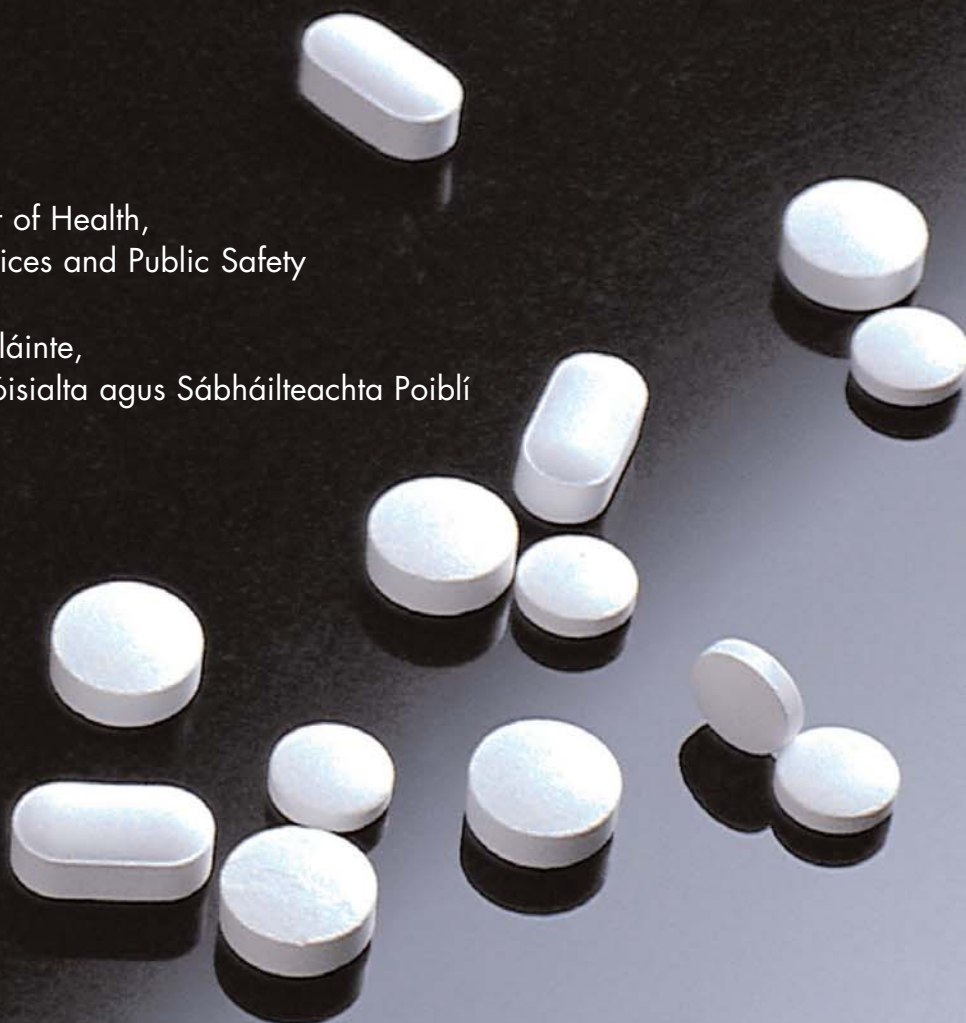


Review of Clinical Pharmacy Services in Northern Ireland

Department of Health,
Social Services and Public Safety

An Roinn Sláinte,
Seirbhísí Sóisialta agus Sábháilteachta Poiblí



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Prepared by Christine Clark MSc FRPharmS
Consultant Pharmacist

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Foreword

Modern clinical practice involves the use of increasingly sophisticated medicines in the management of disease. Such medicines are very powerful therapeutic tools requiring judicious use in order to provide optimal efficacy with minimal risk.

Clinical pharmacy services are increasingly critical to the achievement of this therapeutic balance by virtue of the application of the pharmacist's technical, clinical and biopharmaceutical knowledge.

Clinical pharmacists work in the context of a multidisciplinary care team. The benefits of their contribution include the identification and reduction of clinically important drug related problems, improved patient knowledge of, and concordance with, prescribed therapy, enhanced clinical outcomes, reduced length of hospital stay and improved cost effectiveness.

This Report provides for the first time a comprehensive review of clinical pharmacy services in Northern Ireland. It is a timely and important piece of work particularly as it informs the clinical governance agenda from a medicines perspective, as well as demonstrating the opportunities for, and implications of, extending such services within the HPSS.

I am grateful to all those who contributed considerable time and effort to the production of this document and commend it to you, particularly as it informs the future delivery of clinical pharmacy services.



Norman C Morrow
Chief Pharmaceutical Officer



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Executive summary

Clinical pharmacy services have evolved steadily over the past two decades and now contribute to the 'patient care journey' at all stages. They influence expenditure on medicines, improve the safety and effectiveness of medicines and make a significant contribution to the avoidance of medication errors. These activities are closely aligned with the clinical governance agenda.

Although the implementation of clinical pharmacy services was formally recommended by the DHSS in 1989, no additional resources were provided. As a result, services were developed in an ad hoc fashion and the extent and quality varied considerably.

This report represents a consolidated review of four separate reviews carried out in each Board area, designed to chart the progress of clinical pharmacy services and their future development including extension to the primary care sector.

Findings

The key findings of the review of the current status of services are:

- Clinical pharmacy services are increasingly seen to be critical to patient care particularly because they provide an important element of risk management in an inherently risk-laden area. Currently demand for these services has outstripped supply.
- Clinical pharmacists make numerous routine interventions concerned with improving the safety and efficacy of drug therapy. A small but significant number of these are potentially life-saving and many improve the quality of care.
- Patient education about drug treatment has been well-developed in certain therapeutic areas but overall this service is available to 25% of patients or less.
- Clinical pharmacists have successfully identified opportunities for efficiency savings and have put them into effect through judicious use of policies and guidelines.
- The importance of continuity of pharmaceutical care across the primary/secondary care interface has been recognised and some

Executive summary

services have been developed. Again, these are not available to all patients.

- Overall, good quality clinical pharmacy services have been developed in Northern Ireland but they are not available to all patients because too few pharmacists are employed to deliver them. The staffing establishment for most hospitals in Northern Ireland falls below that of comparable hospitals on the UK mainland.

Priorities for development

The strategic context for future development was analysed and seventeen key factors were identified that will particularly shape the delivery of pharmacy health care. Against this background, the priorities for development were identified.

The most pressing need for clinical pharmacy services is in connection with issues of good governance. The processes of prescribing, dispensing, administering medicines and patients' use of medicines are inherently risk-laden and these risks could be reduced if a pharmaceutical input was made at the appropriate times. Clinical pharmacy services need to be available at all stages in the patient care journey in order to identify and resolve problems promptly. In general, the earlier an intervention can be made, the more effective it is likely to be.

Priority areas for further development of clinical pharmacy services are:

- Admissions
- Discharge/primary care liaison
- Specialist clinics
- Inpatient services
- Medicines risk management

Recommendations

Against this background our recommendations fall into three overlapping areas – staffing levels, career development/structure and service development.



Executive summary

These recommendations are designed to ensure that the progress of clinical pharmacy services and the value that these services contribute to patient care are consolidated: (a) by establishing comparable staffing levels according to national benchmarks; (b) by establishing lead clinical pharmacists and opportunities for career advancement within a clinical speciality; (c) by supporting the care of patients across the primary/secondary care interface especially as it concerns specialist drug therapy and shared care arrangements; and, (d) by applying clinical pharmacy skills to minimise the risk from medicine-related incidents.

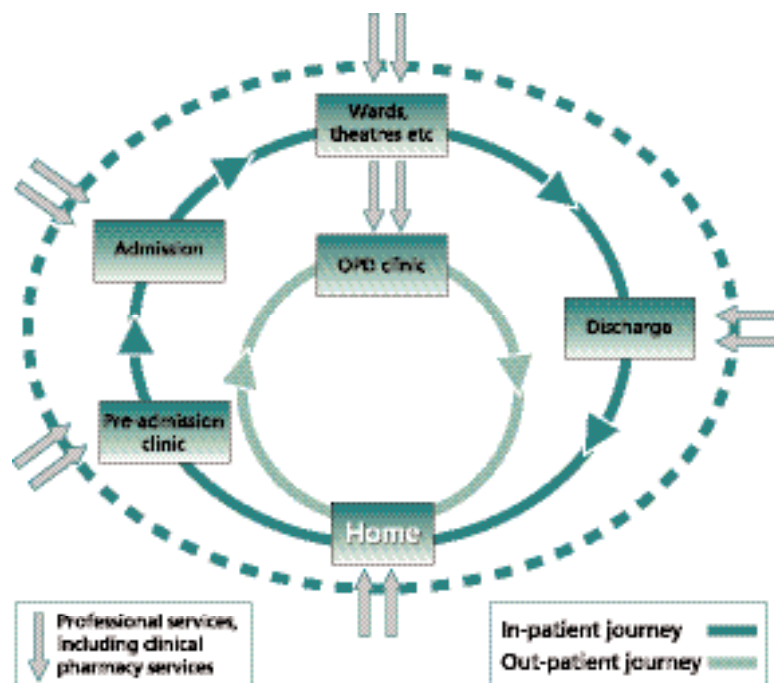
- Numbers of clinical pharmacists in Northern Ireland should be brought into line with the benchmark figures for the rest of the UK by the appointment of 20-25 pharmacists, estimated to be 5 at grade E and 20 at grade D. These posts should be deployed according to needs across Trust areas.
- Four regional specialist clinical leadership pharmacists should be appointed (at grade F).
- Six clinical liaison pharmacists should be appointed (at grade D) to consolidate the implementation of policy in respect of the equitable, safe and convenient provision of specialist medication at the primary/secondary care interface.
- The specialist posts and the clinical liaison posts should be deployed on a Northern Ireland basis to form a management network of pharmacists in designated areas working across boundaries but offering the synergy of team-working.
- Consideration should be given to the development of a career structure that facilitates development and specialisation within the clinical pharmacy arena. This should allow pharmacists to advance in their field of practice without having to move out, with the consequent loss of knowledge and expertise to the service.
- Six clinical pharmacists should be appointed at Grade E to take responsibility for medicines risk management. These posts should be placed in the large hospitals.

2.1 Clinical pharmacy and the patient care journey

In recent years there have been major changes in the provision of hospital pharmaceutical services. Two or three decades ago, hospital pharmaceutical services were almost entirely concerned with the preparation and dispensing of medicines, with little direct patient contact. These technical services are still fundamental to the current service and have become increasingly specialised, but they are now complemented by a wide variety of ward-based, patient-focused activities. These are generally referred to as clinical pharmacy services. Although there is a relatively small number of hospital pharmacists, their input into patient care is disproportionately large. Their activities can influence expenditure on medicines and also improve the safety and effectiveness of medicines' usage. In particular, hospital pharmacists can make a significant contribution to the reduction of medication errors. These activities make up a significant contribution to the clinical governance agenda.

Figure 1 represents the 'patient care journey' and shows how clinical pharmacists are integral to the healthcare team at all stages.

Figure 1: The patient care journey



Introduction

2.2 The review

This report represents a consolidated review of four separate reviews carried out in each Board area, designed to chart the progress of clinical pharmacy services and their future development including extension to the primary care sector.

The review seeks to:

- Describe the nature of clinical pharmacy services and their historical development;
- Outline how these services are organised locally;
- Quantify the existing resources available and the scope of services provided;
- Indicate how the level of service is monitored;
- Evaluate the impact of the services in terms of patient outcomes, risk management and financial considerations;
- Describe the strategic context for future developments;
- Make recommendations concerning models of service delivery and action plans; and,
- Identify priorities.

In addition, the review considers the relevance of these services to the current and future role of services in the primary care setting.

3.1 Background and rationale

This review has been undertaken in response to the HSS Executive Management Plan for 1997/1998 – 1999/2000.¹ Section 4.10.2 of the plan states that “The Executive will expect to see steps taken to implement a review of progress on *The Way Forward for Hospital Pharmaceutical Services*² and its further development, including extension into the primary care sector.”

The Way Forward for Hospital Pharmaceutical Services, which was issued in 1989, set out policy aims for pharmaceutical services taking into account the Nuffield report on pharmacy (1986).³ Boards were asked to review pharmaceutical services and, in particular, to develop action plans for the implementation of clinical pharmacy and formulary management systems. There was no commitment from central government to provide additional resources for these initiatives. Nevertheless, clinical pharmacy services were developed in most hospitals through a combination of in-year bids and redeployment of staff from other areas. This ad-hoc pattern of development led to considerable variation in the extent and quality of clinical pharmacy services in the hospitals in Northern Ireland.

Where successful services have been implemented these have created demand from clinicians in other clinical settings but demand has invariably outstripped the capacity to supply.

The effects of this shortfall in supply are now being felt throughout the four Board areas. Furthermore, the increasing emphasis on clinical governance and risk management has raised awareness about the importance of medicines management and the role of the clinical pharmacy service. There was, therefore, a clear need for a major review to describe the current level of service, to set out the strategic direction for future developments and to recommend priority areas for action.



Outline of the review

3.2 Methodology

In the first stage Directors of Pharmaceutical Services led the review in each of their respective Board areas, working collaboratively with Trust Pharmacy Managers. The approach used was largely one of self-audit set against the standards set out in the document “Standards for the Managed Pharmaceutical Services” (1998).⁴ This resulted in four individual reports.⁵⁻⁸

The second stage built from the first by engaging Directors of Pharmaceutical Services, Trust Pharmacy Managers and representative clinical pharmacists in the production of a composite report during two, one-day workshops. This was aimed at providing an overall strategic approach to the medicines needs of patients with particular reference to the clinical governance agenda. In essence, the focus was on medicines governance and the appropriate application of pharmacist skills to ensure the safety, effectiveness and economic use of therapy.

3.3 Scope of the review

The review concentrates on clinical aspects of the pharmacy service that are mainly concerned with direct patient care. It is recognised that these services are not offered in isolation but often supported by and are closely integrated with other services, such as Medicines’ Information Services, Aseptic Services and Drug and Therapeutics Committees. For these reasons, reference is also made to these related services.

The Product - What is clinical pharmacy?

4.1 Evolution of clinical pharmacy services

Clinical pharmacy was defined in “*The Way Forward*” circular as “the emerging pharmaceutical specialty in which pharmaceutical skills are applied at both policy making level and in the treatment of individual patients.”²

Clinical pharmacy relates to the safe, effective and economic use of medicines. The practice of clinical pharmacy is largely concerned with the application of pharmaceutical expertise to maximise the effectiveness and tolerability of drug treatment and minimise drug toxicity in individual patients.

Clinical pharmacists therefore have a triple function:

- Firstly, in providing advice to doctors, nurses and other health care workers on the clinical use of medicines, economic drug utilisation and safety;
- Secondly, in offering direct patient care services through, for example, medication history-taking, medicines education and advice;
- Thirdly, by offering managers, including clinical managers, informed advice in respect of medicines policy and procedures, again designed to ensure safety, effectiveness and economy in medicines use.

The practice of clinical pharmacy does not diminish the responsibility of clinicians in prescribing for individual patients. Instead, it involves the pharmacist as an integral member of the patient care team.

In the international context clinical pharmacy services have developed over the past thirty years, predominantly in the hospital sector. Over this period successive reports and circulars have reflected the developments.

The Noel Hall Report (1974)⁹ and the Nuffield Report (1986)³ said that pharmacists had a valuable role to play in the treatment of individual patients in hospitals and that clinical pharmacy should be practised in all hospitals. “*The Way Forward*” circular set out the government policy aim of,

“...achievement of better patient care and financial savings through the more cost-effective use of medicines and improved use of pharmaceutical expertise obtained through the implementation of clinical pharmacy services.”



The Product - What is clinical pharmacy?

In 1994 the Scottish Health Management Efficiency Group (SCOTMEG) and the Clinical Research and Audit Group (CRAG) published a report that recognised the value of clinical pharmacy services and advocated their further development.¹⁰ In 1996 detailed guidance was provided in a further publication, *"A Framework for Practice of Clinical Pharmacy in the Hospital Pharmaceutical Service"*¹¹. Similarly, in Wales, in 1996 a document was published that, once again, acknowledged the work of clinical pharmacists and spelled out a clear vision of clinical pharmacy services in both primary and secondary care¹².

The wider applications of clinical pharmacy services were acknowledged in the HPSS Management Executive circular *"Purchasing and Prescribing"* (1995)¹³ which recommended dialogue and co-operation between primary and secondary sectors in the implementation of prescribing protocols and drug use, requiring access to expert advice on prescribing and medicine issues. It also recommended better management of the introduction of new drugs and treatment protocols to the health service.

Rational, safe and cost-effective drug therapy relies on competent diagnosis and prescribing, effective monitoring and evaluation of drug therapy, and patients' understanding and compliance in relation to prescribed medication. Clinical pharmacists contribute significantly to each of these, assuring the quality and effectiveness of medicines' use.

Clinical pharmacy services have been shown to;

- Identify clinically important drug-related problems;¹⁴
- Reduce the incidence of clinically important drug-related problems;¹⁵
- Improve patient education and compliance;¹⁶
- Improve clinical outcomes;¹⁷
- Improve cost-effectiveness;^{18,19}
- Reduce length of hospital stay.²⁰

5

The Structure – How are clinical pharmacy services organised?

5.1 Personnel

Clinical pharmacy services are delivered mainly by pharmacists at grades C to E.

A number of pharmacists have been appointed to posts in which the duties are almost exclusively clinical. However, the majority also have other responsibilities.

Post-graduate training is essential for effective practice. All clinical pharmacists undergo basic induction training in clinical pharmacy and many go on to study for a higher qualification such as a clinical diploma or master's degree. Some also undertake advanced clinical training. However there are insufficient opportunities for advanced training for clinical pharmacy practitioners and few opportunities for clinical pharmacists to advance above grade D unless management duties are also undertaken. These two factors work together to hamper career development for clinical pharmacists. Moreover, there is a sharp contrast with the medical model - consultant surgeons and consultant physicians are senior practitioners who are seen to have expertise in their field whereas, in contrast, most senior pharmacists at present have been obliged to relinquish their direct patient care functions

Clearly there is a need for further resources to be committed to advanced training to make these opportunities available to more pharmacists. In addition, provision should be made for promotion within clinical pharmacy as a specialty, to address the career development issue.

5.2 Management

Clinical pharmacy services are generally managed within the overall management of pharmacy services but there is scope and need to develop greater leadership in this area. This could be facilitated through promotion of clinical pharmacy specialties and also appointments of lead clinical pharmacists at regional level.



The Structure – How are clinical pharmacy services organised?

5.3 Constraints

At many of the sites, clinical pharmacy services are described as being under-resourced. In many cases clinical pharmacy duties have been added on to core duties which has given rise to significant pressures when staffing is short. As a result, some services are provided only on a request basis, provided that staff are available. Despite this approach, it is not always possible to fulfil requests at present because of the severe shortage of staff.

Staffing problems arise from:

- The small number of pharmacists employed. It is noted that the staffing establishments in Northern Ireland fall below the benchmarks for the UK mainland. Comparative benchmarking with hospitals in Great Britain indicates that the staffing establishments in Northern Ireland are significantly below those of hospitals in GB with equivalent workloads. For example, United Hospitals Trust would require three additional pharmacists and five additional technicians to bring it into line with hospitals of a similar size in Great Britain.²¹ Clearly there is a need to address workforce levels in order to support further developments in clinical services.
- Failure to secure locum cover for annual leave, study leave and sickness absence and maternity leave.
- Recruitment and retention difficulties.

Work has been ongoing in relation to recruitment and retention difficulties in hospital pharmacy and a number of measures are now in place to address these problems.²²

The Process – What services are delivered?

Clinical pharmacy services aim to optimise treatment of patients during their hospital stay and ensure that patients and their carers are equipped with adequate medicines management mechanisms to ensure their treatment is continued after they leave hospital.

6.1 Clinical pharmacy activities

Clinical pharmacy services **always** involve the following 'core' activities:

- Prescription monitoring;
- Prescribing advice;
- Optimising therapeutic use of medicines;
- Adverse drug reaction prevention/detection;
- Prevention and detection of medication errors;
- Patient education/counselling;
- Inter-professional education about medicines.

They may also involve some or all of the following:

- Medication history taking;
- Pharmacokinetic/therapeutic drug monitoring;
- Specialist clinic services (e.g. HIV clinics);
- Clinical audit;
- Protocol development (e.g. for self-administration of medicines or for Patient Group Directions).

6.2 Settings in which clinical pharmacy services operate

The effectiveness of clinical pharmacy services is critically dependent on the timing of their delivery. For example, advice on effective prescribing or patient education about how to use a medicine to get the best effect are both services that should be delivered **before** the event rather than after a poor choice has been made or a medicine has been taken incorrectly. For these reasons clinical pharmacy services have been developed in all of the following settings:



The Process – What services are delivered?

- In-patient monitoring schemes;
- Medicines self-administration schemes;
- Individual patient dispensing schemes;
- Discharge planning;
- Specialist clinics (e.g. AIDS, renal clinics);
- Primary/secondary care interface pharmacy services;
- Consultant ward rounds;
- Multidisciplinary meetings;
- Out-patient clinics (e.g. anticoagulant clinics);
- Community services interface;
- Health promotion;
- Education and training;

Increasingly, the deployment of clinical pharmacy services at an early stage in the patient care journey is seen to offer the maximum benefit – on the basis that ‘prevention is better than cure’. Service development initiatives need to take account of this and ensure that clinical pharmacy services are positioned to function most effectively.

Clinical pharmacy support services

Clinical pharmacy services are a key part of the overall hospital pharmaceutical service but integrate particularly closely with other specific services. Typically these include some or all of the following:

7.1 Medicines Information Services (MIS)

A medicines information service typically provides immediate answers to queries about medicines. Many such services also prepare medicines information bulletins on topics of local interest. MIS are an important back-up for clinical pharmacy services as they provide a library service and electronic database searching capabilities. Such services require staff trained in dealing with enquires and library resources to give evaluated, unbiased answers. Medicines information is essential in providing support to review and revise hospital formularies which are key tools used by clinical pharmacists in their work.

7.2 Aseptic services

Aseptic services comprise aseptic facilities and highly-trained personnel who prepare products mainly for parenteral administration. This type of processing is needed for medicines that cannot be sterilised after preparation. Such products include:

- Intravenous feeding solutions (Total parenteral nutrition, 'TPN');
- Pre-mixed intravenous injections (intravenous additives);
- Pre-mixed cancer chemotherapy injections;
- Pre-loaded syringes of analgesic injections for patient-controlled analgesia;
- Eye preparations.

These are complex pharmaceutical preparations requiring both the clinical and technical expertise of pharmacists, for example, intravenous feeding solutions. These are complex mixtures of sterile ingredients that may be devised by a clinical pharmacist to meet a specific patient's nutritional need. They are then compounded by the aseptic service. The ongoing clinical service may also include monitoring of individual patients, dosage adjustment recommendation and ensuring appropriate administration at ward level.



Clinical pharmacy support services

Often patients receiving intravenous treatments are seriously ill and particularly vulnerable to infections and other hazards, therefore the quality of the intravenously-administered products (or other parenteral products) is critically important in minimising further risks. The preparation of these products in aseptic facilities guarantees their quality, safety and integrity and thereby significantly contributes to the management of risk in this critical area.

7.3 Medication error reporting schemes

Medication error reporting schemes collect reports of medication errors, usually anonymised, on a hospital or district-wide basis. This provides an early-warning system if a particular product or prescriber is associated with a specific problem and helps clinical pharmacy staff to identify system or product improvements that are required. Such schemes operate in hospitals in Northern Ireland at various levels of sophistication.

7.4 Drug utilisation review (DUR)

DUR is the process of auditing the use of particular drugs within an indication or therapeutic area with a view to improving drug utilisation in terms of both economic and therapeutic outcomes.

7.5 Clinical trials service

A clinical trials service typically is responsible for the medicines that are used in clinical trials and fulfils a key co-ordination role in relation to medicines supply, maintenance of records and compliance with GCP and GMP in line with ICH guidance and EU Directives. The clinical trials service is usually responsible for holding the randomisation codes for randomised double-blind trials. Pharmacists working in these services may also advise on aspects of trial design and product masking. In addition they play a key role in facilitation and in liaison with the sponsors and investigators.

Clinical pharmacy support services

7.6 Committees and other groups

Pharmacists, who are often clinical pharmacists, serving on Trust committees such as the Drug and Therapeutic Committee, Risk Management Committee, Clinical Audit, Formulary committee, Kardex design group, inform the development of Trust-wide policies and protocols and ensure the contribution of clinical pharmacy services to their implementation.

7.7 Audit, research and service development

Systematic audits of key aspects of the medicines use process provide the clinical pharmacists with facts and figures that can be used to target their efforts more effectively. Recent examples include audits of:

- discharged patients' care;
- the use of specific drugs e.g. antibiotics, heparins;
- prescription writing;
- formulary compliance.



Outputs – How is the level of service monitored?

8.1 Monitoring arrangements

The level of clinical pharmacy activity is monitored quantitatively by means of some or all of the following:

- Number of prescriptions monitored;
- Number of consultant ward rounds attended;
- Number of interventions recorded;
- Number of patients educated/counselled;
- Number of discharges planned;
- Number of computerised records of prescription details entered;
- Number of discharges arranged by liaison pharmacist;
- Number of lectures/hours of training delivered to other health care professionals.

The range of items monitored and the frequency of monitoring depends on the hospital in question.

8.2 Performance in relation to the set standards

There is a published set of standards for hospital pharmacy services (*Standards for the Managed Pharmaceutical Services*, Chief Administrative Pharmaceutical Officers Group, Northern Ireland 1998⁴). When audited against these standards, the service levels in Northern Ireland generally fell below the required standard, largely, if not entirely, due to the number of staff available to deliver services. In general, the staffing establishments were too low to undertake all of the required duties on a consistent basis.

8.3 Composite clinical pharmacy activity levels for Northern Ireland

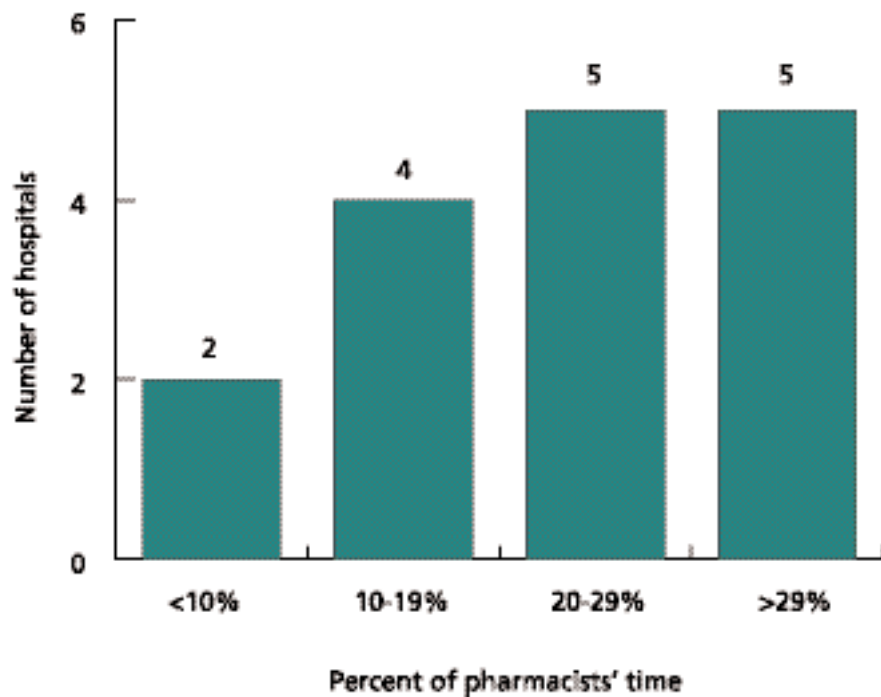
The charts in this section give a summary view of clinical pharmacy activity in hospitals in Northern Ireland. The data are drawn partly from the individual reports from the four Boards and partly from self-assessments by the Directors of Pharmacy Services in the individual hospitals.

Outputs – How is the level of service monitored?

8.3.1 Percentage of pharmacists' time spent on clinical activities

Figure 8.1 shows the percentage of pharmacists' time (as a proportion of the total number of pharmacist-hours available) devoted to clinical activities. It shows that in five hospitals, more than 29% of pharmacists' time was spent on clinical activities. (This is comparable with the highest level of activity in the United States, reported in the ASHP 2000 survey.²³) However, in two hospitals less than 10% of time was available for clinical functions.

Figure 8.1: Percentage of pharmacists' time spent on clinical pharmacy activities



Outputs – How is the level of service monitored?

8.3.2. Percentage of patients receiving clinical pharmacy services

In figures 8.2 and 8.3 the percentages of patients receiving clinical pharmacy services in Northern Ireland are shown together with the percentages of patients receiving clinical pharmacy services in hospital in the United States for comparison. (From the ASHP 2000 survey²³) The results show that, for example, in 50% of hospitals in Northern Ireland fewer than 25% of patients receive a clinical pharmacy service. There were no hospitals in Northern Ireland in which more than 75% of patients were regularly monitored by clinical pharmacists.

Figure 8.2: Percentage of patients monitored by pharmacists in Northern Ireland 2001 (Chart shows percentage of hospitals in each category)

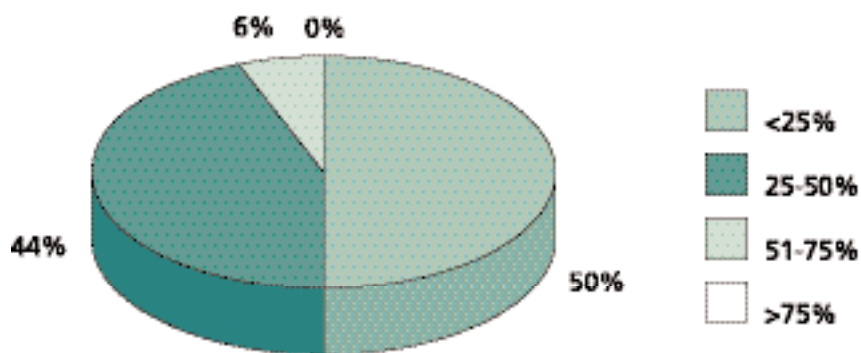
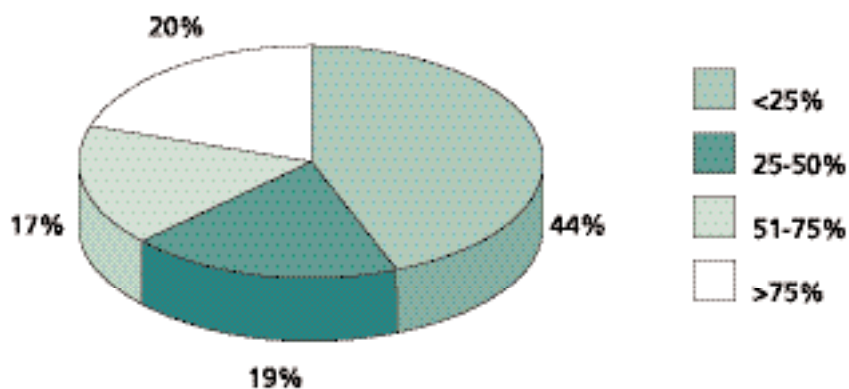


Figure 8.3: Percentage of patients monitored by pharmacists in the United States (ASHP 2000) (Chart shows percentage of hospitals in each category)



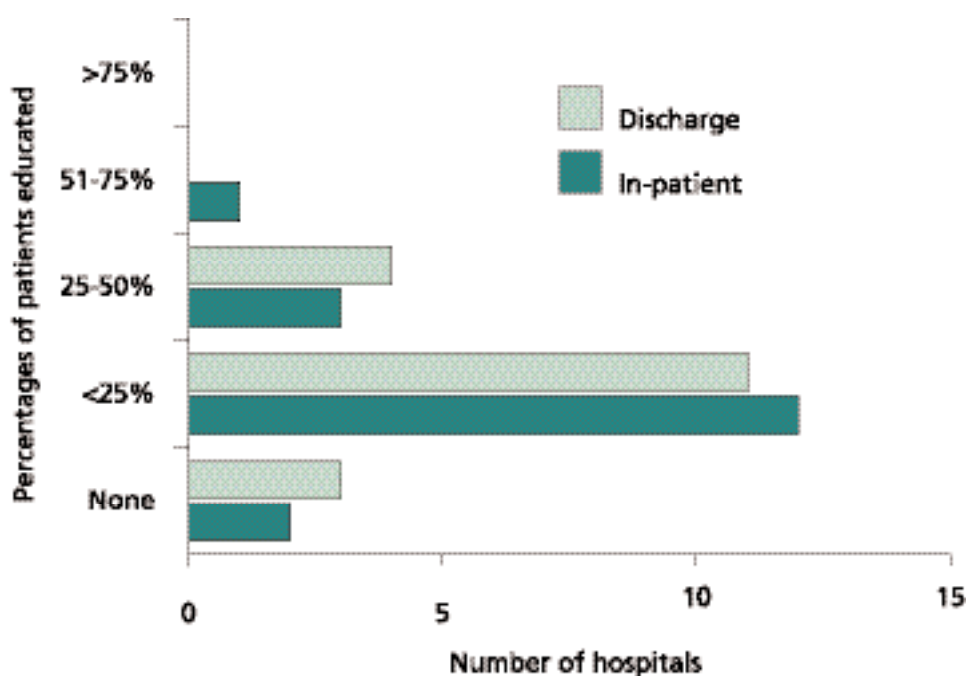
Outputs – How is the level of service monitored?

8.3.3. Percentage of patients receiving patient education about medications by pharmacists

Figure 8.4 shows that in the majority of hospitals fewer than 25% of patients are educated about their medicines either during their inpatient stay or at the time of discharge.

The results show some evidence of 'early intervention' by pharmacists, insofar as inpatient education services appear to be developing in tandem with education at the point of discharge. In view of the recognised benefits of early intervention, it will be important to support this type of development and encourage more widespread implementation of these services.

Figure 8.4: Percentage of patients educated by pharmacists during their inpatient stay or at the time of discharge

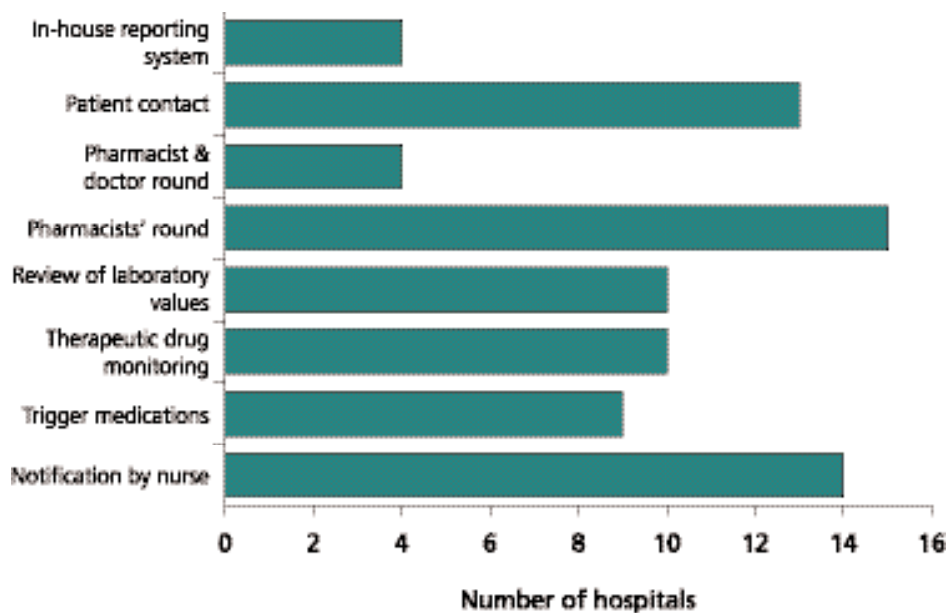


Outputs – How is the level of service monitored?

8.3.4. Methods used to monitor/prevent adverse drug reactions

Figure 8.5 shows the methods used by pharmacists in Northern Ireland to monitor and or prevent adverse drug reactions. In most hospitals more than one methods is used.

Figure 8.5: Methods used to prevent and/or monitor adverse drug reactions

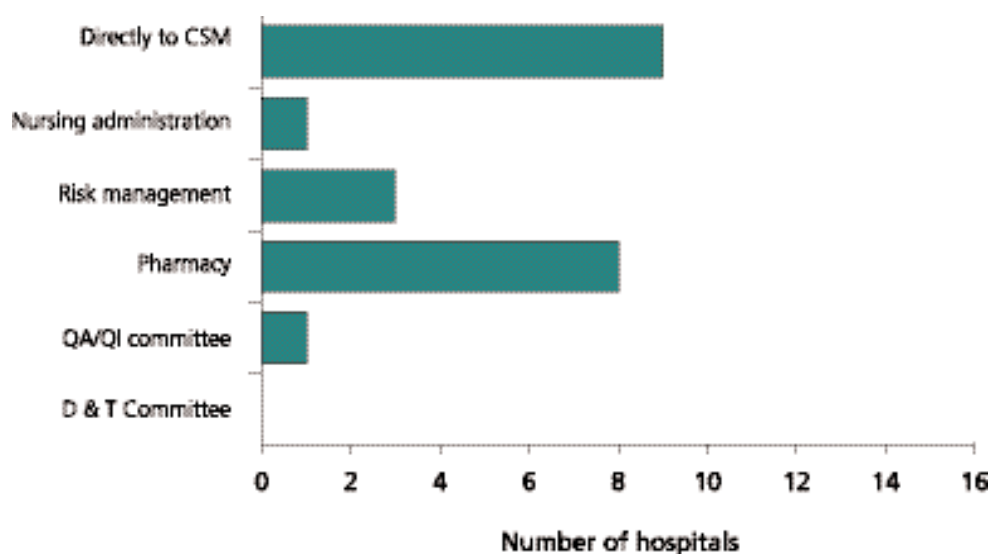


Outputs – How is the level of service monitored?

8.3.5. Adverse drug reaction reporting routes

Figure 8.6 shows how adverse drug reaction reports are handled within Trusts. Many are sent directly to the Committee on Safety of medicines (CSM) and the Pharmacy Department is informed in parallel. In eight Trusts the reports are channelled through the Pharmacy in the first instance.

Figure 8.6: Adverse drug reaction reporting routes



Outcomes – How is the impact of clinical pharmacy services assessed?

It is recognised that results of the clinical pharmacy service are more meaningful than the inputs and several measures to assess and record outcomes have been developed over the past few years.

9.1 Evaluation of interventions by pharmacists

Clinical pharmacists make numerous interventions to improve the quality of drug therapy. Many of these lead to improvements in safety, efficacy, cost or convenience of treatment with a number that are potentially life-saving. Several systems of grading have been devised. An example of an independently-validated scoring scheme is given below.

Intervention scoring scheme

- 1 Intervention that was detrimental to the patient's well-being
- 2 Intervention that was of no significance to the patient's care
- 3 Intervention that was significant but that did not lead to an improvement in patient care
- 4 Intervention that was significant and resulted in an improvement in the standard of care
- 5 Intervention that was very significant and prevented a major organ failure or prevented a drug reaction of similar importance.
- 6 Intervention that was potentially life-saving

This scheme has been used by a team of independent assessors in the Northern Board. The results over a four-year period show that the majority (72%) of clinical pharmacy interventions fall into category 4 and fifteen percent are category 5. Although fewer than 1% fall into category 6 (16 out of more than 12,000) they were judged to have had a significant part in preventing serious injury or death and, in turn, in avoiding costly litigation for the Trust.

Outcomes – How is the impact of clinical pharmacy services assessed?

9.2 Efficiency savings

Clinical pharmacists are in a good position to identify opportunities for efficiency savings by virtue of their broad knowledge of drug products and understanding of the ways in which they are used. Examples of such savings in Northern Ireland are:

- The introduction of a policy for the use of thrombolytic (clot-busting) agents resulted in an annual reduction in expenditure of £8,000, with no reduction in the quality of care.
- A reduction of more than 50% in healthcare costs through the implementation of a sequential antimicrobial therapy (SAT) protocol for the treatment of lower respiratory tract infection in children and adults.^{19,24}
- The introduction of a hospital-based community services liaison pharmacist to manage medicines at patient admission and discharge resulted in a decrease of 2.4% in the readmission rate of the study group compared to patients handled in the conventional way. The annual projected opportunity cost was £83,484.²⁵
- A pharmacy education programme increased the eradication rate of *Helicobacter pylori* by 20%. As each eradication failure cost £130.00, there were considerable benefits in terms of cost-avoidance.²⁶
- The introduction of therapeutic substitution programmes has yielded considerable savings e.g. the substitution of nizatidine for ranitidine saved more than £1000 per month in one hospital.²⁷
- The appointment of an HIV pharmacist achieved a 12-month cost-saving of £30,000.²⁸

These experiences clearly suggest that there are opportunities for “invest to save” measures by putting in the appropriate resources in and targeting them to suitable therapeutic areas.



Outcomes – How is the impact of clinical pharmacy services assessed?

9.3 External evaluation

Customer satisfaction surveys are periodically conducted and several hospitals in Northern Ireland participate in the national benchmarking scheme run by the national Performance Advisory Group for the NHS. The most recent review was carried out in 2000 and has now been published.²⁹ Data from those participating hospitals in Northern Ireland are included.

9.4 Publications

Publications offer another way of assessing the impact of clinical pharmacy activity. A list of papers published by pharmacists from Northern Ireland is shown at Appendix 1.

Clinical pharmacy at the interface with primary care

10.1 Continuity of patient care

The critical issue at the interface between primary and secondary agencies is continuity of care. This necessarily involves a range of clinical pharmacy activities, which may be categorised according to the level at which they take place:

10.2 The patient level

- Drug history-taking and patient education at pre-admission clinics and at the time of admission
- Patient counselling/education prior to and at the time of discharge

10.3 The practitioner level

Liaison with other practitioners such as GPs, district nurses, prescribing liaison forums in order to transfer information about medicines and ensure continuity of prescribing. One critical dimension of this continuity is support for clinicians and patients, particularly in connection with shared-care arrangements involving the use of specialist medicines, for example, services to renal patients at Belfast City Hospital.

10.4 The policy level

Clinical pharmacists can ensure that there are rational links between prescribing policies in primary and secondary care through participation in key committees and the provision of pharmaceutical advice to primary care organisations. There is clear evidence of such practices in Northern Ireland and NHSSB has probably the most highly developed framework, with an Area Prescribing Forum (APF) that deals with dressings, medical and surgical items and documentation. Also included in this framework is an interface sub-group that advises the APF.



Clinical pharmacy at the interface with primary care

10.5 The public health level

Continuity of care can be further reinforced through integrated clinical pharmacy input at the public health policy level. Wider application of clinical pharmacy expertise to the development and implementation of public health policy is needed. This would be valuable for example, in relation to the development of antibiotic policies for primary and secondary care.

Strategic context for future developments in clinical pharmacy

Against the background of poor resourcing, clinical pharmacy services have nevertheless yielded demonstrable benefits. In order to secure full value from such services in future, additional resources will need to be committed. Consideration of the strategic context in which these services will operate lends further weight to arguments for developing and strengthening clinical pharmacy services.

Over the next 5-10 years it is anticipated that the following key developments will shape the health care environment and exert a significant influence on the direction and way in which clinical pharmacy services develop:

11.1 Clinical governance

There will be increasing emphasis on clinical governance. This has been recently reinforced by the DHSSPS consultative paper, Best Practice – Best Care.³⁰ Clinical governance will bring with it the need for:

- Clear lines of responsibility and accountability;
- A comprehensive programme of quality improvement;
- Clear policies for managing risk;
- Education and training plans;
- Procedures in place to identify and remedy poor performance.

Clinical pharmacy services are already strongly focused on safe systems for medicines' use and on reducing the opportunities for medication errors. These activities are naturally in line with the clinical governance agenda and need to be recognised as such. In this connection the NHS Controls Assurance document on medicines management will place increasing demands on clinical pharmacy services.³¹

11.2 Ageing population

The number of elderly (over 65 years) people will continue to increase as life expectancy increases. This group consumes a disproportionate quantity of medicines and individuals are commonly prescribed 3-4 or more regular medicines. This will increase demands for patient education, therapy monitoring, prescribing advice and information for carers.



Strategic context for future developments in clinical pharmacy

11.3 Changing public expectations

Public expectations of the healthcare system are changing as individuals are better informed and adopt an increasingly consumerist approach. In particular there is an expectation that services will be available at times that are convenient to patients and that complete and accurate information will be available on demand.

This will give rise to a demand for clinical pharmacy services that are delivered in a consistent and reliable manner. Primary and secondary care services will also need to be better integrated so that they appear genuinely to be 'seamless' from the patient/consumer perspective.

11.4 Changing model of patient care

As public expectations of health care have shifted so has the model of patient care and practitioners' perceptions of the patient's role. Increasingly, patients are seen as active partners in their own health care and it is recognised that patients may value certain outcomes differently from health care practitioners. A treatment plan therefore becomes something to be negotiated between patient and practitioner rather than something to be dictated. The outcome of a consultation should be 'concordance', that is, agreement between the two parties, even if it is agreement to differ. It follows that compliance with a treatment plan is likely to be better if the patient has had a part in the decision than otherwise.

11.5 Technological advances

The growth in the use of computers, the Internet and mobile telephones will continue. Video-phones will be commonly used and the use of smart-cards, carried by patients, for medical records may also become routine. Electronic prescribing will become the norm both in hospital and in primary care. In hospital this will be linked to electronic systems for medicines administration and possibly also for medicines' distribution. In hospital electronic prescribing will ensure that activity data are more meaningful and will provide the pharmacist with timely information to target high risk patients. In primary care prescriptions will be transferred electronically to the community pharmacy of the patient's choice. It will also be possible for

Strategic context for future developments in clinical pharmacy

some routine monitoring of patients to be undertaken at a distance, with results sent electronically and instructions sent by telephone or email. For example, monitoring of anticoagulation status or cardiac rhythm could be done in this way.

Some of these advances will eliminate things that pharmacy services have traditionally had to do. For example, many of the checking and transcribing functions of ward pharmacists will disappear when computerised prescribing is introduced. This will liberate time for clinical services and also enable some services to be enhanced. For example, patient education could be supported by additional information on websites and email and/or telephone-based 'ask-the-pharmacist' service.

With increased utilisation of IT, there will be a requirement for clinical pharmacists to be involved in the development and quality assurance of systems.

11.6 Extension of prescribing rights

It seems likely that prescribing rights will be extended to groups other than doctors. Although this will embrace nurses in the first instance, pharmacists and others will follow. This will increase the demand for education in therapeutics and practical prescribing advice.

11.7 Growth in the use of alternative/complementary medicines

The use of complementary medicine is widespread and is partly fuelled by mistrust and disappointment with the results of conventional medicines. This is sometimes accompanied by the mistaken belief that products such as herbal medicines are 'natural' and therefore free from side effects or adverse effects. Some complementary treatments have now been adopted by mainstream medicine (e.g. acupuncture, St John's Wort, Evening Primrose oil) and more are likely to follow.

This will give rise to a demand for additional training for clinical pharmacists in order to provide authoritative advice to patients and prescribers.



Strategic context for future developments in clinical pharmacy

11.8 Changing career aspirations of pharmacy technicians

Pharmacy technicians are well-trained in the technical aspects of pharmacy but have little or no training in clinical pharmacy or therapeutics. At present, pharmacy technicians are equipped to take on a number of the technical functions of the pharmacy department and thereby liberate pharmacist time for clinical duties. In the future, pharmacy technicians may be in a position to support the development of clinical pharmacy services further through involvement in ward-based work.

11.9 Developments with medicines

Several developments in this area will have important implications for practice:

- The increase in numbers of biotech medicines;
- The development of pharmacogenetics/genomics;
- The development of drugs to treat previously untreatable conditions;
- Overuse of antibiotics.

As new drugs are created new types of medicines will be developed, some of which will be capable of 'homing' in on specific target organs or types of cells. The growth of the new sciences of pharmacogenetics/genomics will enable selection of drugs on the basis of an individual's genetic make up. Both of these factors will increase the demand for expert advice and information.

11.10 Continued pressure on budgets

The pressure to contain spending within available budgets will not diminish. As debate about rationing of health care services becomes more explicit there will be increasing emphasis on value-for-money and cost-effectiveness information.

This will give rise to an increased demand for information about costs and consequences of drug treatments and additional training will be needed in this area.

Strategic context for future developments in clinical pharmacy

11.11 Growing awareness of medical/medication errors

There is growing awareness of medical errors and medication errors both within the health care community and amongst the general public. Between three and six percent of patients are admitted to hospital as a result of adverse effects of medicines and this figure can reach almost 30% amongst the elderly. It is estimated that 1-2% of patients admitted to hospitals are harmed as a result of medication errors. According to the report, *An Organisation with a Memory*, serious errors in the use of prescribed medicines now account for 20% of all clinical negligence litigation.³² The same report called for a 40% reduction in such errors by 2005. Clearly robust preventative actions are required to minimise the risks inherent in the prescribing, dispensing and administration of medicines.

In many professional circles there is an understanding that many of these errors arise from system errors rather than malign or incompetent members of staff. This has prompted calls for blame-free reporting systems and 'near-miss' reporting so that weaknesses in the system can be identified and eliminated. Some have advocated the use of 'failure-mode and effect analysis' (FMEA) to be applied, as in the aerospace industry.

This presents opportunities and obligations for pharmacy as no other professional group sees the full picture of medicines' use or is so well-placed to implement and monitor safe systems of working.

11.12 'Agenda for Change'

The document, *Agenda for Change*³³, calls for the introduction of a 37.5 - hour working week. This will result in a loss of 240 hours of pharmacist time per week across the hospital service in Northern Ireland (based on 160 established posts).



Strategic context for future developments in clinical pharmacy

11.13 NHS (HPSS) restructuring

Three key issues facing the service will be the outcome of the Acute Services Review, the development of primary care services and the public health agenda. Clearly these will have important ramifications for pharmaceutical services and it will be important to ensure that clinical pharmacy services are properly aligned to deliver optimal patient care, particularly as it relates to the use of medicines

11.14 Competency revalidation

Competency revalidation is likely to become a reality for all healthcare professions as consumers demand assurances that practitioners are offering up-to-date care. This will have obvious implications in respect of investment in the continuing professional development of the workforce.

11.15 Primary/secondary care interface dynamic

The primary/secondary care interface will shift as more services become available to home-based patients. These are likely to include home monitoring of ECGs and anticoagulation status as well as administration of complex treatments in the home, e.g. low-molecular weight heparin for DVT, chemotherapy, antibiotics. These developments will create demands for information, advice and different types of pharmaceutical supply services.

11.16 The 'quality' agenda

Quality improvements will continue to be a goal for public services. Quality in medicines' usage is likely to receive particular emphasis as the public becomes more aware of issues concerning the safe use of medicines. Two recent, high-profile errors have served to underline forcefully the level of risk in the minds of NHS staff and the public. These were, the recent accidental injection of vincristine into a patient's spinal cord, and

Strategic context for future developments in clinical pharmacy

bupivacaine intravenously, both of which were fatal, and are likely to fuel public demands for high-quality, transparent systems for the safe handling of medicines.

11.17 Direct to consumer (DTC) advertising

It is predicted that within five years 'direct to consumer' advertising of prescription only medicines (POMs) will be a reality. This is likely to increase the demand for accurate information about the effectiveness and tolerability of medicines.



12.1 Key considerations

The priorities for development in clinical pharmacy are focused on three fundamental aspects of activity:

- **Prevention** of harm;
- **Protection** from risks;
- **Promotion** of effectiveness.

Prevention

The role of clinical pharmacy in the prevention of harm is largely concerned with the avoidance of harmful situations. This is achieved at the individual patient level by ensuring that unsuitable drugs (e.g. drugs that would interact adversely with co-existing disease states or concurrent medications) are not prescribed. At the population and policy levels it is achieved through the development and implementation of policies, protocols and working systems designed to ensure that inappropriate drug treatments are avoided.

Protection

Protection from risks is perhaps the least well-defined of the functions of clinical pharmacy but potentially the most far-reaching. At the patient level, some drug treatments are inherently riskier than others and the clinical pharmacist's role is to ensure that where risks cannot be avoided altogether, appropriate steps are taken to minimise the risks. However, the clinical pharmacy service also protects other health care practitioners, particularly those at the early stages of their careers, such as junior doctors, by providing timely guidance and advice. The service also protects public organisations from costly litigation by ensuring that the risks of drug treatment are appropriately monitored and managed.

Promotion

Promotion of effectiveness in the use of medicines is the clinical pharmacist's contribution to the overall drive for clinical effectiveness. The evidence-based medicine movement has increased awareness that efficacy (in a clinical trial situation) does not always translate into effectiveness in a real-life situation. The skills of clinical pharmacists can be used systematically to ensure that effectiveness information about medicines is communicated and used in day-to-day practice to improve the quality of care.

Priorities for development

12.2 Medicines' governance.

The most pressing need for clinical pharmacy services is in connection with issues of good governance. This review has identified instances of good practice which illustrate how well-targeted clinical pharmacy services improve the quality of patient care. The processes of prescribing, dispensing and administering medicines are inherently risk-laden and these risks could be reduced if a pharmaceutical input was made at the appropriate times. Traditional ward pharmacy services, involved pharmacists checking prescriptions after they had been written and, in some situations, after treatment had started. It is clear that interventions early in the course of the patient-care journey would have more chance of identifying problems at an early stage and forestalling some problems altogether. In the middle part of the patient-care journey a pharmaceutical input is required to monitor responses to drug treatment. At the end of the journey, pharmaceutical steps are required to manage a safe transition to primary care. We propose that this process, in which the clinical pharmacy service takes responsibility for ensuring safe, appropriate and effective use of medicines at all stages of the patient care journey, should be described as 'medicines governance'.

Bearing in mind the concept of medicines governance and the contemporary needs of the health service, we propose the following priority areas for further development of clinical pharmacy services:

- Admissions;
- Discharge/primary care liaison;
- Specialist clinics (appropriate to the local situation);
- Inpatient services;
- Safe systems of work/medicines risk management.

12.2.1 Admissions

Patients would benefit from a clinical pharmacy service at the time of admission, or in the case of some surgical units, at pre-admission clinics. Many medicines-related problems that arise in hospital could be prevented if a thorough drug history were taken at the time of admission. For surgical patients some cancelled operations could be avoided if advice concerning the use of critical medicines, such as anticoagulants or oral contraceptives) could be given in a timely manner. We believe that the routine availability of clinical pharmacy



Priorities for development

services at the time of admission would make a bigger difference to the overall quality of patient care than any of the other measures listed here.^{25, 33}

12.2.2 Discharge/primary care liaison

Patients in all therapeutic specialities would benefit from the availability of dedicated 'discharge/primary care liaison' clinical pharmacy services. These would be concerned with patient education (explaining the purpose of prescribed medicines, changes made during the hospital stay and ensuring that the patient knew how and when to obtain further supplies) and responsible for liaison with relevant health care professionals in primary care. In this context particular importance is attached to the role of the service in supporting prescribers using medicines from the 'red' and 'amber' lists. (see also paragraph 10.3)

12.2.3 Clinics

The fundamental principles of complexity and risk should drive the implementation of clinical pharmacy services in outpatient clinics.

In situations where drug treatment regimens are complex, either by virtue of the number of medicines in use or the way in which they are used, then patients could benefit from individualised pharmaceutical care. Similarly, patients with complex disease profiles present greater challenges for the prescriber and, again, pharmaceutical expertise could be used to devise rational treatment plans.

High-risk situations in relation to drug treatment are encountered when the drugs are intrinsically toxic, or have a low therapeutic margin, and/or when the patient's capacity to metabolise potentially toxic drugs is compromised by organ failure, concurrent disease or extremes of age.

Two groups of clinic patients would benefit particularly from a clinical pharmacy service:

- Patients who are receiving complex drug regimens (such as AIDS patients and patients with kidney failure/ kidney transplants);
- Patients who are particularly at risk of drug toxicity (such as children, in whom dose requirements may vary considerably, and patients receiving cancer chemotherapy).

Priorities for development

12.2.4 Inpatient services

The inpatient areas in which clinical pharmacy services would make most impact are:

- Cardiovascular disease;
- Care of the elderly;
- Mental health;
- Cancer;
- Paediatrics;
- Adult and neonatal intensive care;
- Antimicrobial use (all specialities).

12.2.5 Safe systems of work/medicines risk management

The importance of safe systems of work and the need for risk management in connection with the prescribing, distribution, administration and use of medicines are clearly recognised by the Department of Health report, *An Organisation with a Memory*.³² In the *NHS Plan* ³⁴ the government made a commitment to implement the recommendations and the document, *Building a Safer NHS for Patients*³⁵, sets out the government's plans for promoting patient safety. It is clearly recognised that the identification and correction of system failures before errors occur should be a specific focus for action, together with the implementation of systems to report and analyse medication errors.

12.2.6 Implementation of the *Agenda for Change*

The implementation of the *Agenda for Change* will unavoidably give rise to the need for an additional 7-10 FTE pharmacists. The reduction in the working week from 39 to 37.5 hours corresponds to a loss of 240 pharmacist hours – approximately equivalent to 7 pharmacists. Clearly this will need to be accommodated.



The key benefits of clinical pharmacy services are:

- Improved risk management in the prescribing, administration and monitoring of medicines;
- Improved clinical effectiveness;
- Improved cost-effective use of medicines.

However, thus far, resource commitment to these services has been ad hoc and inconsistent.

Against this background our recommendations fall into three overlapping areas – staffing levels, career development/structure and service development.

These recommendations are designed to ensure that the progress of clinical pharmacy services and the value that these services contribute to patient care are consolidated: (a) by establishing comparable staffing levels according to national benchmarks; (b) by establishing lead clinical pharmacists and opportunities for career advancement within a clinical speciality; (c) by supporting the care of patients across the primary/secondary care interface especially as it concerns specialist drug therapy and shared care arrangements; and, (d) by applying clinical pharmacy skills to minimise the risk from medicine-related incidents.

1. There is an urgent need to address the identified deficit in clinical pharmacist personnel. As a minimum, this should bring the numbers of clinical pharmacists in line with the benchmark figures for remainder of the UK. This will mean the appointment of 20-25 pharmacists, estimated to be 5 at grade E and 20 at Grade D.

In addition to the above we propose the following posts.

2. Four regional specialist clinical leadership pharmacists should be appointed (at Grade F). Each one would have responsibility for a specialist area but would also cover aspects such as training and development and the development of practice standards in their specialist field.
3. Six clinical liaison pharmacists should be appointed (at Grade D) to consolidate the implementation of policy in respect of the equitable, safe and convenient provision of specialist medication, including shared care arrangements across the primary/secondary care interface.

Recommendations

4. Six clinical pharmacists should be appointed at Grade E to take responsibility for medicines risk management, and be based at the larger Trust hospitals.
5. The pharmacist posts identified in recommendation 1 should be deployed according to needs across Trust areas. In relation to those posts advocated in recommendations 2-4 these should be deployed on a Northern Ireland basis to form a management and professional network of pharmacists in designated areas working across boundaries but offering the synergy of team-working.
6. Consideration should be given to the development of a career structure that facilitates development and specialisation within the clinical pharmacy arena. This should allow pharmacists to advance in their field of practice without having to move out, with the consequent loss of knowledge and expertise to the service.



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Members of the review team

EASTERN HEALTH & SOCIAL SERVICES

Ms Andrée McCollum	Eastern Health & Social Services Board
Mrs Alison Campbell	Belfast City Hospital Trust
Mrs Rhona Fair	Royal Group of Hospitals Trust
Mr Stephen Guy	Knockbracken Health Care Trust
Ms Bernie McCullagh	Ulster Community & Hospitals Trust
Ms Emer McCusker	Mater Hospital Trust
Ms Cora Sonner	Belfast City Hospital Trust
Ms Paula King	Greenpark Healthcare Trust
Dr Jane Whiteman	Greenpark Healthcare Trust
Ms Fidelma Magee	Down Lisburn Trust
Ms Debra Paul	Down Lisburn Trust

WESTERN HEALTH & SOCIAL SERVICES

Mrs Sally O’Kane	WHSSB/Altnagelvin Trust
Mr Joe Brogan	Altnagelvin Trust
Mr Austin Frazer	Sperrin Lakeland Trust
Mr Derek Elliott	Sperrin Lakeland Trust
Ms Anne Keenan	Sperrin Lakeland Trust

NORTHERN HEALTH & SOCIAL SERVICES

Dr Denis Morrison	Northern Health & Social Services Board
Dr Michael Scott	United/Homefirst Trusts
Ms Helen Bolas	United Hospital Trust
Ms Dianne Gill	United Hospital Trust
Ms Maureen Hetherington	United Hospital Trust
Ms Barbara Milliken	United Hospital Trust
Mrs Frances Morrison	Causeway HSS Trust
Mrs Mary Rose Lundy	Causeway HSS Trust
Miss Joanne McDermott	Causeway HSS Trust

SOUTHERN HEALTH & SOCIAL SERVICES

Ms Deirdre Tunney	Southern Health & Social Services Board
Mr Mark Timoney	Southern Health & Social Services Board
Ms Anne Friel	Craigavon Area Hospital Trust
Mr John Carroll	Daisy Hill Hospital Trust
Ms Jayne Agnew	Craigavon Area Hospital Trust



Glossary of terms

Adverse drug reaction

Unwanted reaction to a medicine, such as a rash or headache. An adverse drug reaction is quite different from a medication error – which results from a patient receiving incorrect medication.

Aseptic services

Pharmaceutical services based on the preparation of injections in a germ-free environment, using special techniques to prevent ingress of microorganisms.

Clinical audit

Review and assessment of performance of an individual, team, ward, unit or Trust in the care and treatment of a specified group of patients.

Clinical governance

A framework for continuous improvement in quality of clinical services and the maintenance of high standards of care.

Clinical trials

Experiments in which one medicine, method of treatment or diagnostic technique is compared with another in patients.

Dependent prescribers

A proposed new category of prescriber. A dependent prescriber would be 'a clinician who takes over the continuing care of a patient, which may include prescribing, after initial assessment by an independent prescriber.' (Crown Report)

Discharge planning

The processes of ensuring that patients have all the information they need together with adequate supplies of medicines at the time of discharge. This may also involve informing the relevant community pharmacist if special supplies are likely to be needed.

Drug utilisation review

The process of reviewing the way in which specified drugs are used in an institution against agreed criteria.

GCP

Good Clinical Practice – official guidance on the standards for conduct of clinical trials.

Glossary of terms

GMP

Good Manufacturing Practice – official guidance on the standards for manufacturing and processing and pharmaceuticals.

ICH

International Committee on Harmonisation.

Independent prescribers

A proposed new category of prescriber. An independent prescriber would be 'a clinician who is responsible for the assessment of patients with undiagnosed conditions and for decisions about the clinical management required, including prescribing.' (Crown Report)

Individual patient dispensing

A system in which medicines are issued to hospital wards labelled for individual patients rather than as 'ward stock'.

Medication error

Episode in which a patient receives incorrect medication (wrong dose, wrong drug, wrong route etc). A medication error is quite different from an adverse reaction – where the patient receives the correct medication but has an unexpected response.

Medication error reporting schemes

Schemes that collate and analyse reports of medication errors in order to identify and remedy weaknesses in systems and products.

Medication history

A complete record of prescribed and over-the-counter medicines taken by an individual.

Medicines Information Service

A pharmacy support service dedicated to the provision of information about medicines. Such services are usually staffed by specially trained pharmacists and equipped with reference books, key journals and electronic data-searching facilities.

Medicines self-administration schemes

Schemes in which patients are permitted to take their own medicines while in hospital.



Glossary of terms

Parenteral administration Administration of medicines by any routes other than through the gastro-intestinal tract. This includes intravenous, intramuscular and intrathecal injections.

Patient education/counselling

The process of giving information to patients about their medicines.

Patient Group Directions

A legal instrument allowing nurses and other named professionals to supply or administer Prescription only medicines (POMs) within the Health Service without a doctor's prescription.

Pharmacokinetic drug monitoring

Monitoring of drug treatment by monitoring the levels of the drug in the bloodstream. Also known as 'therapeutic drug monitoring'.

Prescribing advice

Advice concerning the safety, efficacy, convenience or economy of drug treatment, given by a pharmacist to a doctor or other prescriber.

Prescription monitoring

The process of reviewing prescriptions to check for safety and appropriateness.

Protocol development

The process of collecting information about the safety, effectiveness and cost of specific drugs and using it to devise procedures for their use.

Therapeutic drug monitoring

Monitoring of drug treatment by monitoring the levels of the drug in the bloodstream. Also known as 'pharmacokinetic drug monitoring'.

Appendix 1

Northern Ireland Publications in Clinical Pharmacy

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Appendix 2

Cost projections

Demand	Posts recommended	Cost (£)
Meeting national standards/restoring deficit in staffing establishment	20 FTE Grade D 5 FTE Grade E	596,300 166,450
Regional specialists	4 FTE Grade F	149,332
Clinical liaison	6 FTE Grade D	178,890
Medicines risk management	6 FTE Grade E	199,740
		Total: £1,290,712

Notes:

Salaries taken from Advance Letter (PH) 2/2001

Grade D spine point 13

Grade E spine point 17

Grade F spine point 21

No emergency duty commitment (EDC) or local allowances added

