An Information Paper on Pharmacist Prescribing Within a Health Care Facility

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This Information Paper was developed, with consideration of the Direct Patient Care Curriculum, to help support CSHP members in their attempts to expand their practice into the area of prescribing. The document was approved by CSHP Council as an official CSHP publication in August 2001 and is a companion to the CSHP "Statement on Pharmacist Prescribing", approved at the same time.

INTRODUCTION

In the traditional model of health care, physicians have the authority to prescribe medications, order laboratory tests, and conduct or supervise procedures consistent with a patient's diagnosis. More recently, prescribing privileges have been extended to other health care professionals, such as nurse practitioners (NP), expanded role nurses (ERN), clinical nurse specialists (CNS), registered midwives, and optometrists. While the roles of some of these health care professionals have evolved to fill gaps in the health care system where physicians are unavailable, most work within a hospital or specialized clinic affiliated with a health care facility.

There is a continuing attempt in Canadian health care to contain or reduce costs by reducing patient length of stay in hospital and eliminating inefficiencies and duplication of effort. Pharmacists are increasingly aware that the current process of delivering health care to patients frequently results in drug therapy outcomes that are not as effective, appropriate, safe, or economical as possible and desirable.[1-3] They have a responsibility to work toward establishing a better system that could improve the outcomes and cost-effectiveness of drug therapy. It has been postulated that by granting prescribing authority to pharmacists the fragmented and disjointed process of health care delivery could be improved. Improved medication management and continuity of care may be achieved by decreasing the number of steps a patient must take to obtain the optimal medication regimen for their condition.[4]

It has been argued that if pharmacists truly intend to practise and implement pharmaceutical care, then every pharmacist should be able to maximally utilize their extensive pharmaceutical knowledge by prescribing drugs.[5] Having the authority to prescribe medications would facilitate the delivery of more effective pharmaceutical care by some pharmacists. Yet, given the present practice of most pharmacists, it has also been suggested that those with delegated prescribing authority have little advantage over those without it in the overall delivery of pharmaceutical care to patients.[6]

Currently, many pharmacists in organized health care settings in Canada have some form of authority and responsibility for prescribing. It is important to note that in a survey of Canadian institutions, the Canadian Society of Hospital Pharmacists Task Force on Pharmacist Prescribing found a significant amount of pharmacist prescribing occurring with limited control or regulation[7] (see below).

This paper is not intended to examine the current state of provincial legislation regarding prescribing authority in Canada. Various degrees of prescribing authority for pharmacists are currently being examined and implemented in a number of provinces (e.g., specially instructed and certified pharmacists prescribing post-coital contraception).

LEVELS OF PRESCRIBING

Prescribing may be simply defined as "to designate in writing a remedy for administration".[8] However, prescribing involves a number of related and complex steps. The prescriber must first decide whether or not to begin or cease therapy. If therapy is to be initiated, the specific treatment must be selected, prescribed, monitored, and modified as necessary to achieve the desired outcome.[6]

A professional may be granted the authority to prescribe independently, dependently, or collaboratively.

Independent Prescribing

Independent prescribing authority means that the prescribing practitioner is solely responsible for patient outcomes. To be granted independent prescribing authority, health care professionals must possess legally defined levels of knowledge and skill to diagnose conditions. The licensing process for physicians ensures that these conditions are fulfilled. Currently, most Canadian faculties of pharmacy do not teach the diagnostic and physical assessment skills necessary to practise at this level. In addition, these skills are not required to gain licensure as a pharmacist in any Canadian province.

Dependent Prescribing

The dependent form of prescribing involves the delegation of authority from an independent prescribing professional, usually a physician. The delegation of this responsibility involves a formal agreement between the independent and dependent prescribers. Typically, these agreements take the form of a document that provides all or most of the following:

- specific written guidelines or protocols for prescribing;
- a description of the responsibilities of each of the parties involved;
- description of both documentation and feedback mechanisms to the authorizing prescriber; and
- policies for review and revision of the written guidelines or protocols.

Physicians who delegate prescribing privileges must be confident in the knowledge, skills, and professional judgement of the individual receiving the delegated authority. Agreements between professionals imply a shared responsibility for patient outcomes, including the potential risks associated with treatment.

Dependent prescribing has taken a variety of forms when applied in practice. Dependent prescribing by protocol is the most common. The protocol is an explicit, detailed document that describes the activities that the pharmacist may perform in exercising prescribing authority. The protocol may include specific statements of the types of diseases and drugs or drug categories involved. There should also be a general statement of procedure, decision criteria, or a plan that the pharmacist must follow.[9] Another model of dependent prescribing is according to formulary. In these formal agreements, the physician delegates prescribing authority for a limited list of medications. This form of dependent prescribing is usually less explicit than by protocol and may permit greater flexibility for the pharmacist. A third form of dependent prescribing is by patient referral. In this model, patients are individually referred to pharmacists by a physician for management of specific drug therapy or to achieve a specific therapeutic outcome. Pharmacists with this form of dependent prescribing authority most commonly practice in ambulatory care settings within health care facilities.

Collaborative Prescribing

A collaborative prescribing model requires a cooperative practice relationship between a pharmacist and a physician or practice group with the legal authority to prescribe medications. Recognition of physician expertise in disease diagnosis and pharmacist expertise in pharmacotherapy and disease management optimizes the application of the specific training and knowledge of both health care professionals in the provision of patient care. A collaborative prescribing agreement identifies the patient population for which the pharmacist has responsibility. Collaborative agreements are not the same as protocols; they do not dictate the activities the pharmacist will perform in managing a patient's drug therapy. In an ideal collaborative practice, the physician diagnoses and makes initial treatment decisions for the patient and then the pharmacist selects, initiates, monitors, modifies, continues, and discontinues pharmacotherapy as appropriate to achieve the desired patient outcomes. Both the physician and the pharmacist share in the risk and responsibility for the patient outcomes achieved in a collaborative practice model.

While some pharmacists have developed the expertise needed to independently prescribe through clinical experience and/or advanced training, most pharmacists who want or are pursuing prescribing privileges support a model of collaborative practice. Here physicians make the diagnosis and decide whether or not treatment is appropriate, while the pharmacist's specialized knowledge and skills are applied to the selection, monitoring, modification, and discontinuation of appropriate medication according to patient response.

SUPPORT FOR PHARMACIST PRESCRIBING

There are many examples of health care services where pharmacist prescribing is practised in Canada and the United States. In health care facilities, examples of pharmacist prescribing include the following:

- therapeutic interchange;
- selection of non-prescription drugs;
- aminoglycoside and pharmacokinetic dosing service;
- anticoagulant therapy for inpatients and outpatients;
- total parenteral and enteral nutrition support;
- cancer-related analgesic management;
- chemotherapy-related antiemetic management;
- insulin and oral hypoglycemic drug dosing and adjustment;
- antibiotic programs (surgical prophylaxis, pneumonia, etc.);
- renal dysfunction dosage adjustment program;
- hypertension clinic;
- hyperlipidemia clinic;
- clozapine and antipsychotic medication management;
- antiepileptic medication program; and
- ambulatory patient medication refill clinic.

While this is only a list of examples, it demonstrates the already existing range of roles that pharmacists assume. The goal for each of these expanded roles must be to help patients optimize the use of their medications and achieve a positive clinical and pharmacotherapeutic outcome.

Some controlled data do exist to indicate that pharmacists are able to function effectively as prescribers, performing as well as or better than physicians.[10,11]

THE UNITED STATES EXPERIENCE

In the United States, the issue of pharmacist prescribing has been gaining momentum since the late 1970s. It has progressed beyond debates of whether or not pharmacists should assume or are capable of assuming such responsibilities to the establishment of specific state legislation allowing it to occur. Twenty-five states have passed legislation permitting various degrees of prescribing authority for pharmacists. Florida pharmacists have been provided with independent prescribing privileges for a limited number of drugs (e.g., meclizine up to 25 mg per dose, lindane shampoo, naphazoline 1% ophthalmic solution, transdermal scopolamine),[12] many of which are available as non-prescription products in Canada. The State of California has restricted the practice of dependent pharmacist prescribing to institutional settings.[1] Also, Department of Veterans Affairs health care facilities throughout the United States have recognized pharmacists' evolving scope of practice and have formally developed guidelines establishing prescribing authority for pharmacists.[13] (Table 1 in the cited article outlines the regulations governing pharmacist prescribing in some of the states in the United States.)

Various national professional organizations in the United States have also defined and developed statements of their position regarding pharmacist prescribing to help support state legislative and regulatory changes in providing such authority for pharmacists. The term that is currently being used by many of these organizations is collaborative drug therapy management (CDTM). The American Society of Health-System Pharmacists (ASHP)[14] and the American College of Clinical Pharmacy (ACCP)[15] have published position statements endorsing CDTM.

THE CANADIAN EXPERIENCE

In an effort to examine the extent and nature of pharmacist prescribing in Canadian organized health care settings, the CSHP Task Force on Pharmacist Prescribing conducted a survey.[7] All hospitals in Canada with more than 50 beds were surveyed during the months of July and August 1996. To ensure clarity and consistency, prescribing authority was operationally defined in the survey as "pharmacist-managed drug therapy which allows the pharmacist, under order or authorization of a prescriber, to initiate or adjust drug dosages in order to obtain the desired therapeutic response".

There was a 37.2% (231/620) response rate to the survey, with the greatest proportion of responses coming from Ontario (40%) (Figure 1). The demographic description of the respondent hospitals is outlined in Table 1.

A significant number of hospitals reported that pharmacists were involved in "basic prescribing practices", e.g., therapeutic interchange programs, clarification of orders, and ordering of non-prescription drugs. Among the hospitals responding, therapeutic interchange programs for standard doses were reported by 68 (29.4%), standard dosage intervals by 163 (70.6%), therapeutic classes by 189 (81.8%), brand drug substitution by 197 (85.3%) and other therapeutic interchanges by 17 (7.4%) of the hospitals. In addition, 127 (55.0%) of the hospitals responding reported that they had policies in place allowing pharmacists to rewrite orders when the incorrect dose or dosage form of a medication was written for a patient by a physician. "Meds as at home policies" were reported to be in place at 84 (36.4%) hospitals, where the pharmacist was allowed to clarify the medication regimen with the patient and write all of the appropriate medication

Table 1. Characteristics of Hospitals Responding to CSHP Survey on Pharmacist Prescribing

Variable	No. (and %) of hospitals* *n* = 231	
No. of beds		
51–99	66	(28.6)
100–200	58	(25.1)
201–500	74	(32.0)
>500	31	(13.4)
Not indicated	2	(0.9)
Type of institution		
University	39	(16.9)
Community teaching	32	(13.9)
Community	127	(55.0)
Long-term care	12	(5.2)
Other	19	(8.2)
Not indicated	2	(0.9)
Setting		
Urban	139	(60.2)
Rural	89	(38.5)
Remote	3	(1.3)
Pharmacist staffing (FTE)†		
Total (including BScPharm)	7.53	
PharmD	0.41	
MSc	0.82	
Resident	2.30	
Other	0.12	
Practice type		
Pharmaceutical care	17	(7.4)
Transition, clinical to pharmaceutical care	149	(64.5)
Minimal clinical activity	62	(26.8)
Not indicated	3	(1.3)

*Except where indicated otherwise.
†Staffing is represented by mean full-time equivalent (FTE) for pharmacists with various levels of education.

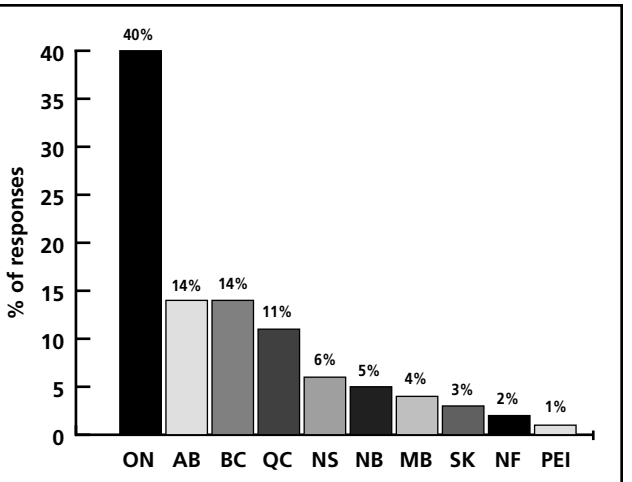

Figure 1. Distribution of responses to a survey about pharmacist prescribing. All hospitals with more than 50 beds were surveyed. Of the responses received, the greatest proportion (40%) came from Ontario.

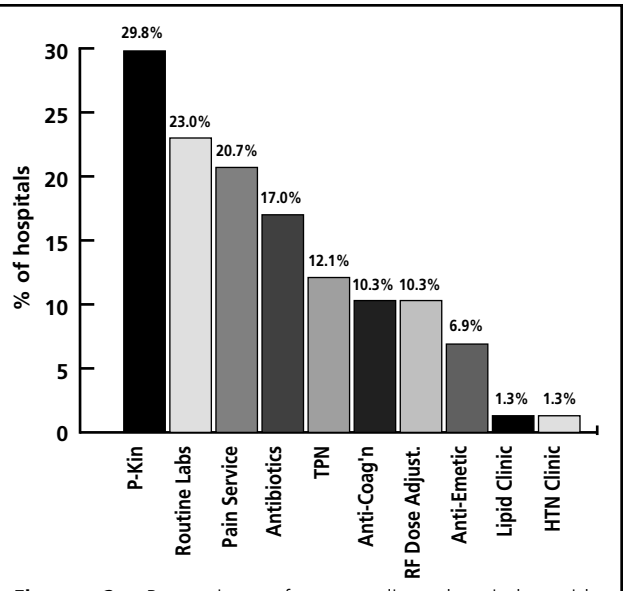

Figure 2. Proportion of responding hospitals with various programs. P-Kin = pharmacokinetic monitoring, TPN = total parenteral nutrition, RF = renal failure, HTN = hypertension.

orders during hospitalization. For non-prescription medications, 4 (1.7%) hospitals allowed the pharmacist to initiate treatment with all non-prescription medications, 8 (3.5%) hospitals allowed the pharmacist to initiate treatment with specific non-prescription medications, and 91 (39.4%) hospitals allowed the pharmacist to modify treatment with a non-prescription medication.

The survey demonstrated that a broad range of pharmacist-managed or collaborative drug therapy programs exists in Canadian hospitals. The reported frequency of selected programs is outlined in Figure 2.

Among those hospitals reporting the existence of these pharmacist-managed or collaborative drug therapy programs, approximately 50% reported that the programs existed in accordance with a protocol. However, they also reported that there was only modest control or regulation over the "prescribing" activities of pharmacists in their facility.

A third of the pharmacist-managed or collaborative drug therapy programs were established between individual pharmacists and physician collaborators. Less than 30% of the programs reported that there was an established quality assurance (QA) or monitoring system in place. Depending upon the specific pharmacist-managed or collaborative drug therapy program, hospitals reported that 0% to 72% of their programs had the approval of the Pharmacy and Therapeutics Committee or the Medical Advisory Committee. In addition, 0% to 46% of the programs required the pharmacist to document their activities in prescribing.

While the results of this survey are 5 years old, they provide some interesting data regarding the nature and extent of prescribing by pharmacists in Canadian health

care facilities. From these data, it is obvious that a significant part of the evolving role of Canadian hospital pharmacists is their increasing involvement in prescribing drug therapy regimens. The motivation for such change is the enhancement of the quality of patient care and optimization of therapeutic outcomes. As the profession continues to advance toward patient-oriented services, emphasizing the pharmaceutical care model, it would be expected that even more pharmacists will become involved in prescribing.

OBTAINING PRESCRIBING PRIVILEGES

For pharmacists to practice effectively in a collaborative prescribing model there are several requirements that should be met. Carmichael and colleagues[15] have defined the conditions that should exist as follows: a collaborative practice environment, access to patients, access to medical records, knowledge, skills and ability, documentation of activities, and compensation for these activities. Pharmacists working in organized health care environments are in an excellent position to obtain prescribing privileges. Pharmacists who work in inpatient and ambulatory settings of health care facilities often have excellent collaborative relationships with their physician colleagues, who respect and trust their knowledge and abilities. In addition, many of the other conditions that are required for collaborative prescribing practice are possible in these settings.

Working alongside physicians and other health care professionals, pharmacists have demonstrated their significant commitment to patient care. Building upon the strength of such existing relationships has already enabled a number of Canadian hospital pharmacists to take on some responsibility for prescribing. However, before pharmacists or pharmacy departments engage in sustained efforts to obtain prescribing authority, the potential goals of this authority and responsibility should be clearly defined. To avoid duplicating the existing functions of other health care providers, as well as to avoid potential conflicts, efforts to obtain pharmacist prescribing authority should only occur if there is the opportunity to improve the delivery of patient care. In addition, it might be argued that there is no point in pursuing prescribing authority unless all aspects of pharmaceutical care are in place and consistently practised.[6] Once this occurs, prescribing authority for pharmacists can be pursued in collaboration with physicians.

The potential of prescribing practices that could be exercised by health care facility pharmacists ranges from very basic (therapeutic interchange) to more complex functions (initiating, monitoring, modifying, and discontinuing specific drug therapy). Consequently, explicit collaborative prescribing agreements should be established that clearly define the delegated authority to the pharmacist. These collaborative prescribing agreements should be reviewed and approved by all of the appropriate governing bodies within the facility, such as the Drugs and Therapeutics Committee, the Medical Advisory Committee, and the Risk Management Committee, and possibly also the insurer and facility lawyers.

Pharmacists can keep in mind that legislative or regulatory changes may not be necessary for achieving prescribing authority within their health care facility. Provincial regulations for the health care professions generally do not prohibit the delegation of medication prescribing from physicians to pharmacists. Pharmacists in Canada with informally delegated prescribing authority should confirm that they are not exposing themselves and their patients to unnecessary risks from such arrangements. The creation of a formal agreement for the delegation of prescribing authority may eliminate misunderstandings and protect all parties involved. A systematic and explicit approach to the delegation of prescribing for pharmacists should be followed in order to avoid potential conflict and to protect both patients and pharmacists from unsafe practices.

The first step in obtaining prescribing authority for pharmacists is acquiring the agreement and support of medical staff. This often occurs with little effort between individual pharmacists and physicians, where it is easy for a physician or a group of physicians to be confident in the skills and abilities of the individual seeking to share their licensed responsibility to prescribe under a collaborative practice agreement. Through the clinical quality assurance efforts of a department of pharmacy the same degree of confidence can be established for the composite group of pharmacists.

After obtaining the support of physicians and other appropriate groups, efforts should be focused on developing documented, clear, and concise collaborative practice agreements that explicitly outline the details of the prescribing activities that pharmacists will be permitted to perform (e.g., for which patients, under which circumstances, when medical input will be required). The development of these agreements requires a significant amount of collaboration between the medical and pharmacy staffs of the hospital. These efforts are often most successful if “champions” lead the development.

Core elements of the collaborative practice agreement document should include the following:[16]

- A written declaration must be created specifying that the prescribing authority of the stated physician or group of physicians is delegated to the pharmacist or group of pharmacists. The names and qualifications of all participants should be included in this document. This will ensure that there is a contractual understanding between the physician and pharmacist participants regarding the shared responsibility for delegated prescribing activities.
- The prescribing activities that are to be delegated to the pharmacist must be explicit and clear to all participants. In some situations the pharmacist may only be permitted to modify or adjust medication dosages, while in others they may be delegated the authority to initiate, modify or adjust, and discontinue therapy. At times it may also be appropriate for pharmacists to order and interpret laboratory tests to determine response to drug therapy. The drug categories and disease states for which the pharmacist is authorized to prescribe should also be specified.
- Each document developed should contain a statement that outlines and clearly defines the scope of practice for the pharmacist. For the most part, Canadian pharmacists do not possess legislated authority to prescribe globally and are required to practise within the legal limits of their provincial licences. Exceptions to this are beginning to appear in Canada with the development of limited prescribing authority for specially certified pharmacists. An example of this is new legislation in some provinces that permits pharmacists to prescribe post-coital contraception. Consequently, expanding the role of pharmacists to include prescribing through a collaborative practice model represents an expansion of their scope of practice. These agreements should formally recognize and outline the expanded practice boundaries.
- Limitations should be identified beyond which the physician must be contacted in order for the pharmacist to proceed. The document should clearly indicate the limits of the pharmacist's authority, so as to ensure the safety of patients. A pharmacist should never perform any activity beyond his or her own knowledge, skills, or abilities.
- Procedures should be clearly outlined for documenting the pharmacist's practice decisions and patient care provided. Such procedures must exist in order to ensure that there is adequate communication of patient care between the physician and the pharmacist. It also serves as a quality assurance mechanism for the protocol and the pharmacist's activities.
- A time limit should be established for the document, after which it should be reviewed and revised, if necessary. This is a quality assurance mechanism to prevent pharmacists and physicians from providing outdated or substandard patient care.

While the discussion of prescribing authority for pharmacists is in its infancy in Canada, the model of pharmacist prescribing authority through collaborative drug therapy management or by protocol has been successfully legislated in at least 25 different US states. These models may be logical to follow in health care facility pharmacy practice. Other settings, such as family practice clinics, may also be appropriate. The application in community pharmacy practice is likely to be more daunting because of the difficulty in meeting all of the conditions required for an effective collaborative prescribing model (e.g., access to medical records/information, compensation for activities). However, if these conditions exist, the community may also be an appropriate setting for collaborative prescribing.

In the setting of a health care facility it is important that there is a clear understanding of the implications of a pharmacist or pharmacy department having prescribing privileges through collaborative agreements with physicians. Beyond the legal issues, pharmacists must clearly understand how assuming that authority will affect their role. Do they have the time and support to complete all of their professional responsibilities? Pharmacists must have sufficient and appropriate knowledge and skills to prescribe in a manner that will ultimately improve patient care. The pharmacists who obtain the authority to prescribe and then successfully demonstrate an improvement in the outcomes and overall care provided to patients may encourage the development of Canadian provincial legislation that authorizes pharmacists to be prescribers.

Legislative and regulatory provisions that authorize collaborative prescribing models should be pursued at the provincial and federal levels. Incorporating collaborative prescribing into the pharmacist's scope of practice will assist in the formal recognition of these activities. These activities may help to ensure that the provision of patient care is as efficient as possible.

A significant issue surrounding the practice of prescribing is competence assessment. This can be done at the facility level (i.e., determining the level of skill required by each activity and determined by a formal committee) or at the college, association, provincial, or federal level (i.e., certification, accreditation, or licensing). The challenge for facilities or provincial regulatory authorities is defining the competency requirements for pharmacists who prescribe.

CONCLUSIONS

Pharmacy practice and health care in Canada have changed dramatically in the past several years. The evolution of pharmaceutical care has enabled pharmacists to break down traditional barriers in the delivery of patient care. The shift in the focus of pharmacy practice (product-focused to patient-centred) has resulted in pharmacists being recognized as important health care professionals who make significant contributions to the optimization of drug therapy outcomes. Together with the changing environment of health care practice — shortages of professionals, increased patient acuity, and the migration to care in the ambulatory setting — the combination of professional evolution and situational analysis offers good support for this direction.

The next logical step in the evolution of pharmacy within the health care facility setting for the purpose of achieving improved medication management and continuity of patient care is the recognition of pharmacists as prescribers. Merely adding pharmacists to the list of professionals with traditional prescribing authority might simply exacerbate existing problems with medication use in society. As is occurring among pharmacists in the United States, Canadian pharmacists should be seeking the right to prescribe or make other complex drug therapy decisions by formalizing collaborative arrangements with physicians. An orderly transition and constructive evolution of the profession toward the expansion of prescribing authority for pharmacists should be followed to ensure success.

Furthermore, it is suggested that any consideration of pursuing prescribing authority by an individual pharmacist or pharmacy department requires the following steps:

- a comprehensive self-analysis of the current professional practice to ensure that all aspects of pharmaceutical care have been optimized;
- consideration of the goals and objectives for pharmacist prescribing; and
- collaboration with physicians to develop a coordinated process by which pharmacists may be delegated the authority to prescribe.

This process can be a useful approach for the health care facility pharmacist or pharmacy department to consider when pursuing prescribing privileges within their scope of practice.

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