



Contents lists available at ScienceDirect

Research in Social and Administrative Pharmacy

journal homepage: www.elsevier.com/locate/rsap

Clinical decision-making: An essential skill for 21st century pharmacy practice

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ARTICLE INFO

Keywords:

Decision-making
Clinical-reasoning
Clinical-judgement
Pharmacy practice
Education

ABSTRACT

Clinical decision-making skills are recognized as a central component of professional competency but are under-developed in pharmacy compared to other health professions. There is an urgent need for a comprehensive understanding of how pharmacists can best develop and use therapeutic decision-making skills in clinical practice. The aims of this commentary are to define clinical decision-making in pharmacy practice, and to present a model for clinical decision-making that aligns with a philosophical framework for pharmacy practice. The model has utility in education programs for pharmacists and provides a framework for understanding patient-facing clinical services in practice.

1. Introduction

In the seminal paper by Donald Brodie, “Drug-use control: keystone to pharmaceutical service”,¹ it was argued that pharmacy lacked a crucial ingredient to unify and define the profession, which he termed a ‘body of practice’. He noted that the prevailing practice model focused predominantly on the manufacture and sale of medicines. Dispensing, he argued, while important, was not a role that would allow pharmacists to fully extend their professional scope. Brodie proposed the concept of ‘drug-use control’, essentially a patient-centered clinical role, as a core function for the pharmacy profession across all practice settings.¹

The sentiment that pharmacy should fully embrace a patient-facing clinical role as a central component of practice has been repeated several times over the past few decades. The findings of the Millis Commission,^{2,3} and the Nuffield Report⁴ stressed that pharmacy should be foremost a clinical profession. However, it was not until 1989 that a coherent ‘body of practice’ was proposed with the publication of Hepler and Strands seminal work on pharmaceutical care.^{5,6} Pharmaceutical care was defined as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life”.⁵ Hepler and Strand suggested that the central purpose of the pharmacy profession should be to ensure the safe and effective use of medicines. Pharmaceutical care was seen as a professional orientation that would facilitate the transition from a traditional focus on dispensing and manufacturing to a practice model focused on clinical services.

In the decades since the introduction of pharmaceutical care, there has been a gradual maturation of pharmacy as a clinical profession. This change has been driven, in part, by the efforts of government bodies, educators, and professional organizations who have raised the issue that pharmacists are under-utilized in modern health care (see for example^{7–11}). The end result is that pharmacists in all practice settings are now increasingly expected to provide a variety of clinical services including, for example, vaccination, anticoagulant monitoring, medicines review services, and prescribing. In many cases, pharmacists are expected to be active members of the health care team with direct responsibility for designing and implementing therapeutic treatment plans. Signals from government bodies in several jurisdictions, including the United Kingdom,¹⁰ United States,¹² New Zealand,¹³ and Canada,⁷ suggest that clinical pharmacy services are expected to grow in the coming years and that practice will continue to expand into new settings. It would appear that, 50 years on, Brodie’s vision for a patient-facing ‘body of practice’ for the pharmacy profession, might finally be close to realization.

The central argument presented in this paper is that, despite promising advances in clinical pharmacy practice over the past several years, we are still falling short of achieving Brodie’s vision of a unified professional ‘body of practice’. We contend that clinical decision-making remains a critical missing ingredient that will allow pharmacists across practice settings to expand their scope of practice beyond the supply of medicines. While clinical decision-making skills related to diagnostic decisions are well-recognized as a fundamental component

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<https://doi.org/10.1016/j.sapharm.2018.08.001>

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of practice in medicine, the decisions-making skills required for therapeutic decisions remain under-developed.¹⁴

The aims of this commentary are to; 1) present a definition for clinical decision-making that will apply across pharmacy practice settings 2) to propose a model for clinical decision-making aligned with a philosophical framework for pharmacy practice, and, 3) to explore the implications for pharmacy practice and education in the 21st century. Note that it is not the intention of this paper to review the vast literature on clinical decision-making and clinical reasoning in the medical profession.

2. What do we mean by ‘clinical decision-making’?

There is no widely accepted definition of clinical decision-making nor any consistent use of terminology. While we do not intend to review the language used by other health professions, we observe that many terms have been used more-or-less interchangeably to describe similar phenomena. These include ‘problem solving’, ‘critical thinking’, ‘clinical reasoning’, ‘diagnostic reasoning’, ‘clinical judgment’, and ‘clinical decision-making’.¹⁵⁻²⁰ In medicine, it is common to refer to the broad decision-making process around diagnosis as ‘clinical reasoning’, while ‘management reasoning’ has been used to describe decision-making around drug therapy.¹⁴ The latter is analogous to our definition for pharmacy (below). ‘Therapeutic decision-making’ in the medical literature, confusingly, generally refers to the computational analysis of decision trees using mathematical models.^{21,22} We will not discuss the latter here. Note that we do not believe that the terminology used by medicine is part of a consistent language but simply reflects the pragmatic development of terms. In this work, and for clarity, we will use ‘clinical decision-making’ to refer to the whole set of cognitive skills required to reach a decision about drug therapy.

3. Current models for clinical decision-making in pharmacy practice

Clinical decision-making has not been explored in any detail in the pharmacy literature compared to other health professions. Most published models are focused primarily on defining the practical steps that might be required to conduct pharmaceutical care services. While the models suggested by Brodie et al.,²³ Strand et al.,²⁴ Hepler and Strand⁶ and Sexton et al.²⁵ provide a useful ‘how to’ guide for the pharmaceutical care process, the specific skills and cognitive processes required for decision-making are not addressed. The overarching impression is that clinical decision-making is tacit and will therefore either be innately obvious or will only be acquired with practice experience and mentoring.

Bryant²⁶ explored the clinical decision-making process by positioning a model for the pharmaceutical care process proposed by Hepler and Strand model within the framework of evidence-based medicine. The author proposed that drug therapy decisions are driven by the quality of the evidence-base, and require ‘logical’ reasoning and clinical judgment skills.²⁶ By teasing apart the components of clinical decision-making, Bryant provides a framework that could be translated into a set of teachable skills. For example, evidence about drug treatments would require critical appraisal skills while ‘logical’ reasoning might require critical thinking skills.²⁶ According to Bryant, clinical judgment is required where there is no evidence-base to aid decision-making and therefore remains the domain of the experienced practitioner.

Other authors have presented the Hepler and Strand model in various forms, although the basic structure remains largely intact (see for example^{27,28}). Some specific skills that are important for the decision-making process have also been explored including critical thinking and problem-solving skills,²⁹⁻³³ information gathering,³⁴ clinical reasoning skills,^{35,36} and decision-making for differential diagnosis in the community pharmacy setting.³⁷⁻³⁹ While this research is encouraging, there is no comprehensive model that defines the processes and skills

required for pharmacists to effectively make independent patient-centered decisions about treatment plans when conducting clinical services.

4. A definition of clinical decision-making for pharmacy practice

Clinical decision-making in pharmacy practice can be conceptualized as a series of cognitive processes and skills that allow pharmacists to make patient-centered, therapeutic decisions. We intend for this definition to be applicable across practice settings, in any environment where a pharmacist would be expected to conduct patient-centered clinical services whether in community, primary care, or hospital practice.

It is important to note that our proposed definition of clinical decision-making differs in some important aspects from that used in medicine. In medical practice, clinical decision-making is used synonymously with the term ‘clinical reasoning’ and it is characterized as the thinking process medical practitioners use “to sort through a cluster of features presented by a patient and accurately assign a diagnostic label ...”.⁴⁰ Clinical decision-making in medicine emphasizes diagnosis rather than therapeutics.⁴¹ Pharmacists, on the other hand, usually interact with patients and health care teams in a setting where the diagnostic label has been assigned but where therapeutic options may not yet be optimal.

5. A revised model for clinical decision-making in pharmacy practice and education

A model for the clinical decision-making process in pharmacy practice has been introduced by the authors previously.⁴² This model has been refined further and is presented in Fig. 1. It builds on the work of Hepler and Strand,⁶ Sexton et al.,²⁵ and Bryant et al.,²⁶ but differs in that it focuses on the cognitive processes required for decision-making. The cognitive processes are represented as a 4-stage cycle and the tasks that enable decision-making are defined within each stage. These tasks are inherently teachable as a series of skills, so the model can be adapted into an education program or personal practice (see for examples^{43,44}). Finally, to highlight the patient-centered intentions of the model the patient is the central axis around which all decision-making activity occurs.

The tasks embedded in each cognitive process in the model are described in detail below.

- 1. Information gathering.** Information gathering is a multifaceted stage and will include a diverse range of tasks including, but not limited to; identifying the need for a decision, an assessment of laboratory results, the identification of drug-related problems, the initial delineation of treatment and patient-centered goals, patient assessment (physical and psycho-social), a review of relevant literature related to therapeutic entities, and a consideration of patient

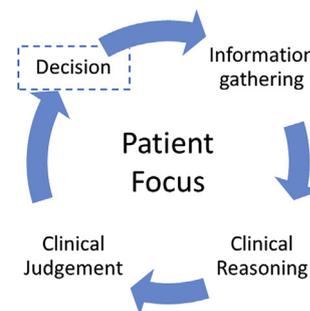


Fig. 1. A general model for the clinical decision-making process in pharmacy. The dashed line around the decision component indicates that this is the final step in process and will be enacted with the patient.

factors that may impact drug therapies (e.g. risk of adverse effects). Unlike the Hepler and Strand model, information gathering is initiated by a signal indicating that a decision is required. This difference is a subtle point, but information gathering, as envisioned here, is related specifically to the problem so it will occur after the pharmacist has identified the need for a decision. This might occur while conducting medicines review services, during a patient consultation, while monitoring the outcomes of a previous decision, or from an external source, e.g. a referral. In some cases, the signal that initiates the decision-making process may be driven by the patient, and in other cases, may occur in the absence of direct patient contact. The types of signals that initiate the decision-making process are diverse, and will inevitably extend beyond 'drug-related problems' as defined in pharmaceutical care. The information gathering stage does not necessarily need to be contextualized to an individual patient. A pharmacist could, for example, research and answer a drug information query without access to detailed patient information. Likewise, a clinical check of a prescription that requires clarification with the prescriber (as may occur if an inappropriate dose is identified) may only superficially extend beyond information gathering in the absence of patient level data.

2. **Clinical reasoning.** From a practical perspective, the clinical reasoning stage requires the pharmacist to appraise the information gathered and to contextualize this specifically to the goals of the patient. The aim of this stage is to curate the information gathered and synthesize a viable set of options in the context of the patient's goals. We consider that clinical reasoning is much more than the collation of options from the evidence-base or from published treatment guidelines. It requires the pharmacist to use critical thinking skills to appraise the information gathered and to ensure that the information is robust so it will suit the needs of the patient. The clinical reasoning step will provide the basic components to enable clinical judgement.
3. **Clinical Judgment.** While previous authors have suggested that clinical judgement is only required when the evidence-base to support a treatment decision is lacking,²⁶ we propose that it is an integral component of all decision-making activities (whether clinical or not). Clinical judgement can be understood as the process of weighing-up the options available, and prioritizing them on the basis of their impact. The impact of a decision will extend beyond the treatment outcomes for the patient's health and may also include financial considerations, social implications, effects on the patient's family, or how the patient interacts with other health services. In all cases, judgement involves a benefit-risk assessment. We note if there were no benefits from an intervention or no risks (health, financial or otherwise) then the judgement is absolute. Otherwise, the assessment carries a trade-off between the benefits and risks of any intervention. The clinical judgement step is one based on ambiguity and uncertainty and is a foundational component in the clinical decision-making process.
4. **Decision.** Making a decision is the final stage in the process and it is made in partnership with the patient. In the judgement step, the practitioner will assign a weighting to each reasoned option. Importantly, this is the transition from a set of weighted options to a patient-centered decision. In this way, the decision step culminates a judgement with an action such that the patient is part of the interpretation of the judgement. In summary, the decision stage has at least two embedded tasks: (i) a patient-centered consideration of the pertinent judgements through an open and supportive communication framework and (ii) the enactment of the decision. In the enactment of the decision, the consultative recipient may either be the patient or another health professional.

We acknowledge that the clinical decision-making process in health care is inherently complex and requires consideration of several factors simultaneously such as the patient goals, the evidence-based for

different treatments, and social expectations. In addition, we propose that decision-making in pharmacy practice, with a primary focus on therapeutic decisions, will differ fundamentally from medicine, where the emphasis is on deductive reasoning to arrive at a diagnosis.

6. Aligning the CDM model with a philosophical framework for pharmacy practice

Prior to developing the clinical decision-making model further, we introduce a previously published philosophical framework for pharmacy practice.⁴² The current work is intended to build on this work by aligning the framework with the decision-making model presented above. The use of bioethical principles is intended to provide a philosophical underpinning for pharmacy practice that will help delineate different approaches to clinical decision-making and which will have important implications for professional identity. We theorize that clinical decision-making will differ depending on the bioethical orientation of the service being delivered.

We have previously proposed that the professional services provided by pharmacists can be aligned with the foundational principles of bioethics, specifically, non-maleficence (to avoid harm) and beneficence (to do good).⁴² For instance, a pharmacy practitioner providing services that are primarily non-maleficent will make decisions designed to mitigate risk.

A non-maleficent pharmacy service may be primarily drug-focused and could occur in a setting with limited access to patient information. An example would be providing a clinical check for drug interactions at the time of dispensing. In this case, the pharmacist is identifying a signal of a potential harm, is acting on this via the decision process, and will follow up with the practitioner or patient. In this example, the pharmacist did not instigate the care process (i.e. the diagnosis and prescription) but rather provides support to the process. Non-maleficent services could also be a primary component of a patient-centered clinical role for the purposes of reducing iatrogenic burden, e.g. identifying medicines that carry risk with limited anticipated benefit in a de-prescribing service.

A pharmacy practitioner providing beneficent services will make decisions that are oriented towards creating benefit. We have identified three main types of services with a beneficent orientation; primary beneficence, secondary beneficence, and co-beneficence.⁴²

A primary beneficent service is one in which the pharmacist is the instigator of a treatment or intervention that has not previously been considered by another healthcare professional. A pharmacist providing primary beneficent services will identify the need for a decision and continue through the process to enact a decision in an independent and autonomous manner. Note here, independent is used to indicate that the clinical decision-making process is internal to the practitioner and not consultative – this does not imply that the practitioner does not work in a collaborative healthcare setting. A primary beneficent service could include a pharmacist vaccinating a patient.

A secondary beneficent service is one where a pharmacist provides support to another (primary beneficent) practitioner. To this end, the pharmacist (the secondary beneficent practitioner) is involved in the overall decision-making process up to and including the clinical judgement step of the other healthcare practitioner (primary beneficent practitioner) who is the person responsible for arriving at and enacting the decision. A secondary beneficent service may also involve a pharmacist acting to influence the reasoning, judgements, or decisions that were initiated by a primary beneficent practitioner to improve patient outcomes. An example of a secondary beneficent service is medicines review that aims to optimize the therapeutic choices of a prescribing physician.

A co-beneficent service requires the pharmacist to work collaboratively with another healthcare practitioner and to share the responsibility for a decision that is made and enacted together. Providing a co-beneficent service may involve asynchronous completion of the

decision-making cycle by the two practitioners in order to complete different aspects of the process. In practice, a co-beneficent service might involve shared prescribing roles between a pharmacist and a medical practitioner in a primary care setting. In this setting the physician may assign the diagnostic label and identify the overall therapeutic approach that aligns with their prognostic reasoning and the pharmacist may identify and enact the particular therapeutic intervention. Separation of the roles of diagnostician and prescriber has potential significant advantages.

We acknowledge that non-maleficent services and beneficent services are not mutually exclusive. The professional activities of a pharmacist may have both non-maleficent and beneficent components, either within the same role or in different roles that they may perform. For instance, the clinical checking of prescriptions (in the absence of information about diagnosis and medical goals) will require predominately a non-maleficent approach where the pharmacist may primarily see their role to reduce harm. A prescribing pharmacist, who may be designing and implementing treatment plans, will adopt a beneficent orientation, which will enhance well-being within an acceptable harm risk. It may be that a pharmacist follows both components, e.g. a prescribing pharmacist who is involved in de-prescribing. Here the orientation of the role is non-maleficent, but the practice setting of prescribing (in this case potentially stopping a medicine) holds a natural beneficent component. In all pharmacy services there will be a dominant philosophical approach that can be identified. The difference in clinical decision-making therefore lies in the underpinning philosophical approach which dominates in any given service. This distinction provides a useful means of understanding professional identity in pharmacy.

7. An expanded model for clinical decision-making

The decision-making model can be expanded to show non-maleficent (Fig. 2), secondary beneficent (Fig. 3), and, co-beneficent (Fig. 4), services and how they interact with the primary beneficent decision-maker. These represent the decision-making cycles associated with services provided by pharmacists in different practice settings. In the case of a non-maleficent service, the pharmacist's clinical decision-making process interrupts that of the primary beneficent practitioner (Fig. 2). The decision of the pharmacist may require contact with the

prescriber or patient as part of the decision step.

Figs. 3 and 4 show the complex clinical decision-making interactions that may occur between different beneficent practitioners. Unlike some non-maleficent practice settings, beneficent practice is always patient-centered, and requires the pharmacist to have access to appropriate patient information, such as clinical conditions and laboratory investigations, to aid in the decision-making process. These services would require pharmacists to move beyond clinical checking of prescriptions to providing services where they are required to take a lead role in therapeutic decisions.

In all settings, the clinical decision-making steps remain equally important and clearly delineated. However, it is apparent that the skills and cognitive processes that underpin each of the tasks will differ dramatically between the four orientations to practice. It is also suspected, but not previously explored, that moving from one orientation (e.g. non-maleficent) to another (e.g. co-beneficent) requires a non-trivial shift in skills and cognition, and importantly, the professional identity of the practitioner.

8. Implications for pharmacy practice and education

Pharmaceutical care, as a body of practice, has a strong non-maleficent tone. The motivation for Hepler and Strand's pharmaceutical care model was the pressing clinical need to reduce drug-related morbidity and mortality.⁵ They suggested that pharmacy's primary mandate is "... to help the patient obtain the best possible drug therapy and especially to protect the patient from harm".⁵ Pharmacists were tasked with resolving 'drug-related problems' such as identifying medicines that were missing or doses that were sub-therapeutic or toxic.^{5,6} While the design and implementation of treatment plans was also stressed as an important function for pharmacists, Hepler and Strand did not provide guidance about how the necessary therapeutic decisions would be reached or what skills would be required to provide such services. Other authors have suggested that the definition of pharmaceutical care is too vague and could just as easily be applied to dispensing and associated clinical check services, as to more patient-centered activities.⁴⁵ In some settings, clinical services such as 'medicines management', an extension of pharmaceutical care, are considered by some to be achievable with minimal patient information,⁴⁶ a situation that would lend itself to a more non-maleficent approach. Importantly, it could be

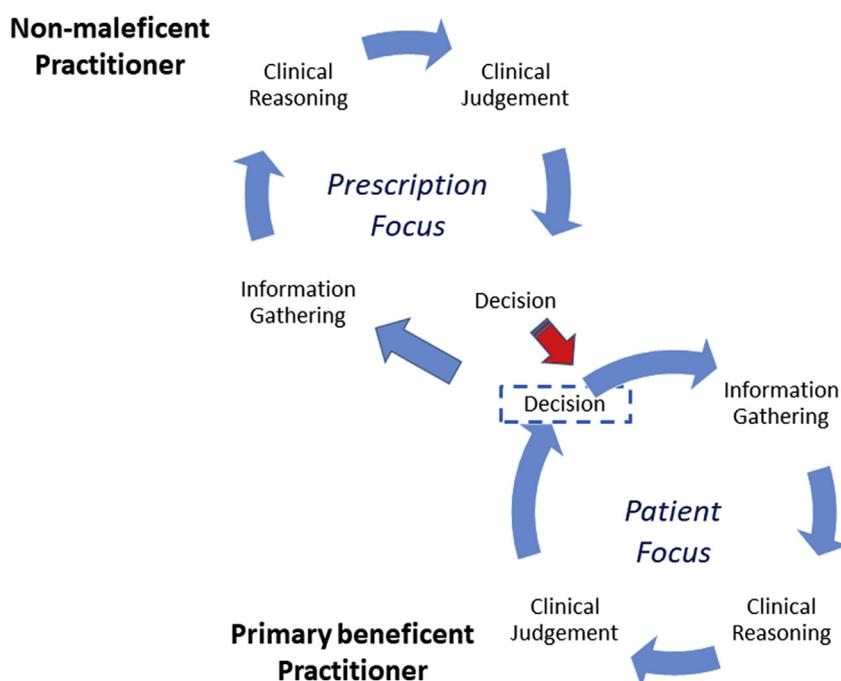


Fig. 2. A model for the clinical decision-making cycle for non-maleficent pharmacy practice. The dashed line around the decision component indicates that this is the final step in process and will be enacted with the patient. The 'decision' component associated with the non-maleficent cycle concerns the interaction with the primary beneficent practitioner.

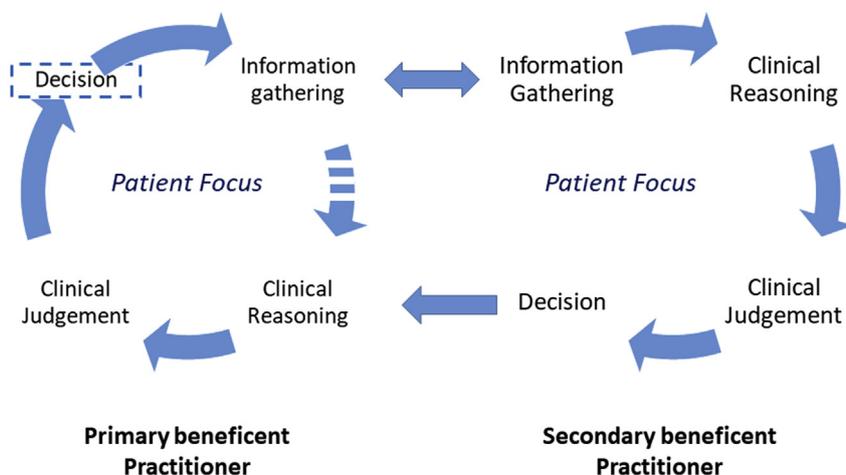


Fig. 3. A model for the clinical decision-making cycle for secondary beneficial pharmacy practice, and the interaction with a primary beneficial practitioner. The dashed line around the decision component indicates that this is the final step in process and will be enacted with the patient.

argued that in the absence of a fully developed range of clinical decision-making skills, those who practice pharmaceutical care might lack requisite skills to extend beyond a non-maleficence (risk mitigation) approach to practice.

There appears to be a general agreement amongst pharmacy educators, licensing bodies, and other stake-holders that the concept of clinical decision-making is important in pharmacy practice and education. Clinical decision-making is noted as a central component of pharmacy competence in different jurisdictions⁴⁷⁻⁵⁰ and in standards of practice documents.⁵¹⁻⁵³ The skills of problem-solving, clinical reasoning, judgement, and decision-making are stressed in documentation associated with schools of pharmacy, and accreditation standards for education programmes.⁵⁴⁻⁵⁷ Yet, despite the importance of clinical decision-making, pharmacists have been found to struggle with this in practice.⁵⁸ Pharmacists are said to feel inadequately prepared to make important therapy decisions, are generally risk averse, and lack confidence to deal with ambiguous situations.⁵⁹ Recent work on the decision-making skills required for differential diagnosis in a community pharmacy setting suggests that pharmacists rarely exhibit a robust decision-making processes, relying instead on mnemonic or acronym-based memory aids for assessing information from the patient and making a decision.^{37,39} The reliance on mnemonics may imply that pharmacists lack confidence when making independent decisions.³⁸

There appears to be a gap between the aspirations of the pharmacy profession and the current skill-base available to pharmacists in

practice. This gap is reflected in patient care settings where pharmacists have not traditionally been primary decision makers. There is, therefore, an urgent need for the pharmacy education community to explore purpose-built curriculum and new teaching methods that can support the development of clinical decision-making skills across practice settings. A critical part of this process is the need to provide support to practitioners who wish to expand their practice into new roles. These updates will ensure that the educators can keep pace with the changing needs of the pharmacy profession in the 12st century.

To support the continued evolution of clinical services in the pharmacy profession we require further research and innovation in our educational programs. We need to better understand how a seemingly risk-averse culture of pharmacy practice has an impact on the curriculum in education programs. We also need to evaluate instructional approaches that are designed to develop effective decision-making skills in different practice settings, including the usefulness of the proposed model for clinical decision-making presented in this paper.

We have presented a model for decision-making in pharmacy that aligns with a philosophical framework for the profession. The model has utility in undergraduate and postgraduate education programs for pharmacists and as a basis for understanding clinical services in current practice. We have suggested that for pharmacy to fully mature as a clinical profession across practice settings, it is time to consider an expanded professional identify accompanied by a formal process of clinical decision-making for pharmacy.

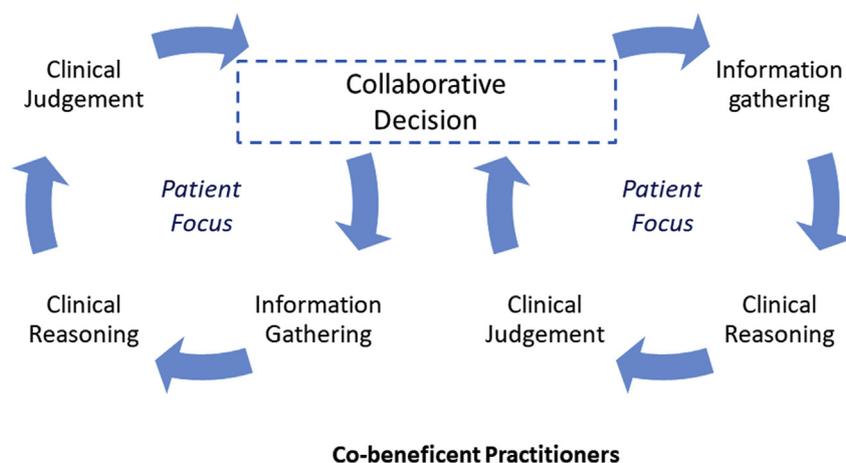


Fig. 4. A model for the clinical decision-making cycle for co-beneficial practice. The dashed line around the decision component indicates a collaborative decision. This is the final step in process and will be enacted with the patient.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of interest

None declared for any authors.

Acknowledgements

We thank Professor Carlo Marra and Dr Linda Bryant for their helpful insights and comments on clinical decision-making in pharmacy practice.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.sapharm.2018.08.001>.

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