety in some cases. It would be necessary to tailor this information following discussion with patients and before treatment decisions are made to aid concordance. Information should be succinct and</td>
</tr>
</tbody>
</table>

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A new type of Medicine information leaflet

Much of the information listed above is either missing from current leaflets available (such as those available via New Zealand Formulary, Canterbury District Health Board, or some manufacturer produced information), or is written in such a way as to make leaflets too long and difficult to navigate and understand (e.g. some manufacturer produced information).

New information for patients will be created by the research team with review and input from practicing healthcare professionals. Information will be sourced from validated resources including the Medsafe approved Data Sheets and Consumer Medicine Information, New Zealand Formulary, and SafeRx. Our project will be a “proof of concept study” where we will develop and test one customisable leaflet for one condition. At a later date, we anticipate that we will work with collaborators to widen the number of medicines included.

2.2. Expected benefits

There will be written point-of-care information for pharmacists to use when speaking to patients in the form of key practice points particularly relevant for each patient. Patients would have a relevant personalised medicine information leaflet to take away, or a digital copy through their patient portal, for them to refer back to if needed.

The following benefits can be measured via user surveys:
• For pharmacists
  o Improvement in pharmacist-patient communications.
  o Improved confidence in information communicated during consultation with support of information tool.
  o Less time wasted searching for appropriate information to give to patient.
• For patients
  o The personalised nature of these leaflets will improve patients’ perceptions of the information leaflet and willingness to read it.
  o Increased patient knowledge about their medicines.
  o Improved intent to adhere to medicines.
  o Increased satisfaction with consultation.

3. Level
Summary (this Use Case occurs as part of a broader context of receiving information about medicines).

4. Trigger
The pharmacist dispenses a prescription for a medicine for the patient and the medicine information is automatically created.

5. Primary Actor
The Primary Actor is the pharmacist who is discussing a patient’s medicines.

6. Additional/Supporting Actors
Secondary Actors:
  • Patients
  • Research team creating medicine information for patients

7. Stakeholders
Stakeholders:
  • Pharmacy staff dispensing the medicines
• Prescribers
• Other health care professionals involved in care
• Patients’ carers (if applicable)

8. Preconditions

1. The pharmacist must be logged into and have entered patient details into the dispensing system correctly.
2. The patient must be prescribed a recognisable medicine in the database.
3. If the patient wants to receive information digitally, they must have access to the internet.
4. The patient must be able to read and understand English (other languages could be created too).
5. Information must be stored within the system to allow the information to be tailored to patients’:
   a. name
   b. gender
   c. age and date of birth
   d. indication medicine is being taken for [an option for including this is required]
   e. dose of the medicine and directions for taking it
6. The tool needs to be aligned with e-health standards already in place in New Zealand e.g. SNOMED CT and the NZULM, be user friendly, and be automated and editable.

9. Main Success Scenario

1. Pharmacist receives prescription from patient or directly from prescriber.
2. Pharmacist enters patient details and medicine details into dispensing system.
3. Using information from the electronic health record or, if unavailable, from their own system (with prompting for inserting further information if necessary), the medicine information tool will auto populate key counselling points for the pharmacist to use during a consultation.
4. The pharmacist can then create a leaflet by clicking a button. Using information from the electronic health record or, if unavailable, from their own system (with prompting for inserting further information if necessary), the medicine information tool will auto-populate a personalised information leaflet for the patient.

5. Pharmacist discusses key counselling points and relevant sections of leaflet.

6. Pharmacist gives the patient the leaflet to take away.

7. The system notes that information about medicine given to patient.

8. Patient leaves pharmacy with medicines and information.

10. Extensions

4. Alternative: Patient want’s digital information:

   1. Pharmacist sends digital leaflet to patient either via email, or sends to patient portal.

   2. Patient receives digital leaflet.

   3. Confirmation of receipt stored in dispensing system and the system notes that information about medicine given to patient.

   4. Patient leaves pharmacy with medicines.

4. Alternative: Pharmacist wants to give more or less information to patient:

   1. Pharmacist can review all stored information about the medicine and can cut and paste leaflet sections in a ‘drag and drop’ format allowing creation of updated information leaflet.

   2. If wanted, the pharmacist can tick a box to indicate if these sections are to be included for all future leaflets for patients, or for all leaflets for this specific medicine.

   3. Pharmacist discusses key counselling points and relevant sections of leaflet.
4. Pharmacist gives the patient the leaflet to take away or sends digitally as described above.

5. The system notes that information about medicine has been given to the patient.

6. Patient leaves pharmacy with medicines and information.

6. **Alternative:** Patient wants further information via their patient portal:

1. Pharmacist sends digital leaflet to patient via patient portal.

2. Patient receives digital leaflet.

3. Confirmation of receipt stored in dispensing system.

4. Once patient opens digital leaflet, the leaflet icon will change to indicate it has been opened (e.g. as emails have a closed envelope for unread and an open envelope for read mail).

6. Patient can review all stored information about the medicine and can cut and paste leaflet sections in a ‘drag and drop’ format allowing creation of own information to refer to.


2. **Exception:** Pharmacy technician is entering patient details into system:

1. Pharmacy technician confirms with pharmacist if a medicine information leaflet is required and details to be included.

2. The medicine information tool can then carry on usual processing.

3. Personalised medicine information can be given.

3. **Exception:** Insufficient information in electronic health record:

1. Pharmacist includes required information in patient record via medicine information tool.

2. The medicine information tool can then carry on usual processing.

3. Personalised medicine information can be given.

3. **Exception:** Medicine indication not included in stored medicine information:
1. Pharmacist prompted to enter the indication. They can select from the patient’s current condition list or another condition searched and selected (this also adds to the patient’s condition list in the dispensing system automatically). There will be the option to include more than one indication for the medicine. If not able to include indication, the leaflet will contain a general overview about how the medicine works with the following statement “please ask your prescriber to enter the reason your medicine has been prescribed the next time you visit”.

2. The medicine information tool then carries on with usual processing.

3. Personalised medicine information can be given.

5. **Exception**: Patient does not want information about medicines:
   1. Pharmacist does not print leaflet.
   2. The system notes a leaflet not given.

6. **Exception**: digital information not sent/received:
   1. The system notes a leaflet not given due to system error.
   2. Pharmacist has option to send again.

**11. Post Conditions**

**11.1. Success End Condition**

The dispensing system notes that medicine information has been given.

The patient receives relevant and instructive information about their medicines.

The pharmacist is confident the required information has been passed on to the patient in order for them to take their prescribed medicines safely and effectively.

**11.2. Minimal Guarantees**

The pharmacist is able to provide and manage patient information as per usual workflow if medicine information tool not in place.
11.3. Failure End Condition

The pharmacist will not have information about medicines at their fingertips, assisting effective and personalised consultation with patients and enabling fulfilment of ethical obligations for informing patients. Their patient will have not have access to well-designed information (i.e. as a personalised summary medicine information ‘leaflet’).

12. Frequency

Pharmacists will see patients and dispense medicines to an exceedingly variable extent. At this time it is unknown how many times a leaflet will be created. Once the test medicine has been confirmed, more accurate frequencies can be calculated.

13. Special Requirements
13.1. Performance

The pharmacist should have the relevant medicines information within 1 second (maximum 3 seconds) of entering the dispensing system. Leaflets should also be created within 1 second (maximum 3 seconds) of pushing the button.

13.2. Privacy

Patient details will not be available for review to any third party not involved in direct patient care.

13.3. Unmodifiable information
13.3.1. Patient specific information

The patient information details included in the leaflet will be obtained directly from the dispensing system. These details will not be able to be changed unless they are updated within the dispensing system. The details include:

a. patient name

b. patient sex

c. patient age and date of birth

d. indication medicine is being taken for [an option for including this is required]

e. dose of the medicine and directions for taking it.
13.3.2. *Medicine specific information*

The information contained in the system will be obtained via an information ‘pool’ and is dragged and dropped from a Source template. The information sections contained in the ‘pool’ are not modifiable. The only changes able to be made will be if the information sections are to be included in the information leaflet or not. The information will be created by the research team and owned and hosted by the University of Otago.

13.4. Usability / Accessibility

Pharmacists and patients must be able to view page in English. Pharmacists will need access to the internet; patients wanting digital information will also require internet access.

13.5. Other

Once the program has been developed the research team will provide medicine information on a group of medicines (e.g. those for gout or hypertension), for initial piloting and analysis. Researchers are flexible as to whether piloting will be undertaken in a small subset of practitioners or will have a national roll out.

The project/trial will be deployed and available for use by pharmacists. In order to determine the usability, usefulness, and effectiveness of the alerts the solution will need to:

1. Record each time consultation points have been produced.

2. Record the pharmacist’s interaction with an alert (i.e. engagement with the program).

3. Record the creation of the medicine information leaflet.
14. Next Steps and future extensions

14.1. Next Steps

Next Steps:

- Finalise requirements with system developers
- Create medicine information for use in practice
- Decide on medicines and conditions to for pilot

14.2. Future extensions

Many enhancements can be made to the medicine information tool once initial development, user testing, and piloting have been completed. User feedback is essential before future extensions can be developed.

Examples of possible future extensions for consideration:

- Further tailoring to health literacy levels
- Translation into different languages
- Different information for new medicine-users compared to chronic medicine-users.
Appendix 16. Questionnaires sent to vendors of GP patient management software

Questionnaire introduction

Prescribers have limited time to talk to patients about medicines, let alone seek out relevant medicine information. Providing patients with accessible personalised information could help General Practitioners (GPs) fulfil their ethical obligations to ensure patients are fully informed about their medicines.

In a recent study\(^1\) we found that more than:

- 70% of GPs want their patient management system to display key counselling points about medicines automatically tailored to their patient for use during consultation.
- 50% of GPs would like patients to receive a medicine information leaflet when they are prescribed a new medicine yet 30% of GPs report they do not think to use them at point-of-care.
- 50% of GPs think that prescribing software that prompts to provide and record the provision of the leaflet automatically, would help them in providing leaflets to patients.
- 50% of GPs think the most beneficial leaflets would be a personalised summary leaflet tailored to patient requirements.

We are undertaking a feasibility study to understand the viability of our proposed project (to develop systems for personalised patient information) and require information from New Zealand vendors to assist our planning. The questions in this study are related to the document *Use case for personalised medicine*, sent as a separate attachment.

Please read *Use case for personalised medicine* and the summary below before answering the questions.

Please note that the information you provide will be used in an anonymised manner.

Summary description of the project

The proposal is for a medicine information tool to be built into existing Patient Management Systems (PMS) in use in medical centres. This will allow fast and simple
information retrieval by the healthcare providers during consultation. The medicine information tool will use the information contained within the PMS about the patient along with details about the medicine to present information to the prescriber that is personalised for each patient. The information will be presented as key practice points particularly relevant for each patient, accessible at point-of-care. The tool will also provide an individualised medicines information leaflet that can be printed during consultation for the patients to read and take away; alternatively it could be emailed to the patient or sent to the patient’s portal for future reference.

**Questionnaire**

**Possible benefits to users**

1. Do you believe there is a need for a tool that could provide individualised medicines information to the prescriber? *(please select one option)*

   | Option                                                                 |  
|---------------------------------------------------------------|---|
| No, a tool is not necessary                                    |  
| No, most prescribers do not need a tool                        |  
| There is some need for a tool providing individualised medicines information for patients |  
| Yes, many prescribers would find this tool necessary            |  
| Yes, this tool is essential for prescribers’ practice          |  

**Any comments**

........................................................................................................................................................................
........................................................................................................................................................................

2. Do you believe that this tool would be used by prescribers? *(please select one option)*

| Option                                        |  
|-----------------------------------------------|---|
| No, prescribers would not use this tool       |  
| No, most prescribers would not use this tool  |  

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Some prescribers would use this tool
Yes, most prescribers would use this tool
Yes, all prescribers would use this tool

Any comments

3. Do you agree with the following statement:
Patients would like to be given personalised information as described in the Use Case? (please select one option)

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
</table>

Please explain your reasoning

4. Does your software currently allow prescribers to print medicines information leaflets?

☐ Yes

☐ No

a. If yes, where are these leaflets sourced from (e.g. NZF, Med+info)?
b. Do you know if this functionality is used? If so, can you give us any figures for how frequently it is used?

………………………………………………………………………………………………………………………………………………

Market Feasibility

1. Do you anticipate this project has future market potential?
   - Yes
   - No
   Any comments

………………………………………………………………………………………………………………………………………………

2. Do you anticipate the addition of the medicine information tool would influence potential buyers of your software?
   - Yes
   - No

3. If you were to develop the software, would it be (please select one option):
   - a. Included in your current software package for prescribers
   - b. Available as a subscription for purchase on top of current package
   - c. Other (please specify)

………………………………………………………………………………………………………………………………………………

4. Do you think the addition of the medicine information tool would increase sales of your product?
   - Yes
   - No
   If so, could you provide an estimate?
5. Do you think the medicine information tool would give you a market advantage over your competitors?

○ Yes

○ No

6. What current innovation do you believe sets you apart from other vendors?

Technical requirements

1. What additional materials or resources would be required to undertake this project? Please list the materials and quantity you estimate will be required (some examples included)

<table>
<thead>
<tr>
<th>Type of resource</th>
<th>Expected number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Servers</td>
<td></td>
</tr>
<tr>
<td>Computer Hardware and Software</td>
<td></td>
</tr>
<tr>
<td>Additional office space for employee(s)</td>
<td></td>
</tr>
<tr>
<td>Telephone with answering system</td>
<td></td>
</tr>
</tbody>
</table>

2. Please indicate current or additional employees that would be required to undertake this project. Assume the research team would be providing the clinical information required for the medicine information tool.
<table>
<thead>
<tr>
<th>Type of employee</th>
<th>Number of Full Time Equivalents (FTEs, 1 FTE = 40 hours/week)</th>
<th>Time employee to be dedicated to project (e.g. in weeks or months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Management</td>
<td></td>
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<tr>
<td>Project Management</td>
<td></td>
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<tr>
<td>Software Developer</td>
<td></td>
<td></td>
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<tr>
<td>Additional clinical support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Are there any other technology requirements not previously mentioned, needed to undertake this project?

- [ ] Yes
- [ ] No

If so, what would these be?

........................................................................................................................................
........................................................................................................................................

Financial requirements

1. What would you estimate the total start-up cost of this project to be?

   (Assuming the information about the medicines being provided will be paid for elsewhere)

........................................................................................................................................
........................................................................................................................................

2. If this was a project that was being undertaken by your company, would external investment be required?

- [ ] Yes
- [ ] No
3. Does your company currently set aside funding for new projects?
   - Yes
   - No

4. Overall, do you believe this project would provide return on investment?
   - Yes
   - No

Scheduling feasibility

1. How long do you estimate it would take to create the software for this project?
   - Please select one option
   - 3–6 months
   - 7 months–1 year
   - Other (please specify)

2. Would this project be disruptive to your current work schedules?
   - Yes
   - No

Barriers

1. Aside from the time and cost, what other barriers to this project would you consider there are?

2. Would you foresee any concerns about data protection with the implementation of this project?
   - Yes
   - No
If so, what could these be?

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…………………………………………………………………………………………………………………………

3. Are there any other potential problems that could occur if this project is pursued?

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…………………………………………………………………………………………………………………………

In conclusion

1. Do you think this project is one that would be worth pursuing for your company?
   ○ Yes
   ○ No

   (NB this is not a commitment to being involved in the project, however if this of interest to you, please contact the research team)

2. What is your company’s overall philosophy and/or goal?

…………………………………………………………………………………………………………………………
…………………………………………………………………………………………………………………………
…………………………………………………………………………………………………………………………

3. Would this project help your company meet this philosophy or goal?
   ○ Yes
   ○ No

4. Do you have any other comments you would like to add?

…………………………………………………………………………………………………………………………
…………………………………………………………………………………………………………………………
Appendix 17. Questionnaires sent to vendors of pharmacy dispensing software

Questionnaire introduction

Pharmacists have limited time to talk to patients about medicines, let alone seek out relevant medicine information. Providing patients with accessible personalised information could help pharmacists fulfil their ethical obligations to ensure patients are fully informed about their medicines.

In a recent study\textsuperscript{174} we found that more than:

- 60\% of pharmacists want their patient management system to display key counselling points about medicines automatically tailored to their patient for use during consultation.
- 70\% of pharmacists would like patients to receive a medicine information leaflet when they are dispensed a new medicine.
- 40\% of pharmacists think that dispensing software that prompts to provide, and record the provision of the leaflet automatically would help them in providing leaflets to patients.
- 60\% of pharmacists think the most beneficial leaflets would be a personalised summary leaflet tailored to patient requirements.

We are undertaking a feasibility study to understand the viability of our proposed project (to develop systems for personalised patient information) and require information from New Zealand vendors to assist our planning. The questions in this study are related to the document \textit{Use case for personalised medicine}, sent as a separate attachment.

Please read \textit{Use case for personalised medicine} and the summary below before answering the questions.

Please note that the information you provide will be used in an anonymised manner.

Summary description of the project

The proposal is for a medicine information tool to be built into existing dispensing software in use in pharmacies. This will allow fast and simple information retrieval by the healthcare providers during consultation. The medicine information tool will use
the information contained within the dispensing software about the patient along with details about the medicine to present information to the pharmacist that is personalised for each patient. The information will be presented as key practice points particularly relevant for each patient, accessible at point-of-care. The tool will also provide an individualised medicines information leaflet that can be printed during consultation for the patients to read and take away; alternatively it could be emailed to the patient or sent to the patient’s portal for future reference.

Questionnaire

Possible benefits to users

1. Do you believe there is a need for a tool that could provide individualised medicines information to the pharmacist? (*please select one option*)

<table>
<thead>
<tr>
<th>Option</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No, a tool is not necessary</td>
<td></td>
</tr>
<tr>
<td>No, most pharmacists do not need a tool</td>
<td></td>
</tr>
<tr>
<td>There is some need for a tool providing individualised medicines information for patients</td>
<td></td>
</tr>
<tr>
<td>Yes, many pharmacists would find this tool necessary</td>
<td></td>
</tr>
<tr>
<td>Yes, this tool is essential for pharmacists’ practice</td>
<td></td>
</tr>
</tbody>
</table>

Any comments

…………………………………………………………………………………………………………………………………………

…………………………………………………………………………………………………………………………………………

2. Do you believe that this tool would be used by pharmacists? (*please select one option*)

<table>
<thead>
<tr>
<th>Option</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No, pharmacists would not use this tool</td>
<td></td>
</tr>
<tr>
<td>No, most pharmacists would not use this tool</td>
<td></td>
</tr>
<tr>
<td>Some pharmacists would use this tool</td>
<td></td>
</tr>
</tbody>
</table>
3. Do you agree with the following statement:
Patients would like to be given personalised information as described in the Use Case? (please select one option)

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
</table>

Please explain your reasoning

4. Does your software currently allow prescribers to print medicines information leaflets?

- [ ] Yes
- [ ] No

a. If yes, where are these leaflets sourced from (e.g. NZF, Med+info)?

b. Do you know if this functionality is used? If so, can you give us any figures for how frequently it is used?
Market Feasibility

1. Do you anticipate this project has future market potential?
   - Yes
   - No

Any comments

2. Do you anticipate the addition of the medicine information tool would influence potential buyers of your software?
   - Yes
   - No

3. If you were to develop the software, would it be *(please select one option)*:
   - a. Included in your current software package for pharmacists
   - b. Available as a subscription for purchase on top of current package
   - c. Other (please specify)

4. Do you think the addition of the medicine information tool would increase sales of your product?
   - Yes
   - No

   If so, could you provide an estimate?

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5. Do you think the medicine information tool would give you a market advantage over your competitors?

- Yes
- No

6. What current innovation do you believe sets you apart from other vendors?

Technical requirements

1. What additional materials or resources would be required to undertake this project? Please list the materials and quantity you estimate will be required (some examples included)

<table>
<thead>
<tr>
<th>Type of resource</th>
<th>Expected number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Servers</td>
<td></td>
</tr>
<tr>
<td>Computer Hardware and Software</td>
<td></td>
</tr>
<tr>
<td>Additional office space for employee(s)</td>
<td></td>
</tr>
<tr>
<td>Telephone with answering system</td>
<td></td>
</tr>
</tbody>
</table>

2. Please indicate current or additional employees that would be required to undertake this project. Assume the research team would be providing the clinical information required for the medicine information tool.
<table>
<thead>
<tr>
<th>Type of employee</th>
<th>Number of Full Time Equivalents (FTEs, 1 FTE = 40 hours/week)</th>
<th>Time employee to be dedicated to project (e.g. in weeks or months)</th>
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<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Are there any other technology requirements not previously mentioned, needed to undertake this project?

- [ ] Yes
- [ ] No

If so, what would these be?

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Financial requirements

1. What would you estimate the total start-up cost of this project to be?
   (Assuming the information about the medicines being provided will be paid for elsewhere)

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2. If this was a project that was being undertaken by your company, would external investment be required?
   - Yes
   - No

3. Does your company currently set aside funding for new projects?
   - Yes
   - No

4. Overall, do you believe this project would provide return on investment?
   - Yes
   - No

Scheduling feasibility

1. How long do you estimate it would take to create the software for this project? 
   *(please select one option)*
   - 3–6 months
   - 7 months–1 year
   - Other (please specify)

2. Would this project be disruptive to your current work schedules?
   - Yes
   - No

Barriers

1. Aside from the time and cost, what other barriers to this project would you consider there are?

2. Would you foresee any concerns about data protection with the implementation of this project?
   ○ Yes
   ○ No
   If so, what could these be?
   ........................................................................................................................................
   ........................................................................................................................................

3. Are there any other potential problems that could occur if this project is pursued?
   ........................................................................................................................................
   ........................................................................................................................................

In conclusion

1. Do you think this project is one that would be worth pursuing for your company?
   ○ Yes
   ○ No
   (NB this is not a commitment to being involved in the project, however if this of interest to you, please contact the research team)

2. What is your company’s overall philosophy and/or goal?
   ........................................................................................................................................
   ........................................................................................................................................

3. Would this project help your company meet this philosophy or goal?
   ○ Yes
   ○ No

4. Do you have any other comments you would like to add?
   ........................................................................................................................................
   ........................................................................................................................................
Appendix 18. Ethical approval D18/285

D18/285

31 August 2018

Dr A Smith
School of Pharmacy

Dear Dr Smith,

I am writing to confirm for you the status of your proposal entitled “Feasibility study about developing systems for personalised patient information and printed leaflets”, which was originally received on August 23, 2016. The Human Ethics Committee’s reference number for this proposal is D18/285.

The above application was Category B and had therefore been considered within the Department or School. The outcome was subsequently reviewed by the University of Otago Human Ethics Committee. The outcome of that consideration was that the proposal was approved.

Approval is for up to three years from the date of HOD approval. If this project has not been completed within three years of this date, re-approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

Yours sincerely,

[Signature]

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8256
Email: gary.witte@otago.ac.nz
Appendix 19. Study protocol

Background
In New Zealand, more than 25,000 patients are diagnosed with new cancer each year and over 69,000 are receiving oral chemotherapy in the community. There are also over 1000 hospital admissions each year because of adverse events from community-dispensed chemotherapies. Toxicity can often be avoided or minimised through early identification and management.

Currently, community-based patients phone either the oncology nurse or the ward if they experience a side-effect. This system relies on patients’ willingness to ring for help or advice.

Aims of project:

1. To explore participants’ perceptions of how they were given information about their chemotherapy, whether they understood this information and could act on it, and whether or not they think this process could be improved.

2. To ascertain participants’ thoughts on using a possible online tool/system that could convey information about chemotherapy medicines

Methods
Participation
We will be holding four focus groups sessions, each with between 6-8 people who meet the selection criteria:

- 18 years of age and over.
- Have previously had chemotherapy and are in remission
- Can read and speak English.

Those who are under 18 years of age, who are currently using chemotherapy medicines, or cannot read or speak English, will be unable to participate in these focus groups. We will not be asking for specific information about participants’ cancer or their treatment.

The first focus group will be a group from the general population from in and around Dunedin. The second will be Māori participants from the local population in and around Dunedin. The third will be Māori participants from a different area of New Zealand (recruitment will be from Northland). The fourth will be with the general population from a more rural/remote location (e.g. Southland).

Recruitment
The recruitment process for people who have been through chemotherapy will be through a number of avenues including local support groups (e.g. the Otago-Southland division of the Cancer Society, EXPINKTM the University of Otago Physical Education School’s exercise programme for women who have had breast cancer surgery), through contacts in oncology organisations in Northland, and through local Māori contacts. We will ask the leaders of these organisations to advertise the project to their members/patients through posters and/or email (if appropriate). Members can contact the research team if they are interested in participating. They will then be provided with a participant information sheet either by post or by email (according to their preference). The participant information sheet has the contact details for the study team for if they have any questions about the study before participating.
Consultation with Māori advisors has been undertaken about recruitment for this study. Through this consultation we have been given valuable contacts to aid our recruitment process. We will also ensure that kai will be provided during the focus group sessions and whānau can accompany participants if they would like them to attend.

The informed consent form will be completed at the beginning of the focus group sessions.

Location of the focus group sessions
The focus groups in Dunedin and Invercargill will be conducted at University of Otago facilities. The focus group in Northland will be conducted at a location such as a community centre or the Cancer society.

Structure of focus group session
The structure of the meeting will be outlined at the start of the meeting. Each focus group will have four parts:

- Questionnaire;
- Focus group discussion about items from questionnaire;
- Capturing Patient Reported Outcomes (PROs) using an online tool;
- Participants’ thoughts on the online tool for capturing Patient Reported Outcomes (PROs).

The first part will be a questionnaire that the focus group members will be asked to complete on their own in the first 5-10 minutes of the meeting. The second part will be a group discussion of the questionnaire and with wider discussion of the topics covered in the questionnaire.

The third part will involve introducing the group to the concept of using an online tool to capture Patient Reported Outcomes (PROs) and how this could be used to provide patients with personalised medicine-management advice.

The fourth part will be discussion of the possibility of using an online tool to determine participants’ ideas about the use of this tool and participants’ thoughts about the advantages/disadvantages of using this for people undergoing chemotherapy.

See below for the focus group outline for more detailed information including the questionnaire to be provided to participants, further questions for discussion, and for information about the online tool.

Consultation with Māori advisors has been undertaken regarding the content of the questionnaire. Following their review, adjustments were made to improve cultural appropriateness.

Those who indicated that they are interested in participating will be provided with a paper or digital version of a Participant Information Sheet (PIS) (attached to ethics application) to read and they can then ask the researcher questions if needed. A consent form will be provided at the beginning of the focus group session.

Upon completion of the survey, participants will receive a $20 supermarket voucher.
Focus group outline
The focus group meeting will involve four parts: i) the individual questionnaire; ii) the discussion about items from questionnaire; iii) capturing Patient Reported Outcomes (PROs) using an online tool (i.e. the introduction of the online tool); and iv) participants’ thoughts on the online tool for capturing PROs.

Part one: Individual questionnaire
The first part consists of a questionnaire. The participants will be asked to complete the questionnaire on their own in the first 5-10 minutes of the meeting. The questionnaire will be provided to participants on a separate standalone document.

Questionnaire for participants
Thank you for showing an interest in this project. We are wanting to know about how you were given information about your chemotherapy before it was started and if this information was suited to you.

This part is about the information on possible side-effects that you were given before you started chemotherapy

1. Thinking about the information you were told about possible side-effects, please tick ONE box on each line below to tell us whether you agree or disagree with the statements:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a) The information was easy to understand</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1b) The information was given to me in a way that helped me to understand it</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>1c) There was too much information given</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1d) There was not enough information given</td>
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<td></td>
<td></td>
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<tr>
<td>1e) I was told how to get more information if I wanted it</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
2. Were you given useful information to take away with you about what to do if you experienced a side-effect with your chemotherapy treatment?

☐ Yes

☐ No (go to question 8)

3. Thinking about the information you were given to take away with you, please tick ONE box on each line below to tell us whether you agree or disagree with the statements:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>3a) The information was easy to understand</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3b) There was too much information given</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3c) There was not enough information given</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3d) I read this information at home</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3e) The information was useful to me at a later time</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Any comment/s?

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410
4. Did you share and discuss this information with anyone else?

- Yes
- No (go to question 6)

5. Who did you share this information with?

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6. Did you follow the information given to you if you experienced a side-effect?

- Yes (go to question 8)
- No
- Sometimes

7. Why did you not follow this information all of the time? You can tick all the boxes that apply to you

- Couldn’t find it
- Couldn’t remember it
- It wasn’t relevant to my symptom/s
- Too difficult to understand
- Other

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8. Did you feel prepared about what to do and who to contact if you had a side-effect from your medicine?

- Yes
- No
- Any comments?

..............................................................................................................................................................................................................................................................................................................................................................................................

411
Some information about you
This part is about your background and use of technology

9. Are You
   - Male
   - Female
   - Gender diverse

10. What year were you born?

11. Which ethnic group do you belong to?
   - New Zealand European
   - Māori
   - Samoan
   - Cook Islands Māori
   - Tongan
   - Niuean
   - Chinese
   - Indian
   - Other (Please state: e.g. Dutch, Japanese, Tokelauan)

12. What type of cancer did you receive treatment for?
13. How often do you usually use the internet on a computer and/or smart device (tablet or smart phone)?
   - Never (go to question 14)
   - A couple of times in the last year
   - About once or twice a month
   - About once or twice a week
   - Often/daily

14. If you use a computer and/or smart device (tablet or smart phone), what are your typical activities on these? You can tick all the boxes that apply to you
   - Buy or make a reservation for travel
   - Email or instant messaging/chat
   - Look up a recipe
   - Look for health/medical info
   - Look for info on a hobby or interest
   - Read the news/weather/sports/blog
   - Online banking or bill paying
   - Shopping
   - Web searches
   - Playing games
   - Watch videos

15. In the last year, how often have you visited a web site to locate health information?
   - A couple of times in the last year
   - About once or twice a month
Part two: Focus group discussion about items from questionnaire
The second part of the meeting will consist of a group discussion of the questionnaire facilitated by Amber Young and/or Alesha Smith. This will involve a wider discussion of the topics covered in the questionnaire in part one.

In this part we will start off by discussing what the participants think might be good for improving the medicine information services for oncology patients.

a. How were they given the information about their treatment and the possible side-effects (e.g. verbal only, written, web addresses)?
b. Could this process of receiving information have been easier?
c. Do participants think the information and how it is given is appropriate for someone from their culture? E.g. Māori or other culture
d. Do they feel this could be improved in any way?

We will also discuss

e. If the information helped them feel well-prepared for any possible side-effects?
f. What they did if they experienced a side-effect and needed help
g. If they looked for information themselves from other sources?

Part three: Capturing Patient Reported Outcomes (PROs) using an online tool
In this part we will describe the use of an online tool to capture Patient Reported Outcomes (PROs) and how this could electronically provide patients with personalised medicine-management advice. We will give a brief summary of what is happening internationally. We will provide participants with the information below. The information for participants will be provided on a separate standalone document.

Information provided to participants
Many oncology services in New Zealand use the UK oncology nursing society traffic light tool when talking to patients about the chemotherapy side-effects they have experienced. The common side-effects that can cause severe problems for patients are contained in the traffic light tool e.g. nausea and vomiting, diarrhoea, pain, and fatigue. By following the questions in the traffic light tool, oncology staff (usually ward nurses) can classify the severity of patients’ symptoms into traffic light colours:

- Green is considered mild, the side-effect can be managed at home; the nurses can provide advice on self-management.
- Amber is considered moderate, the side-effect that may be managed at home; if more than one Amber side-effect occur then consideration is given to bringing the patient to hospital for review.
• Red is considered severe, the patient requires prompt management by oncology team.

There are a number of hospitals in the UK and Europe who are trialling an online tool or application that has taken the traffic light tool and turned it into a questionnaire that patients can complete themselves on the internet. Depending on how patients answer the questions, the tool will provide them with information on how to manage their side-effects at home or will inform them that they need to visit the hospital. (This is similar to the advice a nurse would provide if a patient were to contact them over the phone). The information that patients put into the system will also be automatically logged in their hospital record and will alert the ward staff when the patient requires a review with a hospital staff member. The tool is a secure portal that only patients and the hospital can access.

This tool is designed to help provide patients with appropriate information quickly that is easy to follow. The other potential benefit is that the patient’s hospital records are up to date with how they are tolerating their chemotherapy.

Requirements for this tool are: ready access to a computer, laptop, or smart device (such as tablet or smartphone) and access to the internet.

What we are wanting to know is if this tool would be suitable for use in New Zealand. That is why we are wanting to discuss this with you today.

Part four: Participants’ thoughts on the online tool for capturing Patient Reported Outcomes (PROs)
The fourth part will be discussion of the online tool for capturing Patient Reported Outcomes to determine participants’ ideas about the use of this tool and their thoughts about the benefits of this for patients undergoing chemotherapy.

The following discussion points will be used:

a. Do you think this online tool that we discussed would be something you would be able to use or like to use?
b. What would you like about using the tool for a side-effect you experience? Would you also like to use this to look for other information about your treatment?
c. What concerns would you have about using the tool to report a side-effect or to receive information?
d. What would be useful about using this tool?
e. Would you prefer to use the tool or to telephone the hospital?

Analysis of data
The data from the questionnaire will be entered into data management software and basic descriptive analysis will be undertaken. The focus group data will be transcribed verbatim and a thematic analysis will be completed by Amber Young.
Dissemination of information
The data gathered in this study will be used to form a chapter of Amber Young’s thesis for PhD candidature. Other uses of the data to be used by the research team include an article for publication and conference proceedings.

If the participants indicate they are wanting to be informed of the results, we can record their details independently of the study recordings and create a list of those who want to be informed. We will then send out the documentation once the study review has been completed e.g. once an article has been accepted for publication.
Appendix 20. Ethical approval H19/144

Ethical approval (original)

Dear Dr. Smith,

I am again writing to you concerning your proposal entitled “Receiving information about chemotherapy medicines”, Ethics Committee reference number H19/144.

Thank you for your email of 13th December 2019 with response attached addressing the issues raised by the Committee.

On the basis of this response, I am pleased to confirm that the proposal now has full ethical approval to proceed.

The standard conditions of approval for all human research projects reviewed and approved by the Committee are the following:

Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.

**Final report:** A Final Report is required by the Committee upon completion of the study. The Final Report template can be found on the Human Ethics Web Page

[https://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html](https://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html)

**Adverse or unforeseen events:** Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Academic Committees Office by no later than the next working day after recognition of an adverse occurrence/event. Please note that in cases of adverse events an incident report should also be made to the Health and Safety Office:

**Discontinuation:** Advise the Committee in writing as soon as practicable if the research project is discontinued.

**Amendments:** Make no change to the project as approved in its entirety by the Committee, including any wording in any document approved as part of the project, without prior written approval of the Committee for any change. If you are applying for an amendment to your approved research, please email your request to the Academic Committees Office:

gary.witte@otago.ac.nz
jo.farronadediaz@otago.ac.nz

**Locality authorisation:** Studies requiring locality authorisation, i.e. permission from the organisations at which the study is taking place or from which participants are being accessed, must be confirmed before the study commences.

**Approval period:** Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval or an extension of approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

Yours sincerely,

[Signature]

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8256
Email: gary.witte@otago.ac.nz

c.c. Professor C Marra Dean School of Pharmacy
Dear Dr Smith,

I am again writing to you concerning your proposal entitled "Receiving information about chemotherapy medicines", Ethics Committee reference number H19/144.

Thank you for your email of 11th March 2020 requesting an amendment to the above study.

We note that following consultation with Māori advisors it was felt that you may have difficulty in recruiting Māori participants and may struggle to get attendance at the focus group meeting. As a contingency we note the research team now plan to hold one-to-one interviews with Māori participants if sufficient numbers are not recruited into the focus groups.

The Committee accepts and approves the amendment requested.

Your proposal continues to be fully approved by the Human Ethics Committee. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing. I hope all goes well for you with your upcoming research.

Yours sincerely,

[Signature]

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8256
Email: gary.witte@otago.ac.nz

[cc: Professor C Marra Dean School of Pharmacy]
Receipt of information about chemotherapy medicines

The Ngāi Tahu Research Consultation Committee (the Committee) met on Tuesday, 12 November 2019 to discuss your research proposal.

By way of introduction, this response from the Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the Memorandum it states “Ngāi Tahu acknowledges that the consultation process outlined in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago.” As such, this response is not “approval” or “mandate” for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology as they are separate requirements with other committees, for example, the Human Ethics Committee.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

“Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal.”

The Committee considers the research to be of importance to Māori health and commends the submission which addresses concerns for Māori.

The Committee recommends consultation with the local papatipu Runaka, Te Rūnanga o Holonui, Te Rūnanga o Moeraki, Kītikō Huirapa Runaka i Puketeraki and Te Rūnanga o Otago which may be able to assist in soliciting potential participants. The Committee also suggests consulting with Te Kāiko Health Services Community, in Dunedin.

The Ministry of Health website http://www.health.govt.nz/publications contains a list of.

The Ngāi Tahu Research Consultation Committee has membership from:
Māori health publications some of which may be useful if not already known: Te Ara Tika, Guidelines for Māori research ethics: A framework for researchers and ethics committee members; Māori Health Advancement Guidelines, HRC 2019; Vision Matauranga; Ngā Pou Rangahau, The Strategic Plan for Māori Health Research. These publications provide information on a range of Māori health issues and may assist in guiding your research with an appropriate Māori health focus.

The Committee suggests dissemination of the research findings to Māori health organisations regarding this study.

This letter of suggestion, recommendation and advice is current for an 18-month period from Tuesday, 12 November 2019 to 1 April 2021. The Committee requests a copy of the research findings.

The recommendations and suggestions above are provided on your proposal submitted through the consultation website process. These recommendations and suggestions do not necessarily relate to ethical issues with the research, including methodology. Other committees may also provide feedback in these areas.

Nāihaku noa, nā

Claire Porima
Kaiwhakahaere Rangahau Māori
Office of Māori Development
Te Whare Wānanga o Ōtākou
Ph: +64 3 4758081
Email: claire.porima@otago.ac.nz
Web: www.otago.ac.nz

The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kōti Heiura Rūnanga ki Poāneke
Te Rūnanga o Moweka
Appendix 21. Participant Information Sheet

Participant Information Sheet

<table>
<thead>
<tr>
<th>Study title:</th>
<th>Receiving information about chemotherapy medicines</th>
</tr>
</thead>
</table>
| Principal investigator: | Dr Alesha Smith  
School of Pharmacy  
Senior Lecturer | Contact phone number:  
03 479 5052 |

Introduction

If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

This study is being carried out by researchers at the School of Pharmacy, University of Otago. This project is being undertaken by Amber Young as part of her PhD.

What is the aim of this research project?

The Aim of project is to find out the views of people who have had chemotherapy about:

- How they were given the information about their chemotherapy, whether they understood this and could act on the information given, and whether or not they think this could be improved.
- Using a possible online tool/system that could convey information about chemotherapy medicines.

Who is funding this project?

This project is funded by the University of Otago.

Who are we seeking to participate in the project?

We are seeking participants 18 years of age and over who have taken chemotherapy medicines for cancer but are not currently on these medicines. We will be holding four focus group discussions with 6-8 people in each group.
Two groups will involve the general population; one will be urban-based and one will be rural-based. The other two groups will involve the Māori population; one will be urban-based and one will be rural-based.

We are seeking participants through local support groups and oncology services who meet the selection criteria:

- 18 years of age and over.
- Have previously had chemotherapy.
- Can read and speak English.

Those who are under 18 years of age, who are currently using chemotherapy medicines, or cannot read or speak English, will be unable to participate in these focus groups.

**If you participate, what will you be asked to do?**

Should you agree to take part in this project, you will be asked to attend a focus group discussion. This will involve answering a short questionnaire in the first 5-10 minutes, then participating in further discussion in a group about the medicine information you received concerning your chemotherapy, and possible ways this information could be provided differently.

We expect the focus group session to last approximately one hour.

Please be aware that you may decide not to take part in the project without any disadvantage to yourself.

As a thank you for participating, you will receive a $20 supermarket voucher.

**Is there any risk of discomfort or harm from participation?**

No, you will be asked to share your experiences and opinions about receiving information about medicines.

**What specimens, data or information will be collected, and how will they be used?**

The discussions will be recorded and then transcribed by a member of the research team. This project involves an open-questioning technique. The general line of questioning includes how you were given information about your medicines, if this information was easy to understand, how you think information provision could be improved, and your views on possibly using an online tool to report side-effects and receive self-management information. The precise nature of the questions that will be asked have not been determined in advance, but will depend on the way in which the interview develops. Consequently, although the University of Otago ethics committee is aware of the general areas to be explored in the interview, the Committee has not been able to review the precise questions to be used.

In the event that the line of questioning does develop in such a way that you feel hesitant or uncomfortable you are reminded of your right to decline to answer any particular question(s).
The results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve your anonymity. You are most welcome to request a copy of the results of the project should you wish. If so, your name and contact details will be kept on a separate list, and not linked to your questionnaire responses.

What about anonymity and confidentiality?

The written information provided in the questionnaires will be retained at the University in a locked storage unit with access only by the research team. We will ask questions about your age, sex, ethnicity, and computer use but will not be requiring any identifiable information.

The recording and transcription will be retained on a password protected computer. The data collected will be securely stored in such a way that only the members of the research team will be able to gain access to it. Data obtained as a result of the research will be retained for at least 10 years in secure storage. Any personal information held on the participants (such as name and contact details following recruitment) may be destroyed at the completion of the research even although the data derived from the research will, in most cases, be kept for much longer or possibly indefinitely.

No material that could personally identify you will be used in any reports on this study. Results of this research may be published. The data from this project will be publicly archived so that it may be used by other researchers.

If you agree to participate, can you withdraw later?

You may withdraw from participation in the project at any time before or during the focus group meeting without any disadvantage to yourself. After the focus group meeting, withdrawal will not be possible because de-identified information will already be integrated into the study.

Any questions?

If you have any questions now or in the future, please feel free to contact either:

<table>
<thead>
<tr>
<th>Amber Young</th>
<th>Contact phone number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PhD candidate</td>
<td>03 479 7321</td>
</tr>
<tr>
<td>School of Pharmacy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contact email:</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:amber.young@postgrad.otago.ac.nz">amber.young@postgrad.otago.ac.nz</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dr Alesha Smith</th>
<th>Contact phone number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Lecturer</td>
<td>03 479 5052</td>
</tr>
<tr>
<td>School of Pharmacy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contact email:</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:Alesha.smith@otago.ac.nz">Alesha.smith@otago.ac.nz</a></td>
</tr>
</tbody>
</table>
This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Appendix 22. Research Grants applied for during candidature

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Name of Grant</th>
<th>Amount of grant</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 May 2018</td>
<td>Self-monitoring and reporting of medicine adverse effects in oncology patients</td>
<td>Otago Innovation Proof of Concept Grant, Otago innovation a University of Otago company</td>
<td>NZ$60,000</td>
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<tr>
<td>3 September 2018</td>
<td>Self-monitoring and reporting of medicine adverse effects in oncology patients</td>
<td>Lottery Health Research 2018/19 grants, New Zealand Lottery Grants Board</td>
<td>NZ$190,994</td>
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<td>2 October 2018</td>
<td>Do lifestyle factors influence chemotherapy toxicities</td>
<td>Regular Grant Programme 2018/2019 Seed Grants Application, World Cancer Research Fund</td>
<td>UK£60,000</td>
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<tr>
<td>10 October 2018</td>
<td>Self-monitoring and reporting of medicine adverse effects in oncology patients</td>
<td>National Research Grant Round 2019, Cancer Society of New Zealand</td>
<td>NZ$127,399</td>
</tr>
<tr>
<td>15 February 2019</td>
<td>On-line advice for self-monitoring adverse effects of chemotherapy in breast cancer patients</td>
<td>Innovation and Technology in Breast Cancer, Breast Cancer Foundation New Zealand Research Grant Programme</td>
<td>NZ$118,498</td>
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<tr>
<td>21 March 2019</td>
<td>Revolutionising chemotherapy treatments by predicting adverse effects and optimising care</td>
<td>National Science Challenge Seed Projects 2019, Science for Technological Innovation (SfTI)</td>
<td>NZ$230,000</td>
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</tbody>
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