

SASKATCHEWAN
COLLEGE OF
PHARMACISTS

**Consultation Paper
Enhanced Authority for the Pharmacist
To Prescribe Drugs
In a Collaborative Practice Framework**

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Several authorities have cited the benefits of the pharmacist functioning in an optimal or expanded role. The recently published article¹ (attached) reviews international developments and the relevant issues.

The report of the Commission on the Future of Health Care in Canada states that “....pharmacists can play an increasingly important role as part of the primary health care team, working with patients to ensure they are using medications appropriately and providing information to both physicians and patients about the effectiveness and appropriateness of certain drugs for certain conditions. This expanded role would allow pharmacists to consult with physicians and patients, monitor patients’ use of drugs and provide better information and communication on prescription drugs. In the future, there may also be a role for pharmacists who are not engaged in the retail sale of prescription drugs to prescribe certain drugs under specific, limited conditions.” The key theme throughout this report is the need to review scopes of practice, and develop the roles of pharmacists and other health care providers.² Teams, collaboration and integration are strongly emphasized².

Consistent with these themes, the Saskatchewan College of Pharmacists has been considering strategies to optimize the role of the pharmacist in Saskatchewan in a collaborative practice framework. The purpose of this paper is to describe some of these strategies and invite feedback from interested parties before planning further implementation strategies.

We are proposing **interdependent** prescriptive authority for the pharmacist in collaborative practice environments where pharmacists maximize the use of their current competencies. We are not proposing dependant prescriptive authority where the pharmacist relies on some form of delegation from a legally authorized prescriber. Nor are we proposing independent authority where the pharmacist accepts sole responsibility for prescribing decisions. Both of these concepts are defined in greater detail in the attached article.

We are proposing interdependent authority where the members of the health care team rely upon one another and their respective skills to optimally manage the pharmacotherapy of their patients in collaborative practice environments. In particular, the pharmacist relies upon the diagnostic skills of the physician, the nursing assessment skills of the nurse, while physicians and nurses rely upon the drug therapy knowledge and management skills of the pharmacist. Collaboratively, their common goal is to achieve optimal pharmacotherapy health outcomes.

We are not proposing that pharmacists expand their scope of practice by acquiring new knowledge, skills and training. We are proposing that pharmacists be allowed to practice to their maximum scope of practise within existing competencies.

Furthermore, our proposals attempt to recognize both the realities of the current health care system, and impending reforms. Our proposals do not require broad systemic changes, but require an enabling legislative framework. They are intended to be compatible with enhanced interdisciplinary collaboration in primary care.

To summarize, our proposals are intended to achieve the following goals:

- 1) Expand the authority of the pharmacist to prescribe drugs;
- 2) Optimize the role of the pharmacist;
- 3) Avoid expanding the pharmacist's scope of practice;
- 4) Allow pharmacists to prescribe drugs within current competencies;
- 5) Assist physicians and other health care providers in managing the pharmacotherapy of patients; and,
- 6) Legalize activities that the pharmacist is currently, or is capable of, performing.

We are mainly proposing changes to the law within our jurisdiction to expand the pharmacist's authority to prescribe drugs. Effective September 1, 2003 prescriptive authority was granted to pharmacists when paragraph (i.1) was added to section 14(2) of The Pharmacy Act, 1996 to read:

“14(2) Subject to this Act, regulatory bylaws may be made pursuant to section 13 for the following purposes:.....

(i.1) governing the prescribing and dispensing of drugs by members.”

Subsequent amendments to The Drug Schedules Regulations, 1997 and the bylaws of the Saskatchewan College of Pharmacists authorized the pharmacist to prescribe emergency contraception within the conditions imposed in his/her licence. The main condition was that pharmacists wishing to prescribe emergency contraception must be certified by undertaking accredited training.

As we understand that the amendment to the Act was intended to be broader, we are taking the next steps and propose to allow the pharmacist to prescribe other prescription drugs.

This authority to prescribe extends only to some Schedule I (i.e. prescription) Drugs under certain circumstances. Pursuant to the Drug Schedules Regulations, 1997, Schedule I includes drugs scheduled federally as requiring a prescription either under the Controlled Drugs and Substances Act or the Food and Drugs Act (i.e. Schedule F of the Food and Drug Regulations). Schedule I Drugs also include those drugs that Council is authorized to add by bylaw.

However, the Controlled Drugs and Substances Act (Canada) does not authorize the pharmacist to prescribe Narcotics, Controlled Drugs and Targeted Substances. Section 36 of the Narcotic Control Regulations allows the pharmacist to sell Exempted Codeine Products without a prescription from an authorized prescriber (i.e. licensed physician, dentist or veterinarian). Thus, we are not proposing that the pharmacist be allowed to prescribe these substances, other than for Exempted Codeine Products under the circumstances described later.

We interpret the Food and Drug Regulations as authorizing any person who is designated under provincial law as a prescriber to prescribe Schedule F Drugs. Therefore, we are proposing appropriate regulatory changes in this province to allow pharmacists to prescribe Schedule F Drugs and those other drugs provincially scheduled as prescription drugs, but only under the circumstances that such authority is consistent with the current competencies of the pharmacist.

Pharmacists' extensive drug knowledge ideally positions them to be more actively involved in the pharmacotherapy decision making process. In their consultant role, pharmacists often recommend drug therapy to physicians who in turn, formalize these recommendations by issuing an order or prescription. Collaborative practice agreements are emerging that safely eliminate this last step. In essence the physician diagnoses and determines the indication for therapy, and the pharmacist selects the optimal drug within a predetermined protocol that specifies the limitations to the selection process and acknowledges the existing body of knowledge and scope of practice of the pharmacist. Assisting prescribers this way allows them to focus on other relevant patient care activities.

The underutilization of pharmacists has been widely recognized and several authorities have acknowledged the benefits of the pharmacist in an optimal role. Thus, there appears to be more value in optimizing the role of the pharmacist than expanding it.

We recognize that other health care providers, in particular physicians and nurses, are challenged to meet their patient care responsibilities. Some of these include drug therapy management activities. Thus, allowing the pharmacist to help with those activities within their current knowledge and skills will allow others to focus on the patient care activities pertinent to their scope of practice.

Some common practices of the pharmacist activities are not permitted under the law. For example, pharmacists selecting drugs or adjusting dosages for therapy under collaborative practice agreements in hospitals are not expressly permitted by law. Pharmacists who extend refills of prescriptions when refills have expired or provide emergency supplies of prescription drugs are technically breaking the law even though they are exercising their judgment in the best interests of the patient. While technically illegal, these decisions are almost always safe and result in positive patient outcomes.

To meet these goals, we propose to pursue the following concepts to expand the authority of the pharmacist to prescribe:

1) Altering the formulation or dosage form

Scenario - The physician prescribes a chewable antibiotic for a child and the care-giver advises that she prefers the liquid. The pharmacist prescribes a suspension of the same drug at an equivalent dosage.

Technically under the law, pharmacists should contact the physician to approve the formulation change. We propose to eliminate the legal need for this step.

2) **Altering the dosage and/or regimen**

Scenario - The physician prescribes an antihypertensive regime and advises the patient of the therapeutic goal. Under a written protocol, the pharmacist works with the patient to adjust the dosages and drugs to achieve the target blood pressure.

In this circumstance many information elements required for prescriptions are missing. We propose to eliminate these requirements when a written, formal protocol exists between the pharmacist and physician to allow the pharmacist to select and adjust the drug therapy to achieve the physician's therapeutic goal.

3) **Therapeutic substitution**

Scenario - The physician prescribes an expensive ACE Inhibitor, and the patient asks for the cheapest alternative. The pharmacist substitutes another less expensive drug from the same class at an equivalent dosage.

We propose to amend the law to allow the pharmacist to substitute one drug for another within the same class. Unlike generic substitution through the Saskatchewan Formulary where pharmacists usually substitute less expensive identical drugs made by a different manufacturer, therapeutic interchange involves the selection of a drug by the pharmacist with a different active ingredient than the one prescribed, but within the same class, and it is expected to elicit the same therapeutic outcome. For example, we currently have a maximum allowable cost policy for proton pump inhibitors under the Saskatchewan Prescription Drug Plan. The maximum allowable benefit for a drug prescribed in the category is limited to one of the lowest cost alternative drugs in that category. Based upon evidence and the needs in the community, such concepts could be extended to other categories of drugs without being imposed by the Drug Plan.

4) **Continuing Care**

(a) **Continuing therapy – interim supplies**

Scenario - The patient will run out of chronic medication before his next appointment with his physician. The pharmacist determines that the patient is well stabilized on the medication and advances him sufficient quantities to last until that visit.

(b) **Continuing maintenance therapy**

Scenario - A family is visiting the community, and the mother approaches the pharmacist to ask for inhalers for her asthmatic son. She left the “regular” and the “rescue” medications at home. The pharmacist provides her with the appropriate inhalers after accessing the PIP profile.

(c) **Other drugs in emergency circumstances**

Scenario - A patient presents with a severe migraine headache and has no medication left. Upon checking her PIP profile, the pharmacist discovers that she has had Imitrex. The pharmacist prescribes it and instructs her to see her physician as soon as possible.

Pharmacists often extend prescription repeats or advance prescription drugs in urgent or emergency circumstances where the repeats have expired and the patient needs the drugs, but the prescriber is not available. We propose to allow continuity of care under these circumstances when the patient is stabilized on the medication and providing the drugs would not put the patient unreasonably at risk. The quantity dispensed would be

sufficient to last the patient until they can see their physician. The pharmacist would advise the physician of the quantity dispensed when requesting authorization for a new prescription.

In other urgent circumstances it is not practical or feasible for the pharmacist to contact the prescriber or to arrange for a prescription transfer from another pharmacy. In some cases, due to the dosage form or other factors, the only alternative is to dispense a treatment size package. We propose to allow continuity of care under these circumstances as described above.

5) Emergency and/or oral contraception

Scenario - A woman asks for the morning after pill. Upon counselling the patient the pharmacist determines that oral contraception is indicated. The pharmacist prescribes emergency contraception, and an oral contraceptive according to established prescribing guidelines, and advises the patient that she should consult with her physician for the appropriate physical examination follows up and tests according to the guidelines.

Pharmacists are involved in family planning issues. We propose to allow pharmacists to prescribe oral contraception to enhance public access and the pharmacist's ability to respond to these issues. We will issue prescribing guidelines that would expect the pharmacist to refer the patient to her physician according to the examination, follow up and test requirements in the official product monograph.

6) Collaborative Prescribing Agreements

(a) General protocols or collaborative practice agreements

Scenario - A physician sends a memo to all pharmacies in the community asking pharmacists to refill prescriptions for his patients while he is on a 3 week leave from his practice. The memo limits these refills to three months for existing patients stabilized on chronic medications and asks that pharmacists provide a list of refills upon his return from leave.

(b) Specific protocols or collaborative practice agreements

The pharmacist is a certified asthma educator and has a formal, written collaborative practice agreement with respiratory specialists to select and manage the pharmacotherapy of patients upon receiving the diagnosis and/or therapeutic goal for asthma.

Under collaborative practice or drug therapy management arrangements or agreements, physicians and pharmacists formally determine the circumstances and conditions under which pharmacists make drug therapy decisions on behalf of physicians. These agreements recognize the knowledge, skills and training of the pharmacist and set the limits and boundaries within which the pharmacist may prescribe.

Hospitals in Saskatchewan have well recognized aminoglycoside dosage adjustment programs. Pharmacists routinely adjust dosages for hospital in-patients based upon creatinine clearance to avoid toxic blood levels. Because of their success, other dosing protocols are in place in many hospitals for drugs such as heparin, dalteparin, pediatric acetaminophen, streptokinase, TPA, dopamine, nitroglycerin and oxytocin. Anecdotally we understand that physicians in these hospitals are comfortable with prescribing such

drugs “as per pharmacy” meaning according to the dosing selection protocols agreed to with the pharmacy department.

Similarly, the Regina Qu’Appelle Health Region has recently implemented collaborative prescribing for the Chronic Renal Insufficiency Program. Questions have arisen regarding whether or not the protocol is transferable to the satellite renal units, and whether community pharmacists should be able to honor prescriptions issued by the Renal Pharmacists Group. Thus, changes to the law are urgently needed to address these issues.

An emerging trend is pharmacists adjusting warfarin dosages for both hospital and ambulatory patients to achieve optimal INR results. While sometimes also referred to as co-prescribing programs, credible community based co-prescribing and point of care INR testing training programs are emerging as improved technology is becoming available.

7) **Incomplete Prescriptions**

Scenario – The pharmacist receives a prescription for a pediatric antibiotic for a young child and is given only the weight of the child. The pharmacist calculates the dosage and dispenses the corresponding dosage form.

Pharmacists frequently encounter situations where the prescription is technically illegal to dispense because it is incomplete or does not contain all of the legally necessary detail, but the prescriber’s intent is clear.

Technically, the pharmacist should contact the prescriber to confirm the missing details. This is an unnecessary imposition on the time of both the prescriber and the pharmacist. Thus we propose to allow the pharmacist to dispense the drug and complete the prescription with the proper documentation when the prescriber’s intent is clear.

This would not replace the need for the pharmacist to contact the prescriber to clarify the prescription when the intent is unclear.

8) **Patient Self-Care**

(a) Drugs for minor illnesses and self-limiting conditions

Scenario - A patient presents with numerous severe insect bites. The pharmacist prescribes a topical corticosteroid indicated for this circumstance, and advises the patient to consult with his physician should symptoms persist beyond established prescribing guidelines.

Pharmacists often encounter situations when the patient presents with a minor, self-limiting ailment where the evidence based therapy of choice is a prescription drug. Many Schedule I drugs have indications for both conditions that require a medical diagnosis, and conditions that can be safely self-treated by the patient. Examples include some topical corticosteroids for insect bites or for allergic rhinitis.

We propose to allow the pharmacist to prescribe a drug that is a prescription drug by law, but is the drug of choice in a patient self-care situation. The role of the pharmacist is to be satisfied that the patient has accurately assessed the minor, self-limiting ailment, the

need for treatment, and that the ailment can be safely managed with the drug.

Pharmacists are trained to recognize self-care situations that should be referred to a proper health care professional. Our proposal would not replace the responsibilities of the pharmacist under these circumstances. Pharmacists would continue to be expected to refer patients to their physician for potentially serious conditions.

9) Lifestyle and/or health promotion

Scenario - After receiving training offered by RBSP, the pharmacist offers smoking cessation services. A patient expresses concern with the prospects of success with nicotine patches and gum. The pharmacist determines that Zyban is indicated and prescribes a course of therapy consistent within established prescribing guidelines.

The pharmacist's role in healthy lifestyle and health promotion activities is increasing. We propose to allow the pharmacist to prescribe drugs to supplement their activities and enhance patient access to such services. Prescribing will be allowed only under established guidelines.

10) Exempted Codeine Products

We propose to allow pharmacists to prescribe exempted codeine products so that sales could be captured on the ADAPT database and made available to pharmacists via the Pharmaceutical Information Program Medication Profile Viewer (PIP MPV).

Under section 36 of the Narcotic Control Regulations, pharmacists may sell exempted codeine products without a prescription. To reduce misuse and abuse, we have imposed restrictions limiting the sale to 50 solid oral dosage units, or 100 ml, per occasion. In spite of these restrictions, members report continued abuse and have been asking for a network solution to share sales information. The introduction of the PIP MPV creates this opportunity.

We understand that the Prescription Drug Regulations authorize the Drug Plan to capture data on drugs dispensed only when they are prescribed. This means that the ADAPT database cannot capture non-prescription drug data such as exempted codeine product sales. Therefore, we propose that these products be reclassified as prescription drugs. However, so that public access to these products does not change (i.e. they will not need to obtain a prescription from a physician), we propose that pharmacists be given the authority to prescribe them. We have already submitted this request to Saskatchewan Health, and have also proposed that they be added to the panel of drugs monitored under the Prescription Review Program (formerly the Triplicate Prescription Program).

11) Non-prescription Drugs that Require a Prescription for Payment

Scenario – A Non-Insured Health Benefits program beneficiary attends the pharmacy with a prescription for a gastric motility agent and tells the pharmacist that the doctor wants him to also take an antacid. The antacid of choice is a non-prescription drug but requires a prescription in order to be covered as a benefit. The pharmacist prescribes the antacid meeting all standards, including documentation, and submits the claim for payment.

Under the NIHB Program of Health Canada, and many other third party insurers, non-prescription drugs are benefits only when prescribed by a physician. We propose to acknowledge in the legislation that pharmacists may prescribe such drugs under these circumstances. If third party payers agree to recognize such pharmacist prescribing, this will eliminate the unnecessary step of the pharmacist contacting the physician for a prescription.

To summarize, technically, except for emergency contraception, the foregoing prescribing activities are not permitted under the law. We propose to seek amendments to the regulations and bylaws under The Pharmacy Act, 1996 to allow pharmacists to perform these activities. While specifying the allowable prescribing, the law will also specify when the pharmacist must follow established prescribing guidelines, and the circumstances under which the pharmacist may prescribe within formal protocols or collaborative practice agreements with prescribers.

The foregoing situations contemplate prescribing in collaborative environments between the patient, physician and pharmacist. The physician and patient rely upon the pharmacist to safely extend or initiate therapy within the pharmacist's existing knowledge, skills and training. An important feature of the collaborative environment will be pharmacist to physician communication using the PIP Medication Profile Viewer as the key, but not necessarily the only communications vehicle.

We will consult with our medical colleagues and experts to establish a credible process to determine the established prescribing guidelines, protocols and formal collaborative practice agreements. We will also undertake the appropriate training initiatives for members.

Again, such authority to prescribe does not extend to Narcotics, Controlled Drugs or Targeted Substances until the Controlled Drugs and Substances Act, and corresponding regulations are amended to recognize pharmacists as prescribers.

Issues

The attached paper describes a number of issues associated with pharmacists' authority to prescribe. We believe that these issues do not exist within our model except as follows:

1) Pharmacist not wanting to undertake this responsibility

Our legislative framework will be enabling in nature, rather than mandate practice. We intend to support pharmacists with education to orient them to the framework, provide skills to engage in collaborative prescribing agreements, and to reinforce our current standards of practice. Such support might encourage resistant pharmacists to assume these new responsibilities.

2) Continuing professional development and competency assurance

We will continue our mandatory requirement. Continuing education activities that we sponsor will include elements that reflect these responsibilities so that pharmacists may integrate new knowledge and evidence into their prescribing decisions. We will extend

this philosophy into our competence assurance initiatives.

3) Quality Assurance

Saskatchewan Health has favorably received a proposal to allow us to access the ADAPT database for quality assurance purposes. While members could use this database as it is available through the PIP MPV to assure the quality of their prescribing, we will consider initiatives to access this database to monitor or review pharmacist prescribing habits. For example this could be integrated into our Field Officer's pharmacy practice evaluations when she conducts pharmacy visits.

4) Ethics

An inherent conflict of interest arises from the pharmacist dispensing his own prescription. The usual independent scrutiny of the prescription by a pharmacist will not likely occur. Potential exists for the judgment of the pharmacist to err for reasons other than in the best interests of the patient.

Also, pharmacists must continue to respect the autonomy of the patient to decide whether or not to accept the prescribing decisions of the pharmacist, and freedom of choice of prescribing and dispensing pharmacist.

Our Code of Ethics and Standards of Practice at least implicitly prohibit unethical conduct related to the foregoing, and we will modify our Code and Standards to address such conduct.

To address the conflicts of interest that may arise from functioning in both a prescribing and dispensing role, as the regulatory body for the profession, we propose to establish appropriate ethical rules of conduct. However we believe that accountability will primarily manifest itself through the pharmacist being transparent when collaborating with the patient and other members of the health care team. With proper communications protocols, all should be aware of the decisions of the pharmacist. We propose that the prescribing and dispensing decisions of the pharmacist be recorded on the PIP Medication Profile Viewer, and we intend to describe in our legislation or rules of conduct those circumstances when the pharmacist should communicate directly with the physician, or other team members.

Conclusion

We submit this paper to interested parties to stimulate the discussion that will be needed to gain support for our concept of interdependent authority for the pharmacist to prescribe drugs. Once this support is obtained, we plan to undertake the projects identified in this paper, and to draft the legislative framework. This framework will propose the drafting changes to The Drug Schedules Regulations, 1997 and to the regulatory bylaws of the College needed to enable the pharmacist to prescribe drugs as described herein. Interested parties will be given another opportunity for consultation as the regulations and bylaws proceed through the approval process. In the meantime, we welcome any feedback.

References

¹ Emmerton, et al “Pharmacists and Prescribing Rights: Review of International Developments”; Journal of Pharmacy and Pharmaceutical Sciences (www.cspsCanada.org) 8 (2): 217-225, 2005

² Canadian Pharmacists Association “Background Paper for the Development at the Blueprint for Action for the Pharmacy Profession in Canada”, November 2005

Pharmacists and Prescribing Rights: Review of International Developments

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ABSTRACT. Purpose. Continuity of care, equitable access, and quality and safety are major foci in health services management. The introduction of limited prescribing rights to pharmacists has the potential to reduce fragmentation within the health system, optimise medication management, improve continuity of patient care and improve patient access to medication. **Results.** Eight models for pharmacists' prescribing have been implemented internationally, varying in their dependency on protocols, formularies and collaboration with physicians. These have also been described using terms such as Supplementary Prescribing and Patient Group Directions. **Conclusion.** Issues relating to practical implementation of pharmacists' prescribing include negotiation of national health policy, pharmacists' training and accreditation, liability, reimbursement and documentation.

INTRODUCTION

There has been significant change in the supply of medicines over the last few decades. Technology has made recording of prescriptions less time-consuming and the storage and access of patient histories more reliable. The use of technicians to undertake routine tasks has facilitated the introduction of medication review services utilising pharmacists' drug knowledge. Effective use of professional expertise and health resources should eliminate inefficiency

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and duplication of effort (1-3) in healthcare delivery. Prescribing requires knowledge of adverse effects, doses, optimal routes, drug-drug and drug-food interactions, pharmacokinetics, pharmacodynamics and monitoring of effects. Application of this knowledge requires significant expertise. (4)

Most medication-related interventions by pharmacists occur retrospectively; their earlier involvement in the prescribing process may help optimise the use of medicines. (5-7) Pharmacists' interventions in medication management, including monitoring of therapy, are accepted in the hospital setting. (8) Extending this process by adding the right to prescribe (select) initial therapy and to adjust ongoing therapy is a relatively small step, and arguably, simply formalises a process that is already beginning.

There has been considerable discussion in the literature about the pros and cons of new professional practice models for pharmacists, including prescribing. It has been argued that pharmacists are developing expertise in evidence-based practice and patient-centred care, suiting them to taking responsibility for prescribing and monitoring therapy (2) with potential benefits for medical practitioners.

Over time, pharmacists have been prescribing an increasing range of medications. In many countries, the existence of 'pharmacist only' medicines recognises the expertise and competence of pharmacists to prescribe. (2) Further, in a number of countries, pharmacists are already able to legally prescribe a range of medicines previously only prescribed by medical practitioners. (9-11)

With this general acceptance of pharmacist prescribing in the international pharmacy literature, it is timely to investigate the implementation of pharmacist prescribing models internationally. These models are discussed below, categorised according to their degree of independence.

Independent prescribing

Independent prescribing occurs where the prescribing practitioner is solely responsible for patient assessment, diagnosis and clinical management (2) and requires legally defined levels of knowledge and skill that are usually monitored through a licensing process (2,12). No examples of unrestricted independent pharmacist prescribing were identified in the literature.

Dependent prescribing: prescribing by protocol

'Dependent' prescribing incorporates more restriction on prescribing activities, via protocols or formularies. Prescribing by protocol is the most common form of dependent prescribing, (13) and is defined as "delegation of authority from an independent prescribing professional, usually a physician", involving a formal agreement (protocol). (12) The protocol is a written guideline, (12) an explicit, detailed document that describes the activities pharmacists may perform in their prescriptive authority (12,13).

The protocol lists:

- Types of diseases, drugs/drug categories (12,13) and prescriptive decisions covered by the agreement (7)
- The procedure, decision criteria or plan that the pharmacist must follow when prescribing (12,13)
- The physician and pharmacists party to the agreement (7)
- The time limit for the agreement (7)
- The responsibilities of each of the parties involved (12)
- The documentation required (7,12) and feedback mechanisms to the authorising prescriber (12)
- Policies for review and revision of the protocols. (12)

The level of authority should be determined by physicians' assessments of the pharmacists' competence, pharmacists' assessment of their own competence, and pharmacists' comfort with these roles (11). Both parties should be willing to share responsibility for patient outcomes (12).

Many drug groups have been deemed suitable for pharmacists' prescribing by protocol, including anticoagulants (12,14,15), analgesics (12,14,15), antiemetics (12,15) and antihypertensives (11,12,14).

Nurse prescribing under protocols, known as 'standing orders', is common in hospitals (16). In New Zealand, any registered health professional can enter into 'dependent' prescribing arrangements with authorised prescribers under 'standing orders' or protocols (17).

In the United States of America (USA), protocol-based prescribing had been successfully legislated in at least 25 states by 2001 (1,12). The prescriptive authority requires prior state Board notification of the written protocol (7,11). In the USA, Indian Health Service (IHS) pharmacists can prescribe for patients with disease states including ear infections, urinary tract infections, sexually transmitted diseases, congestive heart failure, hypertension, seizures, bacterial and fungal infections, arthritis and conjunctivitis (11). In 1979, the IHS reported that physicians had judged the quality of pharmacists' care as not significantly different to their own. The IHS model was also beneficial for patient satisfaction and pharmacist-physician relationships, reduction in physician referrals, and improvement in clinic efficiency (11).

Credentialing is another issue addressed in this model. Local pharmacies were permitted to determine the scope of practice and establish the credentials needed for prescribing. Prescribing pharmacists generally required a PharmD or MS degree, or equivalent qualification, specialty board certification or two years of clinical experience (11). The facility's medical committee or chief executive officer then approved the scope of practice based upon competence, not educational attainment.

Policy changes included the application of formal written protocols and standing orders for prescribing, requiring legislative change. Quality assurance was provided by retrospective chart reviews by physicians.

It has been proposed that prescribing by protocol can lead to containment of drug costs (14), reduction of medical practitioner visits, (18) integration with medication reviews, (18) and improving access to medicines, for example the emergency contraceptive pill. (14) In contrast, it may remove some interaction with the physician undertaking diagnosis (18), create extra workload for the prescriber (18), complicate reimbursement for prescribing, (14,18) require pharmacists to compromise other professional duties (17) and arguably lead to more room for error by involving more staff.

Implementation issues include coordination of information and access (17), accreditation, education, accountability and competency assessment, (11,17) determination of scope of practice (17) and gaining of prescriptive authority (15).

Dependent prescribing models: Patient Group Directions

A Patient Group Direction (PGD) is a written direction signed by a doctor or dentist, and by a pharmacist, relating only to supply and administration of a prescription medicine (1,19). The recipients are any patients (1,19,20), who may not be individually identified before presentation for treatment. (21) The PGD applies if a number of specified requirements are met (20), subject to any specific exclusions listed (19).

The PGD is a United Kingdom (UK) model that can be authorised by designated NHS bodies in the UK. (1,19) Trials have been reported in Manchester, two health authorities in London, South Derbyshire, Walsall and Bridgend (19).

The PGD must specifically name the Prescription Only Medicine or class of medicines, dosage form(s), applicable dosage or maximum dosage, route of administration, frequency of dosing, minimum/maximum period for administration, relevant warnings, restrictions on quantity, circumstances in which the medicine can and cannot be supplied, when further advice should be sought, follow-up action, records to be kept, and the valid period for the PGD (19).

Specific drugs listed in the literature for prescribing by PGD are emergency hormonal contraception, (19) combined oral contraceptives (22) and antihistamines (30-day courses) (23).

NHS-accredited pharmacists prescribing by PGD require dedicated training. Privacy during consultations remains an issue (22). Pharmacists should be able to manage this service concurrently with their provision of 'pharmacist only' medicines (19).

Dependent prescribing models: prescribing by formulary

In formulary-based prescribing, local formularies are agreed between participating medical practices and community pharmacies. (1) The formulary is a

limited list of medicines (12,13), including treatable symptoms, length of treatment, criteria for referrals and limitations for prescribing (23). Many of the formulary medicines are those already available without prescription in a similar formulation or lower potency (24). The model is less explicit than protocol prescribing (12,13).

In the UK around 21,700 nurses are reported to be able to prescribe from the Nurse Prescribers' Formulary, and 400 are qualified to prescribe from the Nurse Prescribers' Extended Formulary. As at October 2002, only 11,100 were actively prescribing (25).

A Scottish study of pharmacists' prescribing by formulary included 11 therapeutic areas (23). There was no evidence of abuse of the system in the Scottish trial, and the scheme was well received by patients (23).

The model requires considerable record-keeping, and has been perceived to add liability to pharmacists (24). Policy issues also include prevention of over-prescribing to patients consulting more than one pharmacist (23). The optimal physical environment in the pharmacy should be determined such as an extra pharmacist and private consultation area (23). If this scheme were widely adopted, a national pharmacy formulary would be recommended (23).

Dependent prescribing models: prescribing by patient referral

Patients (1), practice staff (1,12) or another community pharmacist (1) may refer patients to a pharmacist for a prescription. Typically, patients would be individually referred to a pharmacist by a physician for "management of specific drug therapy or to achieve a specific therapeutic outcome" (12,13). The most common example of this model is the ambulatory care setting within a health care facility (12,13).

A trial of patient referral to pharmacists (with formulary-guided prescribing) in Merseyside, UK, involved 12 minor ailments (26). A single medical practice referred 38% of all presentations to one of eight pharmacies. Patients were less likely to accept referral if they perceived a need for a physician's examination, if previous self-treatment had been unsuccessful, if the patient was a child, if the patient had a concomitant condition or influential medical history, or self-perceived a need for an

antibiotic. In this study, physicians' workload dealing with minor ailments decreased from 8.9% to 6.6% due to the referral system, and patients reported saving time and had improved accessibility to providers and treatments. The program costs were "not substantial", and overall prescribing costs did not increase. The referral model involved identification of eligible ailments at the medical practice and offering pharmacists' consultation. A consultation form was completed by reception staff and faxed to the chosen pharmacy, where the pharmacist recommended a medicine from the formulary or referral back to a medical practitioner. Pharmacists were paid £1.50 for their professional input, while medicines were supplied under NHS subsidy.

Dependent prescribing models: repeat prescribing

Repeat prescribing involves pharmacists providing medication-refill services in clinics associated with medical centres, for patients who have exhausted their prescribed drugs before their next physician appointment. The pharmacist assesses the patient and therapy and either:

- Consults the attending physician if there are problems with compliance, disease control and/or side effects (11,27)
- Writes refill prescriptions for dispensing at another pharmacy (14) or
- Refills the medication with a sufficient quantity to last until the next available appointment. (11,27)

Repeat prescribing has been discussed in the UK (28), and is allowed in some 28 states in the USA (14), although there is a paucity of literature on repeat prescribing trials. In the Australian system, the Pharmaceutical Benefits Scheme has in place a procedure for repeat prescriptions written by medical practitioners.

Dependent prescribing models: supplementary prescribing

Supplementary prescribing is a voluntary partnership between the independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement (1,21,29). No clinical situations are listed in the definition, to avoid excluding others

(1,21). Supplementary prescribing is not restricted to one-to-one prescriber partnerships, as patient care is largely delivered by teams (1).

The independent prescribers are doctors or dentists (29,30). Supplementary prescribers are registered pharmacists or nurses (1,21,29,30). The independent prescriber undertakes the initial assessment (21,29) and the supplementary prescriber can then write prescriptions at public expense (1,29), working to a care management strategy that has been agreed by the physician (31).

The supplementary prescriber's roles include contributing to clinical management plan monitoring (1), changing the medicine and referring to the independent prescriber where appropriate (1), and recording clinically relevant facts (1,29).

Central to the prescribing arrangement is the patient-specific clinical management plan that is evidence-based, consistent with recognised clinical guidelines, and agreed by prescribers and the patient or carer (1). Patients are involved in decision-making (29) and provide consent for the transfer of their information between prescribers (1). Prescribing and dispensing should be separate for patient safety and governance (1), if not, clear accountability arrangements should be in place (29).

There is no restriction on the medical conditions to which this model applies (1,21), but supplementary prescribing is unlikely to be used for acute conditions (29). All medicines, excluding controlled drugs (21,29) and unlicensed medicines (21) may be prescribed.

In the UK, supplementary prescribing was introduced in the *Health and Social Care Act 2001*. The Department of Health published an implementation guide in March, 2003. The implementation of this UK model has been thorough, addressing standards of practice to ensure public safety and probity (1) and distinguish between professional and commercial responsibilities (31). The majority of pharmacists trained to date are from hospitals, with the first registered in February 2004 (21).

Although evaluation is ongoing, supplementary prescribing is expected to demonstrate multiple benefits for health care delivery and organization (1), patient convenience (1,32), access (1,21,33), patient safety (21), concordance with clinical management plans (1), efficiency in general practice and hospitals (1), waste reduction

(1), doctors' workload (21,32,33) and professional satisfaction for pharmacists (1).

Collaborative prescribing models

Collaborative prescribing requires a cooperative practice relationship between a pharmacist and a physician or practice group, with legal authority to prescribe medications (12). Explicit collaborative agreements are negotiated within each facility (12), outlining who is delegating and receiving authority, and demonstration of competence. The group of patients may be defined by the pharmacist's expertise. In the USA, agreements must be filed with a State Pharmacy or Medical Board (2).

The physician diagnoses and makes initial treatment decisions for the patient, and the pharmacist selects, initiates, monitors, modifies and continues or discontinues pharmacotherapy as appropriate to achieve the agreed patient outcomes. The physician and pharmacist share the risk and responsibility for the patient outcomes (13).

Informally, clinical pharmacists in public and private hospitals have practised collaborative prescribing to some extent throughout the past 25 years (8,20,34-37). Examples of collaborative prescribing by hospital pharmacists in Canada and the USA include aminoglycoside and pharmacokinetic dosing services, anticoagulant therapy adjustment and chemotherapy antiemetic management (12). By 2001, 27 American States had some form of legislation that allowed collaborative practice between pharmacists and physicians (38). In Minnesota, pharmacists may provide medicines for first dosages and in emergencies (39). Collaborative models are being considered in Canada for pharmacists' prescribing (13,40), including initial drug selection or adjustments (12).

A study has been undertaken to demonstrate the appropriateness of prescribing and monitoring by hospital pharmacists (20). Evidence also supports that provision of cognitive services by community pharmacists improves patient health outcomes and possibly reduces health care costs (41).

An Australian hospital study found that a significant proportion of doctors would welcome pharmacists making written comments in the medical record notes (42,43). UK surveys, however, indicate that pharmacists, doctors and nurses have mixed feelings about the introduction of expanded roles for pharmacists (20,44,45).

Implementation issues

The eight models identified from the USA, UK, Canada and New Zealand have been mapped to demonstrate their variation in pharmacists' authority and restrictions regarding product formularies (Figure 1).

Despite the numerous commentaries in support of pharmacists' prescribing, there is a lack of evidence about the impact of such models on practice and outcomes. There is potential for such models to be implemented in a rapidly changing health care system as the fundamental principles of patient-centered and integrated care in a financially and clinically responsible manner apply. There are many issues that must be addressed before such models can be implemented; these are discussed below.

1. Professional issues

Responsibility must be taken for the whole process of diagnosis, prescribing and follow-up, including an awareness of boundaries or limitations to expertise (46). Not all pharmacists may want to undertake this responsibility.

There is a need for appropriate baseline and continuing professional education (12,46). It is probable that all registered pharmacists have the expertise required to undertake *dependent* prescribing without further intensive education, other than training in the prescribing process itself (2,3). It is important, however, that all pharmacists undertaking *independent* prescribing roles demonstrate competence, and that a register be kept of suitably qualified pharmacists (3). *Collaborative* prescribing may only require the assessment of competence at an institutional level (12). A contrasting viewpoint is the need for a uniform standard of competence for prescribing pharmacists, irrespective of the prescribing model utilised (9,47).

The separation of dispensing and prescribing is seen as an important component of the 'checks and balances' ensuring that the most appropriate treatment is chosen for the patient. Pharmacists currently prescribe and dispense for minor conditions; however, extending this responsibility to prescription medicines may introduce new quality assurance issues.

Periodic review of pharmacists' prescribing practices may be required as a mechanism for

maintaining standards and ensuring optimal patient outcomes (3,11). Audits may focus on such activities as adherence to prescribing protocols, adverse events or outcomes assessment (48).

Maintenance of, and access to, patient records are required when a pharmacist prescribes medication. The system should be comprehensive, effective and time efficient (48,49), and may require transfer of information back to the medical practitioner.

Securing remuneration for professional responsibility is another essential step in the adoption of prescribing rights. Pharmacists who have undertaken additional education and are prepared for the increased responsibility associated with prescribing should be appropriately compensated financially for this task (6,12). There are few models of remuneration available, and their international applicability is questionable.

2. Changes to medication prescribing

International developments show that enhanced clinical roles for pharmacists are valuable, and that

pharmacists have the expertise to contribute to patient care. For widespread acceptance, services provided by pharmacists must be promoted to the public, health care system administrators and government (50). Pharmacist prescribers must also recognise the rights of consumers to choose the practitioner of their choice and to reject recommendations that are made (48).

There may be resistance to change from within the pharmacy profession, and other professions may feel that prescribing pharmacists intrude on their area of professional responsibility (46). The careful development of collegial working relationships is essential in the acceptance of new prescribers.

With successful implementation of alternative prescribing models, costs for patients may decrease (46), as knowledge of the cost associated with therapeutic alternatives may inform treatment decisions. Costs for pharmacists may increase if the physical layout of the pharmacy requires modification to facilitate private counselling (3).

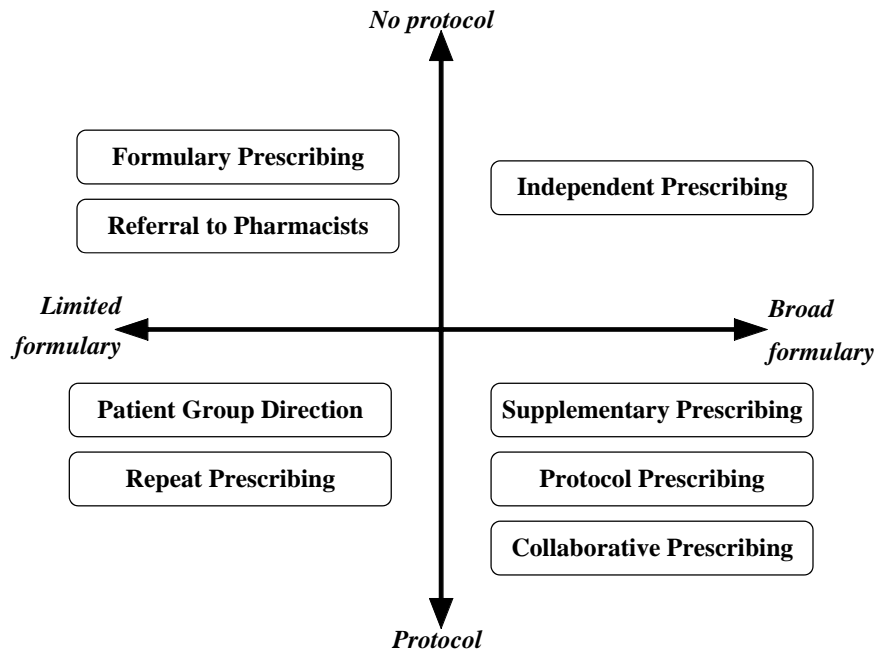


Figure 1: Models of pharmacist prescribing

3. Workload and workforce issues

There are workforce-related issues related to pharmacists gaining prescribing rights. It may be possible that pharmacists who prescribe medicines spend less time seeking approval for changes to existing prescriptions or obtaining 'owed' prescriptions, therefore improving workload. Adopting and maintaining new services may present a challenge for the pharmacy profession in some countries where a shortfall in pharmacists has been predicted (50,51).

4. Legal issues

For successful implementation of pharmacist prescribing models, a statutory framework needs to be in place, and a separate register of those pharmacists who have been judged competent to practise as 'prescribing pharmacists' is recommended (52). Legal requirements may depend on the actual model implemented, considering the degree of responsibility required of the pharmacist.

CONCLUSION

There are many papers that voice opinion and rhetoric about pharmacists' prescribing of Prescription Medicines. From the literature, we identified eight relevant models implemented internationally. The impact of these models on health outcomes and health care systems have not been well studied.

If pharmacists are to be granted the right to prescribe, they must also accept the inherent responsibilities. Establishing a rigorous clinical governance framework will be critical to establishing prescribing models in any setting. There are numerous professional, technological, educational and legal issues that must be resolved before pharmacists can prescribe. The introduction of collaborative or supplementary prescribing models may be an appropriate first step.

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