International Pharmaceutical Federation
Fédération Internationale Pharmaceutique
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FIP REFERENCE PAPER
COLLABORATIVE PRACTICE

Preamble
The FIP Working Group on Collaborative Practice was established in 2007 by the FIP Board of Pharmacy Practice (BPP) with the purpose of developing a robust definition of collaborative practice with particular emphasis on the advanced collaborative practice; to identify the contribution of pharmacists within collaborative practice in terms of evidence based improvements in patient care and/or health economics; and to identify the current status of collaborative practice throughout the world supported by a number of international exemplars of collaborative practice.

This document is the outcome of their work and is aimed to be used as both background information and as directive guidelines for future progress in Collaborative Practice.

FIP commends the efforts of the Working Group on Collaborative Practice as listed by name and affiliation below, with a special thanks to the efforts put forth by Co-Chairs Dr Jill Martin and Mr David Pruce.

FIP Working Group on Collaborative Practice:

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Please note: all reviewers of this document are requested to consider the following issues:

1. What elements are missing in the reference paper and should be added?
2. What are the key issues from this reference paper that should be incorporated or highlighted in the FIP policy statement?

Please submit your comments to generalsecretary@fip.org

Executive Summary

Patient care is becoming increasingly complex with an ever increasing range of medicines and other interventions available to the healthcare team. Pharmacists have particular skills and expertise about medicines and their use that they bring to the multi-disciplinary team and to the patient. Collaboration between healthcare professionals is at the heart of good clinical practice. Multi-skilling and task-shifting are increasingly being viewed as important ways in which to manage the critical shortages of health care workers in many parts of the world.

COMPLEX PATIENT CARE

The degree to which pharmacists collaborate with other members of the healthcare team varies both across healthcare systems, but also within the same healthcare system. The level of collaboration between pharmacists and other healthcare professionals goes from minimal contact through to pharmacists who are seen as a core part of the multi-disciplinary team with the authority to initiate and modify medicine therapy. In more advanced practice settings, termed "Collaborative Pharmacy Practice" (CPP), the pharmacist is recognised by the multi-disciplinary team as the lead professional in managing patients' medication therapy.

COLLABORATION

We have identified five distinct levels of collaborative practice with a number of models across the world within each level. CPP is often reserved for advanced practitioners who are able to demonstrate the competence required to initiate and modify medicine therapy. As pharmacists take on the responsibility for initiating and modifying medicine therapy, the need for collegial interaction with the multi-disciplinary team increases. The pharmacists must be able to recognise the limits of their competence and refer the patient to another member of the team when necessary.

LEVELS OF PRACTICE

There is good evidence that pharmacists intervene on inappropriate prescriptions and that these interventions are clinically appropriate and have a high acceptance rate. There is also strong evidence for medication review services where pharmacists review a patient's medication regime and make clinically appropriate recommendations to physicians. The evidence around pharmacists initiating and modifying medicine therapy directly is less well developed but shows enhanced clinical benefit and good patient acceptability. The level of preventable drug-related problems makes a compelling argument for a collaborative approach to medicines use involving the pharmacist.

REVIEW AND INTERVENTION

We have reviewed the evidence for CPP and the barriers and drivers for the development of this type of advanced practice. Building the clinical competence of the pharmacy workforce and systems to ensure patient safety are critical first steps. Gaining the support of governments, other healthcare professions and of pharmacy itself is also crucial to the development of collaborative practice. We recommend that pharmacy organisations take a stepwise approach to the development of CPP.

EVIDENCE AND SUPPORT

The continued development of the clinical role of pharmacists, in particular CPP, will bring benefits to the future care of patients across the world. This can only occur in collaboration with other healthcare professions and must not be seen as something that pharmacy can do in isolation. Pharmacy has much to offer patients, carers and the public but it can only fulfil its promise by working alongside other members of the healthcare team. We urge all national pharmacy organisations to work with their medical and nursing colleagues to ensure pharmacists have a core place in the multi-disciplinary healthcare team. This is the best way in which we will achieve the optimum outcome for our patients.

WORKING TOGETHER

Pharmacists Collaborative Practice: Pharmacists Managing Patients' Medicine Therapy

Outline

1. Introduction

Collaboration between health professionals is fundamental to good quality healthcare. The International Pharmaceutical Students Federation and the International Federation of Medical Students' Associations produced a joint statement called "Working Together for Better Health Outcomes[1]. In this statement they said: -

"Multi-disciplinary collaboration between health professionals is an essential part of providing comprehensive and patient centred care"

Collaboration between pharmacists and other healthcare professionals takes many forms and is performed to a number of levels. This paper reviews the different models of collaboration from minimal contact; through reactive advice; to Collaborative Pharmacy Practice (CPP). Collaborative Pharmacy Practice is an advanced practice that provides tangible benefits to patients and meets a need for advanced pharmaceutical care. This is a relatively new practice that is only present in a limited number of countries across the world. It has grown out of the development of an advanced clinical practice among pharmacists that has included a high degree of collaboration with other healthcare professionals.

COLLABORATION TAKES MANY FORMS

Even in those countries where models of CPP have been permitted, there are often other levels of collaboration working alongside. For example, a number of countries have passed legislation to enable pharmacists to initiate and modify medication regimes but each also has a number of examples of pharmacists working at lower levels of collaboration.

Every country should be aiming to develop the clinical role of the pharmacist and to build multi-disciplinary collaboration. As this clinical role develops, pharmacists will need to develop models of Collaborative Pharmacy Practice that are applicable to their own particular healthcare system. We would like to see the clinical role of pharmacists develop in every country of the world to the point where Collaborative Pharmacy Practice is a natural step for advanced practitioners. We fully recognise that this goal will be easier to achieve in some countries than in others and that currently it may be easier in a hospital environment. We advocate a stepwise approach to the development of the clinical role of the pharmacist and of collaborative working with other healthcare professionals and have set out some of the steps in the progression towards Collaborative Pharmacy Practice.

STEP WISE APPROACH

2. Definition of Collaborative Pharmacy Practice

Collaborative pharmacy practice (CPP) is defined as: -

The advanced clinical practice where pharmacists collaborate with other healthcare professionals in order to care for patients, carers and public.

DEFINITION – COLLABORATIVE PHARMACY PRACTICE (CPP)

Collaborative pharmacy practice may include, but is not limited to:

- Initiation, modification and monitoring of prescription medicine

therapy
- Ordering and performing laboratory and related tests
- Assessing patient response to therapy
- Counseling, educating partnering with a patient regarding their medications
- Administering medications

An important aspect of collaborative practice that differentiates it from other aspects of pharmacy practice is that the pharmacist works in close collaboration with other healthcare professionals (primarily physicians and nurses*). This is in contrast to the well-established practice of over-the-counter provision of non-prescription medicines by pharmacists. Although collaboration with and referral to other health care practitioners may occur in that process, these practices are not the norm.

3. Levels of collaborative practice

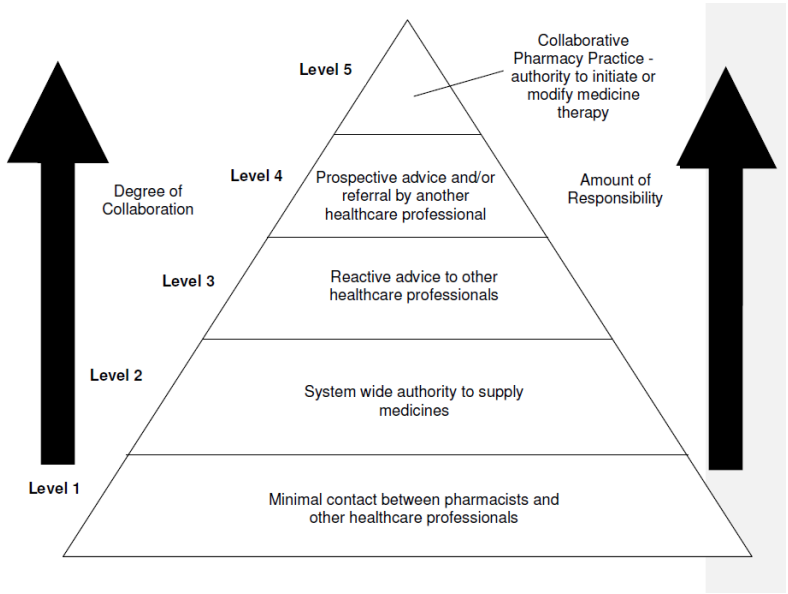
There are a number of levels of collaborative practice depending on the degree of collaboration between pharmacists and other health care professionals. The five levels may all be present within the same system. The higher levels of collaborative practice often are reserved for advanced practitioners and may be relatively infrequent in number in the healthcare system. It is likely that the profession would need to move from one level to the next in a stepwise manner and highly unlikely that pharmacists would be able to move from level one directly to level five without a period of development at some or all of the intermediate levels.

LEVELS OF CPP

The focus of this paper is on attaining the highest level of collaborative practice. However, it is important to recognise that the levels below this are also vitally important. There is good evidence that pharmacists working at levels 3 and 4 make a significant impact on patient care. The pace of change will be different in each health system and the optimal exploitation of levels 3 and 4 will be essential.

* This is particularly important in countries or health systems that have advanced nurse practitioners with prescribing rights

Level 1 – Minimal contact between pharmacists and other healthcare professionals



At this level, pharmacists work in isolation from other healthcare professionals. Each profession has a clearly defined role with separate responsibilities and there is little requirement for contact between the two professions.

At this level, the role of the physician will be to diagnose and prescribe and the pharmacist's role will be to supply the medicines prescribed by the physician (or other authorized prescriber). The pharmacist may advise the patient about how to take their medicines but is unlikely to have a diagnosis communicated to them by the prescriber. The majority of the communication is via a written prescription from the prescriber and formal communication from the pharmacist (for example, to check the prescriber's intentions where a prescription is unclear).

The pharmacist will also have the ability to sell various medicines directly to patients over the counter. The patient's physician will not be informed of the purchase by the pharmacist and it will be the responsibility of the patient to inform the physician if they wish to.

Level 2 – System wide "pharmacy only" or "pharmacist only" authority to supply medicines

In many countries, pharmacists have the national or local authority to supply medicines to patients that cannot be obtained from other retail premises.

<u>National authority</u>

A number of countries have categories of medicines that are classified as either pharmacy only or pharmacist only. Pharmacy only medicines may only be supplied from a pharmacy whereas pharmacist only medicines must be supplied by the pharmacist in person. These are examples of national recognition of the pharmacist's knowledge and skills and national authority to supply medicines that only they may supply without a prescription.

Other examples of national authority are the ability to supply medicines in an emergency that can normally only be obtained on prescription. The examples of a national authority to supply medicines require the agreement of the national government and usually require the endorsement of the national professional leaders. However, they do not require local collaboration between healthcare professionals as part of their authority. They represent recognition at the national level of the ability of the pharmacist and their position in the overall delivery of healthcare.

Local authority to supply

A variety of agreements operate at the local level that enables pharmacists to supply a wider range of medicines to patients without the requirement for a prescription. These may be limited to a particular institution (e.g. a hospital) or it may extend to a local health economy.

Local agreements will cover a variety of situations where local physicians and pharmacists agree that the pharmacist may supply medicines that are either normally only available on prescription or are normally only reimbursed on the authority of a physician. These local agreements will usually include a protocol to be followed to assess whether a patient is suitable for the medicine or for reimbursement through the local scheme.

Examples of this sort of agreement include the UK's Patient Group Directions and protocol supply. In both of these types of agreement, a protocol is drawn up between physicians and pharmacists to agree the criteria that must be met before a patient is deemed to be suitable for inclusion in the agreement and the action to be taken by the pharmacist. The action may include the medicines to be supplied; the counselling to be given, the record keeping and communication with the patient's physician. The level of collaboration involved will vary according to the local agreement but these types of agreement usually allow the pharmacist to operate in an independent manner with communication occurring after the pharmacist has taken action. Most local agreements will stipulate whether the protocol is open to all pharmacists or only to those pharmacists who meet locally agreed criteria. These criteria may be based on levels of competency, specialist knowledge or may limit the agreement to named individuals.

Level 3 - Reactive advice to other healthcare professionals

3 – REACTIVE, MULTIDISCIPLINARY

Pharmacists will be expected to assess a prescription before it is dispensed. If the pharmacist believes it to be clinically inappropriate (e.g. an overdose), they will be expected to refuse to dispense it and to contact the prescriber. The degree to which the pharmacist will intervene on a prescription will be dependent on the amount of information that the pharmacist has about a patient and their professional competence.

Prescription intervention occurs after a prescription has been generated by a physician (or other prescriber) and is a reactive service. It will vary from interventions that are based on preventing a serious error to those that are aimed at optimising therapy to maximise the benefit for a patient. The degree to which a pharmacist will intervene will usually

depend upon the relationship that the pharmacist has with the prescriber, the information about the patient that is available to the pharmacist and the competence of the pharmacist. This type of interaction may happen in primary or secondary care.

Ward pharmacy in hospital is an example of where the pharmacist will review the prescriptions for all the patients on a ward. The pharmacist will authorise supply of any prescriptions where the medicine is not kept on the ward. The ward pharmacy service often goes beyond the supply of medicines and also involves checking the clinical appropriateness of the prescription. This will usually involve looking through a patient's clinical notes and assessing whether the prescription is appropriate for the patient's condition taking into account the patient's overall clinical picture including any test results. This requires a level of clinical knowledge and competence in the pharmacist to understand the clinical diagnosis, the most appropriate treatment for the condition, the effect of any coexisting conditions and the interpretation of clinical tests.

The amount of advice that is accepted by the prescriber will often be a reflection of the degree of collaboration between the two professionals and the amount that the pharmacist is seen as a part of the multi-disciplinary team.

Level 4 – Prospective advice and/or referral by another healthcare professional

4 – PROSPECTIVE ADVICE AND REFERRAL

The next stage of collaboration is where the pharmacist moves from offering advice on the basis of an existing prescription to where the pharmacist becomes part of the decision to initiate or modify a prescription. There are two main models for this type of collaboration – the inclusion of the pharmacist in the team making prescribing decisions or the referral by the prescriber to the pharmacist for advice. Both of these models have grown out of the pharmacist giving post-prescription advice.

<u>Inclusion of the pharmacist in the team</u>

In the hospital setting, many clinical pharmacy services incorporate the pharmacist attending ward rounds with the physicians, nurses and others. The pharmacist will be present at the time that prescribing decisions are made and will be asked for their advice before the prescription is written. The pharmacist is seen as a key part of the multi-disciplinary team and their particular skills and knowledge are valued by the team.

<u>Referral to the pharmacist for advice</u>

Referral of a patient to a pharmacist for assessment may occur in the hospital setting or in primary care. In hospital, patients may be referred to the pharmacist for specialist prescribing such as total parenteral nutrition (TPN) or for a review of their medication (for example prior to discharge from hospital or where the patient is on complex medication such as post renal transplant). In primary care, patients with multiple pathologies taking multiple medications may be referred to a pharmacist for advice on how to rationalise or optimise the patient therapy. This is often referred to as a medication review.

In both of these situations the pharmacist offers advice that the prescriber has the option of accepting or rejecting. No change to the patient's treatment is made without the agreement of the prescriber. In the majority of cases, the pharmacist's advice is accepted in full and the treatment is adjusted as recommended by the pharmacist. The degree of collaboration is dependent on the trust there is between the prescriber and the pharmacist and on the competence of the pharmacist.

Level 5 – Collaborative Pharmacy Practice - Authority to initiate or modify medicine therapy

5 – CPP: AUTHORITY

The highest level of collaboration occurs where the pharmacist is given authority to initiate or modify medicine therapy rather than to advise on the initiation or modification of medicine therapy. At this level, the pharmacist takes responsibility for the decision to prescribe for the patient and has accountability for achieving appropriate medication therapy outcomes. The pharmacist is able to initiate or modify medicine therapy within bounds agreed within the team. These boundaries may be narrow or broad according to the circumstances of the pharmacist, the team and the legal framework that they are operating under.

The multi-disciplinary team will be aware of the pharmacist's role and will have adjusted their role in the team to take account of this role. The team will support the pharmacist to prescribe and will accept referrals from the pharmacist when the pharmacist needs their particular skills (for example if the pharmacist feels that the patient requires further diagnostic investigation). In this model, the pharmacist accepts shared accountability for the outcomes of the medication therapy. This level of collaboration is not setting specific and may occur within a hospital or in primary care. The pharmacist may see patients with other members of the healthcare team or alone. They are, however, part of a supportive collaborative team of professionals treating a patient.

Critically, this level of practice usually requires a system-wide change in national or state/provincial law. In addition to recognition of the unique range of skills and competence of the pharmacist, it may be prompted in response to the need for task shifting or the provision of cost effective patient care.

4. Collaborative Pharmacy Practice (CPP)

The attainment of CPP [Level 5] brings benefits to patients and to health systems. However, it also brings risks that need to be managed before the higher levels can be attained. CPP has a number of assumptions and prerequisites before it can be safely and properly implemented.

- 4.1 Patient focus: Patients are the focus and the beneficiaries of CPP. This requires an environment where health professionals cooperate in sharing information (diagnosis, test results, treatment plans, progress notes, etc), so that each is empowered to make informed decisions about patient treatment and care based on his/her unique knowledge and skills. Decisions in a CPP environment may

PATIENT FOCUS

be made independently or by a team of health professionals, in conjunction with the patient and/or carer. Independent decisions are NOT autonomous, as they rely on cooperation of and partnership with patients and health professionals sharing information and working together to benefit patient care[2].

- 4.2 Collaboration: In order to be able to effectively advise on the initiation or modification of medicine therapies or to personally initiate or modify medicine therapies, pharmacists must be in a collaborative relationship with other members of the healthcare team and have the support of peer professionals to undertake a collaborative service. They must be able to refer patients to other members of the team when issues arise that are outside of their competence.

COLLABORATION

- 4.3 Information access and systematic communication: CPP requires the access to medical records, or other appropriate information for care to both read and to record the interventions undertaken on behalf of the patient. Modern information technology facilitates the sharing of medical records and the development of electronic medical records can be a key step moving towards CPP. In addition, pharmacists will require appropriate access to technical information to support their clinical practice. Pharmacists may need the authority to order clinical tests such as biochemical tests, drug level monitoring. The pharmacist will be expected to undertaken patient interviews and to educate and counsel the patient. Communication of both the interventions undertaken by the pharmacist and the information exchanged with the patient will be shared with other members of the healthcare team as appropriate. The practice should also promote communication across all practice settings to ensure continuity of care.

INFORMATION AND COMMUNICATION

- 4.4 Adequate time to provide care: The pharmacist will need an appropriate amount of time to provide care and appropriate facilities to ensure privacy. If tests are being performed by the pharmacist, the facilities and procedures will have to conform to the accepted standards for such processes.

ADEQUATE TIME

- 4.5 Compliance with clinical standards: Pharmacists should comply with national standards for clinical care such as nationally agreed clinical guidelines and for the generic aspects of care such as consent, confidentiality.

COMPLIANCE WITH STANDARDS

- 4.6 Appropriate education and training: In addition to their knowledge of medicines and medicines use, pharmacists need to have a good understanding of the clinical processes involved in the diagnosis and assessment of patients; the interpretation of test results and the ability to communicate effectively with the patient (interview, educate and counsel) and other members of the healthcare team. It is absolutely

EDUCATION AND TRAINING

essential to assure that pharmacists are properly trained to provide this advanced care. This requires a strong clinical foundation complemented with practical experience. In the United States, over two-thirds of the 4-year curriculum is clinically based and 1-2 years of post-graduate residency training is becoming an expectation for direct patient care in an institutional setting. To provide CPP, this level of training should be considered a minimum. Some states within the U.S. also have specific credentialing processes for pharmacist to meet the criteria to practice in a "collaborative practice agreement" within their state (see under credentialing below).

4.7 Credentialing: In Canada, U.S.A. and U.K., CPP models are seen as advanced practice. This requires an individual pharmacist to be able to demonstrate that he/she has the necessary knowledge, skills and attitudes to undertake such a role. Appropriate education and training is required to prepare the pharmacist for collaborative practice a form of *credentialing* should be undertaken incorporating a competence assessment leading to a record of the accreditation of the individual. . Ideally, this credentialing process should include an assessment of the pharmacist made by an existing prescriber. Credentialing has been defined as the process by which an organization or institution obtains, verifies, and assesses a pharmacist's qualifications to provide patient care services. This may take the form of a national or local registration with an appropriate authority. This is particularly important in situations where the pharmacist is given the authority to initiate or modify prescription medicines.

CREDENTIALING

One example of such a process is in the U.S. state of North Carolina[3]. In this state, there is a specific designation of "Clinical Pharmacy Practitioner" jointly overseen by the State Boards of Pharmacy and Medicine. This pharmacist may engage in collaborative pharmacy practice. For a pharmacist to receive this designation, certain credentials are required including the below:

> "Requirements include a North Carolina pharmacist license, agreement with supervising physician and:
>
> - Certification (BCPS, CGP) or ASHP Residency including two years clinical experience or ...
> - Pharm.D. degree with three years experience, plus completion of one NCCPC or ACPE Certificate Program or...
> - BS degree with five years experience, plus completion of two certificate programs…. "

COMPETENCE NECESSITATES EXPERIENCE

As seen in this example, practical, clinical experience is a pre-requisite for a pharmacist to demonstrate competence and be certified in this state to provide CPP. The amount of experience required by a credentialing process will vary with the degree of the practice and authority being given to the pharmacist. However, clinical experience should be a requirement before undertaking advanced practice.

A second example of credentialing is under the auspices of a national accrediting organization for hospital practice in the U.S.A., theJoint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO requires credentialing of practitioners, including pharmacists, to allow them to practice within the institution. Some of the required documentation for this process includes defining the individual's scope of practice and professional peer review. Since this process is required on an annual basis, it also serves as ongoing assurance of competence for the practitioner at their designated level of care.

NATIONAL ACCREDITATION

4.8 Ensuring quality – The role of pharmacists in CPP makes the participation in relevant continuing professional development mandatory. Many countries require practitioners in the higher levels of collaborative practice to be credentialed or revalidated at regular intervals. This is good practice and should be implemented in every country where collaborative practice is undertaken.

ENSURING QUALITY

The quality of medicine prescribing under CPP should be monitored in the same way and to the same standards as other prescribers. Pharmacists involved in CPP should be expected to meet agreed national professional standards of good practice in all aspects of the care they give including informed consent, confidentiality, etc... National standards for CPP should be developed in each country and each pharmacist should audit their practice and be monitored against these standards. For example - in Alberta in Canada, the Alberta College of Pharmacists has developed Standards for Pharmacy Practice that specifically covers pharmacists who prescribe medicines.[4] These standards have a legal basis under the Health Professions Act. The Royal Pharmaceutical Society of Great Britain has similarly included pharmacist prescribing in its standards documents and has also produced a Clinical Governance Framework for Pharmacist Prescribers[5]. This sets out a number of good practice indicators for individual pharmacist prescribers and what might need to be put in place within organisations in order to support good practice among pharmacist prescribers.

MONITORING

5. Models of Initiating and Modifying Therapy

A recent review of international developments about pharmacists and prescribing rights described a number of different models of

pharmacists being given the authority to initiate or modify medicine therapy[6].

Models of pharmacist prescribing

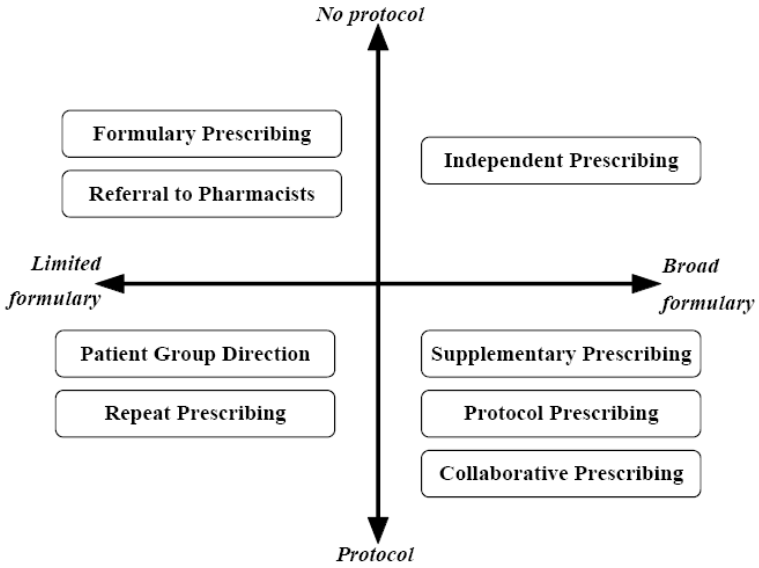


Figure 1: Models of pharmacist prescribing

Independent prescribing

The role of the pharmacist in initiating or modifying prescription medicine therapy can be largely classified as either independent or dependent prescribing. The major difference between the two is that in independent prescribing the pharmacist working within a collaborative multi-disciplinary team is responsible for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing. There are few examples of pharmacist independent prescribing in the world. Independent prescribing by pharmacists is permitted in both the UK and in certain states of Canada.

Dependent prescribing

In the case of dependent prescribing the pharmacist has delegated authority from another prescriber usually a physician. The delegation usually involves written authority in the form of a protocol, agreement or formulary. The written authority may be patient specific (e.g. supplementary prescribing - UK); facility specific (e.g. collaborative practice – USA); health authority wide (Patient Group Directions – UK) or even state/national (repeat prescribing – USA, Australia, UK; emergency sale of previously prescribed medicines – South Africa). In all these examples, the pharmacist and the other prescribers retain their own professional autonomy.

This may be further divided according to whether there is a limited or broad formulary. The degree of autonomy of the pharmacist in initiating or modifying therapy increases as the need for a protocol decreases and the formulary increases.

5.1 Limited Formulary, no protocol - Formulary prescribing and referral to the pharmacist

LIMITED FORMULARY, NO PROTOCOL

In both of these types of prescribing the pharmacist treats the patient in a similar manner to how they would if the patient presented in the pharmacy for advice and treatment. Formulary prescribing involves an agreed local formulary being developed between local physicians and local pharmacists. The formulary often contains a limited list of medicines, symptoms that are covered by the formulary and criteria for referral. The medicines prescribed by the pharmacist may be limited to those available without prescription or may be extended slightly but usually cover minor ailments that the pharmacist is used to treating in their pharmacy.

Referral to the pharmacist is a simple means of enabling the pharmacist to treat patients who have conditions that can be treated with non-prescription medicines. The physician's practice refers any patients with minor, self limiting problems that can be treated with non-prescription medicines to the pharmacist for an assessment and treatment. This is mostly used as a means of educating patients to self refer to the pharmacist rather than taking up valuable physician time. It is estimated in the UK that between 100 and 150 million GP consultations a year are taken up by patients with self limiting illnesses that are capable of being treated by the pharmacist[7].

5.2 Limited Formulary, protocol - Patient Group Directions and Repeat Prescribing

LIMITED FORMULARY, PROTOCOL

Patient group directions in the UK are formal agreements relating to the supply and administration of medicines. In this case the pharmacist is given authority to supply a specific medicine to a patient who meets a number of criteria listed in the Patient Group Direction (PGD). The PGD must be authorised by a physician and a senior pharmacist in a health authority.

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 This may include the symptoms or conditions that the patient must have before the medicine can be supplied.

This type of agreement is usually reserved for situations that do not require complex individualised treatment for example emergency hormonal contraception; azithromycin for the treatment of Chlamydia infections, etc.

Repeat prescribing involves pharmacists providing medication-refill services in clinics associated with medical centres or in community pharmacies. This may be for patients who have exhausted their prescribed medicines before their next physician's appointment or it may be in response to a repeatable prescription. The pharmacist assesses the patient and therapy and either refills the prescription or refers the patient to their physician if there are problems with compliance, disease control and/or side effects.

5.3 No Formulary, protocol - Collaborative Pharmacy Practice, Supplementary prescribing and protocol prescribing

NO FORMULARY, PROTOCOL

These are three examples of dependent prescribing which incorporate some restrictions on the pharmacist's prescribing activities by another prescriber (usually a physician).

Collaborative pharmacy practice in a majority of the United States[8] works on the basis of a relationship between a pharmacist and a physician or group of physician and gives the legal authority to prescribe medicines. The agreements are unique to each facility and outline who is delegating and receiving authority and the competence required. The groups of patients who may be treated may be defined by the pharmacist's expertise. In the USA, agreements must be filed with a State Pharmacy or Medical Board.

The physician makes a diagnosis and the initial treatment decisions while the pharmacist selects, initiates, monitors, modifies and continues/discontinues therapy.
The physician and pharmacist share the responsibility for the patient outcomes.

Supplementary prescribing in the UK involves an agreement between a physician, pharmacist and patient to implement a Clinical Management Plan. The Clinical Management Plan outlines for which conditions the pharmacist can prescribe, the range of medicines that he/she can prescribe and when the patient would need referring back to the independent prescriber. The plan usually gives a number of possible scenarios such as if the patient's condition worsens, then the pharmacist can step up the therapy within a defined protocol. Clinical management plans vary but can be as broad as treating the patient according to a published national clinical guideline. Each clinical management plan is patient specific and supplementary prescribing can be seen as a bureaucratic process.

Protocol prescribing is the most common form of dependent prescribing and is the delegation of authority from a physician involving a formal written agreement or protocol. The protocol will usually be a detailed document that describes what activities the pharmacist may perform. It will often list the types of conditions and medicines that may be prescribed; the procedure to be followed when prescribing; the physician(s) and pharmacist(s) party to the agreement and the time limit to the agreement. It may also include an explicit statement about the responsibilities of each party to the agreement and the feedback mechanisms to inform the physician of the actions taken.

5.4 No Formulary, No protocol - Independent prescribing

NO FORMULARY, NO PROTOCOL

This involves a pharmacist working within a collaborative multi-disciplinary team being responsible for the assessment of a patient with either an undiagnosed condition or a previously diagnosed condition and making decisions about their treatment including prescribing for them.

The pharmacist making the assessment will have been trained in the diagnostic skills necessary to assess the patient's condition. It is important that the pharmacist is not seen as replacing the physician

because the pharmacist's diagnostic skills do not match those of a physician. However, most pharmacists routinely assess patients when they make a sale of a medicine for treating a minor condition or when they provide a clinical pharmacy service in a hospital. They will also have had to acquire the skills to interpret various test results as part of their clinical pharmacy practice.

PHARMACIST ASSESSMENT

The pharmacist will act within their competence and will refer the patient to a physician if there is a requirement for further diagnostic expertise. For example, a pharmacist independent prescriber treating hypertension should be able to take a history, access the patient's medical record, measure the patient's blood pressure, be aware of the development of co-morbidities and be able to interpret the results. The pharmacist will then prescribe on the basis of their assessment of patient.

The term "independent" prescribing suggests that the pharmacist is acting in isolation. This should not be the case and the pharmacist needs to part of a collaborative multi-disciplinary team treating the patient. The other healthcare professionals treating the patient must be confident that the pharmacist is competent to assess and treat the patient and that they will refer the patient to other members of the team when necessary. The "independent" nature of the prescribing refers solely to the fact that the pharmacist is independently legally responsible for their actions rather than having a shared responsibility with another prescriber. The pharmacist's ability to prescribe will be limited by their professional competence rather than by written or legal restrictions. The pharmacist's prescribing will usually be subject to the same peer review arrangements as other prescribers such as physicians.

INDEPENDENT ≠ ISOLATION

5.5 Examples of pharmacists in collaborative practice roles

a. Individual Case Studies [9]

EXAMPLES IN PRACTICE

Helen Williams
Hypertension Pharmacist
Lambeth and Southwark Primary Care Trusts

Helen was initially recruited into the multidisciplinary heart failure team at King's College Hospital, London, because of published research demonstrating that a pharmacist can help reduce heart failure events and mortality. Pharmacist prescribers were then included in the cardiac rehabilitation programme to optimise secondary prevention strategies after an acute cardiac event. Their broad knowledge of medicines also enables them to support patients with complex therapeutic regimes. Using pharmacist prescribers has helped improve patients' knowledge and compliance, which should lead to improved outcomes.

Helen's current role is mainly within primary care where she runs and supports pharmacist-led hypertension clinics in GP surgeries, particularly aimed at patients whose GPs and nurses have not been able to reduce their blood pressure to recommended levels. To date, pharmacist involvement has resulted in 60% of the patients who previously failed to meet blood pressure targets now reaching recommended levels. Helen hopes that the current three clinics per week will increase to 10, managing around 100 patients per week.

HYPERTENSION PHARMACIST

Claire Richardson
Lead Specialist Clinical Pharmacist
HIV and Sexual Health
Brighton and Sussex University Hospitals NHS Trust

As an independent prescriber, Claire is able to hold a clinic where she can initiate antiretroviral therapy according to individualised patient care plans and, at the same time, advise patients on a wide variety of medicines-related issues.

Patients whose condition is failing to respond to their current therapy are able to have their current medicines changed to more effective agents by Claire, in line with test results. This is carried out during one-hour appointments where Claire is able to discuss the new treatment with the patient, while also addressing issues around medicines compliance and side effects.

LEAD SPECIALIST IN HIV AND SEXUAL HEALTH

Ensuring that patients are able to discuss their therapy and be proactive in their own care is an essential component of HIV care, where patients must be compliant with at least 95% of doses to ensure that the drug has maximum efficacy. Poor adherence and increased drug resistance ultimately leads to patients requiring newer and highly expensive anti-HIV agents.

b. Institutional Pharmacist Collaborative Practice Scenarios

Inpatient protocols
University Hospital, Cincinnati, Ohio, USA[10]

At University Hospital in Cincinnati, Ohio, collaborative drug therapy protocols approved by the institutions' Pharmacy and Therapeutics Committee provide authority for pharmacists to initiate, modify and monitor patient medications as directed by the specific protocol One inpatient example is a protocol entitled "Pharmacist-adjusted medication dosing in patients with renal dysfunction" in
which the pharmacist is responsible for daily reviewing the charts of patients with renal insufficiency and assuring that all medications the patient is receiving are appropriately dosed. Based upon the pharmacist's assessment of modifications needed, the needed changes are written as an order "per protocol". All interventions are documented in the patient's medical record. A second example at University

INSTITUTIONAL SCENARIOS

Hospital involves use of low molecular weight heparin (LMWH) therapy.

The pharmacist is consulted by the physician to assess a patient's appropriateness for outpatient treatment with LMWH plus warfarin. The process is initiated inpatient and transitioned to the outpatient setting. The pharmacist evaluates appropriateness of treatment, educates the patient, coordinates all of the drug therapy needs for discharge, completes the referral form for the pharmacy anticoagulation clinic, communicates the acute and chronic plan of care, and documents all interventions in the patient's medical record.

Outpatient protocols

Harborview Medical Center in Seattle, Washington[11]

Ambulatory Collaborative Practice by pharmacists has become standard of care at the Harborview Medical Center in Seattle, Washington. In the state of Washington, the legal definition of pharmacy practice includes "the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs". The practice protocols are all approved by the state board of pharmacy. The physician refers the patient for a "Disease Specific" or "Pharmacotherapy" consult. The patient schedules an appointment with the pharmacist in their clinic. The activities of the pharmacists include:

OUTPATIENT PROTOCOLS

- Conduct direct patient care activities
  - patient visits to establish therapeutic goals,
  - drug-related physical assessment (e.g. BP),
  - lab assessments and
  - telephone calls.
- Design recommend, monitor and evaluate patient-specific therapeutic regimens….
- Appropriate referral to other health care practitioners
- Ensure continuity of care
- Integrate disease prevention

Example disease states that pharmacist are involved in managing the drug therapy per collaborative practice agreements include cardiovascular diseases (hypertension, CHF, CAD, dyslipidemia), diabetes, asthma, depression, pain, seizures, osteoporosis, and smoking cessation. All interventions are appropriately documented in the patients' medical record.

6. Why Collaborative Pharmacy Practice?

CPP – A GOOD IDEA

Throughout the world, there are advances in healthcare and technology. The number of medications available for use is also increasing. More people are taking an increased number of medications than any other time in history. While this expanded access to medications may provide benefits in the treatment of disease, it also heightens the risk of drug interactions, adverse reactions, and non-

INCREASED COMPLEXITY OF

adherence. Management of medication regimens is increasingly complicated requiring more expertise to manage care.

MEDICATION MANAGEMENT

There has also been an exponential rise in the medical literature leading to a challenge to keep up to date with changing healthcare environment. The annual number of MEDLINE articles increased 46% between the periods of 1978-1985 and 194-2001 with a total number of pages increasing form 1.88 million pager per year to 2.79 million, respectively.[14] Further, the growth of drug therapy literature is double that of disease literature.[15] Even with the resulting multiple sources of evidence-based medicine, the task of staying up-to-date, even in one field is quite daunting.

RISE IN MEDICAL LITERATURE

These issues have contributed to the current gap between the potential efficacy and actual effectiveness of medicines as an opportunity to improve health. Much of this gap results from poor systems of medicines-use that results in drug-related problems; many of which are preventable. Studies have shown that errors that result in adverse drug events (injuries resulting from the use of medicines) occur at all steps in this system; prescribing (39%) dispensing (11%), transcribing (12%), and drug administration (38%).[16] Improving the use of medicines requires a collaborative effort among all who are involved in the system to identify, prevent, and resolve drug-related problems (errors), rather than being disconnected and working separately. Pharmacists should participate in this process, and ideally lead efforts to improve the system of medicines use.

GAP BETWEEN POTENTIAL AND ACTUAL EFFECTIVENESS OF MEDICINES

Pharmacists are one of the most accessible healthcare professionals and more fully utilizing their clinical training will extend care. Pharmacists have particularly expertise in the use of medicines. While specific training varies among regions throughout the world, the clinically focused pharmacist curriculum typically has far more medication-focused education hours than other healthcare professionals. This expertise and skill set makes pharmacists' contribution to the healthcare team important to both optimize therapy and to prevent medication related problems. No other profession has the understanding and expertise across the full range of medicines available, including the various formulations and products, as the pharmacist. Pharmacists can also reinforce preventative health measures and medication adherence.

PHARMACISTS – MEDICINES EXPERTS

This escalating complexity of care is demanding of a multidisciplinary approach, incorporating the expertise of the various disciplines to optimize patient outcome. This is particularly true as the range of treatments expands and diseases and procedures that were once reserved for exceptional cases (such as heart transplants) are now becoming routine. The pharmacist, as the medication expert, can provide assistance and leadership in managing the patients' medicine therapy regimens.

ESCALATING COMPLEXITY OF CARE DEMANDS A COLLABORATIVE APPROACH

Other factors in the healthcare landscape lend support for the expanded services of pharmacists. There are current and looming shortages of healthcare professionals in many countries. Currently, there are 2.4 million too few physicians, nurses, and midwives to

EXPANDED PHARMACIST SERVICES

provide essential care.[17] This shortage is currently a crisis for healthcare and expected to worsen before it improves.

The pattern of shortage varies across the world but most countries are instigating policies to deal with shortages of healthcare professionals. These policies include delegation of routine tasks to less qualified staff (for example surgical assistants perform an operative procedure delegated to them by the surgeon such as the initial incision, harvesting a vein or suturing the wound). These staff usually work under the supervision of a qualified healthcare professional (e.g. a surgeon) and may be an existing healthcare professional taking on an extended role that is outside of their normal scope of practice or an individual who has received specific accredited training for the task that they are undertaking. Other policies include developing the scope of practice of non-medical healthcare professionals to allow them to undertake tasks that have previously been reserved for physicians. Nurse and pharmacist prescribing is an example of this type of national policy.

WORKFORCE SHORTAGE

The WHO has suggested that one of the major constraints to tackling both the HIV/AIDS pandemic and global access to essential health care services is a serious shortage of health workers. At least 57 countries have a crisis shortage of health workers; 36 of those are in Africa. It has been suggested that task shifting is one way the public health community and national governments can address this issue head-on[18]. The World Health Professions Alliance issued a Joint Health Professions statement on task shifting in February 2008[19].

Lastly, there is escalating costs with the increased medications, both from the medication themselves as well as the potential complications from medication errors or adverse effects. Global pharmaceutical sales have increased approximately 11% per year from 1999 to 2006 with an estimated increase of expenditures from $3.5 billion to over $650 billion over the same time period.[12] Within the United States, from 1994 to 2004, the number of prescriptions purchased increased 68% (from 2.1 billion to 3.5 billion), compared to a US population growth of 12%. The average number of retail prescriptions per capita increased from 7.9 in 1994 to 12.0 in 2004[13]. Pharmacists' partnering in patient's medication therapy management has been shown to have a significant impact on decreasing medication as well as total healthcare costs [Appendix I].

In conclusion, the vast complexity of healthcare, the growing sophistication of medication therapies, the accessibility of pharmacists in era of increasing healthcare professional shortages, and the medication expertise of pharmacists, all support the need for pharmacist in collaborative pharmacy practice.

7. Current status of collaborative practice/pharmacist prescribing throughout the world

CURRENT STATUS OF CPP

The practice of pharmacy and the training of pharmacists vary greatly throughout the world as does the healthcare structure within each country. While a few countries have minimal controls for patient's access to medications, a majority of countries have restrictions for a large number of medications requiring a prescription. Much of the

worldwide pharmacy practice has a product focus, with the goal of assuring product integrity and proper distribution services. There has also been an escalation in the clinical practices and some with legislative authority for pharmacists to practice at Level 1 (Pyramid Figure 1).

Advancement of practice to the higher levels of clinical practice has been seen most markedly within Great Britain, the United States, and Canada. In all of these countries, pharmacists have the legal authority to practice in advanced clinical roles through "collaborative practice agreements" or with "independent prescribing authority". While the specific terminology of this authority differs among the countries, when closely evaluated, all are based on the foundation of working collaboratively with other healthcare professionals and having the pharmacist responsible for initiating, modifying and monitoring medicine therapy in select patient groups. Practices in which pharmacists are in these roles are primarily in ambulatory care and institutional settings, however, there are some examples in community settings as well. Having access to the necessary patient information, a process for consistent communication with other healthcare providers, and assuring continuity of care are also consistent patterns among the various approaches to this advanced pharmacy care.

Advancement in the West

There are other areas throughout the world that have developed higher level practices to varying degrees. While South Africa initiated a process to train and certify pharmacists to prescribe a limited list of prescription medicines in the late 1980s, a moratorium on the issue of such permits was enforced by the post-apartheid government. This was despite an injunction in the 1996 National Drug Policy that prescribing at primary care level be competence-based rather than profession-based. It did, however, coincide with efforts to separate prescribing and dispensing functions. Australia has developed very innovative pharmacy home-care practice. In this setting, pharmacists provide medicine therapy management to patients in their home via a pre-established relationship with a physician.

Spreading around the world

There are also reports of level 2-4 (Pyramid Figure 1) clinical pharmacy practice in other parts of Europe, Asia and South America, however, no legal authority defining level 5 practice roles. Some of the reported clinical practices in these geographical areas include providing disease state management by pharmacists in community settings and protocol driven practices in hospitals. These practices provide significant benefits to patients.

Training is commensurate with the authority. The countries in which CPP is most prevalent have pharmacy school curriculum with a strong clinical focus combined with additional post-graduate training requirements in most instances. As previously described, within the United States, over two-thirds of the 4-year curriculum is clinically based and 1-2 years of post-graduate residency training is becoming an expectation for direct patient care in an institutional setting. Some states within the U.S. also have specific credentialing processes for pharmacist to meet the criteria to practice in a "collaborative practice agreement" within their state. In Great Britain and Canada, pharmacists desiring to have "independent prescribing authority" must

also have additional training and experience beyond the pharmacy degree as specified in their regulations.

8. Evidence of effect on patient care

EFFECT ON PATIENT CARE

Evidence supports improved patient care when pharmacists are in advanced practice roles. Pharmacists initiating, modifying, and monitoring medicine therapy through established protocols or "collaborative practice agreements" with other healthcare professionals has been shown to significantly impact outcome in both the ambulatory and the institutionalized settings. Not surprisingly, a majority of the literature analyzing advanced clinical roles is from the UK, US, and Canada. Appendix I provides an overview of select references describing outcomes in pharmacist "collaborative practice" and Appendix II summarizes literature reporting the benefits of pharmacists practicing at level 2-4 in a number of settings and countries. Some of these studies are further highlighted below.

PHARMACISTS ENHANCE PATIENT OUTCOMES

Pharmacists have been shown, at least based on surrogate markers, to enhance patient outcomes in clinics managing disease states such as hypertension, cholesterol, diabetes, and anticoagulation. In one study, hypertensive patients had routine monthly visits with their clinical pharmacists in addition to their other medical care were compared to a group of patients that did not routinely meet with the pharmacists. The clinical pharmacist, as necessary, made appropriate changes in prescribed medicines, adjusted dosages, and provided medicine counselling regarding their hypertension. All changes were documented and communicated to their physician. Over a 6 month period, significantly more patients managed by pharmacists (80% vs 21%, respectively) were able to reach their blood pressure goals as compared to those who did not meet with the pharmacists[20]. Similar experience in pharmacist managed anticoagulation clinics. Patients more rapidly achieve therapeutic goals, had fewer complications, and were less likely to have additional thromboembolic events.[21]

IMPROVED PATIENT SURVIVAL

Some evidence based on harder outcomes does exist. The addition of the pharmacist to the team managing heart failure patients resulted in improved patient survival. The pharmacist evaluated medication regimens, made therapeutic recommendations to the attending physician, provided patient education and follow-up telemonitoring to heart failure patients. There was significantly lower all-cause mortality and nonfatal heart mortality in the pharmacist group (p=0.005), largely due to the reduction in hospitalization and emergency department visits[22].

RESEARCH AND EVIDENCE

In institutional settings, Bond and colleagues[23] retrospectively evaluated pharmacist medicine therapy management of 199,000 patients across 961 hospitals in the US (50.4% of these hospitals had a pharmacist for the management of aminoglycosides or vancomycin). The pharmacist, under the authorization of the prescriber was able to order lab tests, initiate or adjust medicine therapy in order to reach target drug levels. The results showed that the hospitals that did not have a pharmacist managing the drug levels experienced 1,048 excess deaths (6.71%

higher than in hospitals that had pharmacist-managed aminoglycosides or vancomycin therapy), 131,660 excess in patient days, $140,757,924 in excess total Medicare charges, $34,769,250 in excess medicine charges, $ 22,530,474 in excess laboratory charges, 134 more patients lost their hearing (46.4% HIGHER), 2,081 more patients had renal impairment (33.95% HIGHER) and 231 more patients died due to complications with aminoglycosides or vancomycin therapy. Further, a separate report from the same authors evaluated clinical pharmacy services within institutional settings which resulted in compelling evidence regarding the impact on patient outcome[24]. Data was derived from 2,836,991 patients in 885 hospitals. Hospitals that had 14 clinical pharmacy services were compared with data from hospitals that did not have these services. Seven clinical pharmacy services were associated with reduced mortality rates: pharmacist-provided drug use evaluation (4491 reduced deaths, p=0.016), pharmacist-provided in-service education (10,660 reduced deaths, p=0.037), pharmacist-provided adverse drug reaction management (14,518 reduced deaths, p=0.012), pharmacist-provided drug protocol management (18,401 reduced deaths, p=0.017), pharmacist participation on the cardiopulmonary resuscitation team (12,880 reduced deaths, p=0.009), pharmacist participation on medical rounds (11,093 reduced deaths, p=0.021), and pharmacist-provided admission drug histories (3988 reduced deaths, p=0.001). Two staffing variables, number of pharmacy administrators/100 occupied beds (p=0.037) and number of clinical pharmacists/100 occupied beds (p=0.023), were also associated with reduced mortality rates. Overall reduced mortality related to clinical pharmacy services

A systemic review of the impact of clinical pharmacists in hospitals in Great Britain similarly showed overall positive outcomes[25]. Thirty-six studies (n=18,553) met inclusion criteria, including 10 evaluating pharmacists' participation on rounds, 11 medication reconciliation studies, and 15 on medicine-specific pharmacist services. Adverse drug events, adverse drug reactions, or medication errors were reduced in 7 of 12 trials that included these outcomes. Medication adherence, knowledge, and appropriateness improved in 7 of 11 studies, while there was shortened hospital length of stay in 9 of 17 trials. No intervention led to worse clinical outcomes and only 1 reported higher health care use. Improvements in both inpatient and outpatient outcome measurements were observed.

When integrated into patient care and allowed to contribute their expertise, the data clearly supports that pharmacist can positively impact patient outcome and medical costs.

9 .System Barriers and drivers to Collaborative Pharmacy Practice

The following issues have proved to be important in driving forward Collaborative Pharmacy Practice: -

- Development of systems to ensure patient safety such as restrictions on pharmacists who are able to undertake collaborative practice; registration or accreditation of pharmacists, credentialing

or revalidation systems to ensure pharmacists remain competent; quality improvement systems such as clinical governance, clinical audit and monitoring of collaborative practice
- Gaining the support of collaborative practice from physicians and other health professionals
- Evidence base for advanced pharmacy practice
- Evidence that pharmacists' recommendations are valued and acted upon clinically
- Evidence of cost savings from pharmacists' actions and/or health economic studies
- Evidence of improved clinical outcomes and/or clinical impact

The first two issues above are essential prerequisites to the development of Collaborative Pharmacy Practice. Collaborative Pharmacy Practice could not be developed without both the systems to ensure patient safety and the support of the healthcare professionals who pharmacists wish to collaborate with.

Evidence base

EVIDENCE

The evidence base for pharmacists undertaking CPP is growing but is not as well developed as for medicine and nursing. The evidence base is greatest at the lower ends of collaborative practice. The evidence base for pharmacists being effective and safe in terms of dispensing is well documented. However, there is little direct evidence relating to pharmacists undertaking independent prescribing because it is such a new development.

There is evidence that pharmacists can bring clinical benefit to patients through an ability to initiate and modify medicine therapy and that there is good patient acceptability of such services. There is also good evidence that suitably trained pharmacists are able to undertake medication reviews and that the suggestions made by pharmacists are clinically appropriate and accepted by physicians. There is good evidence that pharmacists intervene on inappropriate prescriptions and that their interventions are also clinically appropriate with a high acceptance rate. Taken together, this provides evidence that pharmacists should be able to prescribe effectively for patients.

The evidence base contains examples of studies which are able to demonstrate that the use of pharmacists to provide clinical services is cost effective.

The ideal situation is that there is evidence that is generated in the host country of the clinical benefit, patient acceptability and cost effectiveness of pharmacists' collaborative practice. Evidence from other countries is important and the experience of countries that have successfully implemented systems that allow pharmacists to initiate or modify medicine therapy is vital to the development of collaborative practice worldwide.

Evidence of success at the current level of collaborative practice in a host country should be used to enable pharmacists to move to the next level.

Safety

SAFETY FIRST

Pharmacists will be expected to be able to demonstrate that they are capable of taking part in CPP safely and effectively without endangering patients. Governments, patients and other healthcare professionals will want to be reassured that pharmacists recognise the limits of their knowledge and skills and that they will refer at an appropriate point and to an appropriate person. It is likely that they would wish to see the initiation and modification of medicine therapy restricted to advanced pharmacist practitioners.

NATIONAL RESTRICTIONS

A number of countries have introduced systems that restrict the ability to initiate or modify medicine therapies to specific practitioners. This may be a local system of accreditation within a facility or locality or a national system of registration with a regulator. The quality assurance system often includes a number of hurdles that the pharmacist must pass in order to become accredited or registered. This may include successful completion of a period of training or a demonstration of ability and experience. The systems that have been established for some time also include a periodic credentialing or revalidation to ensure that the practitioner remains at a suitable clinical level.

Pharmacists currently both "prescribe" and supply medicines for minor ailments but the extension of this to prescription medicines could introduce additional risks. An important principle that underlies pharmacists initiating or modifying prescription medicine therapy is the separation of prescribing and dispensing. The separation of these two functions helps to ensure that there are adequate checks and balances so that the most appropriate treatment is prescribed for the patient. In addition, the presence of a second check of a prescription by another healthcare professional provides a safety check in case of a mistake being made by the prescriber.

Training/competence

COMPETENCE – A PREREQUISITE

Clinical competence is a pre-requisite for CPP. The required clinical content and clinical experience must be built into the undergraduate programme in order to prepare pharmacists for undertaking a largely clinical role. Post-graduate training, such as residency training, may also be needed to enhance clinical experience. Some organisations have also developed competency frameworks for pharmacists who are initiating or modifying medicine therapy to ensure that pharmacists are competent to undertake these roles. This is vital to ensure that they are safe and effective prescribers.

JOINT LEARNING

Longer term drivers for CPP include building joint learning into the undergraduate curricula of physicians, nurses and pharmacists and into the professions continuing professional development programmes. Another driver for CPP is encouraging face to face meetings between pharmacists and physicians. Examples include attendance at clinical ward rounds or case conferences, education, clinical audit or other clinical reasons. This fosters collaboration and a shared understanding of each others skills, knowledge and role.

Pharmacy service moving from current level to level of collaborative practice

In order to move the profession towards collaborative practice, pharmacists must be ready and willing to advance their practice to incorporate a collaborative practice role. Indeed, there may be some resistance to change from within pharmacy itself. Collaborative practice demands an emphasis on the clinical role of the pharmacist. There are a number of "precursors" to collaborative practice which help to develop the clinical role of the pharmacist and prepare the profession for a time when the pharmacist initiation and modification of medicine therapy is a natural progression. Examples of roles which may prepare pharmacists for a more clinical role include: -

PHARMACISTS MUST BE READY AND WILLING

- Clinical pharmacy in hospitals including regular participation in ward rounds
- Medication review in a number of settings
- Participation in minor ailment schemes in ambulatory/community settings
- Working alongside physicians and nurses in a collaborative manner
- Initiating or modifying therapy under protocol/patient group directions.

As pharmacists develop their clinical role, they will need to develop their support staff to play a bigger part in the supply of medicines. In many settings, the supply of medicines is becoming automated or delegated to support staff (pharmacy technicians and others). The business model for pharmacy changes under collaborative practice with pharmacists being rewarded for their cognitive services rather than their supply services. The model needs to recognise the shift to adequately incentivise pharmacists to undertake cognitive services while support staff gains more responsibility for medicines supply.

BUILD SUPPORT STAFF

Local support

The relationship that is developed between a pharmacist and the other members of the healthcare team often determines the role that he/she is allowed to undertake. Multi-disciplinary teams operate under a high degree of trust between the different members. The rest of the multi-disciplinary team must be able to recognise both the role of the pharmacist in the team and be confident that the individual is capable of performing that role.

In the same way that the other members of the team must feel confident about the pharmacist, the employing or commissioning organisation must also have this confidence. The organisation will often bear the financial risk of any failure to deliver high quality patient care. It must, therefore, be assured that the pharmacist is not going to place them in a position where their risk or cost base is increased.

CONFIDENCE IN EACH OTHER

National support

The support of the government is essential since they will need to introduce or support the legislative changes that are required. The government will have to be convinced of the need for collaborative practice; that it is supported by other healthcare professions; that it is safe and that it will deliver benefits for patients and the healthcare system.

GOVERNMENT SUPPORT IS ESSENTIAL

Potential drivers that will lead to government support include: -

- Recognition of the potential of pharmacy to deliver patient benefits, patient safety and/or cost benefits
- Shortages of physicians or other healthcare professionals (this could lead to a need for pharmacists and others to undertaken roles previously undertake only by physicians)
- Changes to the work patterns of physicians e.g. restrictions on the length of time physicians can work could lead to similar problems that pharmacists could help to solve
- Shortages in a speciality or in general practice e.g. the transfer of care from secondary care to primary care can lead to shortages in general practitioners
- Support from the medical profession and/or other health professions for collaborative practice
- Pattern of advanced pharmacy practice that could benefit from pharmacists being able to initiate and modify medicine therapy
- Patient support for the extension of pharmacy practice
- The presence of appropriate pharmacists at senior levels of the Health Departments to champion pharmacy's case

GOVERNMENT DRIVERS

Gaining the support of physicians and other health professionals can be difficult. Lessons learned from areas where collaborative practice has been successful suggest that it is helpful to be able to build on existing relationships between national pharmacy organisations and medical organisations. Physicians and other health professionals will want to be reassured about patient safety and clinical effectiveness and will expect to see systems in place to assure quality.

BUILD ON EXISTING RELATIONSHIPS

In the same way as the government will want to see evidence, physicians and other health professionals will want to see the evidence base on which collaborative practice is based. It can be helpful to make use of champions for collaborative practice amongst the medical profession to help to reassure physicians and other health professionals of the need and safety of collaborative practice.

Other issues that physicians may need reassurances about: -

- Collaborative Pharmacy Practice will not adversely affect physicians' remuneration or lead to competition between physicians and pharmacists either for patients or for funds
- Physicians' workload will be decreased overall rather than increased
- Pharmacists will not be attempting to replace physicians or to become "mini-physicians" and that physicians status will not be

REASSURING PEERS

undermined

The successful introduction of nurse prescribing has been instrumental in making the case for pharmacist prescribing in the UK and elsewhere. It can be argued that because pharmacists have far greater knowledge about medicines, they would be a natural choice as a prescriber. The successful introduction of non-medical prescribing makes a powerful case for change.

We have previously highlighted that CPP requires the ability to read and write to patient's medical records; to order or undertake clinical tests; to access clinical databases; to hold confidential interviews with patients and the appropriate facilities to undertake this work. The availability of all of these "tools" to aid collaborative practice drives the development of collaborative practice and removes potential barriers.
National support may be required to develop a remuneration system that adequately rewards pharmacists for taking on new roles and responsibilities. This system should not be seen as taking money away from other healthcare professionals or it is unlikely to get the support of the other members of multi-disciplinary team that the pharmacist is collaborating with.

AVAILABILITY OF RESOURCES

Legislation

It is likely that many countries will require changes in legislation to allow the full implementation of CPP. This may include legislative changes to specifically allow pharmacists to initiate or modify medicine therapy. Legislation is the final step in a process of change and requires the support of the government. The content of the legislation is important if CPP is to be encouraged. Pharmacy organisations need to be clear about what they want to achieve from the legislation. Legislation can free up practice but badly thought through legislation can inadvertently place barriers in the way of progress. The model of CPP that the profession wants must be clearly articulated to the government so that the legal draftsmen can frame the law appropriately. If at all possible, it is helpful for the pharmacy organisation to be involved in the process of developing the new laws. This enables sufficient freedoms and safeguards to be incorporated into the law to make CPP effective and safe.

CHANGES IN LEGISLATION

10. Summary

The continued development of the clinical role of pharmacists, in particular CPP, will bring benefits to the future care of patients across the world. This can only occur in collaboration with other healthcare professions and must not be seen as something that pharmacy can do in isolation. Pharmacy has much to offer patients, carers and the public but it can only fulfil its promise by working alongside other members of the healthcare team. We urge all national pharmacy organisations to work with their medical and nursing colleagues to ensure pharmacists have a core place in the multi-disciplinary healthcare team. This is the best way in which we will achieve the optimum outcome for our patients.

BENEFITS TO FUTURE CARE OF PATIENTS

<u>Recommendations</u>

We believe that CPP should be promoted as a goal throughout the world. Each country should take steps to prepare their pharmacists and healthcare systems to undertake this role and to move from level to level of collaborative practice.

There are a number of different models for CPP from protocol driven to supplementary to independent. Each model has strengths and weaknesses and will be appropriate for different clinical situations and the most appropriate model(s) for each country should be chosen that is most appropriate for the local healthcare system. It is a dynamic process that is evolving over time and each country should regularly review its situation.

Recommendations to FIP

WE RECOMMEND

TO FIP

- FIP should hold an international symposium on CPP to publicise its position on Collaborative Pharmacy Practice. There should be sessions on CPP at the next FIP conference
- FIP should hold talks with World Medical Association and International Council of Nursing, appropriate international patient/consumer groups and the WHO to gain support for the concept of CPP. The possibility of joint statements about CPP should be explored
- Fund a survey of all FIP members on their views on CPP and where the organisations are in the development of CPP (formal research project). This should be undertaken now and repeated in 5 years time to measure the change in practice over this period of time.
- FIP should encourage additional research into clinical outcomes, impact and economic effect of CPP

To pharmacy organisations

TO ORGANISATIONS

- Each member organisation should develop a strategy to implement CPP at the earliest possible opportunity and to encourage pharmacists to develop higher levels of collaborative practice.

Pharmacy organisations wanting to drive forward CPP should consider how they can prepare the profession of pharmacy for developing CPP. Pharmacy organisations can have a key role in driving forward CPP. The potential ways in which they can support the development of CPP include: -

- Establishing an environment which encourages pharmacy to develop its clinical practice
- Develop the evidence base for advanced pharmacy practice at a national level
- Establish good working relationships with physicians' organisations and other healthcare professional organisations
- Build a business model for CPP that rewards both pharmacists and the other healthcare professionals with whom they are collaborating
- Develop the regulatory and patient safety systems to allow CPP to develop safely

- Review the undergraduate curriculum, pre-registration and immediate post-registration training to ensure that it delivers sufficient clinical teaching and clinical contact time to support the development of CPP
- Ensure that suitable CPD is available to support CPP
- Ensure that pharmacists have the ability to access patient's medical records, to order or undertake clinical tests; to access clinical databases; to hold confidential interviews with patients and the appropriate facilities to undertake this work

To medical and nursing organisations:

TO PARTNER ORGANISATIONS

- Medical and nursing organisations should work with their pharmacy colleagues to develop a model of CPP that suits their country's particular health system

To governments:

TO GOVERNMENTS

- consider the benefits of Collaborative Pharmacy Practice to both patients and the healthcare system
- integrate Collaborative Pharmacy Practice into reforms mentioned in the 2008 WHO World Health Report

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APPENDIX I

Pharmacists Collaborative Practice – United States, Canada, UK, South Africa and Australia

INSTITUTIONAL SETTINGS

◈ Economic Outcome Studies

⇨ MISCELLANEOUS

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Service: collaborative practice or prescribing under protocol. Data from Hospitals Design: Retrospective Analysis (data was obtained from 1995 from the national clinical pharmacy services database) Time frame for data collection: 1995-96 *199,082 | *Medicare patients	This study evaluates drug therapy management by pharmacist done across 961 hospitals in the US (50.4% of these hospitals had a pharmacist for the management of aminoglycosides or vancomycin). A pharmacist under the authorization of the prescriber was able to: order lab tests, initiate or adjust drug therapy to reach drug target levels	The hospitals included in this study that did not have a pharmacist managing aminoglycosides or vancomycin therapy, had the following: - 1,048 excess deaths (6.71% higher than in hospitals that had pharmacist-managed aminoglycosides or vancomycin therapy) - 131,660 excess in patient days - $140,757,924 in excess total Medicare charges - $34,769,250 in excess drug charges - $ 22,530,474 in excess laboratory charges - 134 more patients lost their hearing (46.4% HIGHER) - 2,081 more patients had renal impairment (33.95% HIGHER) - 231 more patients died due to complications with aminoglycosides or vancomycin	Hospitals without pharmacists to manage aminoglycosides and vancomycin had an average of $1,518 more in charges billed to Medicare, resulting in $140,757,924 excess total Medicare charges.	Limitations: not all Medicare patients who receive aminoglycosides or vancomycin were included in the study. Data collected from 1995-96 but study was published years later (takes time to run such a big study). The causality of the findings were not identified. Not all US hospitals were represented here in this study. Bond CA., Raehl CL. Clinical and economic outcomes of pharmacist-managed aminoglycoside or vancomycin therapy. Am J Health-Syst Pharm. 2005;62:1596-605.

		therapy. Hospitals without pharmacist-managed aminoglycosides or vancomycin therapy required 12.28% more days to care for their patients.		
Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Hospital pharmacy Design: Population based survey study | | * | * 14 clinical pharmacy services and pharmacist staff.	This study has the objective to evaluate the impact of clinical pharmacy services and pharmacy staffing on medication errors. The information gathered for this study came from 1081 hospitals from US. A 1999 report from the Institute of Medicine reviews that medical errors account for 44,000-98,000 deaths/year. The estimated total cost of the medical errors is $17-29 billion annually. Evidence suggests that pharmacists in decentralized patient-care setting can decrease the frequency of medication errors.	Pharmacist providing drug information services had an 18% reduction in medication errors, pharmacist conducting drug protocol management has a 38% reduction in medication cost, pharmacist conducted drug histories had a 51% reduction in total medication errors and pharmacist participating on medical rounds had a 29% reduction in medication errors. "The two most important variables for reducing total medication errors that adversely affected patient care outcomes were pharmacist-conducted drug histories and increased staffing levels of clinical pharmacists."	Pharmacists involved in providing drug information services reduced medication costs by 38% and reduced medication errors by 51%. Pharmacists participating on medical rounds can have a positive impact in health care outcomes.	Limitations: data from this study are from 1992 and may not represent the health care in 2001. The study did not allow the investigators to determine causality, so this study should not be construed as cause and effect. Medication errors could not be determined. Data for this study was self-reported. Bond C., Raehl C. Clinical Pharmacy Services, Hospital Pharmacy Staffing, and Medication Errors in the United states Hospitals. 2002:22(2)134-47.

AMBULATORY SETTINGS

◈Economic Outcome Studies

⇨GENERAL MEDICINE

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
(02) Manage Care Organization Design: Prospective Analysis of a clinical pharmacist services. Studied started in Feb 1991 and was conducted for ~23 months. 836 | *1 * The service is staffed by 1 FT Pharmacist who has a PharmD., 1 yr of residency, & several yrs of practice experience.	The objective of this study was to determine the demand for general ambulatory pharmaceutical services, measure the impact of pharmacist's interventions on overall health care cost and estimate the productivity of pharmacists. Pharmacist roles and interventions: during patient consultation, the pharmacist was able to review each medication on the patient's chart and its clinical response and adverse drug events. The pharmacist was able to educate patients in the appropriate use of drugs. The pharmacist was able to change some aspect of the prescription and was able to schedule follow up visits for patients.	A pharmacist developed a pharmacist-managed medication review service in 1991. The pharmacy and therapeutics committee and physicians approved this service. A pharmacist on a managed care organization reviewed medication charts. On average a total of 64.9% of the medications reviewed per month were problematic. The most frequent problem was not taking meds as directed. Often the pharmacist had to teach the patient how to use their medication correctly. With the pharmacist's intervention patients used fewer health services. Patients in the study: patients with Asthma or COPD, HTN, reproductive system related problems, ulcer, thyroid problem, arthritis, diabetes and hyperlipidemia.	Total saving cost per patient was $644. Savings due to unscheduled physician visits, avoiding ER, and not needing hospitalization due to pharmacist's intervention.	Limitations: inability to show if the sample population would represent the true population due to problems in data compilation. Borgsdorf LR, Miano JS, Knapp KK. Pharmacist-managed medication review in a managed care system. American Journal of Hospital Pharmacy 1994; Mar 15:51 (6):772-7.

⇨DIABETES

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Two primary care clinics in a university affiliated VA Design: Prospective Length of study = patients were followed by a mean of 27 weeks ± 10 weeks 203 | 4	"The goal of this study is to determine the impact of the addition of a clinical pharmacists to a multidisciplinary team involved in direct patient care on the management of patients with type 2 diabetes who require insulin." The pharmacists in this study were able to provide diabetes education, counseling, initiate insulin therapy or adjust insulin therapy for diabetic patients and ordered pertinent laboratory tests to monitor the patient's diabetes. Pharmacists also arranged appointments for patients to meet with physicians, dietitians, social workers and psychologist when appropriate. Patient-pharmacist interactions occurred face-to-face and by telephone contacts.	Pharmacists were members of the two primary care clinic teams in the study. Pharmacists initiated 15 insulin therapies. Primary outcomes changes, HbA1c concentrations were decreased from 11.1% to 8.9% (p=0.00004). This study shows that pharmacists can actively and successfully participate in interdisciplinary teams to better the patient's therapy outcomes.	Cost Savings: after deduction of the costs of the pharmacists' services and deduction of the medical center charges for the appointment, the study saved the medical center a total of saved $103,950.	Limitations: not randomized or controlled but it is more realistic that patients are treated in a collaborative health care environment. Duration of study was short and a third limitation was the small sample size. Coast-Senior EA., Kelley CL., et al. Management of patients with type 2 diabetes by pharmacists in primary care clinics. Ann Pharmacother 1998;32:636-41.

♦RESPIRATORY DISORDERS

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Clinic Design: Outcomes study 52 | n/a	Goals: to evaluate effectiveness of clinical pharmacists in managing anticoagulation therapy, and preventing hospitalization and to determine cost benefits from the intervention. Intervention: provided patient education, monitored patients for complications such as hemorrhagic and thromboembolic complications and adjusted warfarin dosage	As a result from pharmacist's intervention a lower percentage of Prothrombin times were outside the therapeutic range (14.4 ± 9 vs. 37.2 ± 24.4, $p<0.001$).	Net savings in hospitalization per year was $211,776; the cost benefit ratio was 6.55.	Gourley GA, Portner TS et al. Humanistic outcomes in the hypertension and COPD arms of a multicenter outcomes study. J Am Pharm Assoc. 1998 Sep-Oct;38(5):586-97.

AMBULATORY SETTING

✶ Clinical Outcome Studies ✶

♦GENERAL MEDICINE

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Outpatient Clinic Duration: 3 months * | n/a *910 patient visits	Goals: to evaluate the economic impact of clinical pharmacists services in an outpatient clinic. Pharmacists' interventions: interviewed patients; reviewed medical records and drug regimen; recommended refills, change of medication or dosage, discontinuation, or referral to a physician.	The clinical pharmacist's services reduced demand of physicians' time, allowing physicians to spend time with more problematic patients. Having the pharmacists reviewing and making dosage adjustment of medication decreased the number of hospital admissions related to adverse drug reactions.	$2719 was saved in drug costs	Scrivens JJ, Magalian P, et al. Cost-effective clinical pharmacy services in a veterans administration drop-in clinic. Am J Hosp Pharm. 1983 Nov;40(11)1952-3

♦HYPERTENSION

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Randomized comparative trial of pts with uncontrolled HTN. UC (usual care) group managed by educated physician. PPCM (physician-pharmacist comanagement) group followed by MD-RPh team. Duration was 1 year. 197 | 4	To evaluate changes in blood pressure achieved by physician-pharmacist comanagement of hypertension vs usual care. Pharmacist provided patient education, made treatment recommendations and provided follow-up utilizing an evidence-based treatment	Reductions in SBP from baseline for PPCM and UC were 22 ($p<0.01$) and 11 ($p<0.01$), respectively. The difference between the two was also statistically sig ($p<0.01$) Reduction in DBP from baseline were PPCM 7 ($p<0.01$) and UC 8 ($p<0.01$) and not sig different between two groups.	Compared with usual care, an evidence-based, systematic approach using physician-pharmacist comanagement for patients with uncontrolled HTN resulted in improved blood pressure control and reduced avg costs/pt.	Potential selection biases (patient motivation) No real control group. Clinical outcomes related to HTN were not measured. Visit costs/pt projected from salaries of physicians, pharmacist and office

	algorithm. Pts in the PPCM group were managed in a pharmacist-run HTN clinic. RPhs took blood pressure readings, assessed compliance and potential ADRs. Provided drug side effect counseling and education re: dietary and lifestyle modifications.	BP goals reached in 60% vs 43% of PPCM and UC pts (p=0.02). Patients receiving first-line anti-HTN meds according the algorithm increased sig from baseline in both PPCM 68%-80% (p=0.02) and UC 60-70% (p=0.02) Avg visit costs/pt were lower for PPCM then UC ($160 vs $195, p=0.04). Drug costs not significantly different.		personnel. Actual savings in visit costs through the use of clinical pharmacists would occur only if the resulting reduction in physician workload allowed individual physicians to care for more patients. Borenstein JE. Physician-pharmacist comanagement of hypertension: a randomized, comparative trial. Pharmacotherapy 2003;23(2):209-216.
Prospective, randomized, comparative study of pts with mild to mod HTN. Pts randomly assigned to either a pharmacist-managed HTN clinic to physician-managed gen med clinic. Duration of the study was 6 months. 330 | ? Baseline and 6 month BP readings and SF-36 answers. Resource utilization (# of ED visits if BP primary indication, hospitalizations and scheduled clinic visits only if blood pressure was measured. Also included costs related to BP meds (acquisition and AWP). Costs based on 1998.	To evaluate the cost-effectiveness of a clinical pharmacist assisting in the management of pts with HTN and how this affects pt satisfaction with health care. Pharmacists managed dose adjustments and therapeutic changes to optimize blood pressure control.	Pharm managed: SBP decreased from 144.23 to 135.1 (p<0.001) and DBP from 82.70 to 77.65 (p<0.001) MD managed: no significant reductions in SBP or DBP. Between group comparisons mean SBP decrease between pharm run and MD run was 9.13 vs 1.32 (p<0.001) and DBP 4.1 vs 1.46 (p<0.001). The only SF domain difference between groups was role-physical (p=0.03) favoring pharm. In the MD managed clinic, reductions occurred in physical functioning and general health	In a HTN clinic, pharmacists can be a cost-effective alternative to physicians in managing the treatment of patients with benefits of improved clinical outcomes, enhanced patient satisfaction and allowing physicians to spend more time treating other patients.	These were not newly diagnosed patients and may have previously been treated. The study population was taking limited, targeted HTN drugs (nifedipine, verapamil, captopril, diltiazem, clonidine, terazosin, propranolol or lisinopril or taking at least 3 antihypertensives). Results may have differed if all antihypertensives had been included. Costs were only included if documentation supported BP as a cause for the costs. Only baseline and 6 month BP readings were included in the study. Okamoto MP. Pharmacoeconomic

		from beginning to end of study ($p<0.01$) Clinic visits were significantly higher in the pharm group ($p<0.001$). No differences in # of antiBP drugs/pt in either group from beginning to end. No sig difference in drug cost/pt, hospital or total cost/pt between groups. Clinic visit costs were greater in the pharm run clinic $p<0.001$ but avg cost/pt related to ED visits was lower in the pharm group $p<0.04$. Cost:effectiveness ratio was \$27 for pharm and \$93 for MD/mmHg. The cost of decreasing DBP 1 mmHG was \$48 for the pharm run clinic and \$151 for MD run. ICER for SBP was \$1.18 and \$2.51/mmHg		evaluation of a pharmacist-managed hypertension clinic. Pharmacotherapy 2001;21(11):1337-1344.
Veterans Affairs Medical Center, Philadelphia, PA Prospective, controlled, 6-month study. 56 patients with essential hypertension: 27 were randomly assigned to the intervention group and 29 to the control group.	To determine whether a pharmacist-managed hypertension clinic improves treatment outcomes in patients with hypertension. The pharmacist, who had prescribing authority, made appropriate drug therapy changes (in both drug selection and dosage) for BP control in accordance with JNC-VI. The pharmacists did not	21(81%) of patients reached goal BP of less than 140/90 in the intervention group compared to only 8 (30%) in the control group. Of the 11 patients with diabetes in the intervention group, 10 (91%) attained goal BP of 130/90 compared to only 2 (12%) of 16 patients with diabetes in the control group. There were no significant	Pharmacist-managed hypertension clinic improved BP control resulting in more pts reaching BP goals.	Most patients were African-Americans and all were male. The study had inadequate power to detect significant differences in compliance, health perception, or patient satisfaction. Only conducted in one clinical setting, and it was not possible to conduct as a blinded study.

56	3

Patients in the intervention group were scheduled monthly to meet with a clinical pharmacist who made appropriate changes in prescribed drugs, adjusted dosages, and provided drug counseling. Patients in the control group received standard care from their physicians.	change other drugs that could adversely affect BP (e.g. sibutramine, venlafaxine). Other pharmacist roles: 1. Drug counseling 2. Discussion of side effects. 3. Recommendations about lifestyle changes. 4. Assessment of compliance. 5.	differences in patient satisfaction or compliance between the two groups.		Vivian, Eva M. Improving Blood Pressure Control in a Pharmacist-Managed Hypertension Clinic. Pharmacotherapy 2002: 22(12): 1533-1540.

♦DIABETES

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Community Health Center Design: RCT Duration: 9 months 149 | *1	Study goals: To see the outcomes of pharmacist-managed diabetes care services in a community health center and also to develop collaborative practices between physicians and pharmacists. The pharmacist in the study had discussions with patients about their disease states, made lifestyle recommendations, encouraged patients to monitor their glucose levels and reviewed medications charts. Moreover, the pharmacist in this study was able to initiate aspirin therapy, administer influenza vaccinations, made referrals to patients about therapeutic shoes, and made medication evaluations for hypertension and dyslipidemia.	The primary endpoint was met: reduction in the hemoglobin A1c. There was a difference of 1.0 in the HbA1c levels in between groups (95% CI; p<.005). It is noted on the literature that 1% reduction in the HgA1c maintained for a period of 10 years results in a decreased in the relative risk of microvascular complications, diabetes-related deaths and reduction on myocardial infarction. Satisfaction level was also improved compared to the control group. Satisfaction level in the control went from 57.0 to 63.4 (p<0.05) and in the intervention group was from 63.7 to 77.4 (p<0.05).	There was a successful collaborative practice between physicians and pharmacists in the management of patients with diabetes. The patients with diabetes that had a pharmacist manage their disease during this study had an improved HbA1c, their systolic BP was decreased as well as their LDL levels. These patients met treatment goals more often than patients receiving standard care.	Limitations: One limitation of this study was a potential "site-interaction effect" since the intervention group in this study was not blinded. Scott DM, Boyd ST, et al. Outcomes of pharmacist-managed diabetes care services in a community health center. AM J health-Syst Pharm – (63) Nov 1, 2006.

♦DIABETES

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Primary Care Clinic Design: Retrospective Cohort Analysis of glycemic control. A quality assurance project. Time frame: Oct 1997 – June 2000 (data collection period). 172 | * * Part-time RPhs	Objective: To compare the glycemic control in diabetic patients supervised by physicians and pharmacists vs. patients receiving standard care in the same health care system. Pharmacists' interventions: managed drug therapy, including taking detailed medical and drug therapy histories. Pharmacists also educated patients about their disease state and drug use and compliance. Counseled patients in lifestyle modifications such as diet and exercise. Performed physical assessments. Pharmacists also changed drug regimens pertinent to diabetes, which includes drugs for hypertension and hyperlipidemia.	Primary outcomes were differences in fasting blood glucose (FBG) and HA1c levels between the two groups, no statistical differences were noted in FBG or HA1c between groups. However, the relative ratio (RR) in regards to achieving an HA1c of <7% were significantly higher in the cohort group (RR 5.19, 95% CI). Pharmacists were 5 times more likely to have patients achieve HA1c levels of 7% or lower than other health care providers; this result alone has potentially significant clinically and economically.	Having pharmacists be diabetes primary care providers, results in similar or better outcomes as those offered by other providers in the health care system. Multidisciplinary approaches including pharmacists and physicians were successful in managing diabetes, achieving and maintaining glycemic control.	Limitations: retrospective studies are dependent on documentation made by practitioners, if they omit data; bias to the study is introduced. Some data that was expected to collect often was unavailable. Also, this study did not match the control group with specific individuals in the study cohort. Another limitation is that different clinic sites use different glucometers to measure glucose levels and data regarding the different type of glucometers and different brand were not collected. External validity was a concern: the patients in this study were all male offenders in Texas; this could complicate the generalibility of the study. Irons. BK, Lenz RJ., et al. A retrospective cohort analysis of the clinical effectiveness of physician-pharmacist collaborative drug therapy management diabetes clinic. Pharmacotherapy 2002;22(10):1294-1300

♦DIABETES

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Physician Group Practice Office Design: Retrospective Review Time Frame: June 2003-April 2004. 157 | n/a	Objective: "To evaluate changes in clinical outcomes for patients enrolled in a pharmacist-coordinated diabetes management program." Pharmacists' interventions: clinical pharmacists in collaboration agreement with physicians and by approved protocol by the Pharmacy and Therapeutics (P&T) committee had the authority to: initiate, adjust or discontinue medications related to the treatment of diabetes, dyslipidemia, and hypertension. This approach allowed significant clinical judgment by pharmacists.	Because of pharmacists' intervention patients' in this study had their HbA1c decreased by 1.6% (n=109; $p<0.001$). There were 57 patients were their HbA1c was >8.5% the mean reduction was 2.7% ($p < 0.001$). The mean LDL reduction of 16 mg/dl was seen in 73 of the patients, but this was not statistically different. However, in patients with LDL values ≤ 100mg/dL increased from 30% to 56% ($p<0.001$). Microalbumin screenings were increased by 27% ($p<0.001$). Moreover, the number of patients that had annual eye exams as well as foot exams were increased by 27% ($p<0.05$) and 15% ($p<0.05$), respectively. There was an increase of diabetic patients taking aspirin, from a baseline of 42% to 80% again this was statistically significant ($p<0.01$).	This study shows evidence that clinical pharmacists have a tremendous positive impact on the management of diabetes as well as disease related to diabetes such as hypertension and hyperlipidemia. Pharmacists managing diabetes have shown significant improvements on HbA1c and LDL values as well as an increase in frequency of preventive care.	Limitations: Some differences in data availability among patient records. Some missing data such as reports of BP. Sample size small and homogeneous. The study was conducted in a short-term period making it difficult to draw conclusion for a long-term efficacy of the program. No financial assessment of pharmacists' interventions. Lastly, there was not control group in this study, so no comparison can be drawn between the intervention group and the standard of care. Kiel JK., McCord, AD. Pharmacist impact on clinical outcomes in a diabetes disease management program via collaborative practice. The ann of pharmaccother. Nov. 2005;39:1828-32.
Setting: Internal medicine practice Design: One-year randomized	"To assess the effects of a pharmacist-led, primary care-based, disease management program on CV risk factors	SBP and DBP improved more among intervention than controls SBP: decrease of 8 mmHg vs	RPh managed group had significant improvement in SBP and aspirin use.	Baseline differences between groups despite randomization. Single center with imperfect

controlled trial of pts with type 2 DM and HgA1c >/= 8% 217 | 3	and glucose control in patients with poorly controlled diabetes." RPh role: intensive management, applied algorithms for managing glucose control and decreasing CV risk and medication management.	increase of 2 mmHg (p=0.008) DBP decrease of 4 vs increase of 1 (p=0.02) A1c levels improved more in the intervention group; -1.6% control compared with -2.5% among intervention but not significantly (p=0.05) No difference in TC or statin use. More intervention patients were on ASA vs control (91% vs 58%, p<0.0001)	Also had greater decrease in A1c but not significantly so (p=0.05)	follow-up. Both groups received 1 hour of counseling from a pharmacist prior to beginning the study. Not all outcome assessments were blinded and several measures were based on patient self-report. Rothman RL. A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. The American Journal of Medicine 2005;118:276-284.
Venice Family Clinic (VFC), the largest free medical clinic in the U.S. This is a retrospective cohort study of diabetic patients seen at the VFC in the 1997-1998 fiscal year. 181 | ? 89 patients had been referred by their physicians to the pharmacist-run Diabetes Management program and made up the experimental group. 92 patients were randomly selected from a list of all diabetic patients seen at the VFC but not in the	Evaluate and compare diabetes care in the general free medical clinic setting as well as in a Diabetes Management Program carried out by pharmacists in the same free medical clinic. The pharmacists' roles: 1. Deliver diabetes care by following detailed algorithms (covering glycemic & lipid control) written by a diabetologist. 2. Palpate dorsalis pedis pulses in order to diagnose PVD. 3. Monitor lab values (HbA1c, lipids, proteinuria) and ensure	Dilated eye and foot exams, measurement of HbA1c, lipids, and proteinuria were all more frequent in the experimental group than in the control group. Compared with the control group, the initial HgA1c in the experimental group was significantly (P<0.001) higher (8.8+/- 0.2 vs. 7.9+/- 0.2) but fell significantly (P<0.03) more (-0.8 +/- 0.2 vs -0.05 +/- 0.3). Decrease in A1c levels in the experimental group was inversely related (r = -0.36, P<0.03) to the number of missed visits.	A cohort of diabetic patients treated by pharmacists in a diabetes care program in the VFC achieved better outcomes than other diabetic patients treated in the VFC.	There were baseline differences in patients. Patients in the experimental group had a longer duration of DM and more microvascular and neuropathic complications. Also more patients in the experimental group required insulin than in the control group. Thus, more difficult to control and sicker patients were in the experimental group as compared with the control group. Unable to evaluate lipid outcome measures due to small sample size (10 or fewer patients in each group with total cholesterol >240 mg/dl,

pharmacist-run diabetes clinic in that year, and these comprised the control group.	ADA guidelines were followed (appropriate ACE-I therapy, follow-up labs, etc.)			LDL > 160 mg/dl, or TG > 250 mg/dl). Davidson, MB, Karlan, VJ, Hair, TL. Effect of a Pharmacist-Managed Diabetes Care Program in a Free Medical Clinic. American Journal of Medical Quality. 2000: 15(4) 137-142.
12 Community pharmacies in Asheville, N.C. *This is the first article to report on the Asheville Project.* Design: intention-to-treat, pre-post cohort-with-comparison group study. Short-term report of the Asheville project (7-9 months after the pharmaceutical care services started). 85 | * * Pharmacists from 12 community pharmacies.	The goal of this study was to assess the short-term ability of clinical pharmacists in monitoring diabetes patients and improving their diabetic care. This article reports the short-term clinical, economic and humanistic outcomes of pharmaceutical care provided to two groups of patients with diabetes. This project is known as "The Asheville Project". Pharmacists provided education and training, self-monitored blood glucose (SMBG) meter training, clinical assessment, patient monitoring, follow-up and referral. In addition, pharmacists provided physical assessments on patient's feet, skin, blood pressure and weight.	This study recognized the important role of pharmacists in monitoring, educating and counseling patients with diabetes. Pharmacists can improve drug therapy outcomes. "Pharmacists are the most accessible health care providers…" A significant improvement in patient's satisfaction with pharmacy services for all domains was noted. Patients had significant improvements on their hemoglobin A1c. Major outcome of the study: a significant improvement on hemoglobin A1c - HA1c improvement, improves outcomes and decrease mortality.	All costs were adjusted to US $ 1999 using the Consumer Price Index for Medical Care. "Diabetes specific costs increased by 87% ($52) per patient per month (PPPM) p < 0.01. And all diagnosis costs decreased by 16% ($82) PPPM, (not significant; insufficient power to accept the null hypothesis of no difference). *Wagner et al found that diabetes costs, hospitalizations and primary care increase during the early years of intervention increases.(p. 156.)*	Major limitations: missing data, small sample size, not randomized or controlled (could introduce bias). Another limitation was the unequal data-gathering periods pre and post-PCS. Cranor CW., Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc. 2003;43:149-59.
12 Community pharmacies	Objective: "to assess the	This is a long-term study	Mean direct medical costs	Limitations: not a randomized study, the study has missing

In Asheville, N.C. Design: Quasi-experimental, longitudinal pre-post cohort study. *This is the second article to report on the Asheville Project.* Time Frame: May 1997 to Dec 2001 194 | * * Pharmacists from 12 community pharmacies.	persistence of outcomes for up to 5 years following the initiation of community-based pharmaceutical care services (PCS) for patients with diabetes." Patients met with pharmacists, received diabetes education, home glucose meter training and learned the importance of compliance to their meds due to their disease state. Pharmacists managed patient's lipids and also performed physical assessments.	that demonstrates improvements on hemoglobin A1c concentrations, lipids, and direct medical costs of patients with diabetes upon interventions of community care pharmacists.	decreased in a range from $1,200 to $1,872 per patient per year. The costs shifted from inpatient care and outpatient physician services to prescriptions. All costs were in US dollars adjusted to the year 2001.	and/or unreported clinical data. Also, the study has limitations in the level of detail of claims important for economic evaluations. Cranor CW., Bunting BA., et al. The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program. J AM Pharm Assoc. 2003;43:173-84.

♦HYPERLIPIDEMIA

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Setting: 9 VA hospitals. Design: Retrospective subanalysis of the IMPROVE study, a prospective, multisite VAs, randomized, controlled clinical trial. 437 | 78	To determine if routine F/U by ambulatory care clinical pharmacists can improve the percentage of patients achieving LDL goals for dyslipidemia. RPhs made adjustments in pt's drug regimens with their scope of practice and were expected to identify and prevent drug-related problems.	Significantly greater reduction in TC (p=0.028), LDL (p=0.042) and % reductions TC (p=0.022) and LDL (p=0.036). Intervention group had $370 greater difference/pt, but this was not significantly different.	RPhs are able to intervene with high-risk patients with dyslipidemia with improved lipid levels without significantly increasing overall health care costs.	The original IMPROVE study was not specifically focused on lipid reduction. Not all patients had preenrollment lipid levels. Subjective data were not retrievable for classification of CV risk factors. Costs were extrapolated from one site across all sites. Ellis SL. Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults: The IMPROVE study. Pharmacotherapy 2000;20(12):1508-1516.
(09) Patient records from a hospital computer database. Lipids Lowering Therapy in a Primary Care Setting. Design: Retrospective and randomly selected data analysis. 88 | 1	The study goal is to assess the statistical difference between the magnitude of cholesterol reduction in patients seen by clinically trained pharmacists prescribing or adjusting drug therapy vs. other health care practitioners. Pharmacists in this study were responsible for ordering and interpreting laboratory values and for	Clinical pharmacists managing cholesterol was associated with a significant reduction in LDL (mean of 18.5%), compared to the cohort group that did not have a clinical pharmacist as their primary cholesterol manager (6.5%) (p=0.049). The magnitude of LDL reduction was correlated with the number of patient visits:	Clinical pharmacists can have a tremendous impact on the lives of patients that suffer from lipid disorders. Clinical pharmacists were able to statistically significant reduce LDL levels. The LDL reduction may translate into a long-term outcome: fewer cardiovascular events, improved quality of life for patients with dyslipidemia	Limitations: retrospective analysis with no equal number of patients per group. Lipid profiles were only evaluated for 2 points. They did not record the amount of time that pharmacists spent with patients vs. non-pharmacist with patients. No costs study evaluated. Lastly, the investigators don't know what cause the LDL reductions. The LDL reductions could be due to different factors: compliance to medications, patient on a diet or due to merely drug selection.

	prescribing and monitoring lipid-altering pharmacotherapy.	1 visit = 11.4% LDL reduction 2 visits = 23.2% LDL reduction > 3 visits = 23.7% LDL reduction Compare the results with the usual care group: 1 visit = -11.0% LDL reduction 2 visits = 18.0% LDL reduction > 3 visits = 7.4% LDL reduction, (Statistically significant, P=0.038, for >3visits only).	and lower costs associated with the treatment of cholesterol.	Till LT., Voris JC et al. Assessment of clinical pharmacist management of lipid-lowering therapy in a primary care setting. J Managed Care Pharm. May/June 2003(9)3:269-73.
Leeds Teaching Hospital 43	To assess the effects of pharmacist intervention on lipid management in coronary artery bypass graft (CABG) patients. Open study in which total cholesterol (TC) levels were measured in 43 elective CABG patients at visit 1 (pre-surgery) and visit 2 (six weeks postdischarge following surgery). Statin therapy was initiated (using atorvastatin) or statin doses were adjusted according to an agreed protocol.	Prior to CABG surgery, 19 patients (44 per cent) did not have target TC values. Fourteen (74 per cent) of these patients were already receiving a statin while five patients (26 per cent) were not receiving statin therapy. At visit 2, 33 patients (77 per cent) had achieved target TC. Mean (SD) TC was 5.7 (0.72) mmol/L at visit 1 and 4.8 (0.68) mmol/L at visit 2 in the intervention patients ($P<0.01$). There was no significant difference between mean TC at visits 1 and 2 in the non-intervention patients (patients who had target TC values at visit 1).	From a previous meta-analysis, the decrease in TC of 0.9 mmol/L (16 per cent) in the intervention patients equates to a 24 per cent risk reduction in coronary heart disease (CHD) mortality and an 18 per cent risk reduction in total mortality.	Alldred-DP; Booth-C; Chrystyn-H Development of a pharmacist-led cholesterol screening and lipid-lowering medication review service in coronary artery bypass graft patients Int-J-Pharm-Pract (International-Journal-of-Pharmacy-Practice); 2001; 9(4); 275-281

♦ANTICOAGULATION

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Service: Collaborative practice or prescribing under protocol Design1995 National Clinical Pharmacy Services database and the 1995 Medicare database for hospitals. 717,396 | ?	To explore the relationship between pharmacist-provided anticoagulation management in hospitalized patients and death, LOS, charges, bleeding complications and transfusions. RPhs provided management of anticoagulation, heparin or warfarin.	In hospitals without RPh-provided heparin management, death rates were 11.41% higher ($p<0.0001$), LOS was 10.05% higher ($p<0.0001$), MC charges were 6.60% higher ($p<0.0001$), bleeding complications were 3.1% higher ($p<0.0001$) and transfusion rate was 22.49% higher ($p<0.0001$). In hospitals without RPh-warfarin management, death rates were 6.20% higher ($p<0.0001$), LOS was 5.86% higher ($p<0.00001$), MC charges were 2.16% higher ($p<0.0001$), bleeding complications were 8.09% higher ($p<0.0001$), transfusion rates 22.49% higher ($p<0.0001$).	"Pharmacist-managed anticoagulation had a profound effect on improving health care outcomes in Medicare Patients requiring anticoagulants."	Data from 1995 and would be higher if based on 2004 costs. LMWH were only just beginning to be used and data may not reflect current heparin therapy. Database information may not have been accurate. Study design does not allow for causality. Bond CA, Raehl CL. Pharmacist-provided anticoagulation management in United States hospitals: death rates, length of stay, Medicare charges, bleeding complications and transfusions. Pharmacotherapy 2004;24(8):953-963.
Anticoagulation clinic in San Franscisco General Medical Center. Duration: 9 years 140 | n/a	Goal: to evaluate the effectiveness of the pharmacists in managing patients on warfarin therapy in an anticoagulation clinic. Pharmacists: provided patient education, monitored patients for vital signs, performed physical examinations, adjusted	Prothrombin time was within the therapeutic range (59.2%) of determinations, major and minor hemorrhages were 0.002 and 0.05/patient-treatment per month, respectively; recurrence of thromboembolic events was 0.007/patient per month	The management of warfarin therapy by pharmacists resulted in the control of patients' anticoagulation and decreased morbidity.	Conte RR, Kehoe WA, et al. Nine-year experience with a pharmacist-managed anticoagulation clinic. Am J Hosp Pharm. 1986 oct;43(10):2460-4.

	warfarin dosage. Pharmacists' had support from physicians.			
Anticoagulation Clinic Design: Retrospective Duration: pre: 40 months Pos: 30 months 26 | n/a	Goals: to evaluate the effectivess of a pharmacist-managed warfarin anticoagulation clinic in maintaining therapeutic Prothrombin times and preventing hospitalizations. Interventions: Pharmacists provided patient education, monitored patients for hemorrhagic and thromboembolic complication and adjusted warfarin dosage.	Prothrombin times outside the therapeutic range was reduced from 35.8% to 14.4% this was statistically significant ($p<0.005$)	Hospitalizations were reduced in a ratio of 13:1.	Garabedian-Ruffalo SM, Gray DR, Sax MJ, Rufalo RL. Retrospective evaluation of a pharmacist-managed warfarin anticoagulation clinic.
Setting: Kaiser Permanente Colorado region Design: Retrospective, observational cohort study of 6 months duration. 6645 |	To Compare clinical outcomes associated with anticoagulation therapy provided by a clinical pharmacy anticoagulation service compared to usual care. RPh role: Patient education, ordering of relevant lab tests, adjustment of anticoagulation medication, planning for interruption of anticoagulation therapy during invasive procedures and management of adverse events	Patients in the CPAS (clinical pharmacy) group were within target INR range, 63.5% vs 55.2% $p<0.001$. Percentage of CPAS INR values >/=4 or </= 1.5 was significantly lower than the control 15.1% vs 20.4% $p<0.001$. the time between INR testing was significantly lower in the CPAS group $p=0.03$. Pts in the CPAS group were 39% less likely to experience complications. The occurrence of thromboembolic events was	Superior care was demonstrated with use of a pharmacist-managed anticoagulation management service.	No random assignment of patients. Retrospective study with inherent limitations. No blinded review for complications of study patients. Witt DM. Effect of a centralized clinical pharmacy anticoagulation service on the outcomes of anticoagulation therapy. Chest 2005; 127: 1515-1522.

		62% lower than the control group.		
Included in the study were all patients requiring anticoagulation who had been managed by general practitioners (GPs) and subsequently referred to the pharmacist-led outreach service within Gateshead & South Tyneside Health Authority. 51	Fifty one patients who met the inclusion criteria identified from eight practices had been successively treated by GPs and then by pharmacists. Eighteen patients (35·3%) had a diagnosis of non-rheumatic atrial fibrillation, 10 (19·6%) had thromboembolic disease and 13 (25·5%) had valvular disease.	In total, 1782 INR results were analysed. GPs were responsible for 1075 (60·3%) of these estimations and pharmacists for the remaining 707 (39·7%). Of the GP-monitored results the patient-mean proportion of estimates that resided within the prescribed therapeutic range was 0·6 (SD = 0·21, $n = 51$) compared with pharmacist management where patients showed a mean in range proportion of 0·7 (SD = 0·18, $n = 51$, $P = 0·03$). The mean inter-test interval was 28·6 days (SD = 8·65, $n = 51$) for GPs compared with 34·1 days (SD = 12·3, $n = 51$, $P = 0·01$) for pharmacists. The weighted INR index for GPs was 17·2 (SD = 7·93, $n = 51$) compared with 24·7 (SD = 13·15, $n = 51$, $P < 0·001$) for pharmacists. There is no apparent detriment to INR control when pharmacist management is compared with that of GPs. The overall proportion of INR estimations within the		Holden J & Holden K Comparative effectiveness of general practitioner versus pharmacist dosing of patients requiring anticoagulation in the community Journal of Clinical Pharmacy and Therapeutics 25 (1), 49–54 Limitations – small scale study

		prescribed range is greater for pharmacists than for GPs and the interval between tests is longer for pharmacists compared with GPs.		
Anticoagulation Clinic Design: Control Retrospective. Study duration: the inpatient and outpatient medical records of patients who began to receive warfarin between Jan 1991-May 1994 were examined 318 | 1	Study goals: To compare newly anticoagulant patients with who were treated with usual medical care with those treated at an anticoagulant clinic (AC) for patient characteristics, anticoagulation control, bleeding and thromboembolic evens and differences in costs for hospitalizations and emergency department visits. A clinical pharmacist runs an AC, the pharmacist interventions improve patient's anticoagulation control, reduces bleeding and thromboembolic event rates.	Patients treated with blood thinners in a pharmacist-managed anticoagulation clinic had fewer emergency room visits and fewer hospitalizations. A clinical pharmacist with the support of faculty physicians operated the AC clinic.	Pharmacist in an AC was able to save $ 162,058 per 100 patients per year due to reduced hospitalization and emergency room visits. "The improved patient outcomes were achieved with an average savings in health care costs of more than $1600 per patient per year."	Limitations: study was not randomized Chiquette E, Amato MG< Et al. Comparison of an anticoagulation clinic with usual medical care. Anticoagulation control patient outcomes, and health care costs. Archives of Internal Medicine 1998;158:1641-7.

♦ASTHMA

Study Setting/Design # pt	# RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
(12) Pediatric Asthma Clinic Duration: NR 44	n/a	Goals: to evaluate the impact of pharmacokinetic consultation in pediatric asthmatic patients. Pharmacists' interventions: Counseled patients, adjusted theophylline dosage	With the pharmacist's intervention patients experienced a improvement in: wheezing, forced expiratory volume, exercise tolerance, and nocturnal coughing at follow-up ($p<0.0167$).	Asthmatic children after consulting with pharmacists had in their health outcomes.	Botha JH, Tyrannes I. Pharmacokinetic consultation program in a pediatric asthma clinic. Am J Hosp Pharm. 1992 Aug;(49(8):1936-40.

Last updated on: 06/20/07 cam

Systematic review Studies of hospitalised adult patients were eligible for inclusion. The included studies were performed in patients in intensive care units (ICUs) and general medical, surgical and psychiatric units.	Studies that evaluated various clinical pharmacist interventions were eligible for inclusion. Studies in ambulatory settings and those in which pharmacy interventions were part of guidelines, protocol or provider education, were excluded. The interventions in the review were classified as: patient care with pharmacist participation on rounds; admission or discharge medication reconciliation; and drug class-specific pharmacist services. Thirty-six studies (n=18,553) were included: 22 RCTs (n=5,433), 1 non-randomised controlled study (n=165), 1 quasi-experimental study (n=3,081), 8 pre-test post-test studies (n=9,512), 2 prospective cohort studies (n=216), 1 retrospective study with a control group (n=46) and 1 repeated cross-sectional study (n=100).	Thirty-six studies met inclusion criteria, including 10 evaluating pharmacists' participation on rounds, 11 medication reconciliation studies, and 15 on drug-specific pharmacist services. Adverse drug events, adverse drug reactions, or medication errors were reduced in 7 of 12 trials that included these outcomes. Medication adherence, knowledge, and appropriateness improved in 7 of 11 studies, while there was shortened hospital length of stay in 9 of 17 trials. No intervention led to worse clinical outcomes and only 1 reported higher health care use. Improvements in both inpatient and outpatient outcome measurements were observed.		Kaboli P J, Hoth A B, McClimon B J, Schnipper J LArchives of Internal Medicine 2006 166(9) 955-964 Clinical pharmacists and inpatient medical care: a systematic review Limitations – Wide inclusion criteria for studies
Patients were recruited from four general practices in Leeds. 591 | 1	A randomised controlled trial of clinical medication review of elderly patients by a clinical pharmacist on repeat medication in general practice. The control group	97% of the intervention group had medication reviews compared with 44% in the control group. A recommendation was made in 258 of the 591 (44%) patient consultations. Only 28 patients	Medication costs rose in both groups but the rise was significantly less in the intervention group (intervention mean £1.80, control mean £6.53,	Zermansky AG, Petty DR, Raynor DK, Lowe CJ, Freemantle N, Vail A. Clinical medication review by a pharmacist of patients on repeat

	of patients received normal care from their practices.	(5%) needed referral to a GP and 25 patients (4%) needed referral for a test. The pharmacist dealt with all other medication-related problems. A recommendation was made for 603 of the 2927 repeat medications (21%). The most common recommendations were 'stop the medicine' (118 medicines, 4% of all medicines) and 'technical', for example, a generic switch or removal of a 'redundant item' from repeat list (177, 6%). Of the 603 medication interventions, 395 (65%) were dealt with by the pharmacist alone, without reference to a GP. Recommendations were made to and permission was sought from the GPs for 208 interventions (34%). The pharmacist's advice was accepted and acted upon in 179 instances (86%).	group difference –£4.72 (95% CI, –7.04 to –2.41). The cost saving on medication in the intervention group compared with the control group was £4.75 per 28-day month. Extrapolated for 1 year, this is a saving of £61.75 per patient.	prescriptions in general practice: a randomised controlled trial. *Health Technol Assess* 2002;6(20). Limitations – Good study but with a single highly qualified pharmacist and need to extrapolate data to pharmacist prescribing

APPENDIX II

Pharmacist's Clinical Practice – Levels 2-4 United States, Canada, UK, South Africa and Australia

Community/Ambulatory

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Venice Family Clinic (VFC), the largest free medical clinic in the U.S. This is a retrospective cohort study of diabetic patients seen at the VFC in the 1997-1998 fiscal year. 181 | ? 89 patients had been referred by their physicians to the pharmacist-run Diabetes Management program and made up the experimental group. 92 patients were randomly selected from a list of all diabetic patients seen at the VFC but not in the pharmacist-run diabetes clinic	Evaluate and compare diabetes care in the general free medical clinic setting as well as in a Diabetes Management Program carried out by pharmacists in the same free medical clinic. The pharmacists' roles: 1. Deliver diabetes care by following detailed algorithms (covering glycemic & lipid control) written by a diabetologist. 2. Palpate dorsalis pedis pulses in order to diagnose PVD. 3. Monitor lab values (HbA1c, lipids, proteinuria) and ensure ADA	Dilated eye and foot exams, measurement of HbA1c, lipids, and proteinuria were all more frequent in the experimental group than in the control group. Compared with the control group, the initial HgA1c in the experimental group was significantly ($P<0.001$) higher (8.8+/- 0.2 vs. 7.9+/- 0.2) but fell significantly ($P<0.03$) more (-0.8 +/- 0.2 vs -0.05 +/- 0.3). Decrease in A1c levels in the experimental group was inversely related ($r = -0.36$, $P<0.03$) to the number of missed visits.	A cohort of diabetic patients treated by pharmacists in a diabetes care program in the VFC achieved better outcomes than other diabetic patients treated in the VFC.	There were baseline differences in patients. Patients in the experimental group had a longer duration of DM and more microvascular and neuropathic complications. Also more patients in the experimental group required insulin than in the control group. Thus, more difficult to control and sicker patients were in the experimental group as compared with the control group. Unable to evaluate lipid outcome measures due to small sample size (10 or fewer patients in each group with total cholesterol >240 mg/dl, LDL > 160 mg/dl, or TG > 250 mg/dl).

in that year, and these comprised the control group.	guidelines were followed (appropriate ACE-I therapy, follow-up labs, etc.)			Davidson, MB, Karlan, VJ, Hair, TL. Effect of a Pharmacist-Managed Diabetes Care Program in a Free Medical Clinic. American Journal of Medical Quality. 2000: 15(4) 137-142.

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
A substudy of a randomized, multicenter, controlled trial in over 50 community pharmacies in Alberta and Saskatchewan in which a pharmacist intervention program was shown to improve cholesterol risk management in pts at high risk for CV disease. Two perspectives were taken: a gov't funded health care system and a pharmacy manager. (SCRIP trial). 165 | ?	Evaluate the economic impact of a community pharmacy intervention program in cholesterol risk management in view of its clinical benefit. Pharmacist's roles: 1. Screening and identification of CVD risk factors 2. Provide individualized verbal/written education on risk factor management 3. Physical assessments (BP, cholesterol tests). 4. Follow patients for 16 weeks. 5. Provide referrals to family physicians.	Incremental costs to a government payer and community pharmacy manager were $6.40/patient and $21.76/patient, respectively, during the 4 mo. follow-up period (Canadian dollars). The community pharmacy manager had an initial investment of $683.50. The change in Framingham 10-yr risk of CV disease in the intervention group decreased from 17.3% to 16.4% ($p<0.0001$ during the 4 mo).	The intervention program in this study led to a significant reduction in CV risk in the intervention group during the 4-mo. follow-up period. The incremental cost to provide the program appeared minimal from both government and pharmacy manager perspectives. It is hoped that these results could support negotiations for reimbursement of clinical pharmacy services with payers.	Framingham risk could not be calculated for the usual-care group. Duration of follow-up likely limits the evaluation of the full impact of the intervention program. Thus, could not calculate the incremental change in effectiveness for the intervention. Simpson, SH, Johnson, JA, Tsuyuki, RT. Economic impact of community pharmacist intervention in cholesterol risk management: an evaluation of the study of cardiovascular risk intervention by pharmacists. Pharmacotherapy. 2001; 21(5): 627-635.

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Setting: 24 family practice sites in Ontario, Canada over 5 months.	Specially trained community pharmacists acting consultants to PCP to reduce complexity	After 5 months, mean # of daily Rx were similar as was the # of meds taken per	"Demonstrated the feasibility and acceptability of a collaborative	Population with highly variable baseline health status. Short time frame for outcome

Design: RCT 889 | 24	of drug regimens and/or number of medications taken and to improve patient outcomes. RPh role: Face to face medication reviews with patients in the physicians' offices and then written recommendations to the physicians to resolve drug-related problems. RPh met with physician to discuss the consultation letter.	day and medication costs. At least 1 drug-related problem was identified in 798% of the seniors in the intervention group with a mean of 2.5 per senior. Physicians reported intent to implement 76.6% (837/1093) of recommendations and at 5 months had succeeded in fully implementing 46.3%.	relationship between family physicians and specially trained pharmacists"	measurement. The most frequent recommendation was the addition of a new drug for an untreated or under treated condition. Given the short follow-up, outcomes from these interventions may not have been realized. Sellors J. A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients. CMAJ 2003;169(1):17-22.

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Setting: 3 hospice programs in the greater Baltimore area Design: Observational 3 month study. ? | 2	To quantify and describe drug related problems and the recommended interventions to solve them. To develop a tool to assess the severity of drug related problems. RPh role: Provided recommendations to resolve drug related problems.	98 interventions were collected and analyzed,. 87 were considered clinical and 84% of these recommendations were accepted by the prescriber. 56 (77%) out of the 73 helped achieve the desired therapeutic goal. Another 6 out of the 73 achieved partial desired therapeutic goal.	Clinically trained hospice pharmacists can effectively identify and manage drug related problems.	Number of patients involved not identified. Therapeutic goals not defined. No comparison group. Lee J, McPherson ML. Outcomes of recommendations by hospice pharmacists. Am J Health-Syst Pharm 2006; 63:223-2239.

Study Setting/Design	Study Goals/Pharmacist	Results	Economic outcomes or	Limitations/Reference

# pt	# RPh	Roles		Clinical outcomes	
Setting: Ambulatory primary care center over 1 year beginning 10/93. Design: Randomized controlled trial 94 Comparator was usual care without pharmacy intervention.		"To assess the effect of a program that encourages teamwork between physicians and pharmacists on attempts to lower total cholesterol levels and to meet recommended goals proposed by NCEP. RPh role: advised and interacted with patients and physicians on the best course of pharmacologic therapy (drug selection and initiation, dosage recommendations and monitoring).	Physicians accepted 167/186 recommendations (90%). More patients in the intervention group achieved LDL cholesterols to levels described by the NCEP (43% vs 21% $p<0.05$). In the intervention group for patients for whom the physician declined the pharmacists recommendation, only 2 of 12 met the NCEP goals compared with 18 of 35 for whom recommendations were accepted ($p=0.47$). The intervention group had its greatest effect on patients with CHD $p<0..01$ followed by those without CHD but with 2 or more risk factors ($p<0.05$. TC declined more in the intervention arm than the control $p<0.01$, 44 vs 13 mg/dL	Attempts to lower TC levels to achieve NCEP goals appear more likely to be successful when combined with a program which incorporates teamwork between physicians and pharmacists. Using estimates from the Lipid Research Clinics Coronary Primary Prevention Trial, the reduction in TC in this study corresponds to a greater than 24% relative risk reduction in definite CHD deaths and a 19% relative risk reduction in nonfatal MI annually.	LDL was calculated, not measured. Physicians and pharmacists were aware of their roles in the study which may have biased them towards more cooperation than would be the case in a regular day to day setting. Bogden PE. The physician and pharmacist team. An effective approach to cholesterol reduction. J Gen Intern Med 1997;12:158-164.

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Setting: Heart failure clinic Design: Randomized controlled trial 181 | Comparator was usual care (no pharmacist intervention)	To evaluate the effect of pharmacy intervention in heart failure patients on combined all-cause mortality and heart failure clinical events. RPh role: Medication evaluation, therapeutic recommendations to the attending physician, patient education and follow-up telemonitoring.	All-cause mortality and nonfatal heart events were significantly lower in the pharmacist group ($p=0.005$), largely due to reduction in hospitalization and ED visits. This group was also closer to optimal ACE inhibitor dosing $p<0.001$. More patients in whom an ACEI was contraindicated had appropriate alternative vasodilator therapy in the intervention group, 75% vs 26% $p=0.02$.	Outcomes in heart failure can be improved with the addition of a pharmacist to a multidisciplinary team.	This study is not blinded. Acceptance rates of pharmacist recommendations were not evaluated. Dose reductions due to adverse effects were not consistently captured. Gattis WA. Reduction in heart failure events by the addition of a clinical pharmacist to the heart failure management team. Arch Intern Med 1999;159:1939-1945.
Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Setting: Ambulatory primary care center over 1 year beginning 10/93. Design: Randomized controlled trial 94 | Comparator was usual care without pharmacy intervention.	"To assess the effect of a program that encourages teamwork between physicians and pharmacists on attempts to lower total cholesterol levels and to meet recommended goals proposed by NCEP. RPh role: advised and interacted with patients and physicians on the best course	Physicians accepted 167/186 recommendations (90%). More patients in the intervention group achieved LDL cholesterols to levels described by the NCEP (43% vs 21% $p<0.05$). In the intervention group for patients for whom the physician declined the pharmacists	Attempts to lower TC levels to achieve NCEP goals appear more likely to be successful when combined with a program which incorporates teamwork between physicians and pharmacists. Using estimates from the Lipid Research Clinics Coronary Primary Prevention Trial, the reduction in TC in this	LDL was calculated, not measured. Physicians and pharmacists were aware of their roles in the study which may have biased them towards more cooperation than would be the case in a regular day to day setting. Bogden PE. The physician and pharmacist team. An effective

	of pharmacologic therapy (drug selection and initiation, dosage recommendations and monitoring).	recommendation, only 2 of 12 met the NCEP goals compared with 18 of 35 for whom recommendations were accepted (p=0.47). The intervention group had its greatest effect on patients with CHD p<0..01 followed by those without CHD but with 2 or more risk factors (p<0.05. TC declined more in the intervention arm than the control p<0.01, 44 vs 13 mg/dL	study corresponds to a greater than 24$ relative risk reduction in definite CHD deaths and a 19% relative risk reduction in nonfatal MI annually.	approach to cholesterol reduction. J Gen Intern Med 1997;12:158-164.
Pharmacy Asthma Care Program (PACP) improves outcomes for patients in the community Design: Prospective controlled trial 191 | 205 Comparator was usual care without pharmacy intervention.	The impact of a pharmacy asthma care program (PACP) on asthma control was assessed using a multi-site, randomised intervention versus control, repeated measures study design. Methods: Fifty Australian pharmacies were randomised into two groups: intervention pharmacies implemented the PACP to 191 patients over six months, while control pharmacies gave their usual care to 205 control patients. Both groups administered questionnaires and conducted spirometry testing at baseline and six months later. The main	The intervention resulted in improved asthma control: patients receiving the intervention were 2.7 times more likely to improve from 'severe' to 'not severe' than the control patients (OR=2.68, 95% CI=1.64, 4.37, p<0.001). The intervention also resulted in improved adherence to preventer medication (OR=1.89, 95% CI 1.08 to 3.30, p=0.03), decreased mean daily dose of reliever medication (difference -149.11mcg, 95% CI -283.87 to -14.36, p=0.03), a shift in medication profile from reliever only to a	A pharmacist delivered asthma care program based on national guidelines improved asthma control. The sustainability and implementation of the program within the health care system remains to be investigated.	Carol Armour, Sinthia Bosnic-Anticevich, Martha Brillant, Debbie Burton, Lynne Emmerton, Ines Krass, Bandana Saini, Lorraine Smith and Kay Stewart. Pharmacy Asthma Care Program (PACP) improves outcomes for patients in the community *Thorax* published online 24 Jan 2007; doi:10.1136/thx.2006.064709

	outcome measure was asthma severity/control status.	combination of preventer, reliever ± LABA (OR=3.80, 95% CI 1.40 to 10.32, p=0.01) and improved scores on risk of non-adherence (difference -0.44, 95% CI -0.69 to -0.18, p=0.04), quality of life (difference -0.23, 95% CI -0.46 to 0.00, p=0.05), asthma knowledge (difference 1.18, 95% CI 0.73 to 1.63, p<0.01), and perceived control of asthma questionnaires (difference -1.39, 95% CI -2.44 to -0.35, p<0.01). No significant change in spirometry measures occurred in either group.		

Institutional

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
A single-blind, standard care-controlled study of pharmacist rounding on team versus no pharmacist rounding on the team at Henry Ford Hospital from 9/5/2000 through 11/31/2000 of patients admitted to and discharged from the general practice unit and the internal medicine service 165 | 6 Comparator: RPh identified med related problems through order review.	Determine whether there would be a reduction in preventable ADEs for patients cared for by rounding teams with a pharmacist, what the interventions of the pharmacists were during rounding and determine whether the intervention impacted length of stay and resolution of condition Provided patient care services at the bedside including rounding, documenting pharmacotherapy history, providing discharge counseling Pharmacist interventions: 1. order clarification 2. provision of drug information 3. recommendation of alternative therapy 4. identification of a drug interaction 5. identification of a systems error 6. identification of a drug allergy	Pharmacists provided 150 interventions of which 147 were accepted by the physicians. Most common rec was dosage or frequency change. There was a reduction of ADEs of 78% between control and experimental groups and 72% in comparison to the Leape study. Patients with an ADE had a length of stay 1.4 days longer than patients without. No difference in overall LOS or time to resolution. Readmissions were 44% less in the study group, but this was not significant. There was no difference in the cost of medications between groups.	Patients with an ADE resulted in cost increase of $923 per admission. Pharmacists rounding on the team contributed to significantly lower likelihood of preventable ADEs in the general medicine unit of this hospital.	No baseline data for either group; therefore, no control for any changes in standard of care over time. This was not randomized. Limited to patients in a general medicine unit and the results cannot be generalized to specialty units. Kucukarslan SN, Peters M, Mlynarek M, Nafziger DA. Pharmacists on rounding team reduce preventable adverse drug events in hospital general medicine units. Arch Intern Med 2003; 163:2014-2018

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
	7. approval of a nonformulary drug 8. provision of a special order drug 9. identification of an ADE			
Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Setting. General Medicine service of an academic teaching institution. (UCSF) Design: randomized controlled trial 221 |	To determine whether pharmacist involvement in discharge planning can improve patient satisfaction and outcomes by providing telephone follow-up after hospital discharge. RPh role: Patient counseling on all discharge medications, assistance in obtaining meds including phoning discharge scripts to the patient's pharmacy and completing necessary third-party payer forms. Randomized patients received a phone call within 2 days of discharge to reinforce education and evaluate for medication related problems. The RPh intervened to correct med related problems and notified the inpatient medicine team of patient reported symptoms or problems.	25% of patients had questions about meds, 11% regarding care received as inpatient, 11% regarding follow-up care. 19% had been unable to obtain all of their discharge prescription, and in all of these cases, the pharmacist was able to intervene successfully. Patient satisfaction was higher in the phone call group 86% vs 61% p=0.007. 11 pts in the phone call group vs 27 patients in the no phone call group had a visit to the ED within 30 days of discharge. P=0.005	Reduction in ED visits and unscheduled readmissions with total cost aversion of $14,880.	Not all patients who were randomized could be contacted. Only the gen med service was evaluated limiting generalizability. The ED outcome was not set a priori. Baseline differences between the 2 groups. Dudas V. The impact of follow-up telephone calls to patients after hospitalization. Am J Med 2001;111(9B):26S-30S.
Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference

Study Setting/Design	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
A 400-bed University Hospital. Design: Retrospective Analysis, Cohort Matched for warfarin indications. Pharmacist surveillance program. *In 1992 = physician management of warfarin dosage* *In1995 = pharmacist management of warfarin dosage 6 months.* Duration: 6 months 60 | *1.5 *1.5 pharmacists full-time are dedicated to maintain this program seven days of the week.	The objective of the study was to determine the effect of daily consultation by a team of hospital pharmacists on the accuracy and rapidity of optimizing warfarin therapy. Patients starting on warfarin for the first time had a daily consultation with a pharmacist. The pharmacists in this study had an extensive background in therapeutic drug monitoring, critical care, and cardiology and were familiar with warfarin therapy.	The pharmacist intervention resulted on a significantly decreased on the length of hospital stay and on the number of patients who received excessive anticoagulation therapy, from 9.5 +/- 5.6 days to 6.8 +/- 4.4 days (p = 0.009). The benefits of pharmacists providing therapeutic drug monitoring for agents with narrow safety ranges include reductions in cost of care, concurrent interacting drugs and adverse medication-related events while still achieving treatment goals. - Having pharmacists to provide dosing recommendations for initial warfarin therapy improves patient's quality of care and may also provide a financial benefit due to a decreased in the number of hospital stay.	In 1995 mean cost of one-day stay at this institution was $963, the cost to keep 1.5 pharmacists maintaining the program seven days a week was 107,000. The cost avoidance of hospitalization in 1995 was approximately $824,000 meaning for every dollar spent $8 was saved.	Limitations: "one limitation of this study was the influence of other, concurrent medical problems that could have delayed discharge." Dager DE, JM Branch Optimization of inpatient warfarin therapy: impact of daily consultation by a pharmacist-managed anticoagulation service. *The Annals of Pharmacotherapy*: 2000 May;34(5):567-72.
Study Setting/Design	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Setting: Surgical preadmission clinic from April 2005 to June 2005. Design: Randomized, control trial.	"To evaluate whether structured pharmacist medication history interviews with assessments in the surgical preadmission clinic and the use of a postoperative	Patients in the intervention arm vs the standard care arm had a greater # of home meds p=0.001. 20.3% of the intervention	Combined intervention of pharmacist medication assessments and a postoperative medication order form can reduce postoperative medication	This was a non-blinded study. The secondary analysis of the clinical effect of medication discrepancies was performed retrospectively.

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
464 | Comparator was nurse-conducted mediation histories with surgeon generated medication orders.	medication order form reduces the number of patients with at least 1 postoperative medication discrepancy related to home medications" RPh role: structured pharmacist medication history interview with assessment and generation of postoperative medication order form.	group had at least 1 postop med discrepancy vs 40.2% in the standard care arm p<0.001.	discrepancies related to home medications.	This was a per protocol analysis and not intent to treat. Kwan Y. Pharmacist medication assessments in a surgical preadmission clinic. Arch Intern Med 2007;167:1034-1040.
Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Northwick Park Hospital, a district general hospital in north-west London, which provides acute medical services to a population of 300 000. 53 |	A pharmacist was invited to become a member of the post-take ward round team that reviewed medical patients admitted within the preceding 24 hours. Patients also continued to receive care from a ward based pharmacist. Patient notes were analysed for cost of drugs on admission and discharge, discrepancies between admission drug history and pharmacist history, number of admission drugs stopped before discharge, and pharmacist recommendations. Pharmacist recommendations and actions were classified using a National Patient Safety	Discrepancies between the admission and the pharmacist derived drug history were noted in 26 of 50 in the pre-intervention group and 52 of 53 in the intervention group. Recommendations regarding drug choice, dose, and need for drug treatment were most common; 58 minor, 48 moderate and four major risks to patients were potentially avoided.	The annual drug cost per patient following discharge increased by £181 in the pre-intervention group and by £122 in the intervention group. Five pre-admission drugs were stopped in three pre-intervention patients saving £276 per annum, while the 42 drugs stopped in 19 intervention patients saved £4699 per annum	M Fertleman, N Barnett and T Patel *Qual. Saf. Health Care* 2005;14;207-211 Improving medication management for patients: the effect of a pharmacist on post-admission ward rounds Limitations – Small scale study need to extrapolate data to pharmacist prescribing

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
	Agency risk matrix.			

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
14 Nursing Homes (NH), South Manchester, UK 158 |	NHs were paired according to number of beds, resident mix, and status; from each pair 1 NH was allocated to Pharmacist Medication Review [PMR] (n = 158), and 1 to no review (n = 172). After a 4 month observation period, a pharmacist visited the inter-vention NHs and for each resident recorded types and amounts of drugs used, assessed the use of any neuroleptic drugs, and suggested changes. 3 weeks after the inter-vention, NHs were checked for acceptance of the suggestions and any complications from medication changes.	The pharmacist made 261 recommendations resulting in 144 actual medication changes. 128 (81%) residents in the group with PMR had medication changes (mean 2.5 changes, range 0–7). During the intervention phase, the NHs with PMR had fewer deaths and a greater decrease in number of drugs prescribed per resident than NHs with no review (p = 0.03) (table). There were no significant changes in MMSE, GDS, and BASDEC scores. There was a significant increase over the 2 phases in the mean CRBRS score for the group with PMR. Mini-Mental State Examination [MMSE], Geriatric Depression Scale [GDS], Brief Assessment Schedule Depression Cards [BASDEC], and Crichton-Royal Behaviour Rating Scale	Medication costs per resident during the intervention phase were reduced by £27.47 (from £159.01 to £131.54) for the NHs with PMR and £1.29 (from £142.53 to £141.24) for the NHs with no review. The mean number of drugs taken by residents at 4 months was 5.1 for the group with PMR and 4.5 for the group with no review (p = 0.03), and at 8 months was 4.2 and 4.4, respectively (p = 0.07).	Furniss L, Burns A, Craig SK, et al. Effects of a pharmacist's medication review in nursing homes. Randomised controlled trial. Br J Psychiatry 2000 Jun;176:563–7. Limitations – Need to extrapolate data to pharmacist prescribing

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
		[CRBRS]		
Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
450 bed community hospital/prospective randomized controlled trial Took place over 1.5 years 221 | ? An instrument for assessing appropriateness of prescribing practices was developed and used to evaluate each drug in terms of 1) inappropriate choice of therapy, 2) dosage, 3) schedule, 4) drug-drug interaction, 5) unnecessary therapeutic duplication, 6) allergy, 7) omitted but necessary drug therapy Each meds contribution to the severity of a prescribing problem was assessed as follows: 0 (no problem), 1 (clinically significant but not life-threatening), 2 (potentially life threatening) 9 (not enough clinical information to make assessment	Objective: evaluate whether clinical pharmacists' consultation would lead to improvement in appropriateness of drug prescribing for geriatric patients Pharmacists reviewed hospital records and drug regimens to determine the clinical condition and to assess the appropriateness of prescribing 1. drug therapy consults with physicians 2. patient consultation to reinforce physician instructions, enhance patient's knowledge and motivation and to provide resources to facilitate compliance	571 consultations 1046 recommendations 59% were related to modifying regimens in minor ways (taking meds with/without food) 41% (424 were focused on major prescribing-problem categories: schedule, appropriateness, dosage, omitted but necessary therapy	Significant reduction in patients with at least one prescribing problem in any category (p=0.05), less than optimal medication/no indication (p=0.01) and dosage p=0.05) Significant increase in overall-appropriateness of prescribing (p=0.01), dosage (p=0.02) and less than optimal med/no indication (p=0.03) in terms of mean prescribing scores Prescribing errors in appropriateness, drug dosage and drug scheduling were judged to be clinically significant in at least 45% of the study patients	Patient self-report were the source of data on post hospital discharge drug regimen Recommendations were made after meds had been dispensed which may have influenced pharmacists willingness to initiate a change Pharmacists did not have continuous access to patient inpatient and outpatient medical records Lipton HL, Bero LA, Bird JA, McPhee SJ. The impact of clinical pharmacists' consultations on physicians' geriatric drug prescribing: a randomized controlled trial. Med Care 1992; 30(7):646-658

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Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Academic Hospital Design: Clinical intervention documented by a computer-based documentation system. Time frame: Jan-Dec 2002 3978 | * * 4 clinical pharmacy faculty members, 5 pharmacy residents and 44 pharmacy students collected intervention data.	Objective: "To document the contributions that Pharmacy school faculty, residents, and students to the optimization of medical care for pediatric patients."	A total of 4605 interventions were performed. The most common interventions performed were: drug therapy change, pharmacokinetic monitoring, drug information, and medication histories/patient education. The most common indications for which interventions were made were: infectious (39.6%) and respiratory (23.3%) diseases. A total of 223 adverse drug events or medication errors were prevented or detected during the study period. Errors in dosing (overdose or under dose) were the most commonly encountered adverse events. The physician accepted 91% of all recommendations done by the pharmacists. 124	The estimated cost savings from mediation error prevention or detection was $ 458,516 (2002 value). The total cost savings from all interventions were $618,000.	Limitations: Using available literature and CliniTrend for detecting cost avoidance, the total estimated cost avoidance $618,000, may be misleading. This study shows uncertainty about the outcome of its interventions. Condren ME, Haase MR, Luedtke SA, and Gaylor AS. Clinical Activities of an Academic Pediatric Pharmacy Team Published Online, 6 February 2004, www.theannals.com. *The Annals of Pharmacotherapy*: Vol. 38, No. 4, pp. 574-578.

Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
		adverse drug events or medication errors were prevented during the study period.		
Study Setting/Design # pt | # RPh	Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
Randomized prospective study that used computerized alerts to notify pharmacists about patients with elevated troponin levels who then conducted academic detailing for physicians with regard to secondary prevention of CHD versus standard of care in a 1385-bed teaching hospital 853 | ?	To demonstrate the use of academic detailing and reminders to improve adherence to the secondary prevention guidelines in hospitalized patients with MI. Upon notification of an troponin I > 1.4 ng/mL, the clinical pharmacists: 1. determined whether the patients was eligible for intervention 2. assessed whether patient was assigned to control or intervention 3. assessed whether patient was receiving the full complement of meds for secondary prevention of coronary heart disease and whether there were contraindications to such. 4. contacted physicians to provide appropriate recommendations	Increased proportion of patients discharged on ACEI 98.9 vs 93.8 p= 0.02, statins 94.2 vs 89.3 p=0.02. No difference in beta blocker or aspirin use.	Significantly more patients were discharged on a regimen of all secondary prevention medications to which they did not have a contraindication (p<0.001)	Undertaken at an academic institution, not sure of generalizability to other institutions. Using elevated troponin level for patient identification may have excluded some patients who might benefit from secondary prevention Patients with elevated troponins from an outside hospital who transferred to Barnes-Jewish with now normal levels would not be identified by this system. High resource utilization to implement this approach. Bailey TC. An intervention to improve secondary prevention of coronary heart disease. Arch Intern Med 2007;167:586-590.

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Study Setting/Design # pt | # RPh	**Study Goals/Pharmacist Roles**	**Results**	**Economic outcomes or Clinical outcomes**	**Limitations/Reference**
Hospital Design: Comparison of clinical outcomes and IV antimicrobial costs over two two-year periods. Duration: two two-years Period (Dec 1992-Nov 1994 then Dec 1994-Nov 1996). * | 1 clinical specialist in infection disease *A total of 7219 admissions involving at least one infection were reviewed.	Objective: to study the clinical outcomes and cost effectiveness of antimicrobial control program (ACP). Pharmacist approved a non-formulary antimicrobial agent and assisted the team with therapy and culture report interpretation.	The antimicrobial control program - ACP was associated with a 2.4-day decrease in length of stay and a reduction in mortality from 8.28% to 6.61%. A clinical pharmacist trained in infections diseases directed this ACP.	Inpatient pharmacy costs other than intravenous antimicrobials decreased an average of only 5.7% over the two program years, but the acquisition cost of intravenous antimicrobials for both program years yielded a total cost saving of $291,885, a reduction of 30.8%.	Limitations: N/A Gentry CA, Greenfield RA, Slater LN. Outcomes of an antimicrobial control program in a teaching hospital – CA. American Journal of Health-System Pharmacy, Vol 57, Issue 3, 268-274 Feb 1, 2000.
A prospective multicentre study of pharmacist initiated changes to drug therapy and patient management in acute care government funded hospitals Prospective 1399 |	To determine the cost savings of pharmacist initiated changes to hospitalized patients' drug therapy or management in eight major acute care government funded teaching hospitals in Australia. This was a prospective study performed in eight hospitals examining resource implications of pharmacists' interventions	A total of 1399 interventions were documented. Eight hundred and thirty-five interventions impacted on drug costs alone. Five hundred and eleven interventions were evaluated by the independent panels with three quarters of these confirmed as having an impact on one or more of: length of stay, readmission probability, medical	The calculated savings was $263 221 for the eight hospitals during the period of the study. This included $150 307 for length of stay reduction, $111 848 for readmission reduction.	The annualized cost savings relating to length of stay, readmission, drugs, medical procedures and laboratory monitoring as a result of clinical pharmacist initiated changes to hospitalized patient management or therapy was $4 444 794 for eight major acute care government funded teaching hospitals in Australia.

Study Setting/Design		Study Goals/Pharmacist Roles	Results	Economic outcomes or Clinical outcomes	Limitations/Reference
# pt	# RPh				
		assessed by an independent clinical panel. Pharmacists providing clinical services to inpatients recorded details of interventions, defined as any action that directly resulted in a change to patient management or therapy. An independent clinical review panel, convened at each participating centre, confirmed or rejected the clinical pharmacist's assessment of the impact on length of stay (LOS), readmission probability, medical procedures and laboratory monitoring and quantified the resultant changes, which were then costed.	procedures or laboratory monitoring. There were 96 interventions deemed by the independent panels to have reduced LOS and 156 reduced the potential for readmission.		Michael J. Dooley, Karen M. Allen, Christopher J. Doecke, Kirsten J. Galbraith, George R. Taylor, Jennifer Bright & Dianne L. Carey. A prospective multicentre study of pharmacist initiated changes to drug therapy and patient management in acute care government funded hospitals. Br J Clin Pharmacol 57 :4 513–521 513