THE SCOTTISH OFFICE
National Health Service in Scotland

CLINICAL PHARMACY

PRACTICE IN PRIMARY CARE
The Clinical Resource and Audit Group is chaired by the Chief Medical Officer for Scotland. It has a mainly clinical membership and has the following remit:

- to provide advice to the Scottish Office Department of Health on the development of policies on clinical effectiveness issues
- to act as a national forum to support and facilitate the implementation of the clinical effectiveness agenda
- to develop and fund a programme of work to support the clinical effectiveness agenda

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CLINICAL PHARMACY PRACTICE IN PRIMARY CARE

A FRAMEWORK FOR THE PROVISION OF COMMUNITY-BASED NHS PHARMACEUTICAL SERVICES

Statements of Good Practice developed by a Consensus Group set up by the Clinical Resource and Audit Group

Chairman:

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February 1999
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"The Government's vision is a National Health Service for the people of Scotland that offers them the treatment they need, where they want it, and when: a modern "designed" health service putting patients first."

Designed to Care: Reviewing the National Health Service in Scotland. The Scottish Office Department of Health, 1997.

The development of clinical pharmacy practice aims to improve the cost-effective use of medicines in individual patients and patients populations through the optimisation of safety, efficacy and economy. In keeping with the White Paper 'Designed to Care', pharmacists should ensure that wherever patients make use of NHS pharmaceutical services, they receive the highest quality care.

The Clinical Resource and Audit Group (CRAG) has already published two sets of practice guidelines in pursuit of these objectives, "Counselling and advice on medicines and appliances in community pharmacy practice" and "Clinical pharmacy in the hospital pharmaceutical service: a framework for practice" (1996). The guidelines which follow complement these and should help to create a seamless service which assures patients of continuity of care, irrespective of their location.

With the increasing demands on all NHS services, the need to prioritise and document the care which we provide is growing. In common with other health care professionals, pharmacists are required to practice in a way in which uses their time effectively and reflects their responsibility and accountability. These guidelines focus on a systematic approach to patient care which addresses the pharmaceutical needs of individual patients. Of equal importance however, is the need to adopt a pharmacoepidemiological approach to improve the effectiveness and efficiency of health care provision to the population. Thus aspects of caring for patient populations such as needs assessment, formulary management and evaluating and reviewing medicines use are also included.

Pharmacists working in the community are often patients' first point of contact, and sometimes their only point of contact with a health care professional. Community pharmacists are also usually the last point of contact for patients, prior to taking their prescribed medicines. Thus pharmacists in the community have a key role as custodians both of disease prevention and of drug safety. Guidance is provided on aspects of this important role, such as promoting health and near patient testing.

The guidelines are intended to assist pharmacists in their practice within the community and to facilitate continuity of patient care across health sector boundaries.

I am grateful to those who have contributed to their production and commend the guidelines to you.

W SCOTT  
Chief Pharmaceutical Officer 1999
REMIT AND MEMBERSHIP

Remit

To produce statements of good practice on clinical pharmacy for pharmacists based in primary care.

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Grateful thanks are expressed to the individual members of the Consensus Group and their organisations.

The External Assessors deserve special thanks for their support and their detailed and constructive comments on the draft document. Similarly, thanks go to the individuals and organisations within the pharmacy profession who responded to the consultation exercise: The Scottish Executive of the Royal Pharmaceutical Society of Great Britain, Scottish Pharmaceutical Prescribing Advisers, The Chief Administrative Pharmaceutical Officers' Group and the Scottish Pharmaceutical General Council.

Members of the Consensus Group wish to thank both Mrs Elaine M Blaikie and Mrs Kathleen Larssen of the Clinical Pharmacy Practice Unit, The School of Pharmacy, The Robert Gordon University, for their administrative and secretarial support.
SUMMARY AND RECOMMENDATIONS

1. ETHICAL AND PROFESSIONAL ISSUES

1.1 The principal objective of this document is to improve 'pharmaceutical care' through a structured, systematic approach to 'clinical pharmacy' practice (Section 1.1).

1.2 Pharmacists should actively involve themselves in ensuring that new health care structures and services take account of the 'pharmaceutical needs' of 'patients' (Section 1.1).

1.3 Pharmacists are ethically and professionally accountable to patients for the services which they provide (Section 1.2).

1.4 Confidentiality is an essential component of patients' rights and pharmacists are bound by Principle Four of a professional 'Code of Ethics' and by an organisational 'Code of Practice' to respect the confidentiality of information acquired in the course of professional practice (Section 1.2 and Annex A2).

1.5 The relationship between the 'patient' and the pharmacist should be one of 'concordance' in which pharmacists respect the health beliefs, treatment expectations and preferences of patients (Section 1.2).

1.6 The availability, nature and purpose of pharmaceutical services should be described clearly in practice leaflets which are made available to patients and customers (Section 1.2).

1.7 The 'quality' of NHS pharmaceutical services requires assurance and testing through quality systems designed to address patients' needs (Section 1.2 and Annex A4).

1.8 Clinical pharmacy is a discipline concerned with the application of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients and patient populations (Section 1.4).

1.9 Pharmaceutical care is the pharmaceutical contribution to 'patient care' resulting from the practice of clinical pharmacy (Section 1.4).

1.10 Pharmaceutical care can only be achieved in the context of successful multi-disciplinary communication and collaboration (Section 1.3).

1.11 Mechanisms to increase lines of communication between health care professionals and to promote multi-disciplinary collaboration require to be further developed and evaluated (Section 1.2 and Section 1.4).

1.12 Principle 5 of the Code of Ethics of the Royal Pharmaceutical Society of Great Britain (RPSGB) requires a pharmacist to keep abreast of the progress of pharmaceutical knowledge in order to maintain a high standard of professional competence (Annex A3).

1.13 Pharmacy has a responsibility to improve patient care through the timely application of advances in science, technology and professional practice (Annex A5).
2. A SYSTEMATIC APPROACH TO INDIVIDUAL PATIENT CARE

2.1 A documented systematic approach to individual patient care supports continuity of care and audit of clinical practice, generates a medico-legal record and facilitates peer review and performance appraisal and the identification of training needs (Section 2.1).

2.2 A systematic approach to practice within available resources necessitates that pharmaceutical services are geared particularly to those patient groups and individual patients most in need of them (Section 2.2).

2.3 Pharmaceutical needs refer to patients' requirements for pharmaceutical products or services; they may be identified by patients or by any member of the health care team (Section 2.2).

2.4 'Pharmaceutical care issues' are identified and reviewed by the 'assessment of a patient to identify patient and medication risk factors for treatment failure or adverse effects. They are prioritised within the context of the overall clinical management of the patient (Sections 2.3 and 3.1).

2.5 Medication history taking, consulting patient medication and clinical records and talking with the patient, carer and other members of the health care team all contribute to the process of assessment (Section 3.1).

2.6 Pharmacists should work towards maintaining 'Patient medication profiles'. These should be continuously updated to support the pharmaceutical care of patients (Section 3.1).

2.7 Statements of what the pharmacist intends to achieve for a patient in relation to their pharmaceutical care issues, should be identified in terms of one or more 'desired outputs'. This should be achieved in conjunction with the multi-disciplinary team and the patient (Section 3.2).

2.8 A documented 'pharmaceutical care plan' records a patient's pharmaceutical care issues together with associated desired outputs and the 'pharmaceutical actions' proposed to achieve them (Sections 2.3 and 3.2).

2.9 Pharmaceutical care plans are implemented with the agreement of the patient and in co-operation with other members of the health care team (Sections 3.2 and 3.3).

2.10 Where a valid and reliable indicator of disease progress, drug efficacy or drug toxicity is established, the pharmacist can take responsibility for monitoring that indicator and taking action according to an agreed protocol or plan (Section 3.3).

2.11 Pharmaceutical care planning must be subject to continuous review to respond to changes in the patient's pharmaceutical needs, care issues and priorities for care (Section 3.3).

2.12 Continuity of care as a patient transfers from one health care setting to another relies on the identification of, and effective communication with those professionals to whom responsibility is to be transferred (Section 3.3).
3. FACILITATING DISEASE PREVENTION AND DRUG SAFETY

3.1 Pharmacists working in the community may be the patient’s first and/or last point of contact with a health care professional in relation to medicine taking. They may also be a patient’s only point of contact with a health care professional. This confers particular responsibility on the pharmacist as a custodian of disease prevention and drug safety (Section 4).

3.2 Pharmacists should provide health education information and increase patients' and customers' awareness of current issues in health promotion through participation in national and local health campaigns (Section 4.1).

3.3 Pharmacists should participate in disease prevention strategies related to medicines use and lifestyle including travel, sexual practice and social drug use practices (Section 4.1).

3.4 Pharmacists should contribute to health protection initiatives by educating patients, customers and other health care professionals (Section 4.1).

3.5 Pharmacists, in collaboration with other members of the primary care team, should offer appropriate near-patient-testing (NPT) services to screen for undiagnosed disease states and symptoms, and to monitor for drug efficacy and drug safety (Section 4.2).

3.6 Pharmacists and pharmacy staff operating NPT equipment and/or interpreting the results of NPT services should have successfully completed an appropriate education and training course (Section 4.2).

3.7 Patients should be given appropriate counselling and advice on the results of NPT, where appropriate in collaboration with other members of the primary care team (Section 4.2).

3.8 NPT services should be subject to external quality assurance and audit (Section 4.2).

3.9 Pharmacists should anticipate and timeously meet the need for independently evaluated drug information and advice to support formulary review or individual care (Section 4.3).

3.10 Pharmacists should contribute to the education and training of other health care professionals on the safety, efficacy and economy of medicines use (Section 4.3).

3.11 Pharmacists should ensure that prescribing for individual patients takes account of essential drug safety measures (Section 4.4).

3.12 Pharmacists should educate pharmacy staff and other health care staff on the prevention, detection and reporting of adverse drug reactions (Section 4.4).

3.13 Pharmacists should document and encourage reporting of all suspected adverse reactions to newer drugs and suspected serious adverse drug reactions to established drugs, to the Committee of Safety of Medicines via the yellow card system (Section 4.4).
4. CARING FOR PATIENT POPULATIONS: A PHARMACOEPIDEMIOLOGICAL APPROACH

4.1 A pharmacoepidemiological approach to practice permits a better assessment of the risk/benefit ratio for individual patients and aims to improve the effectiveness and efficiency of health care provision to the population (Section 5).

4.2 The accuracy and completeness of patient data depends on effective and efficient information transfer both between the health care professions involved in providing care and between the various health care sectors. Patient data systems which cross health care sector and health care professional boundaries require to be developed and validated (Section 5.1).

4.3 Pharmaceutical needs assessment helps to identify potential under-diagnosis and under-treatment of disease, as well as the potential scope for disease prevention measures (Section 5.2).

4.4 The pharmaceutical service requirements of GP practices should be based on an assessment of the pharmaceutical needs of the practice population (Section 5.2).

4.5 Where a range of pharmaceutical needs are identified, these should be prioritised and all involved in contributing to, or receiving the service should be consulted about the priorities (Section 5.2).

4.6 Medicines resource management aims to maximise therapeutic benefit within available resources (Section 5.2).

4.7 The effective management of 'formularies', 'clinical guidelines' and 'treatment protocols' rationalises the use of drug therapy in groups of patients by ensuring that practice is based on evidence wherever possible. These aspects of medicines resource management aim to improve the safety, efficacy and efficiency of medicines use (Section 5.2).

4.8 In collaboration with other members of the health care team, pharmacists should use all available prescribing data and evaluate up-to-date drug information to support their contribution to practice formulary development and review (Section 5.2).

4.9 All group protocols should be drawn up by a multi-disciplinary professional group, including a doctor, a pharmacist and a named representative of each of the professions likely to contribute to care under the protocol (Section 5.2).

4.10 In collaboration with other members of the health care team, pharmacists should review clinical guidelines and treatment protocols, or group protocols, at appropriate intervals to reflect changes in the evidence-base and changing trends in clinical practice (Section 5.2).

4.11 Pharmacists should develop their own non-prescription medicines formulary and ensure that pharmacy staff have the necessary training to make recommendations to patients requesting these medicines or to refer the patient to the pharmacist, as appropriate (Section 5.2).
4.12 Local treatment protocols should be developed in association with general medical practice staff to cover minor ailments for which patients may seek advice from pharmacists, general practitioners, community or practice nurses, or other community-based health care professionals (Section 5.2).

4.13 'Medicines use evaluation' is a systematic and scientific process of determining the extent to which the use of medicines achieves pre-determined objectives. It is a multi-disciplinary function which requires the involvement and commitment of health care staff, particularly general practitioners, pharmacists and nurses, as well as the involvement of patients (Section 5.2).

4.14 Medicines use evaluation should be performed where it is suspected that pre-determined objectives are not being achieved in relation to patient outcomes and/or cost, or where evidence on best practice supports a change in the delivery of care (Section 5.2).

4.15 'Medicines use or utilisation review' is a process for the identification of those medicines which would be suitable for medicines use evaluation by analysis of data on the prescribing and/or use of medicines (Section 5.2).

4.16 Records of over-the-counter medication represent a useful source of data for the purposes of medicine utilisation review and one which is uniquely available to the pharmacist (Section 5.2).

4.17 'Standards' and 'criteria' for the appropriate use of medicines require to be based on evidence from the literature and discussion and agreement involving primary and secondary care staff. Criteria should be relevant, understandable, measurable and achievable (Section 5.2).

4.18 Costs and patterns of prescribing, documented pharmaceutical care plans and actual outputs for individual patients all contribute to medicines use evaluation (Section 5.2).

4.19 The results of medicines use evaluation should be reported timeously to the clinical team with recommended actions (Section 5.2).
INTRODUCTION

1.1 Purpose
This document is intended as a practitioner's guide to 'clinical pharmacy' practice in primary care. The principal objective of this 'Framework for the Provision of Community-Based NHS Pharmaceutical Services' is to improve 'pharmaceutical care' through the development of a structured, systematic approach to clinical pharmacy practice.

The principles and practice advocated within these guidelines apply to all pharmacists providing NHS pharmaceutical services directly or indirectly to 'patients' within the community, irrespective of their location (whether visiting a pharmacy or surgery, resident in a nursing or residential home, or in their own home). The document applies equally to all pharmacists working on a full-time, part-time or sessional basis for the NHS. The guidelines are based on current best practice and should prove useful to all pharmacists working in primary care, whatever their level of experience and qualification.

It is recognised that guidance is provided on a wide range of pharmaceutical services, not all of which may be provided by individual pharmacists or pharmacies at the present time. However, the range of services covered and the guidance given should be carefully considered by those responsible for the development of primary care trusts and local health care co-operatives. Pharmacists should actively involve themselves in ensuring that new structures and services take account of the 'pharmaceutical needs' of patients.

1.2 The patient perspective
When a patient (or their representative) requires advice, diagnosis or therapy from a health care professional, they have a right to expect services which comply with specified standards of accessibility, efficiency and quality. Such standards may be part of the NHS 'Patients' Charter' or be specified by a particular health care provider. Individual health care professions also require specified professional standards of practice from their practitioners. Pharmacists then, as members of the health care team and their own professional body, are ethically and professionally accountable to patients for the services which they provide.

Confidentiality is an essential component of patients' rights and pharmacists are bound by Principle Four of a professional 'Code of Ethics'¹ and by an organisational 'Code of Practice'² to respect the confidentiality of information acquired in the course of professional practice relating to a patient and the patient's family (see Annex A2). This applies to all pharmacists, irrespective of their location eg whether they are working within or on behalf of a community pharmacy or a GP surgery.

The relationship between the user of pharmaceutical services and the pharmacist should be one of 'concordance' (Royal Pharmaceutical Society of Great Britain, 1997), in which the health beliefs of both the patient and the pharmacist are respected. The relationship should recognise the autonomy of the patient. In facilitating such a relationship, pharmacists should seek to provide quality services which promote health and effectively manage disease. The quality of ‘counselling’ or of explanations and advice offered should
inform the patient’s choice. In turn, patients are required to accept responsibility for the consequences of their choices. This move to empower patients will suit some patient groups and may not suit others. Along with other members of the health care team, pharmacists should respect patient preferences.

The availability, nature and purpose of pharmaceutical services should be described clearly in practice leaflets which are made available to patients and customers. The quality of NHS pharmaceutical services requires assurance and testing through quality assurance systems based on clear pharmacy 'service specifications' designed to address patients' needs. Such systems are likely to be based on a combination of professional standards of practice, performance appraisal, peer review, and professional and clinical audit (see Annex A4). A continuous review of performance by these means should involve patients to ensure that practice is developed to meet their needs.

1.3 Multi-disciplinary health care delivery
Quality in 'patient care' relies on the concerted efforts of a multi-disciplinary health care team. Thus pharmacists should seek to identify and complement the knowledge and practical experience which other health professionals bring to safe and effective drug usage. This 'Framework for the Provision of Services' recognises the need for pharmacists to participate fully as members of the primary care team. The structured and systematic approach to practice described within this document serves to further integrate pharmacists into the team. However, mechanisms to increase lines of communication and multi-disciplinary collaboration require to be further developed and evaluated.
This drive towards multi-disciplinary health care delivery in Scotland is reflected in the NHS Circular, MEL (1995) 52, "A Strategic Framework for Clinical Audit in Scotland"4 in which one of the key objectives is that "Audit should be increasingly undertaken on a multi-professional basis". This philosophy is entirely compatible with the fact that 'pharmaceutical care' can only be achieved in the context of successful multi-disciplinary communication and collaboration. The Government's commitment to improving clinical effectiveness through multi-disciplinary collaboration is an underpinning principle both in the White Paper, 'Designed to Care'5 and the Green Paper, 'Working Together for a Healthier Scotland'.

1.4 Definitions

Within primary care, clinical pharmacy is a discipline concerned with the application of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients and patient populations. Acquisition of the requisite clinical knowledge and skills enables pharmacists to advise on the clinical use of medicines, to promote good prescribing practice and cost effective drug utilisation and to educate, counsel and advise patients on medicines and health care.

Pharmaceutical care has been defined by Hepler and Strand (1990)7 as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life". In this document, the term pharmaceutical care is used to refer simply to the pharmaceutical contribution to patient care resulting from the practice of clinical pharmacy. This involves liaising with other health care professionals, talking with patients, agreeing and implementing care plans; in essence, it involves helping patients to get the most benefit from their medicines.

A Glossary of terms is included within this document to avoid ambiguity (Annex A 1). Those terms for which there are Glossary definitions are presented in bold italics when they first appear in the text. The definitions provided are based on those in two other Clinical Resource and Audit Group publications: "Clinical Guidelines" (1993) and "Clinical Pharmacy in the Hospital Pharmaceutical Service: A Framework for Practice" (1996)
1.5 Clinical pharmacy practice in primary care

The Nuffield Inquiry (1986) concluded that a much fuller exploitation of the pharmacists' knowledge and skills could be achieved by extending the pharmacists' reach both backwards and forwards beyond the dispensing process itself: backwards to meet the request by the medical profession that the pharmacist's knowledge be made available to the GP to assist him to arrive at better prescribing decisions; and forwards to assist individuals most at risk, and most in need of help, in the handling of their medicines.

A series of 30 recommendations was made by the Royal Pharmaceutical Society/Department of Health Report of The Joint Working Party on the Future Role of the Community Pharmaceutical Services (1992). These included recommendations on how pharmacists could increase the cost-effectiveness of prescribing and how they could contribute more effectively to the safe and effective use of medicines. Like the Nuffield Report, the Joint Working Party Report concluded that pharmacists could help in the treatment of certain patients at home and in the provision of pharmaceutical services to nursing homes and other residential establishments.


Pharmacists in community-based pharmaceutical services already work with other members of the health care team, particularly GPs, through the provision of drug information and the interpretation of prescribing data, in facilitating rational and cost effective prescribing, in medication review for patients at risk of medication-related problems and in the management of individual patients with particular chronic diseases, GPs in Scotland have expressed their desire for further collaboration between the two professions. Similarly, close liaison with district and practice nurses is required in relation to nurse prescribing and nurse-led patient management clinics.
1.6 Structure and scope

Section 2 begins by emphasising the need for pharmacists to use their time effectively and to prioritise the delivery of pharmaceutical care. The case for a systematic approach and documentation is made and methods for prioritising and delivering pharmaceutical care are introduced.

Section 3 focuses on a systematic approach to pharmaceutical care planning for individual patients. Methods of identifying pharmaceutical care issues and formulating, implementing and monitoring a pharmaceutical care plan are described and illustrated.

Specific aspects of the important tasks of facilitating disease prevention and drug safety are presented in Section 4. Here again, each of the activities described is dependent on the successful multi-disciplinary collaboration and the development of good relationships with other health care professionals, carers and patients. Counselling and advice on prescribed medication is not dealt with separately in this section as it is the subject of a complementary CRAG publication, "Counselling and Advice on Medicines and Appliances in Community Pharmacy Practice".

The requirement to consider the needs of patient populations and sub-populations (eg particular patient groups) is addressed in Section 5. The pharmacoepidemiological approach described here involves influencing prescribing practice through formulary management systems and medicines use evaluation. In keeping with the pharmacist's ethical and professional obligations, the Annex provides further information on professional ethics, continuing professional development, quality assurance and research and development. It also provides a glossary of terms and further reading.
Section 2
THE NEED TO PRIORITISE AND DOCUMENT PHARMACEUTICAL CARE

2.1 Perspective
The development of clinical pharmacy services and the delivery of effective pharmaceutical care to patients requires pharmacists to practice in a way which uses their time effectively and reflects their responsibility and accountability. This can be achieved by prioritising care through the adoption of a systematic approach to practice.

Documentation of clinical pharmacy practice supports audit of clinical practice and continuity of patient care. It also generates a medico-legal record. By providing a basis for performance appraisal and peer review, documentation also helps to identify training needs. Since a good documentation system is also required to underpin continuous quality improvement initiatives (see Annex A4), there are many sound reasons to support a documented systematic approach to clinical pharmacy practice.

2.2 Prioritising Pharmaceutical Care
A systematic approach to practice within available resources necessitates that services are geared particularly to those patient groups and individual patients most in need of them. The 'pharmaceutical need of a patient refers to his or her requirement for a pharmaceutical product or service. Pharmaceutical needs may be identified by patients or by any member of the health care team. They may include, for example, a requirement for drug therapy, for advice on health, or for counselling and advice on medicines. The process of 'pharmaceutical needs assessment' for patient populations is described in Section 5.2.1. Its purpose is to provide a basis for the planning and prioritisation of pharmaceutical services.

Mechanisms for prioritising pharmaceutical care include:

- Ensure that pharmacy staff regularly involved in the sale of medicines have completed a relevant training course accredited on behalf of the Royal Pharmaceutical Society Council, or are undertaking such a course. This is a requirement within the Royal Pharmaceutical Society's Standards of Good Professional Practice. Pharmacy staff should be competent to refer patients who require to see the pharmacist.
- Review the patient medication records to identify those patients most at risk from patient and medication risk factors (see Section 3.1).
- Collaborate with other members of the primary health care team (for example, GPs, nurses, and health visitors) and social workers to identify those patient groups and individuals most in need of pharmaceutical care.
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- Review the patient medication records to identify those patients most at risk from patient and medication risk factors (see Section 3.1).

- Collaborate with other members of the primary health care team (for example, GPs, nurses, and health visitors) and social workers to identify those patient groups and individuals most in need of pharmaceutical care.

Whilst the provision of pharmaceutical services within a GP practice may be based on a pharmaceutical needs assessment, it is not so straightforward to achieve this within a busy community pharmacy where...
users of the service have free access to the pharmacist. However, it is important, where possible, within community pharmacy practice to establish mechanisms for prioritising the delivery of pharmaceutical care.
2.3 A Systematic Approach to Individual Patient Care

It is important to apply a systematic approach to the care of all patients, to identify those individuals whose pharmaceutical needs have not been met and who, as a consequence, may be placed at risk from a lack of disease prevention measures or from suboptimal therapeutic management. Sections 3, 4 and 5 describe in detail the measures through which pharmacists help to contain this risk.

The assessment of patients identifies 'pharmaceutical care issues' ie those elements of a pharmaceutical need which are addressed by the pharmacist. 'Pharmaceutical care plans' should be formulated, documented, implemented, monitored and reviewed for those patients with pharmaceutical care issues. The process of pharmaceutical care planning, illustrated in Figure 1, is both multi-disciplinary and dynamic, as described more fully in Section 3.

IDENTIFY PATIENTS WITH PHARMACEUTICAL NEEDS

IDENTIFY AND REVIEW PHARMACEUTICAL CARE ISSUES

IMPLEMENT AND MONITOR THE CARE PLAN

FORMULATE A PHARMACEUTICAL CARE PLAN
Section 3
PHARMACEUTICAL CARE OF INDIVIDUAL PATIENTS: A SYSTEMATIC APPROACH

3.1 ASSESSING PATIENTS FOR PHARMACEUTICAL CARE ISSUES

OBJECTIVES

1. Confirm individual patient's pharmaceutical needs and identify actual and potential pharmaceutical care issues.
2. Record the results of the assessment to initiate a patient medication profile.

GUIDELINES

1. Identifying/confirming pharmaceutical needs Pharmaceutical needs may be identified by the patient or by any member of the health care team, including the pharmacist. Pharmacists confirm pharmaceutical needs of individual patients as part of their routine daily practice, irrespective of whether they are based in a community pharmacy or a GP surgery. This involves talking with the patient, carer and other members of the health care team, as well as consulting patient medication and/or clinical records. Pharmaceutical needs can range from the simple requirement for a medicine to treat a symptom to the more complex requirement of anticonvulsant dosage adjustment.

Pharmaceutical needs include:

a) Needs for a pharmaceutical product
   - a medicine
   - a 'compliance aid'

b) Needs for a pharmaceutical service
   - advice on medicines
   - medication review
   - monitoring of drug therapy

2. Patient and medication risk factors

When assessing the patient for pharmaceutical care issues, full account must be taken of all patient and medication factors which may predispose the patient to risk of treatment failure or adverse effects. Here again, the assessment process involves talking with the patient, carer or representative, and consulting other members of the health care team and patient medication and/or clinical records.

It is very often the combination of patient and medication factors which places patients at risk; both types of factor must be taken into account in order to identify actual and potential pharmaceutical care issues.
Patient risk factors may be associated with:

- Patient characteristics such as age, gender and weight
- Relevant past medical history and current active medical problems
- Functional and cognitive factors such as mobility, dexterity and comprehension
- Social and environmental factors such as home environment, social drug use and family support
- Patient's health beliefs including perception of drug therapy and expectation of care

EXAMPLE 1
An elderly patient presents a prescription for a metered dose inhaler (MDI). During the ensuing counselling session, the pharmacist identifies that the patient is unable to co-ordinate their breathing with actuation of the MDI. Thus there is a risk that this patient will not benefit from the use of her prescribed inhaler.

**Pharmaceutical care issue: Lack of ability to use MDI correctly**

Medication risk factors may be associated with:

- Response to current and previous drug therapy
- Drug disposition factors such as reduced renal or hepatic clearance. Toxicity factors such as allergy, contra-indications and interactions
- Drug administration such as complexity of regimen and delivery devices. Use of purchased medicines and/or complementary therapies
- Repeat medicines in the absence of appropriate monitoring and review

EXAMPLE 2
A patient with a known history of dyspepsia and cardiac failure presents a new prescription for ibuprofen which he says has been prescribed to relieve the pain in a recently sprained ankle.

**Pharmaceutical care issue: Risk of exacerbation of dyspepsia and/or cardiac failure**

Pharmaceutical care issues may arise when dispensing a prescription or when a patient requests advice and/or a non-prescription medicine. As well as reacting to care issues identified in such situations, pharmacists should agree with the rest of the primary care team, those patients who are likely to benefit from an assessment.

In the GP surgery, pharmaceutical care issues can be identified from sources such as patient medication reviews, pharmacist-led clinics for the management of specific chronic diseases, screening of hospital discharge letters, or review of repeat prescribing systems.
3. Current and previous medication
Review of the patient's current and previous medication is part of the assessment process. This may help in the identification of risk factors which can then contribute to an assessment of the individual's need for pharmaceutical care. For example, there may be drug interactions, duplication of therapy or inappropriate dosage regimens.

Patient medication records are a useful tool in the community pharmacy, while in the GP, surgery the computerised repeat prescribing system may be utilised. The latter is unlikely to contain information on purchased medicines or complementary therapies. Whenever possible, information from these sources should be supplemented by information from medical notes.

EXAMPLE 3
A patient known to the pharmacy staff requests to purchase Co-codamol tablets and is referred to the pharmacist. Reference to his patient medication record indicates that he obtains regular supplies of Migraleve.

**Pharmaceutical care issue: Potential for toxicity due to duplication of therapy**

4. Talking with the patient
A key component of the assessment process involves talking with the patient (or carer) about their drug therapy. In the busy community pharmacy for the average patient, of necessity this may have to be relatively brief. Where it is deemed necessary, and with the patient's consent, the pharmacist may decide to conduct a structured interview to obtain a more detailed medication history.

Any information obtained from the patient is used solely for the purpose of improving patient outcomes while maintaining confidentiality. A knowledge of therapeutics, product awareness and communication skills are used to collect details of past and present use of all medicines from the patient. The following aspects of medicine use should be determined: the patient's perceived needs, perceived indication, frequency of use, outcomes such as partial or full response, and adverse outcomes such as failure to respond, side effects and adverse drug reaction. In this way, the pharmacist evaluates and documents the patient's perceptions of their disease and their therapy during the course of the interview.

Structured patient interview can reveal useful information on the previous use of all medicines (prescribed, non-prescription and complementary medicines), the patient's perceptions of disease and their therapy, prior experience of efficacy and toxicity including allergies and hypersensitivities and levels of adherence to prescribed regimens.
EXAMPLE 4

Patient interview resulted in the pharmacist becoming aware that the analgesics prescribed were ineffective at relieving pain despite the patient taking the maximum daily dose.

Pharmaceutical care issue: Ineffective pain management

Documentation

Recording information on patient and medication risk factors is the first stage in generating 'patient medication profile'. Documentation of pharmaceutical care issues within the patient medication profile forms the basis of a pharmaceutical care plan. The profile is continuously updated to provide a means of identifying actual and/or potential pharmaceutical care issues and to support continuity of pharmaceutical care.

PATIENT MEDICATION PROFILES

These profiles comprise of patient details including relevant medical and drug histories, patient and medication risk factors specific for the patient which could affect drug therapy, diagnoses and the results of patient interview. Documentation of pharmaceutical care issues within the patient medication profile forms the basis of a pharmaceutical care plan. Profiles may be recorded within paper-based or electronic record systems, as a separate pharmacy record and/or as an integral component of the general practice record system.

Pharmacists who are not currently documenting patient medication profiles should work towards developing them through increasing the range of information which they keep on their patient medication record systems, or select to document profiles in the first instance for "vulnerable" or "at risk groups".

Patient held medication record systems, both paper-based and electronic, have also been evaluated, but are not yet in widespread use.

Documentation systems in community pharmacies and general practices must be designed maintain patient confidentiality.
3.2 FORMULATING A PHARMACEUTICAL CARE PLAN

OBJECTIVES
1. Prioritise pharmaceutical care issues.
2. Identify desired outputs and propose pharmaceutical actions.
3. Document the pharmaceutical care plan.

GUIDELINES
1. Identifying and prioritising pharmaceutical care issues
Pharmaceutical care issues are identified and prioritised within the context of the overall clinical management of the patient.

EXAMPLE 5
Following a decision by the primary care team to review hypertensive patients, an elderly patient attends the surgery for a medication review with the pharmacist. She is hypertensive, hypothyroid and has a recent history of a transient ischaemic attack. From the medical notes it can be determined that she has not had her blood pressure monitored for 13 months, but a recent lipid screen showed a total cholesterol of 7.2mmol.L-1. On interview, the patient complains of tiredness and weight gain. She currently takes thyroxine 50mcg daily and bendrofluazide 10mg each morning.

Pharmaceutical care issues:
1. inappropriate dose of thiazide (potential ADR)
2. lack of blood pressure monitoring
3. no recent check of thyroid function
4. indication for therapy; low dose aspirin
5. management of hyperlipidaemia - secondary to underactive thyroid?

Prioritisation:
1. In view of her recent history, aspirin should be initiated (in the absence of any contraindications).
2. Check thyroid function tests due to symptoms.
3. Reduce dose of bendrofluazide to 2.5mg and check BP in 5/52.
4. Leave management plan of hyperlipidaemia until priorities 2 and 3 are dealt with, as they can both influence total lipids and the lipid profile.

2. Identifying desired outputs and proposing pharmaceutical actions
'Desired outputs' are statements of what the pharmacist intends to achieve for a patient in relation to their pharmaceutical care issues. They should be agreed by the multi-disciplinary team and the patient. Preferably, they should be expressed as measurable endpoints to be achieved within a defined timescale.
Desired outputs may vary, for example, from the acceptance of advice given on the prescribing or use of medicines, through specified levels of improvement in a laboratory or clinical marker of the patient's condition, to particular goals related to the patient's knowledge or understanding of a medicine or their ability to use a medicine correctly.

In considering the most appropriate pharmaceutical actions to achieve a desired output, account should be taken of:

i) the particular needs of the individual patient (for example, drug choice/dosage regimen in relation to concurrent disease states/drug therapy)

ii) any previous adverse drug reactions/hypersensitivities which may present if the causative agent (or a drug within the same class) is considered for use

iii) the acceptability of the action to the patient (for example, patient's health beliefs including their perception of drug therapy and expectation of care)

iv) medicines resource management issues (for example, practice formularies and protocols)

**CLINICAL GUIDELINES**

Evidence-based clinical guidelines produced nationally, for example by the Scottish Intercollegiate Guidelines Network (SIGN), stimulate the development of local 'protocols' and 'standards' of care. Local protocols should specify actions and outputs required to assure the safe, effective and efficient use of medicines in association with local formularies. Where appropriate, pharmaceutical care plans for patients with multiple disease states should incorporate local protocols derived from evidence-based clinical guidelines.

3. Developing a monitoring strategy

The pharmacist agrees a monitoring strategy with other members of the primary health care team and the patient. The responsibilities and activities of different team members requires to be co-ordinated. A monitoring strategy should be identified to measure progress towards achievement of the desired outputs. Monitoring procedures are to be undertaken at specified intervals and for a defined duration prior to further review.
Parameters which could be used for monitoring disease progress and treatment; together with team member allocated responsibility:

- clinical signs such as left ventricular hypertrophy in poorly managed hypertension (GP)
- biochemical results such as serum potassium, creatinine, thyroid function tests, serum lipids, HbA 1C in diabetes (Pharmacist)
- haematological results such as haemoglobin, International Normalised Ratio (INR), or prothrombin time (Pharmacist)
- number of seizures and phenytoin serum drug levels (Pharmacist)
- physiological measurements such as blood pressure and peak expiratory flow rate (PEFR) (Practice Nurse)
- patient self reporting of symptom management (Practice Nurse)

EXAMPLE 6
A patient with Parkinson's disease presents a repeat prescription for his usual medication - Sinemet 275, one four times a day and Sinemet CR, one at night. You notice that he has a marked tremor, which he tells you has become much worse over the past few months.
Pharmaceutical care issue: ineffective treatment (uncontrolled parkinsonian tremor)
Desired output: reduce or eliminate tremor
Pharmaceutical action: contact GP to agree appropriate action; advise adding benzhexol 2mg daily
Monitoring strategy: ask patient about reduction in tremor and symptoms of antimuscarinic side effects after one week

4. Documentation of pharmaceutical care plan
The pharmacist's record of pharmaceutical care issues and the desired outputs, together with the pharmaceutical actions form a documented 'pharmaceutical care plan'. This allows pharmacists to report on their actions and provides a basis for peer review.

Good documentation also supports continuity of care through facilitating information transfer when the patient transfers to another environment, for example at the pre-admission stage of elective surgery, or when they move to another GP surgery. With the patient's consent, pharmacists working in the community should be prepared to transfer relevant patient information to other health care professionals who require it to care for the patient.

Documentation will be facilitated in the future by electronic links between pharmacies and GP surgeries and also by patient-held records. The NHS net linking hospitals and primary care sites should also be used by pharmacists for information transfer on admission to and discharge from hospital, and between and within care environments.
3.3 IMPLEMENTING AND MONITORING THE PHARMACEUTICAL CARE PLAN

OBJECTIVES
1. Implement the pharmaceutical care plan.
2. Monitor progress towards the desired outputs.
3. Evaluate and review the pharmaceutical care plan.
4. Facilitate arrangements for continuity of care when the patient moves between different care environments.

GUIDELINES
1. Implementing the care plan

The pharmaceutical care plan is implemented with the agreement of the patient and, where possible, within the context of the overall care of the patient, in co-operation with other members of the health care team.

Where a valid and reliable indicator of disease progress, drug efficacy or drug toxicity is established, the pharmacist can take responsibility for monitoring that indicator and taking action according to an agreed protocol or plan.

Implementing a care plan may require a pharmacist to:

- discuss pharmaceutical care issues with the patient's GP
- counsel the patient and/or their carer(s)
- arrange for the patient to consult their GP, practice/district nurse (for example to take blood samples for analysis) or other health care professionals
- monitor indicators of disease progress and effects of drug therapy
- arrange for amendments to computer records
- arrange for a prescription to be provided
- liaise with other pharmacists to ensure continuity of pharmaceutical care
EXAMPLE 7

A 65 year old, obese lady is referred to the practice pharmacist for a medication review. Her relevant medical history includes myocardial infarction (5 years), hyperlipidaemia (4 years 7 months), angina (4 years 2 months), ankle oedema (1 year 10 months) and leg cramps (1 year 7 months). Her current drug therapy was as follows:

- Frusemide 40mg in the morning (1-to 80mg)
- Slow K one 3 times daily
- Quinine sulphate 300mg at night j GTN spray when required
- Adalat retard 10mg one twice daily

She had previously come off Atenolol due to tiredness and Aspirin had been discontinued, apparently without reason.

**PHARMACEUTICAL CARE PLAN**

<table>
<thead>
<tr>
<th>Care issue</th>
<th>Desired Output</th>
<th>Pharmaceutical Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) no indication apparent for frusemide</td>
<td>clarify indication (not effective for ankle oedema)</td>
<td>GP to confirm presence or absence of heart failure (HF). If no HF, stop frusemide; if HF present, consider adding an ACE inhibitor (ACEI).</td>
</tr>
<tr>
<td>2) potential ADR to nifedipine (also increased angina)</td>
<td>stable angina without ADR</td>
<td>Recommend review angina therapy; if no HF, start atenolol; if HF present, consider diltiazem with caution. Advise to stop nifedipine.</td>
</tr>
<tr>
<td>3) Slow K ineffective (decreaseK+); non adherence and side effects</td>
<td>K+ normal and no side effects</td>
<td>Slow K not a good choice; action depends on outcome of 1) above. If diuretic stopped, monitor; if not, consider amiloride. If ACEI given, stop Slow K.</td>
</tr>
<tr>
<td>4) leg cramps (? Due to hypokalaemia from frusemide). Non adherence: patient stated taking quinine up to 3 times daily</td>
<td>eliminate drug-related cause</td>
<td>request nurse to monitor U&amp;E to determine electrolyte status</td>
</tr>
<tr>
<td>5) previous MI and angina – indication for therapy</td>
<td>restart aspirin anti-platelet therapy</td>
<td>Suggest patient restart aspirin 75mg in the morning and counsel patient on benefits of life-long therapy and avoidance of OTC aspirin for pain</td>
</tr>
</tbody>
</table>
2. Monitor, evaluate and review the pharmaceutical care plan

Actual outputs are evaluated in relation to the desired outputs to determine whether pharmaceutical care issues have been resolved. If desired outputs are not achieved, the pharmaceutical care plan should be reviewed. The actual output may then be accepted as being the best achievable for the patient, or an alternative means of achieving the desired output may be proposed.

The original pharmaceutical care plan may change as patients develop different pharmaceutical needs. This may result in new care issues, which require further pharmaceutical actions.

EXAMPLE 7 Continued

PHARMACEUTICAL CARE PLAN

<table>
<thead>
<tr>
<th>Care issue</th>
<th>Actual Output</th>
<th>Further Pharmaceutical Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) no indication apparent for frusemide</td>
<td>No HF – stopped frusemide. Patient counselled; repeat prescription updated</td>
<td>no further action</td>
</tr>
<tr>
<td>2) potential ADR to nifedipine (also increased angina)</td>
<td>team decided to stop nifedipine and started atenolol 50mg in the morning. Prescription issued; repeat prescription updated</td>
<td>recommend review angina therapy; if no HF, start atenolol; if HF present, consider diltiazem with caution. Advise to stop nifedipine.</td>
</tr>
<tr>
<td>3) Slow K ineffective (decreaseK+); non adherence and side effects</td>
<td>stopped Slow K and monitor 1/12. Repeat prescription updated. Patient-nurse 1/12 U&amp;E</td>
<td>monitor response to atenolol</td>
</tr>
<tr>
<td>4) leg cramps (? Due to hypokalaemia from frusemide). Non adherence: patient stated taking quinine up to 3 times daily</td>
<td>arranged for patient to see GP, meanwhile removed quinine from repeat prescription</td>
<td>check U&amp;E 5/52</td>
</tr>
<tr>
<td>5) previous MI and angina – indication for therapy</td>
<td>GP and patient agreed and aspirin recommenced. Prescription issued and patient counselled</td>
<td>monitor ongoing quinine use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>monitor requests for aspirin and counsel on continued need 1/12</td>
</tr>
</tbody>
</table>
3. Continuity of care

Continuity of care as patients transfer from one health care setting to another relies on the identification of, and effective communication with, those professionals to whom responsibility is to be transferred. For example, if a patient moves to a nursing home in a neighbouring town, then with the patient's permission the pharmacist should send a copy of the patient's pharmaceutical care plan to the new GP and community pharmacist.

It is essential that the communication and documentation systems for information transfer between health care settings should maintain patient confidentiality.
Section 4

FACLITATING DISEASE PREVENTION AND DRUG SAFETY

The systematic approach to individual patient care described in the previous section contributes substantially to disease prevention and drug safety, as does the pharmacoepidemiological approach which is described in the next section. However, pharmacists working in the community are often the user's first point of contact, and sometimes their only point of contact with a health care professional. Specifically in relation to prescribed medicines, pharmacists are usually the last point of contact with patients before they take their medicines. This confers particular responsibility on pharmacists in the community as custodians of disease prevention and drug safety.

The Government White Paper, 'Towards a Healthier Scotland' (The Scottish Office Department of Health, 1999)23 states that 'informed choice favours healthy choice' and 'being informed means having access to the right amount of information at the right time, information that may be supplemented by discussion with a health care professional'. It further states that 'pharmacists are in constant contact with the public and are well placed to provide health education and advice on health problems'.

The purpose of this section is to focus on those aspects of disease prevention and drug safety measures in which some pharmacists specialise but, with the possible exception of near patient testing, which form essential common core functions of most pharmacists in primary care (Table 1).

1. Promoting Health
2. Near Patient Testing
3. Providing Education, Information and Advice
4. Preventing, Detecting and Reporting Adverse Drug Reactions

Table 1: Pharmaceutical Activities Underpinning Disease Prevention and Drug Safety
4.1 PROMOTING HEALTH

PURPOSE
The World Health Organisation (WHO 1946) defined health as "a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity”. Health promotion refers to any measure designed to achieve health and to prevent disease and is concerned with influencing health choices. Pharmacists in the community are presented with substantial opportunity for both primary, and secondary disease prevention. There is considerable potential for the further development of health promotion activities within clinical pharmacy practice. The pharmacist working within a multi-disciplinary context can help raise awareness, affect attitudes and provide information to promote health.

The term 'Health Promotion' usually encompasses health education, disease prevention and health protection. The fundamental objective of health promotion is to help individuals change attitudes to health damaging behaviour and encourage individuals to change their lifestyle.

OBJECTIVES AND GUIDELINES
1. To provide health education information and increase awareness of current issues in health promotion

Health education is the process of providing people with advice on health matters so that they can make informed choices in their lifestyle and behaviour. Pharmacists and other health care professionals participate in national and local health campaigns to help raise awareness of current health issues.

The promotion of positive health requires a knowledge of the factors associated with good health, such as fitness and diet, and a knowledge of the effective methods of delivery of this information to patients.

2. To participate in disease prevention strategies, reducing the risk of developing preventable illness or progression of disease by encouraging a healthier lifestyle

Pharmacists can help identify those at risk of developing preventable illness. Community pharmacists are often the first point of contact between patients and health care services and they can identify those at risk from onset or progression of disease which may be related to lifestyle or medicines use. They are also a key contact point at which the public may seek advice on smoking cessation.

Pharmacists also reduce the risk of developing preventable illness by assisting the health care team in minimising the risk of adverse drug reactions (see Section 4.4). Mechanisms to achieve this include ensuring that patients are not exposed to unnecessary drug use, identifying potential drug-related problems involving
drugs with a narrow therapeutic index and recognising patients whose clinical circumstances predispose to variability in response.

Pharmacists also participate in measures to reduce the spread of communicable diseases. This includes counselling and advice for travellers, including information on chemo-prophylaxis and immunisation against infectious diseases, or advice on sexual health and practices, including needle exchange schemes, to help reduce the spread of infection.

3. To contribute to health protection initiatives by educating patients and other health care professionals and ensuring that treatment is optimised to prevent further deterioration in health

A contribution to health protection by the pharmacist stems from the production of, and adherence to, safe systems of work and policies and defined procedures for the storage, handling, administration and disposal of medicines.

The systematic approach to individual patient care described in Section 3 also serves to contribute to health protection through helping to minimise drug-induced morbidity and mortality (see also Section 4.4).
4.2 NEAR-PATIENT TESTING ’

PURPOSE

As defined by a Scottish Office Department of Health Working Group (1996)25, 'Near-Patient Testing (NPT) refers to analytical tests undertaken by non-laboratory staff outwith the laboratory setting'. Potential users of NPT, whether in GP surgeries, health centres, community clinics or pharmacies, need to be aware of best practice with regard to quality assurance, cost effectiveness and specialist interpretation.

NPT is used in three main areas by pharmacists -

- Screening for undiagnosed disease states and symptoms (eg diabetes, hypertension and raised cholesterol)
- Monitoring drug therapy for safety and efficacy
- Pregnancy testing

In the first two instances, NPT provides a 'drop-in' service for patients, with immediate access to results and to information.

NPT provides a quick determination of results of biochemical tests which can be useful in clinical decision making, increasing the efficiency of primary care clinics, such as diabetes, anticoagulant or even repeat prescribing clinics. In these situations when alterations to a patient's therapy may occur, the immediate availability of the result without recourse to the hospital laboratory, provides greater opportunity for discussion of any changes with the patient and, through improvements in patient understanding, will improve concordance.

OBJECTIVES AND GUIDELINES

1. To ensure that equipment is accurate in determining the desired parameters

It is essential that any equipment used for NPT is accurate and reliable. When selecting equipment, it may be useful to liaise with the local laboratory for help and advice. Before using the equipment, any internal Quality Control procedures must be carried out to ensure the satisfactory operation of the device(s). Sources of advice on the suitability of equipment include Scottish Healthcare Supplies (Scottish Health Service Common Services Agency).

2. To ensure the accuracy and reliability of the results obtained

One of the prime considerations will be operator training. Training should cover areas of patient preparation, specimen collection, analytical methodology, interpretation and documentation of results, waste disposal, health and safety, quality assurance procedures and their documentation, and routine maintenance. Individual
competence must be objectively and independently assessed before any tests are carried out on patients. Details of staff authorised to conduct NPT should be recorded on a database.

It is vitally important that persons operating analytical equipment are competent to do so, and are able to demonstrate their competency through demonstrated accuracy of results. This can be ensured by participation in an external Quality Assurance scheme, such as those operated by the National External Quality Assessment Scheme (NEQAS) for Cholesterol and for Anticoagulation. Also, the local laboratory may be able to assist through the provision of external Quality Control samples.

Test strips must be stored in accordance with manufacturer's recommendations.

3. To maintain adequate documentation
It is essential that written protocols exist and are adhered to for the following:

- Quality Control (both internal and external)
- Maintenance of equipment (cleaning, servicing etc)
- Action to be taken in the event of failure of equipment or of Quality Control
- Requests for tests - both from patients and GPs. Documented requests are advisable
- For screening purposes, levels at which referral to the patient's general practitioner is necessary
- Where the pharmacist is operating a monitoring clinic (eg for anticoagulant therapy), a written protocol defining limits of responsibility is advisable
- Disposal of contaminated equipment, including test strips and sharps
- Maintenance of appropriate Health & Safety standards

Records should be maintained for all tests carried out and these should be signed and dated by the person carrying out the test.
4. To ensure clear and concise communication of test results and information

Staff involved in counselling and advising patients on the results of NPT should have successfully completed an appropriate education and training course.

It is essential that patients are fully informed about the clinical significance of their test results. This may often involve collaboration with other members of the primary care team. Other relevant information should be supplied to the patient as necessary.

Results should be provided to the patient and/or the general practitioner in written form. Patient's consent must be obtained before informing the GP about the result.

5. To follow specific advice from The Scottish Office Department of Health and The Royal Pharmaceutical Society of Great Britain

Advice on all aspects of NPT is provided by The Scottish Office Department of Health. This statement of best practice for Scotland also provides reference to other sources of advice on matters such as health and safety and consumer protection.

Practice advice on blood pressure measurement, testing body fluids, cholesterol testing and pregnancy testing is provided to all pharmacists by the Royal Pharmaceutical Society of Great Britain.

6. To perform audit on the operation of the NPT service

Regular audits should be performed on the service to ensure continuous quality improvement.
4.3 PROVIDING EDUCATION, INFORMATION AND ADVICE

PURPOSE
The provision of independently evaluated drug information and advice by pharmacists is one of the foundation stones of clinical pharmacy practice. The purpose is to ensure that appropriate advice is available timeously to meet the requirements of health care professionals. Advice ranges from the rational choice of medicines within a particular class of drugs in order to support formulary review, to the selection of an appropriate medicine for an individual patient.

OBJECTIVES AND GUIDELINES
1. To keep up to date with new products and therapeutic advances

Through a variety of continuing education mechanisms (see Annex A3), pharmacists should ensure that they keep up to date with changes in medicinal products, are familiar with the advantages and disadvantages of new products, and are aware of recent changes in clinical practice.

2. To anticipate and identify the need for evaluated drug information to support formulary review or individual patient care

The need for information to support formulary review or prescribing policies is predictable and preparation for this can include the assembly of information from sources as diverse as literature evaluations and the results of drug use evaluations or clinical audits (see Section 5.2.3 and Annex A4).

Anticipating the need for information to support the care of an individual patient is a routine clinical function and part of the pharmaceutical care planning process. Information and advice provided in support of individual patient care should be documented as described in Sections 2 and 3. Where the need for a particular piece of information is vital or arises frequently, the information should be incorporated into a formulary, policy or procedure.

3. To establish the background to requests for drug information and advice from health care professionals and patients

Pharmacists are often in a position to know the background to requests for information and advice through their direct involvement in patient care. When this is not the case, it is important to establish the context within which the request is made by identifying the exact reason for the request and obtaining the clinical information required to ensure that the answer provided is appropriate.
4. To participate in the education and training of other health care professionals

Pharmacists should contribute to the education and training of other health care professionals on the safety, efficacy and economy of medicines use. Both formal and informal opportunities should be taken to maintain the provision of an independent professional source of pharmaceutical education.

5. To advise on the legal and ethical considerations regarding requests for non licensed medications and the use of licensed medicines outwith the terms of their product licence.
All pharmacists should know and understand the legal and ethical aspects of this subject. The use of an unlicensed product is the responsibility of the prescriber. However, in the event of any problems arising from the use of such products, the pharmacists involved in the supply or advice in the use of these products may be held partially liable in law.
4.4 PREVENTING, DETECTING AND REPORTING ADVERSE DRUG REACTIONS

PURPOSE
Pharmacists are well placed to assist the health care team in measures to improve drug safety. It is important to minimise or prevent the risk to patients of known or predictable adverse drug reactions including interactions. The detection and reporting of all suspected adverse drug reactions to newer drugs and of serious suspected predictable or idiosyncratic reactions to established drugs, are vital functions within the overall process of minimising drug induced morbidity and mortality. The pilot studies in England and Wales have also emphasized the importance of adverse drug reactions associated with non-prescription medicines.

Patients require to be well informed to assist health care professionals in preventing, detecting and reporting adverse drug reactions (see the Clinical Resource and Audit Group Guidelines on "Counselling and Advice on Medicines and Appliances in Community Pharmacy Practice").

OBJECTIVES AND GUIDELINES

1. Ensure that prescribing for individual patients takes account of essential drug safety measures

The principal means by which pharmacists can assist in minimising and/or preventing drug-induced morbidity and mortality are as follows:

a) Identify those drugs known to produce predictable dose related adverse effects; avoid their use where an equally effective and safer alternative exists or take steps to ensure their appropriate use, fulfilling particular monitoring requirements in order to minimise the risk of adverse effects
Adverse effects may be minimised through selection of the best tolerated drug within a particular class (which can be facilitated by formulary management). Patients may also be counselled on measures which they themselves can take to reduce adverse effects, how to recognise adverse effects of drugs, and on the action to take should they experience particular types of adverse effects.

b) Identify those patients who will require close monitoring as a result of compromised ability to take or use medicines, or of compromised drug handling ability, and ensure appropriate dosage forms/regimens
Patients may experience difficulty with particular routes of administration or exhibit abnormal drug handling through altered absorption, distribution, metabolism or excretion. For example, care may need to be taken to avoid the oral administration of particular drugs and/or formulations in patients with dysphagia or to reduce the maintenance dose of digoxin in elderly patients.
c) Check that patients are not exposed to unnecessary risk through unnecessary medicines use; disregard for stated warnings, special precautions or contra-indications; or through drug interactions with prescribed medicines, over-the-counter medicines, food, or drink

Medicines should only be used where there is a good indication for use and anticipated benefits are likely to outweigh the risks associated with therapy. In general, medicine use should be avoided during pregnancy and in breast-feeding mothers unless it is essential. Even drugs of choice from within a particular class of drugs, may be contra-indicated in an individual patient due to a concurrent medical problem, or due to concurrent medication.

A complete knowledge of the medication available to the patient is necessary if drug interactions are to be avoided. This may involve the pharmacist in taking a medication history to establish which prescribed and over-the-counter medicines the patient has at home or uses at any time. It will also involve counselling the patient on which medicines he/she should avoid, and whether they need to avoid particular foods or alcohol, during their current therapy.

d) Identify those patients with a history of intolerance or hypersensitivity to a particular medicine or class of medicines and avoid the use of that medicine (or class of medicines) if possible

Patients should be asked if they have ever had any previous adverse reactions to drugs. Details of drug-induced allergic and hypersensitivity reactions should be documented in the hypersensitivities section of patient medication records and in patients' case notes.

e) Ensure that patients receive cautionary and advisory labels and counselling on the correct use, storage and disposal of their medicines

Cautionary and advisory labels are routinely supplied on medicines, wherever appropriate. Counselling and the use of compliance aids may help to resolve any lack of understanding, or inability of the patient to use the medicine properly.

For all medicines, clear instructions on storage and/or disposal will be necessary to prevent accidental poisoning and to ensure appropriate storage conditions.

Counselling and advice is dealt with more fully in the CRAG Guidelines cited under 'PURPOSE' above.

2. Educate pharmacy staff and other health care staff on the prevention, detection and reporting of adverse drug reactions
Pharmacists should participate in the education and training, both of other pharmacy staff and other health care professionals, through a variety of mechanisms including in-service training, continuing education, peer review and clinical meetings.

3. Monitor patients on newer drugs (indicated by the sign "" in the British National Formulary) for any adverse reactions or any unexpected events

All unexpected events as well as adverse reactions which occur in patients receiving newer drugs should be reported to the Committee on Safety of Medicines (CSM) using the "yellow card" system. A number of local adverse reaction reporting schemes exist in England and Wales to facilitate the completion of yellow cards and to raise the awareness of possible adverse drug reactions. Pharmacists in Scotland should consider promoting such a scheme within their practice or locality.

4. Monitor patients for delayed drug effects with both established and newer drugs

Some adverse drug reactions may manifest themselves several months or, possibly, several years following exposure to the drug. For example, it may be necessary to consider all medicines which a mother was exposed to during her pregnancy in detecting the cause of a congenital abnormality in a child.

5. Consider all possible sources of information both on medication to which the patient has been exposed and on symptoms which may be drug related

Full medication history is essential in the detection and reporting of suspected delayed adverse drug reactions. The pharmacist must be alert to, and utilise all sources of information which could be useful in detecting adverse drug reactions. Such sources include medical notes, nursing notes and verbal information obtained from the patient, carers and other health care professionals.

6. For unknown or poorly documented non-serious suspected adverse reactions stopping therapy and re-challenge may be used as an aid to confirmation of the offending medicine

The question of stopping drug therapy and re-challenge is one of risk-benefit analysis. Any decision to undertake this course of action to resolve uncertainty about a causal relationship needs to be taken carefully in conjunction with medical colleagues.
7. Document and encourage reporting of all suspected reactions to newer medicines and serious suspected reactions to established medicines

Pharmacists should do all that they can to facilitate the reporting by clinicians of all suspected reactions to newer medicines and suspected serious reactions to established medicines, to the CSM via the yellow card system.

8. Monitor patients for the use of drugs to treat adverse drug reactions which may have not been previously identified in those patients

A number of common adverse drug reactions which might escape detection can be recognised by pharmacists who are alert to the possibility of an iatrogenic indication for the use of certain medicines. An example of this would be the prescribing of antimuscarinic drugs to treat the extra-pyramidal symptoms produced by drugs such as metoclopramide, antipsychotics or antihistamines.
The majority of patients should continue to receive medicines on an individual basis, as stated in the recent Crown Review Report14. However, the study of medicines use in large numbers of people serves to inform individual patient care through the evaluation of common health care needs and providing information about the beneficial and harmful effects of drug therapy. This pharmacoepidemiological approach to practice permits a better assessment of the risk/benefit ratio for individual patients and aims to improve the effectiveness and efficiency of health care provision to the population.

5.1 PATIENT POPULATIONS AND DATABASES
A patient population can be that of a single general medical practice, a group of practices (a locality), or it could be the database of patients held by a particular community pharmacy in the form of patient medication records (PMRs). Of course, in the absence of patient registration in routine community pharmacy practice there is an inevitable uncertainty about the exact nature of the entire patient population which a particular pharmacy will serve. This is especially so in large urban centres. Nevertheless, most community pharmacies provide NHS pharmaceutical services regularly to a high proportion of their total patient population.

Within any given patient population then, it is possible to adopt a pharmacoepidemiological approach to practice which identifies the needs of particular patient groups. Interrogation of patient databases identifies the characteristics of patient populations. The age/gender distribution is the simplest description of any population and may be extended by inclusion of information regarding deprivation or socio-economic factors within a community. However, of far greater significance with regard to disease management and planning, is the morbidity and co-morbidity of the population. This relies heavily on the accuracy and completeness of data capture within both primary and secondary care. The integrity of this information may be supported and supplemented by a knowledge of pharmacoepidemiology. Whether within or between primary and secondary care, the accuracy and completeness of data depends on effective and efficient information transfer both between the health care professions involved in providing care and between the various health care sectors. Patient data systems which cross health care sector and health care professional boundaries require to be developed and validated.

Particular work environments can facilitate the collection of different data types; for example, the pharmacist working within a GP surgery may have easy access to data on morbidity and co-morbidity, whereas the pharmacist in a community pharmacy may have easy access to data on use of over-the-counter medicines. To an extent, pharmacists in both these situations can rectify potential data deficiencies independently through good history taking, but effective communication between the community pharmacy and the GP surgery is also required. Similarly, good liaison with other professionals working in the community facilitates the
achievement of accurate and complete databases. For example, for particular patients, relevant community-based professionals may include district nurses, practice nurses (particularly those running specialist clinics), social workers, dieticians, general dental practitioners, midwives, health visitors, podiatrists, or residential and nursing home staff. This liaison will be facilitated by the development of the NHS Net, which should enable hospital and primary care sites to be linked electronically. Work on single patient records and the addition of patient identifiers to prescriptions should in the future improve information sources to facilitate collection of data on medicines use.

The opportunity also exists for registration of patients with a primary care team to provide all types of care required. This would reduce the question of access to patient information and promote total integration of the pharmacist into the multi-disciplinary primary care team.

In the absence of accurate or comprehensive records of morbidity or co-morbidity, estimates of disease prevalence can be made by employing individual drug and drug group searches on a basic PMR database. Whilst the limitations of such an approach must be recognised, it is not without value in that it identifies all users of a particular medicine of interest. Where the PMR database contains full documentation of the systematic approach to individual patient care advocated in Sections 2 and 3 (ie patient medication profiles) this would contain diagnostic data on morbidity and co-morbidity and have the potential to identify patient outcomes from drug therapy.

5.2 A PHARMA Cooke EPI DEMIOLOGICAL APPROACH

In order to improve the effectiveness and efficiency of health care provision to the population, three questions require to be answered:

i) Who needs health care and what are their needs?
ii) ii) What constitutes best care to meet those needs?
iii) iii) To what extent is best care being achieved?

With specific reference to pharmaceutical services these questions can be addressed through the following functions, respectively:

i) Pharmaceutical needs assessment.
ii) Managing formularies, clinical guidelines and treatment protocols.
iii) Evaluating and reviewing medicines use.
Each of these functions constitutes an important component of medicines resource management which aims to maximise therapeutic benefit within available resources. A synopsis of each is provided in the subsections which follow.

5.2.1 Pharmaceutical needs assessment

a) Pharmaceutical needs assessment is one aspect of health needs assessment, focusing specifically on the requirements of populations of patients for pharmaceutical products or services. Data on the specific population being assessed are compared with prevalence data on the general population and evidence-based data on effective health care. Pharmaceutical needs assessment may help identify, for example, potential under-diagnosis and under-treatment of disease, as well as the potential scope for disease prevention measures.

b) Whilst it is also possible to assess the requirements of a general medical practice for pharmaceutical services (such as those described in 5.2.2 and 5.2.3 below), the term 'pharmaceutical need' refers specifically to a patient's requirement for a pharmaceutical product or service. Of course, the pharmaceutical service requirements of GP practices should be based on an assessment of the pharmaceutical needs of the practice population. Pharmacists may be specifically involved for this purpose within a more general health needs assessment, undertaken by other health care professionals.

) Where a representative sample of the population has been studied rather than the whole population, it is possible to estimate the extent to which services are required by extrapolating the needs identified to all potential patients. Such an approach is usually necessary to estimate, for example, the numbers of patients who would potentially benefit from general medication review, from regular monitoring of their therapy, or from specific counselling and advice on their medication.

d) The decision to undertake needs assessment implies a willingness and opportunity to change services or to provide new services to meet the needs identified. A number of options for changing services or developing new services to meet the needs should be drawn up for discussion with health care professionals and patient representatives. Where a range of needs are identified, these should be prioritised and all involved in contributing to, or receiving the service should be consulted about the priorities.

e) Roles and responsibilities are changing within the primary care team in relation both to needs assessment and service provision. As stated in Section 1.1, pharmacists should ensure that the pharmaceutical needs of patients are identified and met within the changing health care environment.
5.2.2 Managing formularies, clinical guidelines and treatment protocols

a) The effective management of ‘formularies’, ‘clinical guidelines’ and ‘treatment protocols’ rationalises the use of drug therapy in groups of patients. By ensuring that practice is based on evidence wherever possible, these aspects of medicines resource management aim to improve the safety, efficacy and efficiency of medicines use in patient populations.

b) Formularies contain an approved list of pharmaceutical items for routine use, together with information to assist in rational and cost-effective prescribing. They should be dynamic and able to respond to changing therapeutic practices. In order to achieve this, pharmacists should agree and implement mechanisms for practice formulary monitoring and review in association with general practitioners and practice staff.

c) Area-based general practice formularies and local hospital formularies, or joint local formularies (eg The Grampian Joint Formulary), should be taken into account when developing practice formularies. Items are selected for inclusion by consensus and reflect safety, efficacy, economy, availability and local patterns of use and treatment protocols. Pharmacists should use all available prescribing data and evaluate up-to-date drug information to support their contribution to practice formulary development and review.

d) Pharmacists contribute to the multi-disciplinary production of national evidence-based clinical guidelines, such as those published by the Scottish Intercollegiate Guidelines Network (SIGN). At a local level, pharmacists have a responsibility to facilitate the implementation of these evidence-based guidelines. This usually requires the development of locally agreed treatment protocols and their implementation.

e) All group protocols should be drawn up by a multi-disciplinary professional group, including a doctor, a pharmacist and a named representative of each of the professions likely to contribute to care under the protocol (Crown Review Report).14

Both clinical guidelines and treatment protocols (or group protocols) should be reviewed at appropriate intervals to reflect changes in the evidence base and changing trends in clinical practice.

f) In order to support the rational and cost-effective use of all medicines, pharmacists should develop their own non-prescription medicines formulary and ensure that pharmacy staff have the necessary training to make recommendations to patients requesting these medicines. Pharmacy staff should also know the circumstances in which referral to the pharmacist is necessary.

g) Local treatment protocols should be developed in association with general medical practice staff to cover minor ailments for which patients may seek advice from pharmacists, general practitioners, community or practice nurses, or other community-based health care professionals.
h) While formularies, clinical guidelines and treatment protocols are designed to cover the routine situation, it will sometimes be necessary to deviate to meet the specific care requirements of individual patients. The pharmacist should ensure that such deviations are appropriate and that the reasons are documented in the individual patient's records.

5.2.3 Evaluating and reviewing medicines use

a) 'Medicines use evaluation' is a systematic and scientific process of determining the extent to which the use of medicines achieves pre-determined objectives. The aim is to assure the most effective use of medicines and related resources to meet the clinical needs of a particular patient population. Whilst pharmacists may co-ordinate medicines use evaluation, this is a multi-disciplinary function which requires the involvement and commitment of patients and of other health care professionals, particularly general practitioners and nurses.

b) The specific purpose of a medicines use evaluation is to highlight areas of medicines use where a change in prescribing practice may achieve a better use of resources. Commonly, this is performed where it is suspected that pre-determined objectives are not being achieved in relation to patient outcomes and/or cost, or where evidence on best practice supports a change in the delivery of patient care.

Typical targets for medicines use evaluation are medicines which have a narrow therapeutic index, where the cost per case is high or where prescribing frequency dictates high annual costs. Repeat prescribing is an important target area. It is responsible for a considerable proportion of NHS prescribing and medicines costs and, if not reviewed regularly, can be a cause of iatrogenic disease.

Another important area for medicines use evaluation is in relation to the forecasting of the uptake of new medicines and their likely impact. Once new medicines or therapeutic practices are introduced into practice, medicines use evaluation can ensure the appropriateness of their use.

c) Where evidence-based clinical guidelines or local protocols exist, some measure of, the effectiveness and efficiency of health care provision can be obtained by evaluating the extent to which they are implemented.
EXAMPLE 8

Evidence-based clinical guidelines in a GP practice

Guidelines covering the use of lipid lowering agents, highlight an area which requires detailed investigation.

The following steps should be included:

- First priority to be given to patients requiring secondary prevention.
- Search database to create a sub-population of patients that meet the criteria for secondary prevention (eg myocardial infarction, coronary artery bypass graft, angioplasty, age < 75 years)
- Search database for medicines such as nitrates to enlarge the sub-population identified if medical history recording is either incomplete or inaccurate.
- Identify within the sub-population those patients with established hyperlipidaemia.
- Target those patients with no monitoring and screen to include or exclude.
- Screen the sub-population for evidence of effective management including drug treatment and/or lifestyle modifications.

d) 'Medicines use or utilisation review' is a process for the identification of those medicines which would be suitable for medicines use evaluation by analysis of data on the prescribing and/or the use of medicines. Medicines utilisation data should be accurate, up-to-date and complete. Ideally data should be maintained on a computerised database to allow flexibility of data handling. Sufficient data should be available to demonstrate meaningful trends and to allow year-on-year comparisons.

Scottish Prescribing Analysis (SPA) Data and Prescribing Information System for Scotland (PRISMS) are examples of general practice-specific prescribing data which are produced by the Pharmacy Practice Division of the Common Services Agency. The latter is available on-line in a few practices (PRISMS FP) and the number is scheduled to increase. Pharmacists can help GPs with the interpretation of prescribing data at different levels eg GP, practice, locality or Health Board levels.

Equally, patient medication records represent a useful data source which is available to community pharmacists and which represents encashment of prescriptions and, in some cases, purchase of over-the-counter medicines. Although, in the absence of patient registration with community pharmacies, assurances as to the completeness of this data source is not possible, there is evidence that a large proportion of patients who routinely take medicines obtain their supplies from a single pharmacy.

Records of over-the-counter medication are more difficult to capture and to assure the completeness of than those of prescribed medicines. Again, however, they represent a useful source of data for the purposes of medicines utilisation review and one which is uniquely available to the pharmacist.
Multi-disciplinary collaboration is essential if complete databases are to be generated and evaluations are to be valid. This is obviously of particular importance where prescribed and over-the-counter medicines taken concomitantly constitute either duplicated or contra-indicated therapy.

e) Defining acceptable 'standards' and 'criteria' for the appropriate use of medicines usually requires a search of relevant literature and discussions with other primary care staff (and, where relevant, secondary care staff) about the source and collection of data. Pharmacists undertaking medicines use evaluation require to consider the information sources which are necessary to define best practice and to establish standards.

Criteria for the appropriate use of medicines should be relevant, understandable, measurable and achievable. The targets for compliance with these criteria, and allowable exceptions, must be defined in relation to the desired outcome and availability of resources. Where National Guidelines or published evidence on best practice exist, these can be used to facilitate the establishment of local standards.

f) Measuring and documenting outcomes against standards involves different types of activity for medicines use review compared with medicines use evaluation.

At a basic level, linking with general medical practices, medicines utilisation information on the amount, cost and patterns of prescribing can be collected and reviewed against agreed medicines use standards and criteria which involve, for example, the extent of formulary use or of generic name prescribing. Further information may be elicited from prescribers as required, for example reasons for deviation from the use of formulary medication. This process is considerably enhanced by access to individual patient clinical data which enables both quantitative and qualitative evaluations to be performed.

At a more advanced level, the documentation of pharmaceutical care plans and actual outputs for individual patients (Section 3) facilitates medicines use evaluation. Other data to support medicines use evaluation include workload and financial statistics.

g) It is important to report the results of the medicines use evaluation to the clinical team and to recommend appropriate action. Where significant deviation from agreed standards is identified, action should be taken to improve or review the situation. This may involve development of education programmes using bulletins or newsletters, the organisation of audit meetings or educational seminars or the development or review of prescribing formularies or treatment protocols. Alternatively, a reassessment of standards may be required.
1. KEY DEFINITIONS

Much of the terminology used within clinical pharmacy has been variably defined, including the term "clinical pharmacy" itself. The addition of the term "pharmaceutical care" has introduced an added dimension. The definitions provided in this document are based on those in two other Clinical Resource and Audit Group Publications: "Clinical Guidelines" (1993) and "Clinical Pharmacy in the Hospital Pharmaceutical Service: A Framework for Practice (1996). There remains a real need to clarify definitions relating to clinical pharmacy and pharmaceutical care and a clear understanding of the following definitions in particular will aid the reader. Their use should serve to inform and improve discussion in this field.

Clinical Pharmacy: A discipline concerned with the application of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients and patient populations.

Pharmaceutical Care: The pharmaceutical contribution to patient care.

Pharmaceutical Need: A patient's requirement for a pharmaceutical product or service.

Pharmaceutical Care Issue: An element of a pharmaceutical need which is addressed by the pharmacist.

Desired Output: A statement of what the pharmacist aims to achieve for a patient in relation to a pharmaceutical care issue.

Pharmaceutical Action: An action by a pharmacist to address a pharmaceutical care issue for a patient.

Pharmaceutical Care Plan: One or more pharmaceutical care issues for an individual patient, together with the desired output(s) and the action(s) planned to achieve the output(s).

Actual Output: The response of the health care team and/or the patient to the pharmacist's actions and/or the clinical outcome for the patient.

Patient Medication Profile: A document which is maintained by the pharmacist to support the pharmaceutical care of a patient.

Patient: A person seeking or requiring health care services.
### 2. DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Assessment</td>
<td>The identification and review of an individual patient's pharmaceutical care issues.</td>
</tr>
<tr>
<td>Clinical Audit</td>
<td>The systematic, critical analysis of the quality of clinical care. This includes the procedures used for diagnosis and treatment, the associated use of resources, and the effect of care on the outcome and quality of life for the patient.</td>
</tr>
<tr>
<td>Clinical Guideline</td>
<td>Systematically developed statements which assist in decision making about appropriate health care for specific clinical conditions.</td>
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<tr>
<td>Clinical Outcome</td>
<td>Alteration in the health status of the patient directly attributable to clinical action or inaction.</td>
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<tr>
<td>Compliance</td>
<td>Adherence to a course of instructions for the use of a medicine or an appliance.</td>
</tr>
<tr>
<td>Concordance</td>
<td>A negotiated agreement between a health care professional and a patient which aims to optimise health gain from the best use of medicines and is compatible with what the patient desires and is capable of achieving. (The term describes the consultation, not the patient, and may often represent an agreement to differ).</td>
</tr>
<tr>
<td>Counselling</td>
<td>The interactive process involving a consultation about medicines or appliances between a pharmacist and a patient.</td>
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<tr>
<td>Criterion</td>
<td>A single variable selected to facilitate measurement of an element of care, particularly in relation to meeting quality standards. A criterion may be qualitative or quantitative.</td>
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<tr>
<td>Effectiveness</td>
<td>The degree of conformity between actual and desired outputs.</td>
</tr>
<tr>
<td>Efficiency</td>
<td>The extent to which a desired goal is reached for the minimal effort and resource use.</td>
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<tr>
<td>Formulary</td>
<td>An approved list of pharmaceutical items for routine use together with information to assist in rational prescribing.</td>
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<tr>
<td>Formulary Management</td>
<td>The infrastructure required to initiate, monitor, manage System and review local formularies and protocols.</td>
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<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>Medicines Resource</td>
<td>The system to optimise the use of medicines, Management maximising therapeutic benefit within available resources.</td>
</tr>
<tr>
<td>Medicines Use Evaluation</td>
<td>The systematic and scientific process of determining the extent to which the use of medicines achieves predetermined objectives.</td>
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<tr>
<td>Patient Care</td>
<td>The clinical activities undertaken by health professionals in pursuit of a specific outcome for an individual patient.</td>
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<tr>
<td>Peer Review</td>
<td>A continuous systematic and critical reflection by a group of health care professionals on their own and colleagues' performance, using structured procedures.</td>
</tr>
<tr>
<td>Performance</td>
<td>The quality of pharmaceutical care achieved as judged by both the process of that care and by its output.</td>
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<tr>
<td>Pharmaceutical Needs</td>
<td>The identification and review of the requirement for Assessment pharmaceutical products or services in individual patients or in patient populations.</td>
</tr>
<tr>
<td>Protocol</td>
<td>An adaptation of a clinical guideline to meet local conditions and constraints.</td>
</tr>
<tr>
<td>Quality</td>
<td>Level of excellence related to structure, process and/or outcome.</td>
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<tr>
<td>Screening</td>
<td>The process of selecting patients within a group who have potential pharmaceutical care issues.</td>
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<tr>
<td>Service Specification</td>
<td>A description of the range of services provided and the standards on which these services are based.</td>
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<tr>
<td>Shared Care Protocol</td>
<td>A signed agreement between a hospital specialist and a GP which outlines the arrangements and clearly defines respective clinical roles and responsibilities when a patient requires care from both the hospital and the primary care services.</td>
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<tr>
<td>Standard</td>
<td>Specification of process and/or output against which performance can be measured.</td>
</tr>
<tr>
<td>Target</td>
<td>The specification of the expected level of achievement which performance should meet or exceed.</td>
</tr>
<tr>
<td>Targeting</td>
<td>The process of selecting patient groups to receive particular clinical pharmacy services.</td>
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ANNEX A2
PROFESSIONAL ETHICS

1. Introduction

The Code of Ethics of The Royal Pharmaceutical Society of Great Britain sets the standard of professional conduct for all pharmacists. The Code details nine principles supplemented by more detailed obligations and further guidance is provided in an Appendix on "Standards of Good Professional Practice". The reference figures given below refer to sections in the Code and its Appendix which should be referred to for a further explanation.

The pharmacist's approach to all professional activities is governed by Principle 1 of the Code which states that pharmacists' prime concern must be for the welfare both of the patient and of other members of the public, and specifically (obligation 1.14), a pharmacist must conform to the obligations in the Standards of Good Professional Practice and with other guidelines or codes of practice appropriate to the relevant field of work.

2. Confidentiality Principle 4 of the Code requires a pharmacist to respect the confidentiality of information acquired in the course of professional practice relating to a patient and the patient's family. Such information must not be disclosed to anyone without the consent of the patient or appropriate guardian unless the interest of the patient or public requires such disclosure. Information includes that retained through memory as well as that held in records, whether mechanically or electronically maintained. Any disclosure of information relating to a patient and the patient's family should be limited to the minimum necessary for the specific purpose involved (obligation 4.3). It should be noted that information can be shared with others who participate in, or assume a responsibility for, the care or treatment of the patient and who would be unable to provide that care or treatment without the necessary information; this is the "need-to-know" concept.

Information acquired by a pharmacist in the course of his professional practice other than that relating to patients may also be confidential. In particular, information relating to the prescribing practices of identifiable doctors or doctors' practices, and other prescribers, is confidential and must not be disclosed, other than for necessary purposes of the NHS, unless the prescriber has given informed written consent to the disclosure (obligation 4.5).

The Scottish Office Department of Health (SODoH) Code of Practice on "Confidentiality of Personal Health Information" gives further guidance to all those employed by or contracted to the Scottish Health Service. Particular guidance is given on "Disclosure by Implied Consent" and "Disclosures Without Consent". The Code of Practice advises that disclosure without consent always raises extremely difficult questions involving moral, ethical and medical issues and such cases must be considered with great care. It points out that the Chief Administrative Medical Officer or his nominated deputy has responsibility for confidentiality, security and access to personal health information held by a Health Board and should be regarded as a source
of advice on all aspects of disclosure. All disclosures and their extent should be recorded on the patient's record.

3. Records

In the Appendix to the Code of Ethics, the Guidance notes under Section 5 (Standards for dispensing procedures) state that "it is beneficial to maintain pharmacy records of medicines dispensed for and purchased by patients". The Guidance notes continue: 'Where these records are kept on a computer, the pharmacy must register with the Data Protection Registrar' . . . 'Whatever method of keeping patient medication records is used, a pharmacist must ensure that the information held remains confidential and full regard is paid both to Principle 4 of the Code of Ethics and the Data Protection Act 1984"27.

Within paragraph 3 on "Records" of the Guidance Notes (under Section 5 of the Appendix to the Code of Ethics) is reference to the need to add any relevant patient information arising from pharmaceutical services to the patient's medical record, regardless of whether the pharmacist has direct access to these records. Also within Section 5, further guidance is given on "Counselling/Information and advice" and "Adverse reaction reporting".

4. Professional Development and Relationships

Section 7 of the Appendix, entitled "Standards for education, training and development" deals with issues such as competency, self-assessment (self-audit) and new services. Within the guidance under Section 8 on "Standards for relationships with patients and the public" two sub-sections deal with "Response to symptoms" and "Advice on general health care matters". Section 9 on "Standards for relationships with other health care professionals" stipulates that "co-operation must be offered to a professional colleague and members of other health care professions so that the patient, and public may benefit". The pharmacist should establish and maintain regular contact with those health care professionals with whom he is involved in daily practice.

The recent Government White Paper, "Designed to Care", concluded that "a partnership approach based on co-operation, not competition, is the way ahead for Scotland's Health Service". Community pharmacists and primary care pharmacists based in general practice require to co-operate with each other, as well as with other relevant members of the health care team, to help fulfil the NHS objective of delivering good quality health care consistently.

5. Summary The pharmacist is strongly urged to consult the ethical guidelines of the Society, as outlined above in conjunction with the SODoH Code of Practice, the Data Protection Act 198427 and the information given in these practice guidelines. The Society's Code of Ethics, and the appendix relating to Standards of Good Professional Practice are found for example in the publication "Medicines, Ethics & Practice" sent to all practising pharmacists. As well as a professional requirement to observe the Society's Code of Ethics,
pharmacists who fail to perform to an acceptable professional level could find themselves in a position of legal liability.
ANNEX A3
CONTINUING PROFESSIONAL DEVELOPMENT

1. Background
The Royal Pharmaceutical Society of Great Britain (RPSGB) requires in the Code of Ethics (Principle 5) that a pharmacist must keep abreast of the progress of pharmaceutical knowledge in order to maintain a high standard of professional competence relative to his sphere of activity. To help fulfil this responsibility, the RPSGB recommends that pharmacists adopt the concept of Continuing Professional Development (CPD). The RPSGB definition of CPO is:

their careers according to a plan formulated with regard to the needs of the professional, the employer; the profession and society”.

The good practice cycle sets out a process by which pharmacists fulfil their CPO.

2. Identification of CPD Needs Identification of CPO needs may be undertaken by yourself in your own practice, or may be as an outcome of performance review or appraisal, or as an audit exercise undertaken on your own or with others. Personal identification of CPO needs may be facilitated by questions relating to your practice now (eg within a community pharmacy setting) and your future practice (eg within a general practice environment).

For example:

- What new knowledge and skills do you need?
- Are there any patient clinical needs in relation to medicines management which you are unable to meet at present?
- Where are you not confident in your clinical pharmacy knowledge?

3. How to Meet CPD Needs
There are many ways in which CPO needs can be met, including: direct learning courses, distance learning course provision, self-directed reading of standard reference works or key journals, postgraduate formal courses, study groups, and in-service education and training. This list is not exhaustive.

4. Participation in CPD CPO is more than just engaging in continuing education; the range, extent and number of CPO activities is for the individual pharmacist to decide. It is important to dispel the misapprehension that to learn "one has to attend a course", and that education does not become divorced from practice. Opportunities to work or work-shadow within the primary care setting with pharmacy
colleagues, medical and other healthcare professionals, can meet identified needs and fulfil learning opportunities as they present in practice.

With increased focus on primary care, continuing education in Scotland is offered by a variety of providers, including: the Scottish Centre for Post Qualification Pharmaceutical Education (SCPPE), Health Boards, Schools of Pharmacy, the Pharmaceutical Industry, Independent Companies and others. The pharmacist working, or intending to work, within the primary care environment, should prioritise the education and training offered in line with their individual identified CPO needs, in order to maximise their contribution to patient care.

5. Documenting CPD Needs, Provision and Outcomes The RPSGB and others advise pharmacists to document their individual learning needs, identify a plan on how they expect to meet them, and record how the needs have actually been met. The RPSGB issues to all pharmacists a simple planner and record of CPO but other documentation systems are also available, for example, the College of Pharmacy Practice portfolio. It is important to document learning that is both through experience and learning from experience, and to encourage pharmacists to reflect on past experience as a means of discovering solutions to present problems.

6. Evaluation of CPD Outcomes
It is important to evaluate any benefits gained from CPO on a personal basis, perhaps from an area of new knowledge gained or a patient benefit from a medicines management perspective. CPO outcomes that are reflected in developments in practice can contribute greatly to the quality of pharmaceutical care.
1. Introduction

Quality assurance (QA) is all the activities and functions concerned with the attainment of quality which has been defined as a level of excellence related to structure, process and/or outcome. A quality system consists of the roles, responsibilities, processes and procedures which those individuals operating within the system must ensure they are capable of, and perform to the specified level. Quality systems promote and assure consistent service provision to an appropriate quality. Within these systems there are various assessment measures such as audit and peer review.

Since 1989 when medical audit was introduced as part of the NHS reforms, audit has become the main method used to improve the quality of health care services. The term clinical audit refers to audit undertaken by health care professionals of any discipline.

2. Clinical Audit

Clinical audit has been defined as the systematic, critical analysis of the quality of clinical care. This includes the procedures for diagnosis and treatment, the associated use of resources, and the effect of care on the outcome and quality of life for the patient.

The audit is the classical diagrammatic way of showing the audit process. This process involves setting standards, measuring current practice against those standards, identifying problem areas or shortfalls, and confirming either that procedures are effective or the need to implement change.

2.1 Identification of suitable areas

All services should be subject to audit. However since audit can be time-consuming, activity should be directed to areas where problems or deficiencies have been perceived or where there is a desire to and a probability of improving the service. Pharmacists should actively seek to participate in clinical audit initiated by other health care professionals and involve all relevant staff in audit they initiate.

2.2 Setting criteria and targets for clinical audit

All staff involved in the delivery of services, which contribute to the care of patients in an organisation or locality, who are being audited must be involved in setting criteria and targets. Criteria are explicit statements describing the service which should be provided and may be derived from guidelines or protocols. Targets are the level of service which the audit team agree should, be met for each criterion or aspect of the service.
Pharmacists should ensure that criteria are clearly written and that targets are set as high as practicable and do not simply reflect current practice.

Pharmacists should ensure that all relevant health care workers agree with the criteria and targets to maximize the likelihood of change in practice should this prove necessary. In many clinical areas some patients will move from primary to secondary care and vice versa; it is therefore essential to ensure liaison with relevant hospital pharmacists on criteria and targets for audit in such areas.

2.3 Data collection There are many methods of collecting data for clinical audit. Pharmacists should ensure that they keep complete records of clinical activity to facilitate audit. Pharmacists may be responsible for data collection in multi-disciplinary audit and should ensure relevant data is collected, using appropriate sampling techniques. They should also make records available to others responsible for data collection when participating in audit, whilst ensuring patient confidentiality at all times.

2.4 Identifying problems in current practice
An essential part of audit is determining whether current practice meets pre-set targets and, if not, reasons for this failure. Audit design should therefore build in data collection methods which assist in this process. This may involve questionnaire or interview techniques and will require honesty on the part of responders. Failure to identify problems and the reasons for them will result in a reduced ability to change practice to improve the service. Pharmacists must ensure that this aspect of audit is addressed in any audit they initiate and undertake to assist in identifying problems in audit initiated by others.

2.5 Liaison to implement changes to improve practice As the purpose of audit is to ensure high standards of practice, a willingness to change practice is a vital pre-requisite of undertaking audit. Changes in practice may require liaison with a range of staff in primary care. Any education and training requirements to enable staff to implement changes in practice must be identified as part of the audit and met. Pharmacists should contribute to this education and training where appropriate. Where the aspect of care being audited involves secondary care, pharmacists should ensure they liaise with hospital pharmacists to ensure that changes in practice are complementary.

2.6 Re-audit to assess the impact of changes in practice If changes in practice have been implemented as result of audit, it is necessary to determine whether these changes have led to improvements in service and taken current practice up to the pre-set targets. Pharmacists should ensure that when changes in practice have occurred in any audit initiated by them, re-audit against the same targets is carried out. Where audit showed that services met targets, it may not be necessary to undertake re-audit, however in some circumstances where for example that targets set were low, it may be appropriate to implement changes to improve practice, increase the target level and re-audit.
3. Peer Review
The objective measures achieved by audit alone are limited for a profession and where complex areas such as professional judgement prevail, subjective measures such as peer review are required. Peer review is undertaken by members of the same profession as programmes of professional evaluation. The peer review process follows a sequence of steps which aim to test and develop individual competence. Peer review methods may also be used for consensus development, continuing education, case presentations and as part of the audit process.

4. Service Specifications
Service specifications are an important element in a quality system, they are a description of the range of services provided and the standards on which these services are based. Written specifications of the pharmaceutical service clarify the service for both the provider and user, and encourage professional identity and continuity. Specifications allow for negotiation in service development and expansion, standards to be developed, and the monitoring of the service, using a method such as audit.
"No scientific profession will acquire (or retain) the public recognition to which it aspires unless it proves able to make significant contributions to the advancement of science and technology. Such achievements have a direct effect upon its prestige, its image and its self-confidence."

Dr Joaquen Bonal
Former President of the European Society of Clinical Pharmacy

1. Introduction
As a scientific health care profession, of course, pharmacy also has a responsibility to improve patient care through the timeous application of scientific and technological advances within professional practice. Devising effective mechanisms for achieving this requires a strategy and active practice research and development programmes. Research into the professional practice of health care professions and health care systems is known as 'health services research' of which 'pharmacy practice research' (PPR) is an important component.

The Scottish Office Department of Health published its first "Research and Development Strategy for the NHS in Scotland" in 1993. Further guidance on supporting research and development in the NHS was provided by the NHS Circular MEL (1995) 3329 and the 'Research Capacity Strategy' 30 and 'Research and Development: Towards an evidence-based health service' 31, both published by the Department of Health in 1996. At the same time, the Royal Pharmaceutical Society of Great Britain published the report of its Pharmacy Practice Research and Development Task Force, entitled 'A New Age for Pharmacy Practice Research: Promoting Evidence-based Practice in Pharmacy' 32. Specifically addressing 'Research and Development in Primary Care', the NHS Executive published its National Working Group report in 1997. The current 'Research Strategy for the National Health Service in Scotland' was published by the Scottish Office Department of Health in 1998. Collectively, these documents examine strengths and weaknesses, promote an evidence-based culture and recommend strengthening research capacity in order to develop and maintain a multi-disciplinary workforce capable of delivering high quality research.

Much of the evidence required by primary care can only be obtained by research and development in primary care involving primary care practitioners and their patients. Whilst this requires the participation of pharmacists and other health care professionals as researchers, of equal importance is the need for their participation in studies investigating the services which they themselves provide. Thus all pharmacists should accept the need to subject their everyday practice to critical evidence-based review. They should also be aware of the potential and limitations of research in general, and in PPR and health and social care research in particular, such that they can assess the strengths and weaknesses of any relevant piece of
research. Leadership and educational support is required for both activities within community-based NHS pharmaceutical services.

2. What is Involved?
Research involves the systematic and objective collection and analysis of data to aid decision-making through the development and testing of hypotheses. Objectivity being a basic requirement, it is important that research is conducted in accordance with accepted principles. Those involved in undertaking research should be familiar with fundamental research methods and with the terminology relevant to their area(s) of study. A vital first stage in any research project is the statement of a research question that makes explicit the particular area of the investigation and the specific aspects that are to be covered. If phrased correctly, the research question should provide guidance in terms of the kinds of information needed and the ways in which it should be collected and analysed.

Clinical pharmacy practice research aims to improve patient care through the collection of information and testing of hypothesis to support decisions regarding the nature, extent and quality of pharmaceutical care. Areas suitable for research within clinical pharmacy generally are diverse and may be selected on the basis of characteristics of patients, medicines, pharmacists or services. To maximise benefits to patients and to the service, it is important that the results of research are widely disseminated.

3. Support for Research and Development
Locally, nationally and from within professional organisations there is considerable support for research. Formal training may be obtained through courses of study including those leading to postgraduate diplomas and degrees. Pharmacy Practice Groups represent a useful forum for developing and disseminating research principles and ideas; information on local Pharmacy Practice Groups can be obtained from the Chief Pharmacist, SODoH or from the National Specialists. Considerable experience and advice can also be obtained through approaching The Schools of Pharmacy or by attendance at professional meetings such as those organised locally and nationally by the Scottish Centre for Post Qualification Pharmaceutical Education, the Royal Pharmaceutical Society of Great Britain, the United Kingdom Clinical Pharmacy Association, the College of Pharmacy Practice and the Guild of Healthcare Pharmacists.

Financial assistance may be sought from a variety of sources. Locally, funding is periodically made available through Health Boards or NHS Trusts for research and/or development within primary or secondary care, or across the interface; further information can be sought through Chief Administrative Pharmaceutical Officers or Trust Chief Pharmacists.

The Royal Pharmaceutical Society of Great Britain offers research awards for practice research. The Chief Scientist's Office, SODoH supports health services research projects and also offers annual training research
fellowships. The College of Pharmacy Practice publish an annual Practice Research Diary which gives details of research awards.

Funding for service-led development in health care is also available from the National Health Service in Scotland Management Executive. Dedicated funds for Pharmacy Practice Research are available annually through the Chief Pharmacist, SODoH.

Finally, the question of ethical approval should be considered for any project which directly affects individual patients. Local ethical committees will advise on whether and how it should be sought.
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