Chapter 13

Pharmaceutical care

The concept of pharmaceutical care

Pharmaceutical care was probably first defined by Mikeal *et al.* in 1975 as '*the care that a given patient requires and receives, which assures safe and rational drug use*'.[1] Hepler, in 1988, described pharmaceutical care as '*a covenantal relationship between a patient and a practitioner in which the pharmacist performs drug use control functions governed by the awareness of and commitment to the patients' interest*'.[2] The term has caught the imagination of pharmacists and is frequently applied indiscriminately to describe pharmacy activities. The term 'patient-centred care' is gaining wider acceptance and is similar in principle.

Definition

The widely accepted definition by Hepler and Strand states '*Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life*'.[3] This definition built on earlier one describing pharmaceutical care as '*a practice in which the practitioner takes responsibility for a patients drug-related needs and is held accountable for this commitment*'.[4] Early in these debates, the issue of drug-related morbidity was seen as a major problem and, in part, led to the final definitions outlined here.

Pharmaceutical care differs from traditional drug treatment because it is an explicitly outcome-orientated cooperative systematic approach to providing drug therapy directed not only at clinical outcomes, but also at activities of daily life and other dimensions of health-related quality of life. Historically, pharmacists have used a variety of methods to improve drug therapy, including formularies, drug-use reviews, prescriber education, and clinical pharmacy, but these have all been drug or prescription focused.

Pharmaceutical care involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing, and maintaining a therapeutic plan that will produce specific outcomes for the patient. This, in turn, involves three major functions:

- identifying potential and actual drug-related problems
- resolving actual drug-related problems
- preventing drug-related problems.

1 Mikeal RL *et al.* (1975). Quality of pharmaceutical care in hospitals. *American Journal of Hospital Pharmacy* **32**: 567–74.
2 Hepler CD (1988). Unresolved issues in the future of pharmacy. *American Journal of Hospital Pharmacy* **45**: 1071–81.
3 Hepler CD, Strand LM (1990). Opportunities and responsibilities in pharmaceutical care. *American Journal of Hospital Pharmacy* **47**: 533–43.
4 Strand LM (1984). Re-visioning the professions. *Journal of the American Pharmacy Association* 100–258.

Core elements of pharmaceutical care

The pharmacist

- Collects and documents relevant information in a systematic, structured manner for the purpose of determining whether the patient is experiencing potential or actual drug-related problems.
- Identifies and lists the drug-related problems the patient is experiencing or is at risk of experiencing.
- Establishes and lists the desired therapeutic outcomes for each drug-related problem identified.
- Considers and ranks all the therapeutic interventions that might be expected to produce the desired therapeutic outcomes for each problem.
- Decides which therapeutic alternative to select and records the dosage regimen for each medication for each patient.
- Formulates and documents a pharmaco-therapeutic monitoring plan to verify that the drug-related decisions implemented have resulted in the outcomes desired and not in undesirable ADRs or toxicities.[1]

All must be in place for a comprehensive pharmaceutical care service. The only variable that affects the level of service is the patient's needs. This is assessed by determining the patient's risk factors. Patients who are considered at low risk might only require minimal intervention, whereas high-risk patients, by definition, require a higher level of pharmaceutical care.

Identifying risk in clinical practice

Risk factors fall into three distinct areas.

- Patients' clinical characteristics—these include physical and readily determined characteristics, such as age, gender, ethnicity, pregnancy status, immune status, kidney, liver and cardiac functions, nutritional status, and patient expectations.
- The patient's disease—some assessment of the rate and extent of harm caused by the disease and the patient's perception of these factors.
- The patient's pharmacotherapy—the risk is determined by an assessment of the toxicity of the drug therapy, the ADR profile, the route and techniques of administration, and the patient's perception of these three elements.

1 Strand LM (1991). Pharmaceutical care: challenge of implementation. *ASHP Annual Meeting* **48**: PI–28.

Medication problem checklist

The following list covers the range of potential medication problems that could be encountered by pharmacists seeking to deliver pharmaceutical care.

- Medications without medical indications.
- Medical conditions for which no medications are prescribed.
- Medications prescribed inappropriately for a particular medical condition.
- Inappropriate medication dose, dosage form, schedule, route of administration, or method of administration.
- Therapeutic duplication.
- Prescribing of medications to which the patient is allergic.
- Actual and potential ADRs.
- Actual and potential adverse clinically significant drug–drug, drug–disease, drug–nutrient, and drug–laboratory test interactions.
- Interference with medical therapy by social or recreational drug use.
- Failure to receive the full benefit of prescribed medication therapy.
- Problems arising from the financial impact of medication therapy on the patient.
- Lack of understanding of the medication therapy by the patient.
- Failure of the patient to adhere to the medication regimen.

There have been a number of attempts to formulate these problems into an easily remembered checklist. One of these is called PRIME, which is an acronym for Pharmaceutical Risks to patients, Interventions Mismatch between medications and indications, and Efficiency issues (Table 13.1). The key message behind these detailed checklists is that pharmacists must move from a prescription focus to a patient focus.

Table 13.1 PRIME pharmacotherapy problem types

Pharmaceutical—assess for incorrect factors, as follows

- Dosage
- Form
- Route
- Timing
- Duration
- Frequency.

Risks to patients—assess for risks, as follows

- Known contraindication
- Medication allergy
- Drug-induced problem
- Improper use (i.e. risk if misused)
- Common/serious ADRs
- Medication error considerations.

Interactions—assess for the following:

- Drug–drug
- Drug–disease/condition
- Drug–food
- Drug–laboratory test

Mismatch between medications and indications/conditions—assess for the following

- Medication used without indication
- Indications/condition untreated.

Efficacy issues—assess for the following

- Suboptimal selection of pharmacotherapy for indications
- Minimal or no evidence of therapeutic effectiveness
- Suboptimal pharmacotherapy (taking/receiving medications incorrectly)—e.g. patient preference considerations (undesirable prior experiences with medications or does not believe it works)
- Medications availability considerations (e.g. no access to medications)
- Compliance/administration considerations (e.g. inability to pay or unable to administer correctly or at all).

Pharmaceutical care economics

Clinical pharmacy services can be perceived as expensive by hospital managers. The reality is that clinical pharmacy can significantly improve patient outcomes and ↓ drug budgets. The following data are presented as a sample of what is available in the wider pharmacy literature and can be used to improve facilities and funding.

Clinical pharmacy interventions ↓ costs. In a large annual pharmacy staff survey, Bond[1] showed that each whole-time pharmacist ↓ the drug budget by approximately US $22 000 per hospital and that each US dollar spent on a pharmacist resulted in savings of just under US $50 in the drug budget. The same survey, in a different report,[2] also showed that although there was no association between number of medical staff and hospital mortality rates, pharmacists were one group demonstrating ↓ mortality rates as staffing levels ↑. The authors were unable to identify reasons for this finding but surmised that preventing adverse events could be significant. In yet another report on the same data the authors claim that hospitals that provide the services outlined in Table 13.2 within their pharmacy are associated with a reduction in deaths.

An Australian trial on fee for service[3] demonstrated savings in the intervention group. This was a randomized controlled trial of four parallel groups of community pharmacies conducted in 1996. The numbers in each group are small, but the authors claim that it was based on sufficient differences in intervention rates. The basic education covered drug information, attendance on hospital-ward rounds, basic therapeutics, and problem-solving. The advanced course included a weekend university-based course, covering complex medication reviews, attendance on ward rounds, advanced therapeutics, multiple coexisting disease states, and problem-solving. The cost was A$1500 per person.

Outcomes were based on cost savings or healthcare costs avoided based on healthcare costs, increased charges in medication costs, pharmacy times, and telephone calls. The savings were as follows (except in group D which showed an ↑ in costs).

• Group C	Professional fee + advanced education	$85/1000 prescriptions
• Group B	Professional fee + basic education	$26/1000 prescriptions
• Group A	No fee or education	$14/1000 prescriptions
• Group D	Professional fee + no education	$1/1000 prescriptions

The study is particularly interesting because a fee for services alone did not ↓ costs; the most effective contribution was a fee plus advanced education.

1 Bond CA *et al.* (1999). Clinical pharmacy services, pharmacist staffing, and drug costs in United States hospitals. *Pharmacotherapy* **19(12)**: 1354–62.
2 Bond CA *et al.* (1999). Health care professional staffing; hospital characteristics and hospital mortality rates. *Pharmacotherapy* **19**: 130–8.
3 Benrimoj SI *et al.* (2000). Economic impact of increased clinical intervention rated in community pharmacy. *Pharmacoeconomics* **18**: 459–68.

Table 13.2 Impact of pharamaceutical care on hospital deaths: reduction in mortality

Service	Reduction in mortality
Clinical research service	195 deaths/hospital/year
DI services	41 deaths/hospital/year
Drug-administration histories	128 deaths/hospital/year
Pharmacist on CPR team	18 deaths/hospital/year

Staffing

This information is provided to help clinical pharmacists make a case for establishing additional clinical services. There is good evidence that ↑ clinical pharmacy time has a major positive affect on budgets.

Work by Bond and Raehl[1,2] was referred to in the monograph on pharmaceutical care.[3] These authors have been responsible for regular useful publications in the USA. Bond and Raehl are based at the Texas Tech University Health Services Centre. Although the work is hospital-based, it does give an indication of the investment being made. The National Clinical Pharmacy Services study is seen as the largest hospital-based pharmacy database in the USA. The work involved a postal questionnaire to >3500 acute care hospitals with >50 beds. The percentages of patients receiving clinical pharmacy services was calculated for each hospital during a 10 year period from 1989 to 1998. Pharmacist numbers ↑ by 23%, pharmacy technician numbers ↑ by 43%, and pharmacy clerk numbers ↑ by 25%. This is in contrast with a rise in total hospital personnel of 55%. This represented an ↑ from 4.2(92.6) pharmacists per 100 occupied beds to 5.35(±2.7) pharmacists per 100 occupied beds in 1995—an ↑ of 5% per annum.[4]

Although 71% of hospitals surveyed stated that pharmacists had the authority to document pharmaceutical care in patient's notes, in practice this only happens in 31% of hospitals. When the levels of pharmaceutical care were analysed according to the training of the hospital, it was found that 64% of hospitals training PharmD students provided pharmaceutical care, which fell to 42% of hospitals who trained graduates and 33% of non-pharmacy-teaching hospitals.[5] By 1998, 52% of hospitals provided some level of pharmaceutical care and time spent had ↑ to a mean of 25min/patient/day.[3]

The authors analysed the total cost of care in relation to clinical pharmacy services for earlier (1992) data in a population of 1016 hospitals. Although the study was designed to show relationships rather than cause and effect, there is a strong hint that establishing additional clinical pharmacists is associated with ↓ total care cost; conversely, an ↑ in the number of dispensing pharmacists is associated with ↑ total cost of care.

1 Bond CA *et al.* (1999). Clinical pharmacy services, pharmacist staffing, and drug costs in United States Hospitals. *Pharmacotherapy* **19**: 1354–62.
2 Bond CA *et al.* (1999). Health care professional staffing, hospital characteristics and hospital mortality rates. *Pharmacotherapy* **19**: 130–8.
3 Raehl CL, Bond CA (2000). (1998). National Clinical Pharmacy Services Study. *Pharmacotherapy* **20**: 436–60.
4 Bond CA *et al.* (1999). Staffing and the cost of clinical and hospital pharmacy service in United States hospitals. *Pharmacotherapy* **19**: 767–81.
5 Raehl CL *et al.* (1998). Clinical pharmacy services in hospital educating pharmacy students. *Pharmacotheraphy* **18**: 1093–102.

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Standards for research

Pharmaceutical care is an obvious research area for pharmacists, but many of the publications in this area have been of poor quality. Two checklists are presented here in to aid those who read pharmaceutical care literature and those who undertake research into pharmaceutical care.

A review of pharmaceutical care by Kennie *et al*[1]. led to the authors to make 15 recommendations which are aimed at improving the quality of further research:

- Pharmacists must exercise discipline when using the term 'pharmaceutical care'.
- Database systems should take measures to ensure that pharmaceutical care research literature can be correctly and easily extracted.
- A standard reporting method should be adopted that clearly describes the pharmaceutical care process in the research methodology.
- Randomized controlled studies should be conducted to measure the affect of the provision of pharmaceutical care.
- Pharmaceutical care research should contain a clear description of the pharmacy practice setting and patient demographics.
- Consistent methods for data collection for different practice sites should be created and validated.
- Informed consent should be obtained for all patients involved in pharmaceutical research, and the procedure should be stated.
- A pharmacist's qualifications and/or certification in providing pharmaceutical care should be addressed and described.
- Pharmaceutical care research should not only emphasize the evaluation of patient outcomes, but must also first evaluate the structures that exist for the provision of pharmaceutical care.
- The three aspects of evaluation (i.e. structure, process, and outcome) should be linked when assessing the quality of pharmaceutical care.
- The economic impact of pharmaceutical care should be evaluated.
- Standards for pharmaceutical care research should be developed and accepted by the profession.
- Further pharmaceutical care research needs to be conducted, with an emphasis on community-based pharmacy.
- A pharmaceutical care research network should be developed to co-ordinate efforts and identify areas where research is required.
- Research should be conducted to determine the feasibility and extent of implementation of pharmaceutical care in various practice sites.

The authors concluded that few studies have evaluated the provision of pharmaceutical care in a defined population, and that the volume of research is painfully low.

1 Kennie NR *et al.* (1998). Critical analysis of the pharmaceutical care research literature. *Annals of Pharmacotherapy* **32**: 17–26.

Plumridge *et al.*[2] stated that research into patient perceptions and the patient–pharmacist relationship are needed, because these are critical success factors for pharmaceutical care. Patient understanding and involvement in the process are essential. Furthermore, reliable information is required about patients' willingness to pay for pharmaceutical care. Currently, a dilemma exists because pharmacists want to charge for services but cannot demonstrate improvements on clinical, economic, or quality-of-life outcomes.

When research is undertaken, the pharmaceutical care process used should be such that the study results can be critically analysed and the process replicated as necessary.

The authors made 13 recommendations for future research, which overlap with the previous list but are worth reproducing here.

- The paucity of published studies on the economic value of pharmaceutical care reinforces the requirement for additional well-conducted research in appropriate practice settings to address the high cost of drug-related morbidity and mortality. Descriptive reports, or inadequately conducted studies of the pharmaceutical care process do little to advance our present knowledge.
- Studies should use, and be refereed on, the correct definition of pharmaceutical care. If this is not done, the confusion that already exists with other pharmaceutical interventions will be exacerbated.
- The quality of pharmaceutical care requires the development of systems for documenting delivery processes and outcomes. Systems for documenting patient satisfaction are also required.
- Variable study design and lack of standardization in reporting causes difficulties in comparing study results. Uniformity is desirable for comparative purposes and to enable valid conclusions to be made.
- Comparative groups must be more fully described and consistent with intervention groups. Patients should be randomized.
- Evidence that external factors affecting outcomes have been controlled is desirable.
- Practice settings should be fully described to enable readers to understand the processes used, facilitate replication, and further develop future pharmaceutical care practice.
- All relevant direct and indirect costs should be considered. When this is achieved, attempts to use appropriate pharmacoeconomic methods (e.g. cost-effectiveness and cost–benefit analyses) can be considered. These will probably require specialist expertise.
- Structure and process should be described and appropriate outcome measures used. Process measures, intermediate outcomes indicators, and outcomes need to be correctly identified because these terms are often confused by researchers. If feasible, the link between structure, process, and outcomes should be evaluated.
- Outcomes must be identified in terms of the feasible effect of pharmaceutical care because certain outcomes can present difficulty in measurement (e.g. outcomes requiring years to observe, such as the treatment of osteoporosis).

2 Plumridge RJ, Wojnar Horton RE (1998). A review of the pharmacoeconomics of pharmaceutical care. *Pharmacoeconomics* **14**: 175–89.

- Research is needed to determine the value that specific interventions have on health outcomes so that effect is optimized. This includes identifying structures and processes that improve specific health outcomes and the types of outcomes that are most effected by pharmaceutical care programmes.
- Each study should attempt to address relevant pharmacoeconomic parameters, including clinical, economic, and quality of life.
- The potential for assessing opportunity costs, especially because healthcare resources are in cost-containment mode, should be considered. This is important in determining the best way of implementing pharmaceutical care as practice is evolving.

Chapter 14

Medicines management

Medicines management

Medicines management is made up of two components:
- clinical and cost-effective use of medicines
- safe and secure handling of medicines.

Each hospital should have a strategic plan for medicines management which reflects the following.
- The strategic direction for the local health economy.
- Priorities of the local population.
- Targets relating to NSFs and implementation of National Institute for Health and Clinical Excellence (NICE) guidance.
- Communication strategy for the dissemination of information.

Hospitals should ensure that the following systems are in place to ensure effective medicines management.
- Drug and therapeutics committee (or equivalent).
- Targeting clinical pharmacy activity to patients requiring early assessment following hospital admission.
- Patients should ideally have a complete DHx review within 24h of hospital admission.
- Acute medical admissions should be prioritized and, if possible, seen by a pharmacist.
- PODs should be used if they have been reviewed and considered suitable for continued use.
- As appropriate, all patients should be given the option of self-administering their own medicines while in hospital.
- Dispensing for discharge (or one-stop dispensing) systems should be in place to ensure that patients receive their discharge medication in sufficient quantity and in a timely manner, with the appropriate patient information leaflet.

The multidisciplinary team should be trained on medicines management.
- All doctors, nurses, pharmacists, and other relevant healthcare professionals should receive training on medicines management as part of their induction programme, including the legislative and GCP aspects of controls assurance (in particular, the safe and secure handling of medicines) and clinical and cost-effective use of medicines.
- Medicines management systems and policies should be incorporated into ongoing clinical training programmes.
- Information technology system support should be available to provide healthcare staff with accurate information on the use of medicines.
- The risk of medication errors occurring should be minimized.

Medicines management policies and procedures should be in place to minimize the risk of medication errors occurring during the medication process, i.e. for prescribing, dispensing, and administration.

Further reading

Department of Health (2003). *A Vision for Pharmacy in the New NHS*. London: Department of Health.
Audit Commission (2001). *A Spoonful of Sugar*. London: Audit Commission.
Smith J (2004). *Building a Safer NHS for Patients: Improving Medication Safety*. London: Department of Health.
Nursing & Midwifery Council (2010). *Standards for Medicines Management*. http://www.nmc-uk.org/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf
National Prescribing Centre. *Medicines Management*. http://www.npc.co.uk
National Prescribing Centre (2008). *Moving Towards Personalising Medicines Management: Improving Outcomes for People through the Safe and Effective use of medicines*. www.npc.nhs.uk/resources/personalising_medicines_management_web.pdf

Evaluating new drugs

New drugs appear on the market all the time and healthcare professionals are constantly bombarded with promotional material from the pharmaceutical industry. The pharmaceutical industry's business is to sell drugs—otherwise it would not survive—but promotional material should be reviewed with a critical eye.

Just because a drug has received regulatory approval, does not necessarily mean that it is a clinically significant advance, because regulatory authorities evaluate quality, safety, and efficacy, not therapeutic value. Assessments of the value of new drugs from Canada, France, and the USA have shown that, at best, only one-third offer some additional clinical benefit and as few as 3% are a major therapeutic advance.[1]

Premarketing trials are often placebo controlled, so they don't give comparative data. Ideally, the trial should compare the new drug with an established reference treatment. Even if the trial compares the new drug with a reference treatment, it might be too small or too short to provide meaningful data—in particular, rare ADRs or differences in response in subgroups of patients are unlikely to be identified.

Much of the data presented by the pharmaceutical industry is disease-orientated rather than patient-orientated, and this can make a difference to the patient outcome. For example, disease-orientated evidence (DOE) demonstrates that cyclo-oxygenase 2 NSAIDs cause fewer endoscopically detected ulcers than standard NSAIDs. However, many of these ulcers would not be clinically significant. A more relevant evaluation is to determine the difference between cyclo-oxygenase 2 NSAIDs and standard NSAIDs in causing symptomatic or bleeding ulcers. This latter approach is known as 'patient-orientated evidence that matters' (POEM) and is more relevant to clinical practice.

The STEPS acronym is a useful tool for evaluating new drugs.[2]

- **S**afety—evaluate the safety of the new drug versus a standard reference preparation, ideally using comparison studies that reflect the real-life situation. Pharmaceutical companies often highlight differences in ADRs that are relatively trivial or rare. Check especially for ADRs that would place the patient at particular risk, notably the following:
  - liver, kidney, or bone marrow toxicity
  - cardiovascular events
  - CNS events (e.g. fits)
  - significant skin or hypersensitivity reactions (e.g. Stevens–Johnson syndrome)
  - GI bleeding
  - congenital abnormalities.

1 Lexchin J (2004). Are new drugs as good as they claim to be? *Australian Prescriber* **27**: 2–3.
2 Preskorn SH (1994). Antidepressant drug selection: criteria and options. *Journal of Clinical Psychiatry* **55**(suppl A): 6–22, 23–4, 98–100.

Look at the frequency of these events versus the significance of the disease. A 5% risk of hepatotoxicity in a life-threatening disease is a more acceptable level of risk than if the disease is self-limiting.

- **T**olerability—are side effects likely to affect adherence? Look at drop-out rates in clinical trials. If there is a high drop-out rate because of ADRs versus the reference drug, this makes the new drug of less therapeutic value. If patients don't take the drug, it won't work!
- **E**ffectiveness—look at head-to-head trials of the new drug versus the reference drug, rather than comparing different trials. Ask 'Does this new drug work as well or better than the reference drug?'. The NNT is the best way of assessing therapeutic value. If the NNT of the new drug is the same or lower than the reference drug, it is worth considering.
- **P**rice—consider all the costs associated with the new drug versus the reference, not just the purchase price. This might include the following:
  - administration cost (e.g. IV giving sets)
  - monitoring costs
  - additional time/travel if patient has to attend more frequently at the start of therapy
- **S**implicity of use—is it relatively easy for the patient to use the drug? This includes considering the following:
  - dosage schedule
  - number of tablets
  - liquid versus tablets
  - parenteral versus enteral administration
  - special storage requirements (e.g. refrigeration).

WHO criteria for drug selection are listed in Table 14.1.

Table 14.1 WHO criteria for drug selection[1]

- On the WHO essential drug list
- Relevance to pattern of prevalent disease
- Proven efficacy and safety
- Evidence of performance in different settings
- Adequate quality, bioavailability, and safety.
- Favourable cost–benefit ratio, in terms of total treatment cost
- Preference for drugs that are well known or familiar to use and locally manufactured
- Single compounds

[1] World Health Organization (1988). *How to Develop and Implement a National Drug Policy*. (2nd edn). http://whqlibdoc.who.int/publications/924154547X.pdf.

How to write a drug protocol

Drug protocols are evidence-based documents that specify the indications for which a drug treatment can be prescribed within defined clinical settings. They help to ensure that drugs are used cost effectively and safely within the clinical setting.

The need for a drug protocol is usually highlighted for an area by the multidisciplinary team. Initially, the evidence base must be established. Literature searches, protocols from other hospitals or institutions, and information on local practice are used as the basis for the protocol.

Ensure that local practice is followed to implement new drug protocols. This might include approval by a hospital or primary care committee, such as a drugs and therapeutics or formulary committee.

A drug protocol should include the following.

- Drug name—international approved name and trade name.
- Formulation.
- Dose.
- Frequency of administration.
- Administration details.
- Side effects and their treatment.
- Dose reductions required for changes in organ function—e.g. impaired renal or liver function.
- Drug interactions.
- Indications for use.
- Place in therapy—e.g. if another option should be tried first (especially if use is restricted).
- Restrictions of use.
- Cost.
- References.

Stages of protocol development

Identification of need

A new or existing practice is recognized as being cumbersome, unsafe, or otherwise in need of revision. For example, a new use for a drug is developed that requires compounding in a specific way, additional monitoring, and adjunctive medication therapy. It has begun use with these orders written in longhand, but the inconsistency of this practice and increased likelihood of error make clear the need for a pre-written protocol.

Assignment of responsibility

A leader should be identified for the project. Although a group may be responsible for the final form, projects such as this typically require a leader who is responsible for moving the work along.

Gathering evidence and best practice

The leader and group obtain other similar protocols and enquire about their strengths and weaknesses. Other departments that will be affected by the protocol or whose work contributes to the project should be contacted with questions, although they may not need to sit on the committee. Literature searches are made to collect current evidence and best practices. These data should be reviewed and vetted, and the most useful results distributed to those working on the project, if applicable.

Draft compilation

After reviewing the available evidence, the leader or committee drafts a protocol. The protocol should be reviewed and revised by the committee or its writer until no major flaws remain. At times, substantive decisions must be delayed until the protocol can be reviewed by the next committee, or committee members from the next committee may be asked their opinion so that the protocol-drafting group can deliver a better result. After the draft has been rewritten and edited, the protocol is submitted to the appropriate hospital committee. After review by this committee, the protocol should assume a final or near-final form.

Education and roll-out

The completed protocol is often submitted to an education department to gain their expertise in training staff members. The date to begin using the protocol may also be set according to the time it will take for staff to be educated. It is important to remember that implementation of a protocol may need to be delayed after its approval if staff education is required. Staff members should be allowed to have the opportunity to familiarize themselves with a protocol before being expected to act on it.

It is imperative that pharmacists are able to review a protocol during its development. The protocol should be reviewed with great scrutiny because it will be used many times. A protocol containing drugs or focused on drug therapy should be reviewed for the following details.

- Generic and trade names for each drug, with emphasis on the generic name.
- Correct route, dose, and frequency for each medication.
- Frequency of administration.
- Dilution instructions for each drug present.
- All ambiguous statements clarified.
- Contraindications or reasons not to use drugs prominently placed.

Limitations

A protocol may not be made to deal with every eventuality. Rather, a well-designed protocol will succinctly provide a framework for dealing with a particular set of circumstances. Patients will inevitably fall outside these circumstances; thus a protocol should be developed with these limitations in mind so that it does not become inappropriately complex.[1]

1 American Society of Health-System Pharmacists (US). *Best Practices for Hospital and Health System Pharmacy 2011–2012.* http://store.ashp.org/Default.aspx?TabId=216&ProductId=22953360

Unlicensed use of medicines

- The product licence of a medication defines the therapeutic purpose for which the product can be used.
- Unlicensed medicines have not been formally assessed through the licensing process for safety, quality, and efficacy. The risks associated with their use might not have been evaluated. Some unlicensed medicines may have been fully evaluated and licensed in another country, but not in the country of use.
- If a prescriber uses a licensed medicine for an unlicensed indication, this is outside its product licence and is sometimes referred to as 'off licence' or 'off label'.
- The same principles apply to unlicensed medicines as to licensed medicines used for unlicensed indications, e.g. in paediatrics (see 📖 'Medicines for children', p.210).
- Medicines that are not covered by a product license include the following.
  - Medicines prepared by a manufacturer but not on sale in this country. A specialist importer with the appropriate importing licenses can obtain these.
  - Medicines prepared for a specified patient in accordance with a prescriber's instructions. This includes any form of extemporaneous dispensing.
  - Unlicensed medicines obtained from a hospital or a commercial supplier with a special manufacturing license. These medicines are often known as 'specials'.
  - Repacked medicines—the product license regulates the container in which a medicine is sold. If a medicine is removed from its original container and repacked, it technically becomes an unlicensed product.
- Implications for the prescriber, pharmacist and nurses of prescribing, dispensing, and administering unlicensed medicines are as follows.
  - Prescribers need to be aware of the license status of medicines they prescribe. The responsibility of prescribing unlicensed medicines lies with the prescriber. The manufacturer takes no responsibility for any safety or efficacy of unlicensed medicines.
  - A pharmacist shares the responsibility with the prescriber, as the product purchaser, or if the pharmacist's actions or omissions have contributed to any harm.
  - Pharmacists should ensure that the prescriber is aware that they are prescribing an unlicensed drug, or a drug outside its license.
  - Nurses are responsible for administering medication that is administered outside of its license and must ensure that the relevant hospital or institution policies have been adhered to.
- A hospital or institution should have a clear written policy for the 'use of unlicensed medicines', outlining the responsibilities of all those involved in the prescribing, purchase, supply, and administration of this category of medicines. It should be a summary document, supported by standard operating procedures and making reference to existing

documents and sources of information. The drugs and therapeutics committee, or equivalent, should approve this.

The use of unlicensed medicines in a hospital or institution needs to be controlled and monitored. A risk assessment should be undertaken before an unlicensed medicine, or medicine outside its license, is prescribed. This is often done through the drugs and therapeutics committee, or equivalent.

- Written notification, signed by the prescriber and returned to the pharmacy department, is usually used. This usually includes the patient details, the name of the product and its specification, the reason for using an unlicensed medicine, and the prescriber's name and signature. The manufacturer, date ordered, quantity ordered, and batch number received are usually recorded in the pharmacy department. Check what documentation is used in your local hospital or institution.
- Some hospitals or institutions require that informed consent is obtained from patients for some unlicensed medicines to be supplied (e.g. thalidomide).
- Prescribing a medicine by a route for which it is not licensed is unlicensed but is often 'accepted practice' (e.g. subcutaneous cyclizine).

Further reading

Department of Health (2003). *A Vision for Pharmacy in the New NHS*. London: Department of Health.

Parkinson R *et al.* (2004). *Guidance for the Purchase and Supply of Unlicensed Medicinal Products: Notes for Prescribers and Pharmacists* (3rd edn). NHS Pharmaceutical Quality Assurance Committee.

Royal Pharmaceutical Society of Great Britain (2007). *Legal and Ethical Advisory Service Fact Sheet: Five. The Use of Unlicensed Medicines in Pharmacy*. http://www.rpharms.com/archive-documents/factsheet5.pdf

Medicines and Healthcare Products Regulatory Agency (MHRA). (2010) *Review of Unlicensed Medicines*. http://www.mhra.gov.uk/Howweregulate/Medicines/Reviewofunlicensedmedicines/index.htm

NHS Choices (2009). *Why are medicines licensed by the MHRA?* http://www.nhs.uk/chq/Pages/1004.aspx?CategoryID=73&SubCategoryID=101

Drug and therapeutics committees

Each hospital has a drug and therapeutics committee, or an equivalent committee. This committee is responsible for ensuring that the introduction of new drugs to the hospital formulary is cost-effective, safe, and has an acceptable evidence base. Before new drugs are bought by the pharmacy department and used in the hospital, they need to be approved by the drug and therapeutics committee using the principles of EBM. The ↑ cost of new drugs being licensed causes financial pressures on hospitals, which leads to some prioritization of drugs available for use.

Generally, the membership of a drug and therapeutics committee comprises representatives from the following disciplines.

- Medical staff—including medical director, surgeon, anaesthetist, clinical pharmacologist, and paediatrician.
- Nurse (chief nurse or nominee).
- Pharmacist—chief pharmacist and medicines management/formulary pharmacist.
- Finance (director or nominee).
- Commissioner.
- Primary care prescribing lead.
- Specialists—e.g. paediatrics, oncology, or clinical pharmacology.
- Public health.
- Medical microbiologist.
- Patient representative/lay member.
- Management.
- Administration.
- Executive board member (if not one of the disciplines already listed).
- Other members are co-opted, as needed.

The drug and therapeutics committee should have terms of reference and a membership list. There may be subcommittees, to whom decision-making may be devolved for some specialist areas (e.g. antimicrobials), which are responsible to the drug and therapeutics committee. In addition to making decisions on the introduction of new medicines into a hospital according to assessment of the clinical evidence, a drug and therapeutics committee can also have a role in the following areas.

- Maintenance and updating of a hospital formulary.
- Review of medicines expenditure.
- Horizon scanning of medicines to be licensed or those with national approval.
- Prioritization of new drugs.
- Overseeing safe medication practice systems, including maintaining policies and procedures for medicines, overseeing education and training for safe medication practice, and analysing medication error incident reports.

Evidence that is used by drug and therapeutics committees includes the following.

- Results of clinical trials.
- Scientific evidence.
- Cost-effectiveness.
- Safety.
- Effect of adopting a new drug.
- Pre-existing prescribing.
- Decisions of drug and therapeutics committees in other hospitals.
- Restrictions of use of a new drug.

Drug and therapeutics committees should meet regularly (monthly or bimonthly). Decisions made at the committee meetings are made available through minutes, newsletters, e-mail, or intranets.

Further reading

Fullerton DS, Atherly DS (2004). Formularies, therapeutics, and outcomes: new opportunities. *Medical Care* **42**(4 Suppl): III39–44.

Jenkings KN, Barber N (2004). What constitutes evidence in hospital new drug decision making? *Social Science Medicine* **58**:1757–66.

Martin DK *et al.* (2003). Priority setting in a hospital drug formulary: a qualitative case study and evaluation. *Health Policy* **66**: 295–303.

Schumock GT *et al.* (2004). Factors that influence prescribing decisions. *Annals of Pharmacotherapy* **38**: 557–62.

Department of Health. *A Vision for Pharmacy in the New NHS* (2003). London: Department of Health (℔ http://www.dh.gov.uk).

Patient group directions (PGDs)

Definition

- Written instruction for the sale, supply, and/or administration of a named medicine for a defined clinical condition.
- PGDs allow a range of specified healthcare professionals to supply and/or administer medicines, including PODs, directly to a patient with an identified clinical condition, without them necessarily seeing a prescriber. The healthcare professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD.
- Implementing PGDs might be appropriate both in circumstances where groups of patients might not have been previously identified (e.g. minor injuries and first-contact services) and in services where assessment and treatment follow a clearly predictable pattern (e.g. immunization and family planning).
- In general, a PGD is not meant to be a long-term means of managing a patient's clinical condition. This is best achieved by a healthcare professional prescribing for an individual patient on a one-to-one basis.
- Legal requirements and guidance on PGDs are set out in the circular HSC 2000/026.

Health professionals allowed to use PGDs

- Nurses
- Midwives
- Health visitors
- Optometrists
- Pharmacists
- Chiropodists
- Radiographers
- Orthoptists
- Physiotherapists
- Ambulance paramedics.

The pharmacist's role in PGDs

- Apart from developing practice using a PGD, pharmacists are expected to be involved in various aspects of PGDs.
- Development of a PGD for other healthcare professionals.
- Responsibility to ensure that only fully competent, qualified, and trained professionals operate within PGDs.
- Organization of arrangements for the security, storage, and labelling of PGD medicines. Such medicines would normally be expected to be supplied pre-packaged and robust reconciliation system for stock use is established.
- Checking that the use of the medicine outlined in a specific PGD is consistent with the summary of product characteristics, although off-licence use could be considered in exceptional circumstances, provided that it is justified by current best clinical practice.

Further reading

A Practical Guide and Framework of Competencies for All Professionals Using Patient Group Directions. http://www.npc.nhs.uk/non_medical/resources/patient_group_directions.pdf

National Electronic Library for Medicines. *Patient Group Directions (PGDs).* http://www.nelm.nhs.uk/en/Communities/NeLM/PGD

Department of Health website (UK) (http://www.dh.gov.uk) has PGDs for drugs and chemical and biological counter-measures.

Supplementary prescribing

Pharmacists in the UK can train to become supplementary and/or independent prescribers. It is mandatory that specific supplementary and/or independent prescribing training is undertaken at a designated university, followed by a period of supervised practice. Supplementary prescribing is detailed here. For independent prescribing see 📖 p.272.

Definition

Supplementary prescribing is a '*voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan with the patient's agreement*'.

There are some key principles that underpin supplementary prescribing. These principles emphasize the importance of the prescribing partners. The prescribing partners include the independent prescriber, the supplementary prescriber, and the patient.

- The independent prescriber is responsible for the assessment and diagnosis of patients, and deciding on the clinical management required, which includes prescribing.
- The supplementary prescriber is responsible for prescribing for patients who have been clinically assessed by the independent prescriber according to an agreed patient-specific clinical management plan.
- The patient must be treated as a partner in their care and be involved at all stages of decision-making, including the decision for part of their care to be delivered by supplementary prescribing.

The criteria that are set in regulations for lawful supplementary prescribing include the following.

- The independent prescriber must be a doctor (or dentist).
- The supplementary prescriber must be a registered nurse, midwife, pharmacist, or other healthcare professional (e.g. podiatrist, physiotherapist, optometrist).
- The patient must be involved in the decision for a supplementary prescriber to be involved in their care. The patient must be provided with written information, and informed consent must be obtained from the patient before supplementary prescribing starts.
- There must be a written clinical management plan relating to a named patient and to that patient's specific conditions. Both the independent and supplementary prescribers must record agreement to the plan before supplementary prescribing begins.
- The independent and supplementary prescribers must share access to, consult, and use the same common patient record.

There are no legal restrictions on the clinical conditions that supplementary prescribers can treat, and there is no specific formulary or list of medicines for supplementary prescribing. The independent and supplementary prescribers decide when supplementary prescribing is appropriate and when the clinical management plan is drawn up (Fig. 14.1). The medicines to be prescribed by the supplementary prescriber must be prescribed by an independent prescriber at NHS expense and referred to in the patient's clinical management plan. Some of the areas where supplementary prescribing might be of most benefit include the treatment of long-term medical conditions, such as asthma, coronary heart disease, or patients requiring anticoagulation.

Supplementary prescribers are able to prescribe the following

- All general sales list (GSL), pharmacy medicines, appliances and devices, foods, and other borderline substances approved by the advisory committee on borderline substances.
- All POMs.
- Controlled drugs.
- Medicines for use outside their licensed indications (i.e. 'off-label' prescribing), 'black-triangle' drugs, and drugs marked 'less suitable for prescribing' in the *BNF*.
- Unlicensed drugs that are part of a clinical trial which has a clinical trial authorization.

Benefits of supplementary prescribing include the following:

- Quicker access to medicines for patients.
- ↑ efficiency.
- ↓ in doctor's workload.
- Improved use of skill mix.

The supplementary prescriber should not be required to enter into a prescribing partnership that entails them prescribing any medicine that they do not feel competent to prescribe. It is recommended that supplementary prescribers prescribe generically if possible, except where this would not be clinically appropriate or if there is no approved generic name.

Further reading

Department of Health. *Supplementary Prescribing* http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/TheNon-MedicalPrescribingProgramme/Supplementaryprescribing/index.htm

Hospital name and department
Clinical management plan

Name of patient:
Patient medication sensitivities/allergies:
Patient identification (e.g. ID number or, date of birth):
Independent prescriber(s): Name and profession
Supplementary prescriber(s): Name and profession

Condition(s) to be treated:

Might be specific indications or broader terms and might also include treating side effects of specified drugs/classes of drug (e.g. treatment of HIV and related opportunistic infections/complications or treatment of side effects of antiretrovirals and other drugs used in treatment of HIV).

Aim of treatment:

Medicines that could be prescribed by supplementary prescriber:

Preparation
Drug names and preparations
Can also be drug classes (e.g. antiretrovirals)
Indication—does not have to be very specific
Dose schedule—does not have to be very specific (e.g. could say 'as *BNF*')

Specific indications for referral back to the independent prescriber:

Guidelines or protocols supporting the clinical management plan:

Frequency of review and monitoring by:

Supplementary prescriber

Supplementary prescriber and independent prescriber

Process for reporting ADRs:

Shared record to be used by independent prescriber and supplementary prescriber:

Agreed by independent prescriber(s): (signature and name)

Agreed by supplementary prescriber(s): (signature and name)

Date agreed with patient/carer:

Fig. 14.1 Example of a clinical management plan for supplementary prescribers.

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Independent prescribing

Pharmacists in the UK can train to become independent prescribers when they are registered pharmacists, have at least 2 years experience practising as a clinical pharmacist, and have completed an independent prescribing education and training programme, which includes a period of supervised practice. Independent prescribing is detailed here. For supplementary prescribing see 📖 p.268.

The Department of Health defines independent prescribing as '*prescribing by a practitioner (e.g. doctor, dentist, nurse, pharmacist) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing*'.[1]

The practitioner is required to assess the patient, interpret the assessment, and make a decision on the appropriate therapy including safety and a process for monitoring. Independent prescribing usually takes place as part of a multidisciplinary team using a single healthcare record, and the practitioner is accountable for their prescribing. Patients need to be informed that a non-medical practitioner is prescribing their medicine and give their consent. The pharmacist prescriber must ensure that their prescriptions are checked and dispensed by another pharmacist, in accordance with local clinical governance procedures that are in place for all prescribers.

Pharmacists are able to prescribe any licensed or unlicensed medicine for any medical condition for which they are competent and experienced to prescribe independently. At the time of publication the exceptions to this are that pharmacists are unable to prescribe controlled drugs independently. Pharmacists are able to prescribe licensed medicines for unlicensed indications, i.e. 'off label', independently if it is accepted clinical practice and supported by a local policy. Pharmacist prescribing must be in accordance with the RPSGB's *Medicines, Ethics and Practice—A Guide for Pharmacists*. Pharmacists are required to demonstrate Continuing Professional Development (CPD) in their area of prescribing practice. The RPSGB have published a clinical governance framework for pharmacist prescribers[2] and a Pharmacist Prescriber Pack.[3] Organizations should have a 'non-medical prescribing policy' in place to support pharmacist independent prescribing. Some specialist organizations also have guidance on pharmacist independent prescribing in a specialist area—e.g. the British Oncology Pharmacy Association (BOPA) *Guidance for the Development*

1 Department of Health (2006). *Improving Patients' Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the NHS in England*. London: Department of Health.

2 Royal Pharmaceutical Society of Great Britain (2007). *Clinical Governance Framework for Pharmacist Precribers and Organisations Commissioning or Participating in Pharmacist Prescribing* (GB wide).

3 Royal Pharmaceutical Society of Great Britain. Pharmacist Prescriber Pack.

of Pharmacist Non-Medical Prescribing and Review of Patients Receiving Anticancer Medicines.[1]

Benefits

The benefits of pharmacist independent prescribing are to improve patient care without compromising patient safety, make it easier for patients to get the medicines they require, increase patient choice, make better use of healthcare professional skills, and contribute to more flexible team-working in the NHS.

1 Faculty of Cancer Pharmacy and the British Oncology Pharmacy Association (2009). *Guidance for the Development of Pharmacist Non Medical Prescribing and Review of Patients Receiving Anti-cancer Medicines.* http://www.bopawebsite.org/contentimages/publications/Non_Medical_Prescribing_Review_Best_Practice_Guidelines_FINAL.pdf

Community (FP10) prescription use in hospitals

Hospital out-patient departments can use community (FP10) prescriptions, according to local policy. In the UK, these are prescriptions that can be written by hospital doctors and dispensed by a community pharmacy, ↓ workload of busy pharmacy departments.

Who is it appropriate to use them for?

- Patients who are mobile and can easily get to a community pharmacy.
- Patients requiring an item that cannot be easily obtained by the hospital pharmacy.
- Patients who don't have time or would rather not wait in the hospital pharmacy.
- Patients on hospital transport who are unable to wait in the hospital pharmacy.

Who is it inappropriate to use them for?

- Patients requiring expensive items, unless they are part of a shared-care arrangement.
- Patients on clinical trials.
- Patients on drugs that are only available from hospitals.
- Patients requiring items that can be purchased without a prescription.
- Patients on complex therapy who may need counselling, but might miss out if they don't attend the hospital pharmacy.

Things to remember

- These prescriptions incur a dispensing fee for each item prescribed.
- Prescriptions are removed from the hospital and dispensed by community pharmacists and, as such, could be vulnerable to loss or tampering.
- The pharmacist who dispenses the prescription might not be familiar with prescribing habits or handwriting.
- It is very difficult for the dispensing pharmacist to contact the doctor in the event of error, omission, or illegible prescribing.
- The hospital is charged the commercial costs, in addition to the dispensing fees for the items prescribed. The resulting cost can be more expensive than if it were dispensed from the hospital pharmacy.
- The hospital is reimbursed for any prescription charge, so for cheaper items, they can be cheaper or issued without charge using an FP10 prescription.
- Drugs supplied are exempt from value added tax (VAT); hence it might be cost-effective to prescribe some drugs on FP10 prescriptions.

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Electronic prescribing

Electronic prescribing systems are available commercially and are fully implemented by some hospitals and institutions, often linked to a patient management system. The NHS is aiming for all prescribing in secondary care within the UK to be undertaken electronically.

Some systems ensure a paper-free environment because an electronic prescription is used for patient care, electronic signatures are used for drug administration, and electronic transfer is used for ordering drugs from the pharmacy. Fully implemented electronic systems can mean that all patient records are electronic.

Electronic prescribing systems are often intelligent and flag areas of drug interaction, incorrect dosing, other prescribing errors, additional information required for safe drug administration, and formulary issues. These systems require input and maintenance by pharmacy and information technology teams.

High-risk areas, such as chemotherapy prescribing, should be implemented as a high priority. Most cancer hospitals and networks have implemented or are working towards implementing electronic prescribing systems for oral and injectable chemotherapy to minimize the risks associated with the prescribing and administration of these drugs for adult and paediatric patients.

Pharmacy staff using an electronic prescribing system require training in its use before working with the system. These systems have various levels of security, depending on the role of the professional in the use of the system. It is essential that there is good security for any electronic prescribing system, with frequent back-ups, and a system must be in place in case of system failure. Standard operating procedures should be in place for all aspects of the system.

Benefits

- Safer use of medicines.
- ↓ in medication errors.
- Improved quality and safety of prescribing.
- Improved safety of prescribing medication to patients with drug allergies.
- Prescriptions are legible.
- Accessibility of information between primary and secondary care.
- Improved patient compliance with protocols.
- Management of formulary compliance.
- Supports decision-making when prescribing.
- Implementation of policy decisions.
- Improved use of staff time.
- Pharmacy can make early identification of new scripts for screening and supply.
- Audit trail of transactions.
- Drug-usage reports for individual patients.
- Aids clinical audit.

Further reading

Smith J (2004). *Building a Safer NHS for Patients: Improving Medication Safety*. London: Department of Health.

Donyai P *et al.* (2008). The effects of electronic prescribing on the quality of prescribing. *British Journal of Clinical Pharmacology* **65**: 230–7.

Incident reporting

- Each hospital or institution should have a policy in place for reporting incidents. An incident reporting policy often covers all incidents, including adverse events, hazards, and near misses of an adverse event or hazard. Such a policy applies to all hospital staff. An induction programme to a hospital usually covers details of any local policy.
- An incident reporting program identifies, assesses, and manages risks that could compromise or threaten the quality of patient services or staff working in a safe environment, as part of the overall management of risk. It is a confidential process, and all staff should complete the appropriate documentation if they are involved in, or aware of, an incident.
- An 'incident' is usually defined as an event or circumstance that could have, or did, lead to unintended or unexpected harm, loss, or damage. Incidents might involve actual or potential injury, damage, loss, fire, theft, violence, abuse, accidents, ill health, and infection.
- It is necessary for incidents to be reported to ensure that the hospital can analyse the data for trends, causes, and costs. Action plans can then be developed to minimize future similar incidents. Reporting of incidents is also a mechanism for staff to have input into change of practice and procedures. Incident reporting follows a 'no-blame' culture.
- Medication incidents must be reported through this mechanism to ensure that there can be a review of trends, a root-cause analysis, arrangements for improvement, and a follow-up audit. This is a requirement of medicines management in hospitals.
- The types of incident that a pharmacist can report include medication errors and failure of systems or processes that affect patient care.
- In addition to reporting an incident, a pharmacist must also deal with an incident by communicating with the relevant members of staff involved (see 📖 p.72).

Further reading

Department of Health (2003). *A Vision for Pharmacy in the new NHS*. London: Department of Health.

National Patient Safety Agency. *National Reporting and Learning Service*. 🔗 http://www.nrls.npsa.nhs.uk

Medical representatives

- Medical representatives provide information to healthcare practitioners, but their prime function is to promote and sell their products and services.
- Medical representatives should provide their services according to the Association of the British Pharmaceutical Industry (ABPI) code of practice (or similar). If the code of practice is breached, medical representatives can be reported to the director of the Prescription Medicines Code of Practice Authority (PMCPA).
- Most hospitals have a policy for dealing with medical representatives—check the local policy.
- Some hospitals do not allow medical representatives to leave samples. Check the policy for the local hospital before accepting trial samples from medical representatives.
- It is GCP for medical representatives to make an appointment before meeting with a member of staff. Some hospital policies restrict the grades of staff that are allowed to meet with medical representatives.
- Medical representatives are not allowed to promote unlicensed indications for their products or products that have not yet been licensed. However, they are allowed to answer specific questions on unlicensed use (see 📖 p.262).
- Hospital drug prices are confidential to the hospital and under no circumstance must they be revealed to a medical representative.
- Most hospitals limit the level of hospitality provided by representatives. For example, it is reasonable for representatives to provide food for a working lunch, but not expensive meals at a restaurant.

Further reading

Guidance Notes for Health Professionals, Understanding the ABPI Code of Practice for the Pharmaceutical Industry and Controls on the Promotion of Prescription Medicines in the UK. 🖱 http://www.abpi.org.uk

Overseas visitors

- The term 'overseas visitor' is used for patients who have fallen ill unexpectedly while visiting the UK and who, consequently, require standard NHS emergency care.
- People who do not normally live in the UK are not automatically entitled to use the NHS free of charge.
- Patients who are eligible for full NHS treatment include the following.
  - Anyone legally living in the UK for ≥12 months.
  - Permanent residents.
  - Students in the UK for >6 months.
  - Refugees or asylum seekers who have made an application to remain in the UK and are waiting for a decision on their immigration status.
  - People detained by the immigration authorities.
  - People from countries with a reciprocal agreement—e.g. European Union residents.
- Patients who are not eligible for full NHS treatment include the following.
  - Students on courses in the UK for <6 months.
  - Refugees or asylum seekers who have not yet submitted applications to the Home Office.
  - Those who have had an asylum application turned down and exhausted the appeals process.
  - Illegal immigrants.
- The NHS hospital is legally responsible for establishing whether patients are not normally resident in the UK.
- If patients are not eligible for free NHS care, the hospital must charge the patient for the costs of the NHS care.
- When the patient is charged depends on the urgency of the treatment needed.
  - For immediately necessary treatment, treatment must not be delayed or withheld while the patient's chargeable status is being established.
  - For urgent and non-urgent treatment, patients should pay a deposit equivalent to the estimated full cost of treatment in advance.
  - Any surplus can be returned to the patient on completion of the treatment.
- Treatment that is available to overseas patients free of charge is as follows.
  - A&E visits. However, treatment in other departments following an A&E visit (e.g. X-ray) is charged.
  - Emergency or immediately necessary treatment.
  - Treatment of sexually transmitted diseases (except HIV).
  - Treatment of diseases that are a threat to public health (e.g. tuberculosis (TB)) and acute treatment of all infectious diseases.
  - Family planning.
  - Compulsory psychiatric treatment.
- If an overseas visitor chooses to be treated privately, they are classed as an 'international private patient'. These patients are treated as private patients (see 📖 p.282).

Further reading

Department of Health (2007). *Implementing the Overseas Visitors Hospital Charging Regulations*. London: Department of Health.

Department of Health. *Overseas Visitors*. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4080313

Department of Health (2010) *Overseas Visitors*. http://www.dh.gov.uk/en/Healthcare/Entitlementsandcharges/OverseasVisitors/index.htm

Pollard AJ, Savulescu J (2004). Eligibility of overseas visitors and people of uncertain residential status for NHS treatment. *British Medical Journal* **329**: 346–9.

Private patients

In the UK, patients can choose to have treatment either from the NHS or privately. Private patients usually have private health insurance, which covers some, or all, of the costs of private treatment. Patients can be treated privately either in a private hospital or in NHS hospitals. Private patients treated in NHS hospitals are discussed in this section.

- NHS hospitals either have specific wards for private patients or private patients are treated on the same ward as NHS patients, often in a side room.
- Patients who are treated privately either have private health insurance or are paying themselves.
- Before the patient receives treatment, the private health insurance company must confirm what they will cover, according to the patient's insurance policy.
- Patients' drugs must be charged accurately to the private health insurance companies to ensure that the NHS generates income from using NHS facilities to treat these patients.
- If a patient is having private treatment, this should be annotated in some way on the patient notes or identification labels.
- Any prescription for a private patient must be annotated as 'private patient' to ensure that the pharmacy department can charge appropriately for the drugs.
- Private patients do not have to pay NHS prescriptions charges.
- Charging and systems can vary for in-patients and out-patients.
- An on-cost is usually added to the drug price when charging for private patients' drugs.
- Clinical pharmacists' input into patient care for drug review and counselling might be appropriate.
- Check what systems are in place for private patients' drugs in your hospital.
- Patients can choose to change from being a private patient to an NHS patient between consultations.

In 2009, the Department of Health issued guidance for patients to enable them to remain NHS patients, but to pay for additional private care, such as drugs, not available in or funded by the NHS.[1] The NHS continues to provide the care the patient is entitled to in the NHS, and the private care has to be delivered separately from the NHS care. Hospitals should have specific policies in place for patients requesting additional private care in accordance with this guidance.

1 Department of Health (2009) *Guidance on NHS patients who wish to pay for additional private care.* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096428

Professional supervision skills

- Start with goals or an action plan for the member of staff you are supervising.
  - These should be SMART—i.e. **S**pecific, **M**easurable, **A**chievable, **R**elevant,and **T**imescale.
  - Effective goals have five parts:
    - — intentions
    - — outcomes
    - — methods and resources
    - — midpoints and deadlines
    - — action plans.
- Prioritize the workload with your staff.
- Set timelines.
- Time management—ensure that time is managed effectively.
- Listen effectively to your member of staff.
- Review and monitor action plans and progress at regular intervals.
- Support and coach, as necessary.
- Be available to discuss ways forward with the member of staff.
- Communicate the 'bigger picture', so that staff understand why tasks are being undertaken.
- Be honest.

Tips on day-to-day supervision

- Some of the professional supervision skills should be used on a daily basis to help with day-to-day supervision.
- Be aware of the workload to be covered that day and the staff available to undertake the work.
- If necessary, prioritize the day's work with the staff.
- Be available to trouble-shoot.
- Support the staff with the urgent and important work, if necessary.

National Service Frameworks (NSFs)

NSFs are national standards for specified clinical areas to ensure equality of NHS services throughout the UK. NSFs were developed by the Department of Health, with the help of external reference groups. These groups are made up of health professionals, service users and carers, health service managers, partner agencies, and other advocates. Usually, one new framework is developed each year.

National Service Frameworks:

- establish national standards and promote specific service models
- identify key interventions for a defined service or care group
- put in place strategies to support implementation
- establish ways to ensure progress within an agreed timescale
- are a measure to ↑ quality and ↓ variations in service within the NHS
- drive the delivery of the NHS modernization agenda.

Some examples of NSFs developed to date include the following:

- coronary heart disease
- cancer
- paediatric intensive care
- mental health
- older people
- diabetes
- long-term conditions (e.g. neurological)
- renal services
- children.

Opportunities for pharmacy

Some NSFs specifically mention pharmacy or medicine-related issues.

- Become familiar with the framework standards, and consider how to contribute to the achievement of the standards.
- A pharmacist should be involved with the local implementation team responsible for the development and delivery of a service plan and identifying what has to be done to implement the NSF.
- Decide on the services that can be initiated and the relevant links to the NSF standards.
- Identify links to the local delivery plan and other local priorities.
- Participate with an existing or developing service where possible.
- Identify the opportunities for pharmacy.
- Consult with other stakeholders who can influence the development of a proposed service.
- Identify training needs to provide a new service.
- Identify the outcomes proposed—are they realistic and measurable?
- Develop a business case which refers to the NSF, local priorities, and needs, and includes integration into local services.

Further reading

Stanley J (2004). Benchmarking the role of pharmacists in implementing NSFs. *Pharmacy Management* **20**: 2–5.

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Appraisal

An appraisal meeting provides a formal opportunity for managers and staff to meet and discuss job performance, achievements against objectives previously set, future work objectives and priorities, career aspirations, and training and development needs. This process should ensure that staff are clear about what they are trying to achieve and why, and managers are clear on the progress being made by everyone in their department.

Definitions

- **Appraisal** is a dynamic ongoing process of performance management through objectives and staff development.
- **Performance management** is a system to align the work of individuals as closely as possible to the work of the organization.

The appraisal process

- Appraisal supports effective performance and personal development.
- Appraisals should take place annually, according to the local hospital policy.
- The line manager usually conducts the appraisal.
- Both the appraiser and the appraisee should prepare for the annual appraisal meeting. It is good practice to have at least 2wks notice to enable an individual to have time to prepare.
- In preparation for the annual appraisal, the appraisee should list their strengths and weaknesses, achievements, and performance highs and lows for the previous 12 months. There may be specific appraisal paperwork that needs completing by both the appraiser and the appraisee prior to the appraisal, according to local policy.
- The annual appraisal should be conducted to ensure an open two-way discussion, and usually lasts for ~2h.
- During the appraisal, the following areas are usually covered.
  - Introduction and purpose of an appraisal.
  - Review of the objectives set at the last appraisal, a discussion of which ones are met, and resolving difficulties with those that have not been met.
  - Review of an individual's work over the past year.
  - Outline and agree future objectives.
  - Review of individuals current knowledge and skills.
  - Prioritization of areas requiring development to improve effectiveness at work.
  - Agree a personal development plan for the next year.
  - Discussion of how an individual's objectives fit within the team and organization's objectives.
  - Discussion on how the organization/line manager can help the appraisee achieve their objectives.
  - Constructive feedback on performance.
  - Recognition of an individual's performance.
  - Discussion of any of the appraisee's concerns.
  - Review of job description and plans to update it accordingly.

- A paper record of the appraisal, which is signed by the appraisee and the appraiser, should be kept.

Review of performance should be continuous, and any concerns should be raised throughout the year and not left to the annual appraisal.

Further reading

Naisby A (ed) (2002). *Appraisal and Performance Management*. London: Spiro Press.
Chartered Institute of Personnel and Development (2010). *Performance Appraisal*. http://www.cipd.co.uk/subjects/perfmangmt/appfdbck/perfapp.htm

Confidentiality

Pharmacists and pharmacy staff are expected to maintain the confidentiality of any patient or customer they have contact with during the course of their professional duties. Information that should remain confidential includes the following:

- patient's identity and address
- diagnosis
- details of prescribed and non-prescribed medicines.

Pharmacists must also ensure that any written or electronic patient information is stored and disposed of securely and that electronic systems are password protected.

To avoid unintentional disclosure, it is important to develop good habits when dealing with patient information.

- Discussing a patient with colleagues is often necessary for patient care or training purposes, but be cautious about revealing names or other patient identifiers.
- Do not discuss patients in public areas—e.g. the lifts or the front of the shop.
- If talking about your work to family or friends, only talk about patients in very general terms.
- Ensure that written information (e.g. patient handover lists and prescriptions) is not left lying where other patients or the public can see it.
- If discussing medication with a patient, try to do this in a reasonably private area. If hospital in-patients have visitors, ask if the patient would like you to return when they have gone.
- Ensure that computers have passwords and always log off at the end of a session.

Disclosure of information

In certain situations, pharmacists might have to disclose confidential information. The UK pharmacy code of ethics allows this in the following circumstances.

- With patient consent or parent/guardian/carer consent for a child or adult not competent to give consent themselves. Information about adolescent patients should not normally be revealed without their consent.
- If required by law or statute.
- If necessary to prevent serious injury or damage to the health of the patient, a third party or the public health.

The RPSGB has published a fact sheet on confidentiality, which includes guidance on disclosure of information.[1] In addition, advice on disclosure of information if necessary to protect children and vulnerable adults can be found on the *Pharmaceutical Journal* website.[2]

Confidentiality when a friend, relative, or colleague is a patient

Pharmacists and pharmacy staff can be put in a difficult position in this situation, especially if others know that the patient is in their care. Well-meaning questions about the patient's welfare might be difficult to deal with without causing offence.

- Explain to the patient what level of involvement you have in their care and that you would have access to their medical notes. Ask whether they would prefer that another pharmacist deals with their care (although this might not always be feasible).
- If at all possible, discuss the situation with the patient and ask them what information they are willing for you to reveal to other friends, family, or colleagues.
- If the patient is unwilling for you to reveal any information, or if you are unable to discuss this with the patient, any enquiries should be dealt with by politely explaining that you cannot provide information about the patient. Bear in mind, however, that simply making this statement potentially discloses the fact that the individual is known to you as a patient.
- Try to avoid compromising your integrity by denying all knowledge of the patient, but in some situations this might be necessary.
- Inform the medical team that the patient is known to you socially.
- Personal information known to you because of your relationship to the patient should not be revealed to medical or nursing colleagues without the patient's consent.
- The patient might use your relationship to ask you to provide medical information that you would not normally reveal. Provide only the same information as you would to any other patient.
- If a colleague is a patient, be especially sensitive to any aspect of care that could breach confidentiality. As appropriate, you might need to consider the following.
  - Avoid writing your colleague's name on ward order sheets.
  - Use an agreed alias for labelling of medicines.
  - Label, dispense, and deliver medicines yourself.
  - Keep any written records separate from those to which other pharmacy staff have access.

1 RPSGB. http://www.rpsgb.org/pdfs/factsheet12.pdf
2 http://www.pjonline.com/libres/pdf/society/pj_20050806_childprotectionguidance.pdf

Gene therapy

The development of genetically modified viruses and advances in cloning and sequencing the human genome have offered the opportunity to treat a wide variety of diseases using 'gene therapy'. The term 'gene therapy' applies to any clinical therapeutic procedure in which genes are intentionally introduced into human cells. Gene therapy clinical trials have been undertaken in cystic fibrosis, cancer, cardiac disease, HIV, and inherited genetic disorders. Preparation of gene therapy products is a pharmaceutical preparation process that should be carried out under the control of a pharmacist in suitable facilities to minimize the risk of microbiological contamination and medication errors.

Gene therapy can be divided into two main categories: gene replacement and gene addition. Gene replacement tends to be used for monogenic diseases, in which a single 'faulty' gene can be replaced with a normal gene. For example, an abnormal cystic fibrosis transmembrane conductance regulator (CFTR) gene can be replaced in cystic fibrosis. Currently, the majority of gene therapy clinical trials use a gene- addition strategy for cancer, whereby a gene or genes can be 'added' to a cell to provide a new function, e.g. addition of tumour suppressor genes to cancer cells.

For gene therapy to be successful, a therapeutic gene must be delivered to the nucleus of a target cell, where it can be expressed as a therapeutic protein. Genes are delivered to target cells by vectors in a process called 'gene transfer'. The greatest challenge to gene therapy is finding a vector that can transfer therapeutic genes to target cells specifically and efficiently. Gene transfer vectors can be broadly divided into non-viral and viral systems. Non-viral vectors, such as liposomes, have limited efficiency. Genetically modified viruses have proved to be the most efficient way of delivering DNA. Viruses are merely genetic information protected by a protein coat. They have a unique ability to enter (infect) a cell, delivering viral genes to the nucleus using the host cell machinery to express those viral genes. A variety of viruses have been used as vectors, including retroviruses, herpes viruses, and adenoviruses. Many viral vectors have been genetically modified so that they cannot form new viral particles and so are termed 'replication-deficient' or 'replication-defective'. Replication-deficient viruses have had the viral genes required for replication and the pathogenic host response removed. This prevents the virus replicating and the potential for the therapeutic virus to reverse back to a pathogenic virus. The deleted genes are replaced by a therapeutic gene, thus allowing the delivery and expression of the therapeutic gene without subsequent spread of the virus to surrounding cells. Future gene therapy vectors will be able to replicate under genetically specified conditions.

There are potential infectious hazards with gene therapy, including possible transmission of the vector to hospital personnel. Therefore gene therapy products should be manipulated in pharmacy aseptic units, because of the uncertain effects of specific genes on normal human cells, potential for operator sensitization on repeated exposure, and the potentially infective nature of some products. Consideration has to be given to protecting both the product and the staff handling these agents. Some gene therapy agents might require handling in negative-pressure isolators in separate specific aseptic facilities.

A risk assessment should be made for each product, with input from the lead investigator or trust biological safety officer, because they should have a good understanding of molecular biology and virology.

Further reading

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Pharmacogenetics

Pharmacogenetics is defined as the study of human genetic variation, which causes different responses to drugs. The differences in response can be both in the therapeutic effect and in ADRs.

For example, genetic make-up may determine variations in liver enzymes that are produced, which in turn affect drug metabolizm. One of the cytochrome P450 liver enzymes, CYP2D6, metabolizes drugs (e.g. β-blockers, antidepressants, and opioids) in the liver so that they can be eliminated. The level of this enzyme in the liver is genetically determined. Patients are classified as 'slow metabolizers' if they have low levels of CYP2D6 in the liver, which means that the drug is eliminated from the body more slowly, resulting in additional toxicity. 'Fast metabolizers' have a high level of CYP2D6 in the liver and therefore metabolize the drug more quickly, resulting in a possible reduced therapeutic effect. In practice, 'slow metabolizers' may require a lower dose of drug than 'fast metabolizers' for the same effect. An example of a drug metabolized through this mechanism is warfarin: 40% of the variability in warfarin levels is accounted for by the CYP2C9 enzyme.

Another example of genetic influence on drug response is via receptors. If drugs bind to specific receptors to generate a response and the number of receptors present is genetically determined, the response to the drug will vary according to the patient's genetics. This has enabled drug development to be much more targeted, so that only patients with specific characteristics receive the appropriate drugs. For example, breast cancer patients who have the HER2 receptor present on their breast cancer cells will be the only group of breast cancer patients who respond to trastuzumab. This highlights that in cancer patients, the presence or absence of some genes will determine the patient's response to some anti-cancer drugs.

Genetic testing of individuals is usually done from a saliva or blood sample. There will be issues regarding the quality of the tests, their initiation, communication to the patient, and the implication of the test to treatment. The general public would need to be more widely educated about pharmacogenetics and its implications. Tests would need to be rigorously evaluated. Currently there are some home test kits available, but the sale of these is not regulated. This means that some of the test kits available have no guarantee of being validated or of producing accurate results.

There are ethical issues that need to be considered in genotyping individuals. (The genotype is the genetic make-up of a cell or individual. Genotyping is the process of determining an individual's genotype using biological assays to find out the genetic make-up of an individual.) This could lead to discrimination of individuals who carry specific genes and affect the allocation of resources. For example, there is concern that some individuals may not be able to obtain insurance policies if their genetic test results are considered negatively. There is also concern about the privacy and confidentiality of genetic information, where it should be stored, and who would have access to it. Drug companies may only research drugs for diseases that are straightforward to treat, rather than those that could be used for rarer diseases. In addition, pharmacogenetic testing may predict

for future risks of disease or raise implications for other family members, which adds to the ethical issues of informing patients and their families.

Pharmacogenetics will enable more cost-effective and targeted prescribing that will optimize the use of drugs, avoiding the prescribing of drugs that will be ineffective, and reduce the medical and financial impact of adverse drug reactions. This means that in the future patients will be prescribed drugs specific to their conditions, taking into account genetic factors when deciding on dosage regimens. However, targeted drugs may be more expensive. In addition, there may be a loss of any benefit of, for example, racemic mixtures.

Standards of business conduct for clinical pharmacists

Declaration of interests has become an integral part of professional life, and pharmacists are not exempt from showing that they are independent and unbiased. In addition, clinical pharmacists have access to valuable confidential data and can influence purchasing decisions that can have a major effect on a particular company's products. Therefore it is important that pharmacists are aware of relevant guidelines. In the UK, Department of Health guidelines have been produced on these issues and it is prudent to have a local policy designed using this or similar guidance.

The Department of Health guidelines cover the standards of conduct expected of all NHS staff, where their private interests could conflict with their public duties, and the steps that NHS employers should take to safeguard themselves and the NHS against conflict of interest.

Details can be found in the Code of Conduct for NHS Managers 2002; which is available on the Department of Health website.[1] Some key relevant issues are as follows.

- Avoid conflict of interest between private and NHS interests. It is a well-established principle that public sector bodies, which include the NHS, must be impartial and honest in the conduct of their business, and that their employees should remain above suspicion.
- NHS staff are expected to ensure that the interest of patients is paramount at all times, to be impartial and honest in the conduct of their official business, and to use the public funds entrusted to them to the best advantage of the service, always ensuring value for money.
- It is also the responsibility of staff to ensure that they do not abuse their official position for personal gain or to benefit their family or friends.
- Modest hospitality, provided that it is normal and reasonable in the circumstances (e.g. lunches in the course of working visits), are acceptable, although it should be similar to the scale of hospitality that the NHS, as an employer, would probably offer. Anything else should be declined.
- Casual gifts can be offered by contractors or others (e.g. at Christmas time). Such gifts should nevertheless be politely, but firmly, declined. Articles of low intrinsic value, such as diaries or calendars, or small tokens of gratitude from patients or their relatives, need not necessarily be refused.
- NHS employers need to be aware of all cases in which an employee or their close relative or associate has a significant financial interest in a business.

1 http://www.dh.gov.uk (accessed October 2011).

- Individual staff must not seek or accept preferential rates or benefits in kind for private transactions carried out with companies with which they have had, or might have had, official dealings on behalf of their NHS employer.
- All staff who are in contact with suppliers and contractors, in particular those who are authorized to sign purchase orders or place contracts for goods, are expected to adhere to professional standards of the kind set out in the ethical code of the Institute of Purchasing and Supply (IPS).[1]
- Fair and open competition between prospective contractors or suppliers for NHS contracts is a requirement of NHS standing orders and of EC directives on public purchasing for works and supplies.
- NHS employers should ensure that no special favour is shown to current or former employees in awarding contracts to private or other businesses run by them.
- NHS employees are advised not to engage in outside employment that could conflict with their NHS work or be detrimental to it.
- Acceptance by staff of commercial sponsorship for attendance at relevant conferences and courses is acceptable, but only if the employee seeks permission in advance and the employer is satisfied that acceptance will not compromise purchasing decisions in any way.
- Pharmaceutical companies, for example, might offer to sponsor, wholly or partially, a post for an employing authority. NHS employers should not enter into such arrangements, unless it has been made abundantly clear to the company concerned that the sponsorship will have no effect on purchasing decisions within the authority.
- Staff should be particularly careful of using, or making public, internal information of a 'commercial in confidence' nature, if its use would prejudice the principle of a purchasing system based on fair competition.
- Finally, many employers maintain a record of interests and pharmacists should cooperate with such practices.

1 Chartered Institute of Purchasing & Supply. http://www.cips.org

Waste management of medicines

Pharmaceutical waste refers to the disposal of unwanted medicines, out-of-date or obsolete stock, sharps, and waste arising from diagnostic testing. The current regulations are detailed in the Hazardous Waste Regulations 2005, and further guidance specifically for community pharmacies are detailed in the Department of Health document *Environment and Sustainability Health Technical Memorandum 07-06: Disposal of Pharmaceutical Waste in Community Pharmacies*.

The legislation relevant to pharmaceutical waste derives mainly from European directives. The storage, carriage, processing, and supply of waste are all subject to stringent controls designed to minimize the negative effects of waste on the environment.

The Environment Agency or the relevant local authority is the enforcement authority for the legislation. Depending on the circumstances, and in cases of doubt, either can be contacted for advice. The Environment Agency helpline number is 08708-506-506.

Policies

Your hospital or community pharmacy must have a waste management policy that details general themes, including dealing with pharmaceutical waste such as cytotoxics. Key requirements that need specification in your policy are as follows.

- Detail how returned controlled drugs should be denatured and recorded—see Royal Pharmaceutical Society (RPS) on the denaturing of controlled drugs.
- Include a list of hazardous medicines that may be encountered in the pharmacy.
- Include instructions to staff on dealing with products other than medicines that are handed in to the pharmacy.
- Include instructions on identifying incompatible products such as flammable products and oxidizing agents.
- Include the protective measures to be adopted by staff when segregating controlled drugs and incompatible products.
- Include reference to monitored dosage system trays and the disposal of blister packs.
- Set out the retention and audit requirements for transfer notes, consignment notes, and quarterly returns.

The guidance also details the types of containers that need to be used for segregation and transportation of the different types of waste. For example:

- a purple-lidded sharps bin should be used for medicines or sharps contaminated with cytotoxic or cytostatic medicines
- a yellow-lidded sharps bin should be used for all other medicines or sharps contaminated with non-hazardous medicines
- other sharps (e.g. fully discharged syringes) may be disposed of in an orange-lidded sharps bin.

When completing any documentation needed for the transfer and transportation of waste from the pharmacy, pharmacies are advised to ensure that all waste coding and descriptions are robust and accurate, particularly with regard to the presence of medicinal waste and medicinally contaminated sharps.

Waste generated

The waste generated is likely to consist of the following.

Community pharmacy

- Pharmaceutical products returned from individuals and households as part of the essential services (i.e. the disposal of unwanted medicines—a service provided by all pharmacies).
- Out-of-date or obsolete stock.
- Needles and syringes.
- Waste arising from diagnostic testing such as blood glucose and cholesterol monitoring.

Hospital pharmacy

- Unwanted items from ward/department, including controlled drugs, PODs, fridge items, and hazardous, harmful, or toxic pharmaceuticals, require processing as many items can be recycled if storage conditions have been complied with.
- Otherwise waste will contain out-of-date dispensary stock, items that are not economically viable to recycle, and PODs that may have been returned to pharmacy for a variety of reasons.

Medicines brought into hospital by patients

Medicines brought into hospital by the patient are the property of the patient and should only be sent to pharmacy for destruction with the prior agreement from the patient or their agent. It is GCP to record the details of PODs sent to the pharmacy for destruction.

Carriage of waste and community pharmacy

Ensure that a carrier's licence is held if the pharmacy carries waste medicines from a patient's home or residential home to the pharmacy.

Handling waste within the pharmacy

The Hazardous Waste Regulations 2005 introduced significant changes for pharmacies. They required pharmacies to separate hazardous waste medicines from non-hazardous waste, if this is economically viable.

Staff safety is paramount. Handling of waste should be minimal and carried out with great care. Acceptance of waste other than medicines returned from households should not be undertaken.

It is not absolutely necessary for pharmacies to separate hazardous waste medicines from non-hazardous waste medicines before they are sent to a suitably authorized waste contractor for incineration. However, whenever waste that may contain some hazardous waste medicine is sent for incineration, it is required to be consigned as though it were hazardous and needs to be accompanied by a hazardous waste consignment note.

► Under the Hazardous Waste Directives, only cytotoxic or cytostatic medicines are classified as hazardous waste.

As an aid to pharmacists, a suitable starting point for identifying hazardous medicines is to adopt the list of hazardous drugs provide by the National Institute for Occupational Safety and Health (NIOSH).

Liquid medicines

Liquids should generally not be decanted and mixed. Where liquid medicines are being discarded, they should be retained within their individual containers and placed in the waste bins provided for the purpose.

If the waste contractor has provided a waste bin specially designed for liquids and suggests that the liquid medicines can be emptied from containers and mixed in the waste bin, the pharmacist has a duty of care to ensure that only compatible products are mixed

Empty medicine containers that have held liquids must be disposed of as waste medicines for incineration as it is not possible to ensure that the contents have been completely removed (containers cannot be rinsed into the sewerage system). If residues of liquid controlled drugs are present, these should be emptied, as far as possible, and denatured before the container is placed in the waste container.

If segregation is not being undertaken, purple-lidded burn bins should be used for all pharmaceutical waste, including cytotoxic agents and antibiotic products.

Transfer of waste to a waste carrier

A consignment note is required to list the hazardous medicines that are being consigned so that they can be handled safely and disposed of appropriately (no list of individual non-hazardous medicines is required). Refer to *Health Technical Memorandum 07-06* for details of completing required documentation.

Radioactive waste

Radioactive waste is governed by the Environmental Agency, which issues organizations with certificates of authorization that regulate the routes of disposal, limits of disposal, and type of radioactive material disposed of.

Disposal and destruction of controlled drugs

A controlled drug ceases to be classified as a controlled drug after it has been rendered irretrievable, i.e. all controlled drugs that are disposed of should be unrecognizable as controlled drugs (Misuse of Drugs Act 1971).

Hospital only—controlled drugs must be returned to pharmacy

All controlled drugs (e.g. expired stocks, PODs, and excess stock) must be notified to the pharmacist responsible for the ward/unit/ department. These controlled drugs must not be destroyed on the ward.[1]

The pharmacist must return the controlled drugs to the pharmacy to either the pharmacy controlled drug record book for destruction (in the case of expired stock or PODs) or the pharmacy controlled drug record book (in the case of excess stock of controlled drugs, which can be entered back into pharmacy stock).

1 Royal Pharmaceutical Society of Great Britain (2005). *The Safe and Secure Handling of Medicines: A Team Approach.* http://www.rpharms.com/support-pdfs/safsechandmeds.pdf

Departments who do not receive a pharmacy visiting service must either arrange for a pharmacist to come to the ward or agree a mutually convenient time for the nurse to take their controlled drugs and the controlled drug record book to the pharmacy, where a pharmacist will sign for their return.

Records of CD destruction

In both cases outlined, an entry must be made in the ward controlled drug record book or the patient's own controlled drugs record book on the appropriate page for the drug in question, specifying 'destruction' or 'return to pharmacy', the quantity involved, the new stock balance and the signatures of the two persons involved.

Prefilled PCA/PCEA/epidural syringes and opiate infusions

Part contents of opiate infusions/PCA/PCEA/epidural syringes that were initially set up and issued in theatres but are no longer needed must be destroyed on the ward where the patient resides.

Opiate infusions/PCA/PCEA/epidural syringes containing residual unused injections must be emptied into an in-use sharps bin, in addition to the empty syringe. Empty bags can be disposed of in a clinical waste bag according to procedure for disposing of empty infusion bags. This must be witnessed by a second person. One of the two witnesses should be the nurse looking after the patient.

Responsible pharmacist

The responsible pharmacist

The responsible pharmacist regulations came into effect on 1 October 2009. Prior to this date, in order to conduct a retail pharmacy business lawfully the Medicines Act 1968 specified that there had to be a pharmacist in 'personal control'. 'Personal control' meant that the pharmacist needed to be physically present in the pharmacy. Furthermore, sales of prescription and prescription-only medicines had to be under the supervision of a pharmacist. However, the Medicines Act did not define 'supervision', although it was interpreted as needing a pharmacist to be able to 'intervene and advise'.

It was recognized that, to improve the range of services available in pharmacies, pharmacists must be able to work more flexibly and be allowed to undertake their role out of the pharmacy for a limited period to make better use of their clinical training and the skills of pharmacy staff, and hence the concept of the responsible pharmacist was developed.

The Health Act 2006 amends relevant sections of the Medicines Act 1968. Instead of requiring a pharmacist in 'personal control', there must be a 'responsible pharmacist' in charge of each registered pharmacy.

Responsible pharmacists—community pharmacists

The responsible pharmacist has to:

- secure the safe and effective running of the pharmacy, including during periods of absence;
- display a notice with their name, registration number, and the fact that they are in charge of the pharmacy at that time;
- complete the pharmacy record to identify who the responsible pharmacist was for a pharmacy at any one time;
- establish (if not already established), maintain, and keep under review procedures for safe working.

Responsible pharmacists—hospital pharmacists

The responsible pharmacist changes to the Medicines Act only affect those hospitals that have registered all or part of their pharmacy premises with the General Pharmaceutical Council.

Hospitals may choose to have registered pharmacy premises for a number of reasons including the following.

- Operation of a retail pharmacy, which allows dispensing of prescriptions that have not originated within their hospital and selling prescription medicines to visitors and staff.
- To allow the dispensing of private prescriptions when consultation is not covered as part of the business of the hospital.
- To allow for self-prescribing by medical staff.

If you have a registered pharmacy within the hospital, the law and standards for responsible pharmacists will apply. This means that the registered pharmacy is required to have a responsible pharmacist when it is operating as a pharmacy business. As a hospital pharmacist you are advised to check with your chief pharmacist for clarity concerning responsible pharmacist requirements within your pharmacy.

Requirements of responsible pharmacist legislation

The law covers four key areas.

- Have a responsible pharmacist to secure the *safe and effective* running of the pharmacy.
- Conspicuously display to the public the name and registration number of the current responsible pharmacist.
- Maintain a pharmacy record detailing who has been the responsible pharmacist at any particular time.
- Maintain and operate pharmacy procedures on a range of specified matters.

The responsible pharmacist is the pharmacist appointed by the employer, who is responsible for securing the safe and effective running of the pharmacy at that time. The responsible pharmacist continues to be responsible for securing the safe and effective running of the pharmacy during any periods of absence.

If there is more than one pharmacist working in the pharmacy at any one time, only one can be the responsible pharmacist. A pharmacist cannot be the responsible pharmacist for more than one pharmacy at any one time.

A hospital department has to be registered with the Council for 3 years before EU-trained pharmacists can assume responsible pharmacist responsibility.

Absence of the responsible pharmacist

A responsible pharmacist can be absent from the pharmacy for a maximum of 2 hours during the business hours of the pharmacy when the pharmacy is operational. The responsible pharmacist continues to be responsible for the safe and effective running of the pharmacy throughout this absence. A responsible pharmacist must comply with the conditions for absence, which are as follows.

- They remain contactable throughout their absence.
- They return with reasonable promptness.
- In the event that they cannot remain contactable, they must arrange for another pharmacist to provide advice during their absence.

Examples of standard operating procedures that need to be established

- Medicine management that describes procedures for ordering, storage, preparation, sale and supply, delivery, and disposal.
- Advice about medicinal products that includes:
  - staff training to be undertaken to provide advice.
  - those products for which staff may/may not provide advice.
  - when staff should refer to a pharmacist and what to do if a pharmacist is not physically present.
- Pharmacy staff listing based on competency.
- Management of records including controlled drugs, invoices, training details.
- Arrangements during absence.
- Change of responsible pharmacist.
- Complaints and incidents procedures.
- Changes to the pharmacy procedures and how staff are notified.

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