The Kings Fund

Ideas that change health care

Research paper

Authors
Dr Martin Duerden
Professor David Millson
Professor Anthony Avery
Dr Sharon Smart

The quality of GP prescribing

An Inquiry into the Quality of General Practice in England

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Dr Martin Duerden
Professor David Millson
Professor Anthony Avery
Dr Sharon Smart

The King's Fund

Dr Martin Duerden, GP and Assistant Medical Director, Betsi Cadwaladr University Health Board, North Wales, Honorary Senior Lecturer, Cardiff University and Bangor University

Professor David Millson, GP and former RCGP Prescribing Champion, Visiting Professor of Medicines Management, Keele University, and Principal Physician, AstraZeneca Rheumatology Research

Professor Anthony Avery, GP and Professor of Primary Health Care, Nottingham University Medical School

Dr Sharon Smart, Director of Clinical Knowledge, Sowerby Centre for Health Informatics at Newcastle (SCHIN), and Editor for NHS Clinical Knowledge Summaries

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1 Executive summary

This section summarises the findings by making recommendations and suggesting potential indicators that describe high-quality prescribing. It sets out the approaches to improvement that were identified by our review, and draws conclusions. Some of these recommendations are based on expert opinion and some are from the focus group meeting and seminar.

Recommendations and proposals for quality indicators

The level at which these indicators can operate is indicated by **GP**, **practice**, or primary care organisation – which may now include GP commissioning consortia in England (**PCO/GPCC)**. Where there may be an overall responsibility this is flagged up, for example, where the Department of Health (**DH)** or other regulatory bodies are involved.

Safety

Demonstrate use of systems to reduce medication error and potential for drug interaction *(GP, practice)*

GPs should be able to demonstrate that they have systems in place to help guard against medication errors. These include: ensuring that prescribers have access to all necessary information about the patient and their medication at the point of decision-making; use of computerised hazard alerts and reference sources such as the *current* BNF when making prescribing decisions; and having robust systems for repeat prescribing, laboratory test monitoring, and medication review.

Evidence of significant event reviews arising from prescribing errors *(GP, practice, PCO/GPCC)*

Significant events relating to medication error should be investigated and lessons learned within an 'appropriate blame' culture. If there is an obvious theme (ie, similar packaging resulting in two drugs being confused) that might affect other practices, this should be flagged up to the PCO/GPCC and the National Patient Safety Agency. For individual GPs these events could be reflected on at the time of appraisal.

Assess individual GPs' prescribing against safety indicators developed by the Royal College of General Practitioners *(GP)*

The intention is that prescribers will be able to use the RCGP prescribing safety indicators to audit their prescribing and to make improvements. The indicators could be used to prompt significant event audits and as evidence for discussion at appraisals. In the future, it is possible that prescribing safety indicators could form part of revalidation of GPs.

Reduce risk of dispensing errors by uptake of electronic transmission of prescriptions *(practice, DH, regulatory level)*

The Electronic Prescribing Service has potential to reduce the risks of dispensing errors and its continued roll-out and evaluation should be encouraged.

Demonstration of response to National Patient Safety Agency (NPSA) alerts (*GP*, *practice*)

Each GP and practice should be able to clearly demonstrate the action they have taken in response to NPSA (or its successor organisation) alerts: recent examples are for warfarin, lithium and 'loading doses'. Ideally, audit material should be provided as evidence.

Patient-centred

Demonstration that patients' views about medicine-taking is explored and their choice considered at the point of prescribing *(GP, practice)*

This could be investigated using patient experience surveys. GPs could develop systems to record and demonstrate that discussions have taken place, particularly with high-risk medicines and/or those used for the treatment of long-term conditions. GP training needs to reinforce the communication skills aspect of this.

Suitable, accredited information on medicines and the medical conditions they treat are provided on the internet (or supplied) for patients to access *(GP, practice)*

Ready access to patient decision aid material can be provided – usually via computer. The GP computer system can be configured to indicate when a patient information leaflet has been issued and this can be recorded in the medical record.

Repeat prescribing systems have been audited to ensure accurate and timely supply of medicines in accordance with a written repeat prescribing protocol *(practice)*

Practices should have a written repeat prescribing protocol and should undertake audits to help ensure compliance with this. Patient surveys may also be valuable in assessing patient views on the repeat prescribing system. Practices will need to adapt their repeat prescribing protocols in light of the introduction of electronic transfer of prescriptions from general practices to dispensing contractors.

There is demonstrable co-ordination of prescribing between hospitals and general practice *(hospital, practice)*

The Care Quality Commission already requires that, in England, discharge summaries are shared with patients and issued to GPs within 72 hours of discharge. These summaries should contain details of any medication prescribed at the time of discharge along with any adverse reactions or if allergy to medication is experienced by the patient during admission. There should be a regular audit of both admission letters and discharge summaries to determine that they contain accurate and useful information about medicines. General practices need to be able to demonstrate robust systems for medicines reconciliation after patients are discharged from hospital.

Practices should demonstrate that medication review is done regularly and effectively and to a high standard. Clinical pharmacists should be involved where practicable *(GP, practice, PCO/GPCC)*

Careful assessment of medication reviews should be conducted to determine that they are of high quality. This is already required by the

Quality and Outcomes Framework but scrutiny has proved difficult. Review by experienced practice pharmacists should flag up areas of concern or significant events, and these should be considered at practice level, and lessons learned.

Close co-operation between the practice and community pharmacy should be demonstrated *(practice)*

This may be difficult where there are many local pharmacies. Ideally each practice should have regular meetings with the pharmacies that are most closely related to them. Where pharmacists flag up significant medication issues they should be given feedback on how these have been dealt with. Likewise, if GPs encounter dispensing errors or inappropriate advice has been given to patients there should be a frank and open discussion.

Extra support is provided to assess patients who need to take six or more medicines (necessary polypharmacy) *(GP, practice)*

Six-monthly reviews of patients on four or more medications is already a Quality and Outcomes Framework target. GPs and practices should be able to demonstrate that they have robust systems for review of more complex patients and that this process is clearly recorded and audited.

Information support

GPs should have ready access to accredited, concise, high-quality information on drugs. Access to this high-quality information should be demonstrated as part of appraisal and revalidation (linkage at point of access is ideal) *(GP)*

GPs should have systems to demonstrate how they access prescribing support materials and drug information. Ideally a record should be kept of these access events. Examples of the use of these materials should be demonstrated at the time of appraisal; for example, where an important learning point has been encountered, this can be discussed. Systems for electronically logging access to information could be used.

All prescribers should have ready access to fast and reliable internet access *(practice, PCO/GPCC)*

This should be happening already but we encountered evidence that internet access could still be a problem for some prescribers. There should be scrutiny to ensure that practice NHS internet access is 'fit for purpose'.

Multi-faceted systems are used to inform GPs and keep them up-to-date (newsletters, email, events etc) *(PCO/GPCC, regulatory)*

The PCO/GPCC should ensure that sufficient effort is made to supply practices with relevant information and have a medication/prescribing communication strategy. Funding may be required for high-quality medicines information. This needs regular review.

Practices should have agreed preferential drugs that they become familiar with (formularies) and demonstrate adherence to, that are relatively cost-effective to the health care economy *(practice, PCO/GPCC)*

The practice or area should have an agreed formulary. This has important safety implications as well as ensuring cost-effectiveness and consistency.

By developing familiarity this ensures quick recognition of problems, such as incorrect doses.

Practices should have agreed policies on their interaction with drug company representatives. GPs should be aware of potential biases in information sources *(GP, practice, PCO/GPCC)*

Having an explicit policy or 'rules of engagement' ensures a consistent approach to drug company representatives and helps in consideration of conflicts of interest. There should be regular training in critical appraisal skills and understanding of sources of bias for all prescribers. Such training could be explored and reflected on at the time of appraisal.

Ne*tworks are in place and active between GPs and other informed prescribing advisers (GPs, PCO/GPCC*)

A Quality and Outcomes Framework target already encourages regular meeting with the locality prescribing adviser. Topics like comparative prescribing information or local policies can be discussed with a view to encouraging reflection and, where appropriate, change. GPs should be able to demonstrate that they have regularly attended such meetings. They can give feedback on the usefulness, or otherwise, of these encounters.

Value for money

Switching of medicines to reduce costs is accepted by patients but there should be careful communication of the reasons and ready access to the prescriber, if required *(GPs, practice, PCO/GPCC)*

Patients generally have a preference for face-to-face encounters if medication switches are made. However, we came across evidence that this can be successfully achieved using written communication. If medication switches are made for economic reasons there should be explicit and careful communication of the reasons for such changes, under agreed operating procedures. The programme should be carefully evaluated and there should be collation of information about the success, or otherwise, of the change process. If patients are unhappy or concerned they must have ready access to the prescriber.

Systems to enable GPs to be more cost-aware in prescribing choices should be developed and used. Patients should have greater understanding of the cost of medicines *(practice, PCO/GPCC, computer system suppliers, regulatory)*

It is generally agreed that GPs do consider costs when making drug choices. More could be done to flag up cost implications at the time of prescribing. It is also possible that drug wastage by patients would be less if the costs of medication supplied were made explicit. Consideration should be given to research to see if medication adherence can be improved by labelling prescriptions with the cost to the NHS.

Generic prescribing rates are a good indicator of quality and value for money *(GP, practice)*

Generic prescribing is clearly regarded as a marker of quality prescribing in the UK as long as due regard is given to when generic prescribing may be inappropriate. GPs or practices with low generic prescribing rates should be encouraged to increase their use of generic preparations.

Pricing structure of drugs should ensure that brands are not priced more cheaply than generics *(DH, regulatory)*

The system that causes branded generics to undercut generic prices in the Category M basket requires urgent revision. It can perversely encourage switching from generic prescribing back to brand prescribing which is counter to years spent encouraging generic prescribing as a principle. This is also confusing for patients.

Use of decision support prescribing systems *(practice, PCO/GPCC)*

Increasingly, prescribing support software (eg, ScriptSwitch®) is being commissioned and programmed by PCOs. Such software links to GP clinical systems, to provide prescribers with local formulary choices and advice on the latest cost-saving, safety and effectiveness issues relating to medicines. At the point of prescribing, the software will offer alternative prescribing options if these are cheaper than the one initially selected, or messages reminding clinicians of any relevant information. This support software has an important role in offering cost-effective prescribing choices and in keeping prescribers updated and engaged with local decision-making. Appropriate use of these systems seems a valuable intervention and should be supported as an example of intelligent 'decision support'.

Other indicators

Robust training of prescribers-in-making and junior prescribing *(DH, government)*

Unfortunately the funding for the eLearning for Healthcare *Prescribe* project has now been withdrawn as part of the government's financial cuts. The project has been mothballed. When we prepared this report our view was that this was a vital development to ensure better education of medical students and young doctors and to encourage them to be better and safer prescribers. By helping doctors to avoid medication errors, and by making junior prescribers cost-aware, it was highly likely to be cost-effective. The *Prescribe* project should be reinstated.

Regular updating on therapeutics demonstrated via appraisal and revalidation *(GP, PCO/GPCC)*

Our review concluded that formal, continuing postgraduate training in prescribing and therapeutics is necessary. PCOs could be measured against how many of their contracted GPs have undergone such training. This training should also be part of the GP appraisal and revalidation process as it is essential that all doctors keep up-to-date in this area of their work.

Transfer of admission medication and discharge medication streamlined *(practice, PCO/GPCC, hospital)*

It seems strange that after so many years of concern communication between practices and hospitals remains poor, as pointed out in the recent Care Quality Commission report. Robust systems for electronic transmission of vital medication and other clinical data should be developed rapidly. We are aware of exemplar practice and this should be shared and disseminated.

Transfer of knowledge from exemplary systems demonstrated – implementation of best practice (practice, PCO/GPCC, other bodies)

As with admission and discharge data there are many examples of good practice that can be shared and promulgated. The National Prescribing Centre has been very effective in providing the mechanism for this on a national basis. This promulgation should be maintained and enhanced and should focus on stimulating good prescribing and medicines management practice by GPs, alongside educational support.

2 Introduction and scope

This part of the Inquiry has examined the quality of general practitioner prescribing with specific reference to the patients' perspective and to their 'journey'. The other key feature of this review is the effect of prescribing on patient safety. The King's Fund Inquiry into the Quality of General Practice is specifically focused on England.

In a workshop in July 2009 to develop the scope for this review a number of patients and other stakeholders were asked for their view of good prescribing practice, including how medicines are managed within the NHS. The following criteria were derived:

- establishing concordance
- digestible information
- appropriate and informed
- value for the NHS
- safe: risks identified and minimised.
- convenient, timely
- error minimised
- seamless communication – between health care professionals, 'the interface', pharmacy etc.

In March 2010 the Inquiry held a seminar on prescribing at The King's Fund, kindly sponsored by First DataBank Europe, with participants including GPs, practice nurses, NHS executives, health academics and patient representatives.

Key issues raised in discussion include:

- How can better use be made of prescribing data and IT to improve the quality and safety of prescribing?
- What are the appropriate roles for nurse, independent and other non-GP prescribers in primary care?[1]
- To what extent should general practice take patient views on board and ensure that their choices have been explored at the time of prescribing?

1 This review has not examined non-medical prescribing in detail.

3 Context: Scale of prescribing and repeat prescribing

In England in 2009 the number of prescription items issued by general practitioners was 886 million (Prescribing Support Unit 2010). The net ingredient cost (that is, the cost of the drug and the additional cost related to supply) of these prescription items was £8,539 million. This is roughly 15 per cent of all NHS costs.

The average net ingredient cost per item was £9.64 in 2009 and the number of prescription items per head was 17.1, making the average spent per person in England on GP prescribing £165. The number of items dispensed per person has roughly doubled in the past 10 years (Prescribing Support Unit 2010). In the last decade the average number of items prescribed to people aged 60 or over is much higher and has also almost doubled from 21.2 to 40.8 items in 2006, for each person per year (NHS Information Centre 2007).

Of the total, 83 per cent of the items were written generically, but only 66 per cent of all prescription items were dispensed generically, representing 28 per cent of the total cost (Prescribing Support Unit 2010). This is because some drugs prescribed generically are only available as a brand product (they are still 'in patent') and a small number cannot be supplied as a generic product because the pharmacist (or dispensing doctor) does not have the generic version in stock.

GPs wrote 98.5 per cent of all prescriptions and an estimated 1.5 per cent were written by nurses and other non-medical prescribers, of which 0.6 per cent were written by dentists (Prescribing Support Unit 2010).

Estimates vary but GPs issue a prescription in around two-thirds of their consultations. Although there has been no recent assessment of the scale of repeat prescribing it is estimated that around 70–80 per cent of all prescriptions are issued 'on repeat'; that is the prescription is signed by the GP at the request of the patient for a medicine or product that has been previously prescribed, but the patient is not seen at a consultation (Harris and Dajda 1996).

A large study on hospital admissions in Merseyside published in 2004 estimated that 6.5 per cent of all admissions could be attributed to, or associated with, adverse drug reactions, with up to two-thirds of these being preventable (Pirmohamed *et al* 2004).

4 Methods

Literature review

This is a narrative review and not a systematic review. A literature review was conducted to identify relevant published articles and research. Ovid Medline and Embase were searched for articles on GP prescribing and quality of prescribing as a whole. Those incorporated were supplemented with other articles identified by the authors, including a number of articles recommended by experts in the field.

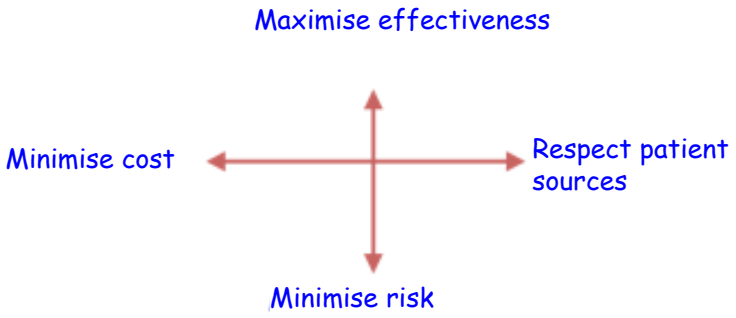
The websites of the Royal College of General Practitioners, British Medical Association, General Medical Council, and Department of Health and other national authorities and bodies were also searched for relevant professional guidance and commentary.

5 Defining good prescribing

What constitutes good prescribing? (Barber 1995)

'Drugs are the mainstay of medical treatment, yet there are few reports on what constitutes "good prescribing". What is more, the existing guidance tends to imply that right answers exist, rather than recognising the complex trade-offs that have to be made between conflicting aims. This paper proposes four aims that a prescriber should try to achieve, both on first prescribing a drug and on subsequently monitoring it. They are: to maximise effectiveness, minimise risks, minimise costs, and respect the patient's choices. This model of good prescribing brings together the traditional balancing of risks and benefits with the need to reduce costs and the right of the patient to make choices in treatment.

'The four aims are shown as a diagram plotting their commonest conflicts, which may be used as an aid to discussion and decision making:'



Assessing good prescribing:

'…Whereas consensus may be gained within medicine on how to balance effectiveness, risk, and cost of drug treatment for a condition, including the patient makes judgement on the quality of prescribing difficult to conduct at a distance. In contrast, drug and therapeutics committees, pharmacists, medical advisers, and commissioning agencies are increasingly making judgements on the acceptability of prescribing. These approaches need not be mutually exclusive. The model of good prescribing proposed … can be integrated with the proscriptive, protocol driven approach currently gaining favour – for example, by setting a standard that 80 per cent of prescribing meets the protocol. The level at which the standard is set must come from debate among prescribers, patients, and commissioning agencies.'

Quality from whose perspective?

What is good prescribing and how can we define it? The term 'good prescribing' is widely used by health care policy-makers, politicians and practitioners alike, yet a clear definition is elusive. There is a range of people involved in prescribing, including the recipients of the prescription, and each might define good prescribing differently. The NHS as a whole might define it as the lowest-cost prescribing that meets public health needs. The Department of

Health and commissioners are keen to monitor prescribing and may measure good prescribing according to the available information and, as this largely relates to drug costs, their definitions of good prescribing tend to use cost as the focus. The pharmaceutical industry may look on good prescribing as prescribing of the latest drug to all patients who have need of treatment on the basis that new equals better. Evidence-based practitioners tend to define it as the use of therapies proven to be most effective in randomised controlled trials (RCTs), or according to evidence-based guidelines.

Therefore it can be seen that good prescribing is a phrase describing a range of values and behaviours. Many words are used to describe prescribing quality, such as good, poor, appropriate or inappropriate, optimal or sub-optimal, and error. A review of appropriate prescribing in older people by Spinewine *et al (2007)* identified terms which were specific to some types of inappropriateness. For example, 'underprescribing' refers to failure to prescribe drugs that are needed; 'overprescribing' refers to prescribing more drugs than are clinically needed; and 'misprescribing' refers to incorrectly prescribing a drug that is needed (Spinewine 2007). However, there are many other elements of prescribing and medicine management that go beyond this, for example, prescribing an evidence-based treatment to someone who is not keen to take treatment and for that reason is unlikely to comply, which results in failure to achieve concordance (and, potentially, waste). Much of the published work on good prescribing has looked at appropriateness of prescribing from the aspect of pharmacological correctness, that is, whether a drug was seen as safe and effective, or sometimes cost-effective. This review intends to go beyond this narrow focus and look at prescribing from the perspective of the patient, examining such things as convenience and the communication and systems between health care providers that ensure patient safety.

There has been a lot of research directed at whether evidence-based medicines have been prescribed for the right patient. Criteria to detect under-utilisation of drugs usually state that a drug should be prescribed to treat or prevent a specific condition, unless there is a contra-indication. These criteria have been applied to different areas, such as heart failure and myocardial infarction, osteoporosis and fractures, atrial fibrillation, pain, and depression in the literature. But alongside these treatments not being appropriately used for people who 'need' them, the prevalence of not taking the treatment (non-compliance or waste) is usually high in those that do get them. The National Service Framework for Older People suggested this might be as high as 40 per cent (Department of Health 2001a).

The main restrictions of present studies are that few have examined prescribing of medicines for several medical conditions simultaneously, which can potentially lead to harm and polypharmacy. The prescriber might decide, quite correctly, that the burden of drugs is already excessive, and adding to the list of medication the patient is expected to take would be excessive and potentially harmful. Also criteria and guidelines for appropriate prescribing may not take into account factors such as life expectancy and time needed to derive clinical benefit which might provide a good reason not to prescribe.

Poor prescribing choice criteria usually focus on choice of drug, dose, drug interactions, duration of therapy, duplication, and follow-up. The 'drug-to-avoid' criteria have been the most frequently used, usually in relation to older people. This consists of a list of drugs that should be avoided in older people

because the risks of use outweigh benefits (for example, Beers criteria – see later). Such lists include drugs that should be avoided in any circumstances, doses that should not be exceeded, and drugs to avoid in patients with specific disorders. These criteria have been frequently applied to examine prescribing in aggregate on large databases. A study in Europe found that 20 per cent of elderly patients cared for at home used at least one inappropriate drug as defined by the Beers or McLeod criteria, but there were substantial differences between countries. One question is the extent to which such lists can be generalised across different countries as prescribing practice varies significantly (Spinewine 2007). The Beers criteria, for example, developed for the USA, seem largely irrelevant to the UK. As pointed out by Spinewine the prescription of drugs that should be avoided can be a relatively minor problem compared with other categories of inappropriate prescribing such as not taking medicines (non-compliance), failure to monitor medication, or failure to identify drug-drug and drug-disease interactions.

Despite all of this there is surprisingly little information or evidence on what patients would regard as good prescribing. One can surmise that people want to access their medication readily, have uncomplicated drug regimens and keep adverse effects to a minimum. They may want easily digestible information on their treatment and they would want the prescriber to be up-to-date and well informed. Some of these elements were explored at our stakeholder meeting.

Evaluation of an 'episode of prescribing'

Several attempts have been made in the literature to describe a high-quality act of prescribing. A useful summary of these is to consider the following to determine if the act of prescribing is of high quality (derived from stakeholder meeting, July 2009):

- what are the needs of patient? Will these be met?
- what does the patient desire? Is this considered?
- is it necessary to prescribe?
- if so, what are the prescribing options? Consider: products that are effective, relatively safe, value for money
- achieve concordance: come to a shared decision with patients about whether to prescribe, what to prescribe, how to take the medicine and what follow up is needed
- consider the need to review the patient: in terms of: assessing therapeutic benefits, potential side-effects and need for laboratory test monitoring
- record information accurately
- develop robust systems for safe and effective repeat prescribing, medication review and error trapping
- ensure that the prescription has been guided by an informed prescriber who has ready access to decision support and educational resources
- the prescriber should be able to audit and review prescribing decisions and discuss these with others.

6 Background on development and use of prescribing indicators

Indicators are commonly used in the public sector to gain an impression of a quality of services. If they are developed and used appropriately they can help to identify potential problems and encourage quality improvement and/or improved safety.

In the UK, there is a long history of indicators being used to show how prescribing performance of NHS general practices might compare with other practices, local and national averages or with themselves over time. The National Prescribing Centre and the Prescribing Indicators National Group recommend that prescribing indicators should:

- be based on scientific evidence supplemented in a systematic way by expert opinion
- cover a range of process and outcome measures
- represent areas where change is largely within the control of the clinician
- represent areas of practice that are regarded as important by clinicians and consistent with national health policy initiatives
- represent areas of practice where the most important case mix and risk adjustment factors are known and data about them can be collected
- be based on clinical data that:
  - should be recorded by clinicians as part of the process of clinical care
  - should be electronically recorded in clinical records using current clinical terminologies and codes
  - can be extracted in a timely manner
  - are sensitive to changes in quality of care
  - can be easily checked for validity and reliability.

(Prescribing Support Unit 2009b)

Further information on the selection and use of indicators is available from *The Good Indicators Guide* (NICE 2011). Key points to recognise are that 'indicators only indicate'; they never capture the full complexity of the system, and they must be understood in context.

There have been many attempts over recent years to develop prescribing indicators in the UK and other countries. For example, numerous indicators have been developed based on the interrogation of prescriptions issued by general practitioners (eg, using PACT data (Avery *et al* 1998)). These types of indicators have been particularly helpful in making comparisons in aspects of prescribing quality and cost between general practices, PBC clusters and PCTs, and in tracking changes over time. Many indicators were spawned by the Audit Commission document *A Prescription for Improvement* (Audit Commission 1994) and have been used to investigate changes in general practice prescribing (Avery *et al* 2000). Other indicators have been

developed by the Prescribing Indicators National Group (Prescribing Support Unit 2009b).

Indicators based on the use of GP prescribing data continue to be employed regularly in the UK, and continue to form part of local prescribing incentive schemes. Nevertheless, while potentially extremely useful for analysing prescribing patterns, these data are rarely linked to diagnoses and patient characteristics and so they have limitations when assessing quality and safety.

Other indicators have required very detailed analysis and assessment of clinical records (eg, the medication appropriateness index (Bregnhoj *et al* 2005)). These are potentially very useful for research purposes, but are not feasible for the large-scale assessment GP prescribing.

A major advance in recent years in terms of developing and using more sophisticated indicators of quality and safety of prescribing has involved the interrogation of electronic medical records. This has come about because of considerable improvements in the quality and completeness of electronic records in general practices, and also due to developments in the ability to run electronic searches and analyse the results across large numbers of practices.

It is this latter type of indicator that we will focus on primarily in this document in relation to the identification of potential prescribing safety indicators. We have identified the following potential sources for these indicators:

ACOVE (Assessing Care of Vulnerable Elders) – this RAND project (Wenger and Shekelle 2001) aimed to develop a set of evidence-based, quality of care indicators relevant to vulnerable older people using systematic literature reviews, expert opinion and guidance from expert groups and stakeholders. The indicators have been considered for use in the UK and the Netherlands. A multidisciplinary panel of 10 health professionals in the UK accepted 102 (86 per cent) of the 119 quality indicators as being valid for use in England (Wenger and Shekelle 2001).

Beers criteria (Fick *et al* 2003) – this is a set of criteria from the US for assessing potentially inappropriate medication use in people aged 65 years and older. The original list of criteria was published in the 1990s and updated in 2003.

British National Formulary (Joint Formulary Committee 2010) – this is a highly respected source of drug information for prescribers in the UK.

National Patient Safety Agency (NPSA) documents – the NPSA has produced a number of documents that are relevant to the safety of prescribing in primary care (NPSA 2009). For example, the fourth report from the Patient Safety Observatory (NPSA 2011) highlighted medication incidents in the community and at the interface between community and hospital care and also suggested ways in which risks of harm could be reduced. In addition, the NPSA has highlighted a number of specific safety issues relevant to primary care including anticoagulant prescribing, dosing errors with opioid medicines and the prescribing of methotrexate (NPSA 2009). A number of these issues could be incorporated into indicators.

PINCER trial indicators – a cluster randomised trial took place in the UK between 2005 and 2009 to assess a pharmacist-led intervention versus

simple feedback in correcting clinically important problems in medicines management in general practices in England (Avery *et al* 2010). This was a parallel-group, pragmatic, cluster trial in which 72 general practices in England were randomised to either: (1) computer-generated feedback ('simple feedback') in which practices were asked to make changes to patients' medication within a 12-week period, or (2) the pharmacist-led intervention comprising computer-generated feedback, educational outreach and dedicated support. The pharmacist-led complex intervention was successfully delivered in all 36 general practices. Preliminary results indicate that compared with simple feedback, the pharmacist-led intervention resulted in reductions in the proportion of patients at risk of prescribing and monitoring errors.

STOPP and START tools (Gallagher *et al* 2008) – these sets of indicators have been developed to assess the appropriateness of prescribing for older people (the STOPP tool relates to potentially inappropriate drugs and the START tool relates to potentially indicated appropriate drugs). The tools have been developed and validated by a team from Cork, Republic of Ireland.

Quality assessment for general practice, NPCRDC Report Nov 2001 – this research indicates that GPs value process indicators particularly highly:

- repeat prescribing system
- repeats reviewed at least annually
- audits of prescribing
- regular prescribing meetings
- formulary development with regular review.

7 What is known about variation in prescribing practice?

Variation at PCT level

Most interest in variation in prescribing practice has concentrated on the potential to save money. This assumes that prescribing patterns that are less costly do not reflect poorer quality of care, and for many drugs this appears to hold true. In 2007 the National Audit Office (NAO) review of *Prescribing Costs in Primary Care* examined variation in prescribing between PCTs. It stated that £200 million could be saved if all PCTs in England used statins and a number of other drugs in the same way, or at the same standard, as the 25 per cent most efficient PCTs (National Audit Office 2007a). In particular this highlighted the use of generic simvastatin rather than other brand statins and aspirin as an alternative to clopidogrel (although a generic clopidogrel has subsequently emerged). The use of low-cost statins has become one of the *better care, better value* indicators of the Institute of Innovation and Improvement in England (Institute for Innovation and Improvement 2010). This advises that GPs can switch patients to low-cost statins provided there are no clinical reasons for them to remain on the more expensive drug and increases pressure on NHS bodies to be seen to actively pursue productivity gains.

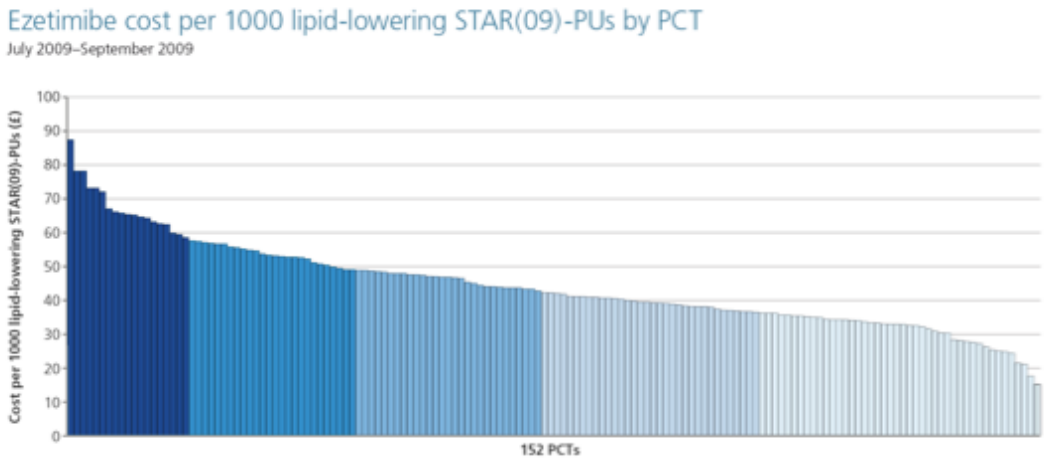
The NAO published a follow-up report in 2009 saying its recommendations had been successful based on an estimate of the savings that PCTs had achieved through changing prescribing patterns in four therapeutic areas, it calculated that the total saving in 2008, across all PCTs in England, was £394 million.

A further report in November 2010 from *QIPP/Right Care* again highlighted some prescribing elements as part of the new government policy to improve efficiency in the NHS through health care reforms (Department of Health 2010a). The White Paper in July 2010, *Equity and Excellence: Liberating the NHS* gave a commitment to increasing value from the resources allocated to the NHS (Department of Health 2010b). The report entitled *The NHS Atlas of Variation in Healthcare: Reducing unwarranted variation to increase value and improve quality* explores ways that those working in the NHS can address variations and reduce unwarranted variations in activity and expenditure (Department of Health 2010a). It states that any such variation indicates the need to focus on appropriateness of the clinical service and to investigate the possibilities that there is over-use of some technologies, with some activities being undertaken which are not as cost-effective. It asserts that if these 'lower value' activities are reduced, the savings could be used to commission higher value activities which are not funded at present. This is the health economic argument of opportunity costs. It states that addressing the appropriateness of services is vital for the optimal health care of patients and populations irrespective of the existence of financial constraints. The report argues that variation is an in-built process within the NHS, and may be appropriate, but when identified requires careful inspection to determine if it represents good quality practice. The natural reaction to variation is to challenge whether the data are correct or to determine if the population is different and have different needs, and this challenge is healthy within the system. In much the same way as the NAO report from 2007 it looks at

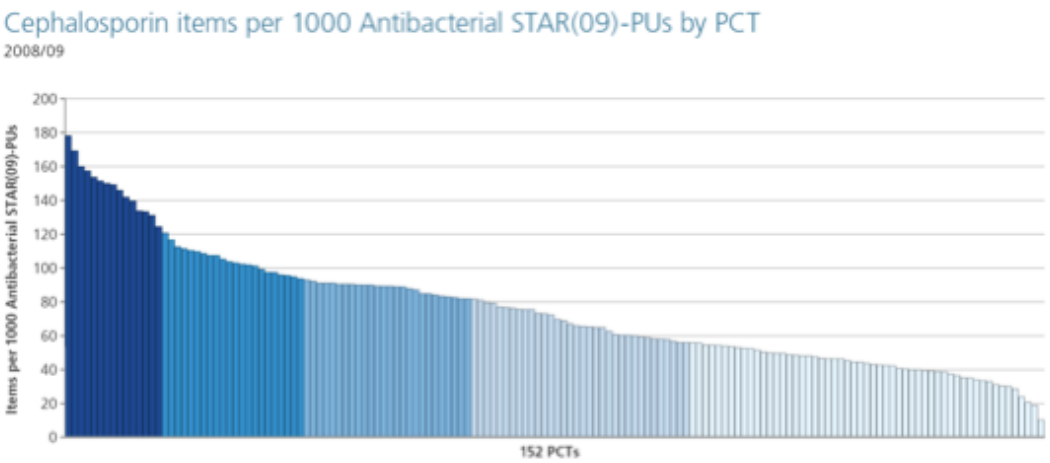
several examples of prescribing where there is clear evidence of variation and points out that quality of care and costs of prescribing can be improved by reducing variation. The examples provided in the report are the use of the cheaper generic statins and the place of ezetimibe for lipid-lowering, and the place of the quinolone and cephalosporin antibiotics to treat infections (Department of Health 2010a).

Examples in variation at PCT Level: Ezetimibe and cefalosporins

There is an almost six-fold variation in the ezetimibe cost per 1000 lipid-lowering STAR(09)-PUs items across England (Department of Health 2010a). The use of *specific therapeutic group age-sex weightings related prescribing units*, or STAR(09)-PUs, is a system of normalising prescribing data to enable more balanced comparison within specific therapeutic domains. When the five PCTs with the highest rates and the five PCTs with the lowest rates are excluded, there is a greater than three-fold variation. The report concludes that this variation in prescribing practice for ezetimibe is greater than can be explained by differences in the population. There seems to be a significant opportunity for cost-saving.



There is an almost 18-fold variation in the prescription of cefalosporin items per 1000 antibacterial STAR(09)-PUs (see chart below). When the five PCTs with the highest rates and the five PCTs with the lowest rates are excluded, there is a five-fold variation. The report points out that broad spectrum antibiotics such as cefalosporins, need to be reserved to treat resistant disease and should generally be used only when standard and less expensive antibiotics are ineffective. In primary care in England usage of cefalosporins, at 9 per cent, accounts for a substantial proportion of all antibiotic daily doses.



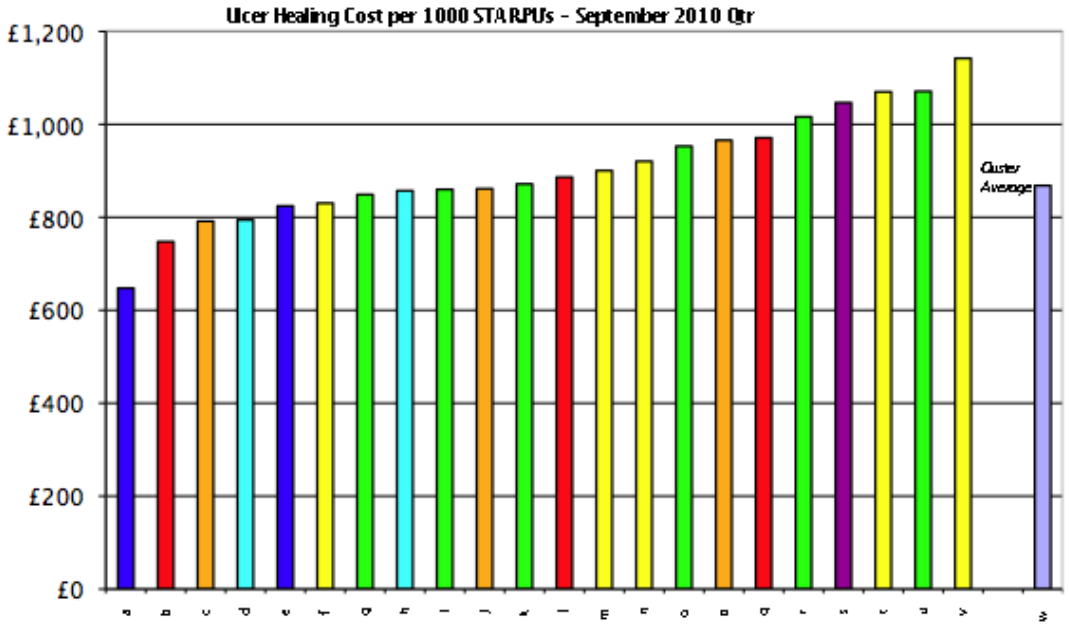
Variation between practices

PCT prescribing advisers regularly review prescribing data and will have a good knowledge of variations in prescribing practice. These variations can be very marked, often with significant differences between geographically close practices with similar demographics. It can be difficult to determine why these variations exist but individual GPs and their practice teams often have very different philosophies and culture. Some people might argue that this variety is one of the strengths of general practice and the diversity helps patients choose the style of general practice they prefer. However, these differences may reflect differences in quality of care and can lead to extra expense and potential waste of valuable resources. An example might be choice of antibiotic where inappropriate excess use of certain types of broad spectrum antibiotics could potentially lead to problems with resistant organisms in the community (see example below of variations in use of formulary antibiotics). These variations might be a particular challenge for fledgling GP commissioning consortia.

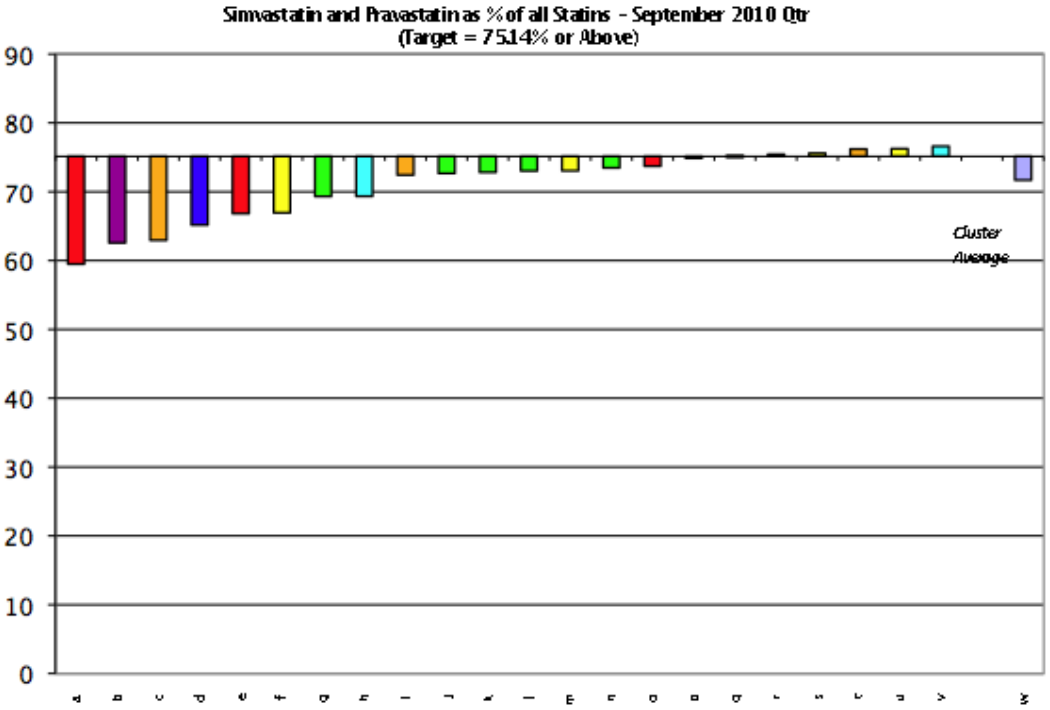
The NAO advises that benchmarking, where practices are given regular feedback on this variation (such as illustrated below) can have a significant impact on prescribing behaviour in its own right, probably due to peer pressure (NAO 2007a). There is reasonable evidence that incentive schemes providing financial incentives can also change prescribing behaviour and have a net effect on reducing overall costs of prescribing (NAO 2007a). Many PCTs have set up local enhanced services on improving quality of prescribing and reducing costs. These schemes are usually based on drawing practices towards a common level of accepted good practice.

Example of variation in prescribing between practices in a sample GP commissioning cluster

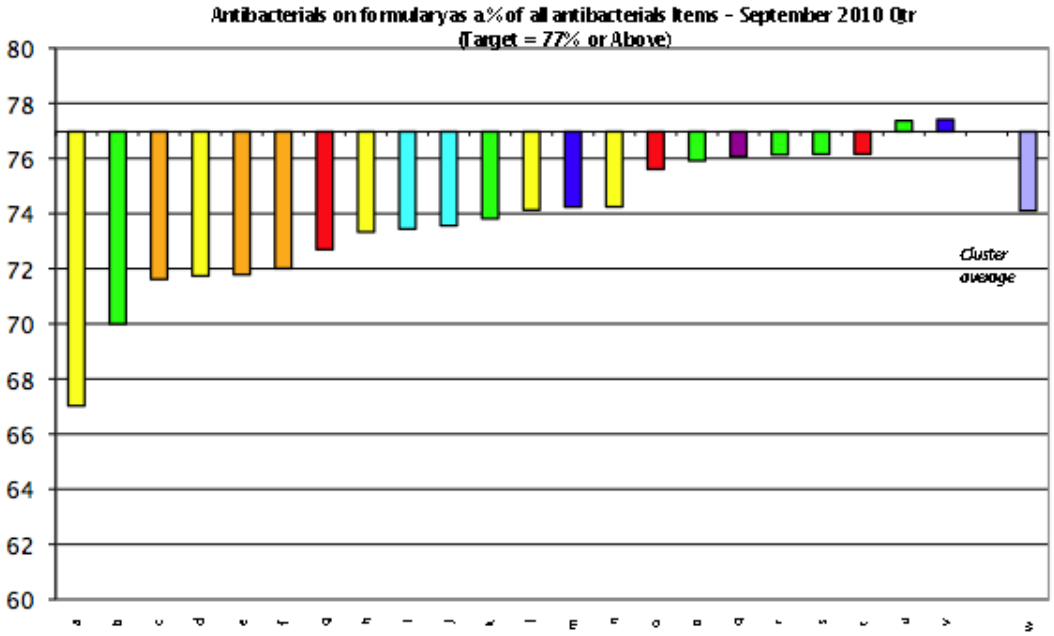
There is a roughly two-fold variation in the cost of proton-pump inhibitors.



Example of sample GP commissioning cluster variation: Proportionate use of low cost statins



Example of sample GP commissioning cluster variation: Proportionate use of formulary antibiotics



Variation in waste

In 2007 the National Audit Office (NAO) estimated that drugs wastage is a significant cost for the NHS in England (NAO 2007a). It estimated at least £100 million a year, and perhaps considerably more than this, although its view was that lack of robust data, and the wide range of reasons for waste, makes quantification difficult. It highlighted that there are local examples of anti-wastage procedures in place, such as limiting the initial time period of new prescriptions, or the length of time between repeat prescriptions, and information campaigns to raise public awareness about the cost of medicines to the NHS. The NAO pointed out that the Department of Health recognises that wastage is a serious problem, and has pursued policies to reduce this, such as medicines use reviews for patients with long-term conditions, and repeat dispensing schemes that allow patients to collect repeat prescriptions directly from pharmacists, who then check whether the patient is still taking their medicine or experiencing difficulties with it. The NAO was concerned that wastage of drugs, under-prescribing, and over-prescribing, whenever they occur, represent poor value for money.

A more recent report commissioned for the Department of Health indicates that the NAO report may have been too conservative and estimates that primary care in England wastes £300 million every year on unwanted medicines (York Health Economics Consortium, University of York, and the School of Pharmacy, University of London 2010). They estimate that this sum represents approximately £1 in every £25 spent on primary care and community pharmaceutical and allied products use. Not all of this is avoidable however; the researchers estimate that less than 50 per cent of this total figure is cost-effectively preventable. Their report suggests that about one in five people admit to having a 'waste' medicine in their possession.

The extensive research undertaken by the authors found the causes of medicines wastage to be complex. However, they suggest that the root causes of medicines wastage encompass:

- patients recovering before their dispensed medicines have all been taken
- therapies being stopped or changed, for example, because of ineffectiveness and/or unwanted side-effects
- patients' conditions progressing, so that new treatments are needed
- patients' deaths which, as well as revealing previously unused medicines, may involve drugs being changed or dispensed during the final stages of palliative care
- factors relating to repeat prescribing, which may cause excessive volumes of medicines to be supplied
- the failure to support medicines-taking in vulnerable individuals living in the community.

The authors propose several measures to tackle waste by building on and refining existing policies and encouraging pharmacists and practice nurses to support patients. For example:

- providing targeted support for patients starting new therapies and those on unusually costly and/or difficult-to-take treatments
- supporting high-quality prescribing, and ensuring that medication and associated treatment regimens are effectively reviewed
- incentivising closer professional management of medicines supply at the point of dispensing
- encouraging the flexible and informed use of 28-day and – where it benefits patients – either longer or shorter prescribing periods
- caring better for 'treatment resistant' patients who may not be taking their medicines correctly
- providing better quality pharmaceutical care for isolated patients and other vulnerable groups of patients
- undertaking audits of the supply and use of monitored dosage systems
- enhancing hospital and primary care liaison, eg, improving the quality of care at the time of hospital discharge
- delivering better-integrated terminal care in home settings
- developing more effective national or local waste medicines return and related public information campaigns.

The NAO view was that there is no systematic approach in monitoring levels of drugs wastage, so it is difficult to form a view on whether current anti-wastage measures are effective (NAO 2007a). This has implications for understanding quality measures in prescribing as assessing whether local prescribing volumes are consistent with clinical need becomes more complex. However, combining prescription data with local prevalence data can provide benchmark information for PCTs and GP practices to help identify opportunities for improving the value for money they get from their prescribing.

8 Improving the quality of prescribing and improving patient safety

Safety is an essential element of prescribing quality. In this section we examine how improvements in the quality of prescribing can improve patient safety.

A review of medication errors in general practice

First, this review highlights current concerns about the safety of prescribing in general practice. We then illustrate the improvements in quality that are likely to lead to safer care for patients, which include:

- better education and training in therapeutics for prescribers
- access to all necessary information on the patient and the drug at the point of decision-making
- improving strategies for avoiding errors and error-trapping (including the use of electronic prescribing)
- improving communication with patients over medicines
- improving systems for patient review, the monitoring of medicines and repeat prescribing
- improving communication at the interfaces in health care.

Prescribing safely

Medication errors are an important cause of patient morbidity and mortality. Problems occur at all stages of the medicines management process, but particularly in relation to the prescribing decision, issuing of prescriptions, patient counselling, medication monitoring and the interface between primary and secondary care. Adverse events are more common and serious for patients in high risk groups and for certain groups of medications. Taking particular care in these situations can help to minimise the risks of patient harm.

Recommendations to GPs to improve safety of prescribing (Avery 2010a)

10 top tips for safe prescribing

1. Keep yourself up-to-date in your knowledge of therapeutics.
2. Before prescribing make sure you have all the information you need about the patient, including co-morbidities and allergies.
3. Before prescribing make sure you have all the information you need about the drug(s) you are considering prescribing, including side-effects and interactions.

4. Sometimes the risks of prescribing outweigh the benefits and so before prescribing think: 'Do I need to prescribe this drug at all?'
5. Check computerised alerts in case you have missed an important interaction or drug allergy.
6. Always check the prescription for errors before signing it.
7. Involve patients in prescribing decisions and give them the information they need in order to take the medicine as prescribed, to recognise important side-effects and to know when to return for monitoring and/or review.
8. Have systems in place for ensuring that patients receive essential laboratory test monitoring for the drugs they are taking, and that they are reviewed at appropriate intervals.
9. Make sure that high levels of safety are built into your repeat prescribing system.
10. Make sure you have safe and effective ways of communicating medicines information between primary and secondary care, and acting on medication changes suggested/initiated by secondary care clinicians.

Quantifying prescribing errors in general practice

There have been numerous studies investigating the incidence of errors (and preventable adverse events) in different aspects of medicines management process in general practice and these come up with a wide range of estimates of the size of the problem. The following bullets give some examples.

- It has been estimated that there are around 3,500 hospitalisations and 400 deaths per year in the UK in patients aged 60 years and older taking aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) (Langman 2001).
- Around 7.5 per cent of prescriptions in general practice contain an error (although probably less than 1 per cent contain errors that are likely to result in harm to patients) (Shah *et al* 2001).
- In a practice with a population of 1,000 patients aged 65 years and older living in the community there will be approximately 14 preventable adverse drug events per year and five of these will be serious (Gurwitz *et al* 2003).
- Around one in 25 hospital admissions is drug-related *and* preventable (Howard et al 2007).
- Patients in care homes have a roughly 50:50 chance of having a preventable adverse drug event each year (Gurwitz *et a*l 2005).

Whether prescribing errors result in harm to patients depends on a number of factors, but it is important to recognise that certain patients are at particularly high risk and to be aware of which drugs are commonly associated with morbidity in general practice.

Which patients are most at risk?

Risks associated with medication errors are particularly high in the following groups of patients:

- the elderly, particularly when frail
- those with multiple serious morbidities taking several potentially hazardous medications
- those with acute medical problems
- those who are ambivalent about medication-taking or have difficulty understanding or remembering to take medication.

This means that it is particularly important to try and take the time necessary to ensure that prescribing, patient and carer education, and monitoring arrangements, are as safe as possible for these patients.

Drugs commonly associated with preventable harm in general practice (Avery 2010b)

Drugs with low therapeutic index:

- warfarin
- methotrexate
- amiodarone
- digoxin.

Other commonly used drugs:

- antithrombotics, such as aspirin
- NSAIDs
- cardiovascular drugs, including diuretics, beta-blockers and ACE inhibitors
- CNS drugs including anti-epileptics, opioid analgesics and psychotropics
- systemic corticosteroids
- drugs used for the treatment of diabetes mellitus.

What are the drugs most commonly associated with preventable adverse events?

The box above shows a number of drugs commonly associated with preventable adverse events in general practice. It is worth noting that just four classes of these drugs are associated with around half of preventable medication related hospital admissions (Howard *et al* 2007; Pirmohamed *et al* 2004). These are antiplatelets such as aspirin, anticoagulants, NSAIDs and diuretics. The major risk from the first three of these drug groups is gastro-intestinal bleeding and when used (as they often are) in patients at high risk of adverse events it is critically important to ensure that they are prescribed as safely as possible.

This means, for example:

- when prescribing aspirin as an antiplatelet for long-term use, keep the dose to 75 mg daily as higher doses increase the risks of bleeding while making no difference to effectiveness of the drug
- minimise risks of over-anticoagulation with warfarin through patient education, regular monitoring of international normalised ratio (INR) and exercising extreme care when considering the prescription of other drugs that may increase the risk of bleeding
- keep the use of NSAIDs to a minimum in high-risk patients, and opt for the lowest daily dose of the least hazardous drug wherever possible, eg, ibuprofen
- minimise the co-prescription of aspirin, NSAIDs and/or warfarin
- use ulcer healing drugs, such as proton pump inhibitors, in patients at high risk of gastrointestinal bleeding.

What are the underlying causes of drug errors and how can these errors be prevented?

Most drug errors are associated with one or more of the following problems:

- not knowing enough about the patient
- not knowing enough about the drug
- slips and lapses when prescribing
- communication problems
- failures in the monitoring and review of medications.

Not knowing enough about the patient

Sometimes adverse events occur because we do not have enough information about the patient when making prescribing decisions. The major problem here is prescribing without realising that there is a contra-indication, caution or history of allergy. A classic example is the prescription of penicillin to a patient with previously recorded hypersensitivity. Other common examples include prescribing an NSAID to a patient with a history of peptic ulcer or a beta-blocker to a patient with a history of asthma.

The key to preventing these types of error is to have all necessary information about the patient available at the point of decision-making. Having up-to-date, properly coded, electronic health records helps with this as well at having electronic hazard alerts. Nevertheless, a high level of vigilance is necessary on the part of the prescriber, particularly when using high-risk drugs in high risk patients.

Not knowing enough about the drug

Lack of knowledge of drugs, including how they should be prescribed, their contra-indications, side-effects and interactions is an important cause of medication error. Sometimes the problem occurs in relation to high-risk drugs initiated in secondary care such as methotrexate and amiodarone. At

other times GPs do not recognise serious hazards such as the prescribing of NSAIDs in renal failure or hazardous drug–drug combinations.

For those drugs initiated in secondary care with shared care arrangements, it is important to learn about the key hazards associated with those drugs and to stick closely to the advice given on prescribing, monitoring and when to refer back to secondary care.

For those drugs more commonly used in primary care it is helpful to work from a relatively restricted range of drugs where one can build up a good knowledge and understanding. Opting for relatively safe drugs that have few serious interactions makes sense wherever possible. For example, in choosing a calcium channel blocker for the treatment of hypertension it is safer to select a dihydropyridine such as amlodipine than to opt for verapamil, which has a cardiac depressant effect and is contraindicated in a number of cardiac conditions while also being associated with potentially fatal interactions with beta-blockers.

Overall it is very important for prescribers to be as aware as possible of any gaps in their knowledge about drugs they are considering prescribing for patients: if in any doubt, they should check things out. Also, while the drug interaction checks on practice computer systems can be annoying at times, they can sometimes alert us to very serious hazards and therefore it is worth noting these before deciding whether or not to prescribe. A source of further information on drug interactions is Stockley's Drug Interactions (see next section). For general updates on prescribing safety monthly drug safety updates from the Medicines and Healthcare Products Regulatory Agency(MHRA) provide a useful resource, replacing the previously rather infrequent *Current Problems in Pharmacovigilance*.

Slips and lapses when prescribing

In addition to knowledge-based mistakes, there are also slips, lapses and failures to check actions that can lead to patients receiving the wrong prescription, the wrong drug, the wrong dose or the wrong instructions. Sometimes this can have potentially fatal consequences for patients, for example:

- accidentally selecting penicillamine rather than penicillin from a computerised drop-down menu
- incorrectly calculating, or accidentally selecting, an inappropriately high opiate dose
- accidentally prescribing methotrexate tablets on a daily rather than weekly basis.

These problems often occur against the background of overwork, stress and multiple competing demands. Nevertheless, the risks can be minimised in several ways. First, as slips and lapses occur without conscious knowledge it is essential to check prescriptions before signing them. Second, it is important to have a low threshold for double-checking things when dealing with high-risk drugs or high-risk patients, particularly with dosage calculations. Third, teamwork can be helpful. This includes having well-informed patients who may be able to spot an error, as well as good working relationships with community pharmacies.

Communication problems

Communication problems often contribute to the creation of adverse events associated with medication errors; sometimes, communication failures are the main cause of the adverse event. The most common problems with communication occur between the doctor and patient, but there are also major issues at the interface between primary and secondary care.

Communication with patients

It is not uncommon for patients to suffer from medication-related adverse events because either they do not have sufficient knowledge of their medical conditions and the drugs they are taking, or they have not been given an adequate explanation of how to take the drugs, the side-effects to look out for and what monitoring is needed.

Communication problems resulting in under-use, over-use or incorrect use of medication are particularly important in the following conditions where preventable drug-related hospital admissions may result:

- asthma
- coronary heart disease with angina
- diabetes mellitus (particularly with patients taking insulin)
- epilepsy
- heart failure.

For these conditions it is particularly important to try to make sure that patients have a good level of knowledge and understanding of drugs they are taking. It is often difficult to provide all of this information in a busy GP consultation, but it is possible to build up patients' knowledge and understanding over time and also to enlist the support of practice nurses and community pharmacists in providing education. The use of patient information leaflets or websites may also be helpful.

Communication between primary and secondary care

In terms of communication between primary and secondary care, it is not uncommon for patients to suffer harm as a result of lack of information, inaccurate information, incomplete information or failure to act upon information that has been provided.

Considerable efforts are being made in various parts of the UK to address these gaps. Approaches that appear to be effective include faxing medication histories (or sending details in a letter) when patients are admitted to hospital; having admissions ward pharmacists to help with medicines reconciliation; rapid transfer of accurate and complete medicines information to general practices when the patient is being discharged from hospital, and the setting up and use of joint district-wide drug formularies and shared care protocols. In the future, access to electronic information on patients' medications may become routine in the NHS if the rollout of NHS Connecting for Health programmes is successful.

One very important issue to raise is the dangers associated with transfer of medicines information onto the practice computer once a patient has been

discharged from hospital, or following outpatient visits. Unless this is done carefully, by clinically trained staff, there are serious risks of inadvertent transcription errors or duplication of medicines. Doctors may be as prone to transcription errors as reception staff, but at least they have the clinical knowledge to recognise a potentially dangerous dosage or therapeutic duplication.

A recent report on *Managing Patients' Medicines after Discharge from Hospital* (Care Quality Commission 2009) highlighted how patients could be at risk unless the management of medicines between GP practices and hospitals is improved. They visited 12 primary care trusts and surveyed 280 of their GP practices. During visits, they saw some evidence of good practice, but also found the following concerns:

- information shared about patients moving between GPs and hospitals was often patchy, incomplete and not shared quickly enough
- GP patient records were not always updated by clinical staff
- too few patients were offered discussions with their GP about managing their medication
- GPs were not consistently reporting medication incidents and errors, and PCTs are not always monitoring them.

The CQC, which is championing joined-up services across the health and adult social care system, found that GP practices overall have good repeat prescribing systems in place to reduce risks associated with patients taking medication for longer than necessary, particularly if their medication changed while in hospital. It also found patients taking high-risk medicines, such as treatment for thromboembolic disease, generally have their medication reviewed by a GP soon after discharge from hospital to spot potential problems and discuss any side-effects of newly prescribed drugs.

However, 81 per cent of GP practices surveyed said that when hospitals sent them summaries of the care they had provided to patients, details of medicines prescribed were incomplete or inaccurate 'all of the time' or 'most of the time'. This is particularly concerning as a GP may subsequently prescribe incompatible drugs, which may lead to harm.

These communication problems work both ways. The CQC found some practices were not systematically providing hospitals with information on: previous drug reactions (24 per cent); other existing illnesses, known as co-morbidities (14 per cent); or known allergies (11 per cent), when patients are admitted. This means hospitals could unwittingly prescribe medicines that are already known to be harmful in primary care.

The CQC pointed out that, 'Not all adverse drug reactions are preventable, but the potential risks are clear. It is important that basic systems to share essential patient details are working effectively to get the right information to clinicians at the right time to minimise these risks. It is clear from this study that services have some way to go before this routinely happens in the way it should'. Further to this, they state, 'People have a right to expect clinicians to know details about each stage of their care, and in this day and age they are right to do so. It's not possible for a clinician to make good decisions about care unless they have key information about a patient'.

Failures in the monitoring and review of medications

Medication monitoring

It is important to monitor patients for the effects of medications and any side-effects, particularly for high-risk drugs in high-risk patient groups. Indeed, inadequacies in patient monitoring account for around a quarter of preventable medication-related hospital admissions.

Monitoring for side-effects may be particularly important in older people and with polypharmacy. Also, in patients with hepatic or renal impairment, drug metabolism or excretion may be reduced which can result in the build-up of toxic levels of drugs.

Effective medication monitoring can help to identify drug-related problems before they result in serious patient harm. Examples include monitoring of:

- differential white cell count for drugs that can cause neutropenia, eg, methotrexate
- drug plasma levels to identify potential toxicity, eg, lithium
- electrolytes for drugs which can cause electrolyte disturbance, eg, diuretics
- hepatic function for drugs that can cause liver damage, eg, methotrexate
- international normalised ratio (INR) to ensure correct levels of anticoagulation for patients taking warfarin
- renal function for drugs that can potentially cause renal damage, eg, ACE inhibitors
- thyroid function for drugs that can cause thyroid dysfunction, eg, amiodarone.

The evidence base for the benefits of medication monitoring is not strong for many drugs, particularly in terms of the frequency of monitoring. Nevertheless, it is important for individual GPs, or practices, to have policies for laboratory test monitoring of drugs so that patients do not slip through the net and suffer from a complete lack of monitoring. Advice on laboratory test monitoring is available in the British National Formulary and drug datasheets. Also, the North West Medicines Information Service produced useful guidance in 2002 which could be adapted to the needs of individual general practices.

Medication review

It is important for patients' medications to be reviewed periodically to ensure that essential laboratory tests are undertaken; side-effects are detected; patients are given essential information and are involved in decisions about their medicines, and that therapy is optimised.

Nevertheless, undertaking high-quality medication reviews can be a challenge in busy general practices. There is always a temptation to simply click the return button rather than address the review in detail and efforts have been made to avoid this possibility by making compliance with the review more complicated. Where things are relatively straightforward,

reviews can be done as part of normal follow-up consultations. In more complex cases it is important to find ways of ensuring that adequate time is given to medication review so that discussion around medicines does not get squeezed into the final couple of minutes of the consultation. One option is to make it clear to patients that the consultation is primarily for the purposes of reviewing medications. Another option is to make use of pharmacists to help with these complex medication reviews.

Repeat prescribing

Repeat prescribing brings benefits of convenience to both doctors and patients. However, repeat prescribing systems are complex and there are safety risks at various points in the process. Some of the key points are outlined in the following box, but more detailed advice is available in *Saving Time, Helping Patients:* A *good practice guide to quality repeat Prescribing* (National Prescribing Centre 2004).

Practices need to be aware of changes that will affect repeat prescribing systems with the introduction of the electronic prescriptions service that will allow for electronic transfer of prescriptions between general practices and community pharmacies.

Key points for safe repeat prescribing (from NPC 2004)

Authorising repeat prescriptions

- Only appropriately qualified prescribers should be allowed to put medications on repeat prescription.
- An appropriate review date needs to be set taking account of the need for monitoring of therapeutic benefits and potential adverse effects.

Dealing with requests for repeat prescriptions

- Patients need to know how the practice repeat prescription works and what the rules are.
- Requests must be dealt with accurately, securely and within an agreed timeframe, eg, 48 hours.
- With paper-based systems, patient should be encouraged to use the repeat prescription request slip rather than giving oral requests.

Deciding if the repeat prescription should be generated

- An administrative check needs to be done to determine:
  - is the drug on the repeat prescriptions list?
  - is the drug within its review date?
  - is the request earlier (or later) than expected?
- If in doubt, the responsible prescriber should be asked to make the decision about whether a further prescription should be generated

Prescription production, signing and return to patient

- Most repeat prescriptions are generated electronically and there are significant safety benefits to this.
- A qualified prescriber needs to check that the prescription is safe (with reference to the patient's records where appropriate) before signing.
- If a review is required the patient should be advised and an appointment should be made.

Electronic prescribing and repeat dispensing

An NHS project in England managed by Connecting for Health is enabling direct transfer of prescriptions from general practice to the pharmacy. This is called the Electronic Prescription Service (see Connecting for Health 2010) and is intended to largely replace paper prescriptions from general practice in the future. The same system can allow reimbursement of the prescription cost to the pharmacy without the need for an invoice to be sent to the prescription pricing service. This has considerable potential to reduce dispensing errors and streamline care for patients. Around 1.5 million prescriptions are issued every working day in England and this figure is expected to rise by 5 per cent each year. By removing paper from the system this should be more efficient, consistently accurate and able to cope with expected further increases in the number of prescriptions issued. The Electronic Prescription Service allows prescribers working in primary care settings to generate and transmit electronic prescriptions using their computer system which is directly sent to the Electronic Prescription Service and downloaded by a dispenser in a specified pharmacy. The intention in the near future is to have the option to choose, or 'nominate' a dispensing contractor to receive their electronic prescription automatically. It is expected that, over time, the need for paper prescriptions will reduce significantly.

Alongside this initiative is the development of repeat dispensing. Traditional repeat prescribing systems usually require the patient to contact their GP practice every time they need a new repeat prescription and then take this to their local pharmacist to have the medicines dispensed (unless it is a dispensing practice). Inevitably this process involves a significant workload for the GP practice and community pharmacy involved. The patient may also have to make several journeys each time they request repeat medication, especially if their local pharmacy is some distance away from their prescriber. Repeat dispensing is a system that enables community pharmacists to dispense regular medicines to suitable patients, according to an agreed protocol, without the direct involvement of the GP surgery on each occasion a repeat medicine is required (National Prescribing Centre 2008c). Repeat dispensing can thus save time and improve choice and convenience for patients and it can help reduce the risk of medicine-related problems.

Under the repeat dispensing system, the prescriber produces a master 'repeatable' prescription on a standard FP10 prescription form for the patient's repeat medicines. This is annotated to distinguish it from a standard prescription form and also gives details of how many instalments the prescription contains. A series of accompanying 'batch issues', one for each time the prescription is to be dispensed, is supplied at the same time. These

enable the pharmacist to continue to dispense the medicines by instalments for the duration of the original repeatable prescription. This can be up to 12 months and each accompanying batch issue is annotated with the number of the batch.

Over time it is envisaged this system will be integrated with the Electronic Prescription Service, and when fully implemented will allow patients to pick up their repeatable prescription from any pharmacy in England.

Obviously repeat dispensing will be much more convenient for patients as it will obviate the need to order prescriptions (usually monthly). However there is a risk that this might mean that prescriptions are supplied without determining if irregular intervals of supply are occurring (indicating intermittent use or generally poor adherence which could be detrimental to care and increase waste). To safeguard against this the National Prescribing Centre has advised that the pharmacist should ascertain if the medication on the repeatable prescription is still required on each occasion of supply (National Prescribing Centre 2008c). It advises that the pharmacist could use the following questions before any medication is handed over to the patient.

- Have you seen any other health professional(s) eg, GP, nurse, consultant, since your last prescription was issued?
- Are you having any problems with your medication or experiencing any side-effects?
- Do you have any items available on repeat, which you would like deleted or do not need on this occasion?
- Are you taking any over the counter medicines, herbal remedies or food supplements at the moment?
- Have any new problems/symptoms developed recently?

Identification of potential prescribing safety indicators

Recent work done by the Royal College of General Practitioners (RCGP) has identified a number of potential prescribing safety indicators which may be suitable for use in UK general practice. These may have value in the future to assess fitness to practice and have a role in revalidation. Here, we briefly describe the methods used to identify these indicators.

It is generally agreed that potential prescribing safety indicators should describe patterns of prescribing that are potentially hazardous and may put patients at risk of harm. This research focused on indicators that could be attributed to the actions of individual prescribers.

The work drew upon various sources of information to draw up potential indicators to identify those that might be suitable for use in UK general practice. The list of potential indicators was shown to the team at the British National Formulary, who then suggested a small number of additional indicators. In total, 50 potential indicators were identified.

For each of the potential indicators identified a rapid review of the literature was carried out to produce 1–2 page summaries of the evidence base associated with each indicator.

The RCGP team then recruited a panel of 12 GPs, from a wide range of backgrounds, to undertake a two-round consensus-building exercise using

the RAND appropriateness method. (Campbell et al 2002, Shekelle *et al* 1998, Rand 2001)

For the first round of the exercise of the GPs were sent the indicators, the evidence-based summaries, instructions for completing the exercise and a response sheet. They were asked to rate the appropriateness of the different potential indicators for the assessment of the safety of prescribing of individual GPs. As a separate question, they were also asked to rate the appropriateness of the indicators for the purposes of revalidation of GPs. In total, 68 indicator statements were rated (because of variations in wording for some of the indicators).

The findings from the first round of the exercise were collated and fed back to GPs at a face-to-face meeting in July 2009. At this meeting, which was facilitated by Dr Stephen Campbell from the University of Manchester, participants were invited to discuss the indicators in detail, to propose changes in wording and to propose any additional indicators. In total, 92 indicator statements were produced. The appropriateness of each of the indicators was rated by the individual GPs and the findings were entered onto computer and analysed.

Using standard RAND appropriateness method techniques, those indicators were identified for which there was agreement among the panel as to their appropriateness for use in assessing the safety of GP prescribing.

Findings

Detailed findings from this study are available through the RCGP (www.rcgp.org.uk/_revalidation.aspx). The box below shows 34 indicators rated as appropriate for assessing the safety of GP prescribing (see also, Avery *et al* 2011).

Indicators rated as valid for assessing the safety of prescribing of individual GPs

A Cardiovascular and respiratory disease

- Prescription of a beta-blocker to a patient with asthma (*excluding patients who also have a cardiac condition, where the benefits of beta-blockers may outweigh the risks*).
- Prescription of short-acting nifedipine (excluding patients with Raynauds disease).
- Prescription of digoxin at a dose > 125 micrograms daily in a patient with renal impairment (eg, CKD 3+).
- Prescription of digoxin at a dose of greater than 125 micrograms daily for a patient with heart failure who is in sinus rhythm.
- Prescription of diltiazem or verapamil in a patient with heart failure.
- Prescription of aspirin at a dose >75mg daily for ≥ one month in a patient aged >65yrs.
- Prescription of a long-acting beta-2 agonist inhaler to a patient with asthma who is not also prescribed an inhaled corticosteroid.

B Central nervous system (including analgesics)

- Prescription of aspirin to a child aged ≤16yrs.
- Prescription of metoclopramide or prochlorperazine in a patient with Parkinson's disease.
- Prescription of a benzodiazepine or Z drug for more ≥21 days, in a patient aged >65yrs, who is not receiving benzodiazepines or Z drugs on a long-term basis.
- Initiation of prescription of benzodiazepine or Z drugs basis for ≥21 days in a patient >65yrs with depression.

C Anti-infective agents

- Prescription of mefloquine to a patient with a history of convulsions.

D Women's health and urinary disorders

- Prescription of a combined hormonal contraceptive to a women with a history of venous or arterial thromboembolism.
- Prescription of oral or transdermal oestrogens to a woman with a history of breast cancer.
- Prescription of oral or transdermal oestrogen without progesterone in a woman with an intact uterus.
- Prescription of a combined hormonal contraceptive to a woman aged 35 years or older who is a current smoker.
- Prescription of a combined hormonal contraceptive to a woman with a body mass index of ≥40.

E Musculoskeletal

- Prescription of an NSAID, *without co-prescription of an ulcer healing drug*, to a patient with a history of peptic ulceration.
- Prescription of an NSAID in a patient with heart failure.
- Prescription of an NSAID In a patient with chronic renal failure, e.g. CKD 3 or worse.
- Prescription of a long term (> 28 days) NSAID (except for ibuprofen ≤1200mg daily) in a patient aged >65yrs.

F Hazardous co-prescriptions, interactions and allergy

- Prescription of warfarin in combination with an oral NSAI
- Prescription of a phosphodiesterase type-5 inhibitor, eg, sildenafil, to a patient who is also receiving a nitrate or nicorandil.
- Prescription of clarithromycin or erythromycin to a patient who is also receiving simvastatin, *with no evidence that the patient has been advised to stop the simvastatin whilst taking the antibiotic.*
- Prescription of a potassium salt or potassium sparing diuretic (excluding aldosterone antagonists) to a patient who is also receiving an ACE inhibitor or AR-II receptor antagonist.
- Prescription of verapamil to a patient who is also receiving a beta-blocker drug.
- Prescription of a penicillin containing preparation to a patient with a history of allergy to penicillin.

G Laboratory test monitoring

- Prescription of warfarin to a patient without a record of INR having been measured within the previous 12 weeks (excluding patients who self-monitor).
- Prescription of amiodarone without a record of liver function being measured in the previous nine months.
- Prescription of amiodarone without a record of thyroid function being measured within the previous nine months.
- Prescription of an ACE inhibitor or AR-II receptor antagonist without a record of renal function and electrolytes being measured prior to starting therapy.
- Prescription of lithium without a record of a lithium level being measured within the previous six months.
- Prescription of methotrexate without a record of a full blood count within the previous three months.
- Prescription of methotrexate without a record of liver function having been measured within the previous three months.

9 Optimising drug use, reducing waste and improving outcome

Patient-centred care and the place of patient choice

All NICE clinical guidelines state that treatment and care should take into account patients' needs and preferences and patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their health care professionals (see www.nice.org.uk). The guidelines say that good communication between health care professionals and patients is essential. It should be supported by evidence-based written information tailored to each patient's needs. If the patient agrees, families and carers should also have the opportunity to be involved in decisions about treatment and care. Families and carers should be given the information and support they need.

NICE further advise that if patients do not have the capacity to make decisions, health care professionals should follow the Department of Health guidelines *Reference guide to consent for examination or treatment* (Department of Health 2001b). Health care professionals should also follow the code of practice that accompanies the Mental Capacity Act (summary available from www.publicguardian.gov.uk).

A recent policy in the NHS in England has been to promote the concept of patient choice (Department of Health 2003). The policy states that giving people more choice is a priority of the modern NHS because research in the UK and overseas has shown that treatments are more effective if patients choose, understand and control their care (NHS Choices 2010). The choices highlighted include the right to:

- choose a GP and to change to another if not happy with the service received
- choose which hospital to go to if the GP refers to see a specialist
- be involved in decisions about health care and to be given the information needed to do this.

People in the NHS in England are asked to see these choices alongside their lifestyle choices. The policy states that other decisions to consider are about treatment and the way in which people interact with doctors and other health professionals that can affect health.

This policy has also been reinforced by the coalition government in its White Paper *Equity and Excellence: Liberating the NHS*. This adopts the mantra, 'nothing about me, without me' (Department of Health 2010b).

There are some arguments against such policy. The first of these is that it may reflect the desire of people to access health care and treatments rather than strictly reflecting the needs of the individual or the effectiveness of interventions. Another concern is the costs or affordability of allowing choice in this way in a publically funded health care system when resources are finite; for example should patients be allowed to select an expensive brand-name drug when a generic drug will do much the same? In Wales the policy has been different and NHS bodies are encouraged to allow 'patient

voice' (One Voice Wales 2008). The subject of choice or voice needs careful consideration when considered alongside the quality of GP prescribing.

When examining this patient-centred approach to health care and the choice (or voice) agenda, one of the challenges for health care professionals lies in acknowledging the reality that it is the patients' agendas and not their own that determine whether patients will take medicines. For example, it has been stated that in the past the concerns of health professionals have focused almost exclusively on improving the quality of their own prescribing choices (Marinker and Shaw 2003). Patients have their own beliefs about their medicines and medicines in general. They have their own priorities and their own rational discourse in relation to health and care, risk and benefit. These may differ from and sometimes contradict those of the doctors but they are no less cogent, coherent, or important (Marinker and Shaw 2003).

Supporting: adherence, concordance

Definitions

Some Definitions (Horne 2005)

Compliance is defined as: 'The extent to which the patient's behaviour matches the prescriber's recommendations.'

Adherence is defined as: 'The extent to which the patient's behaviour matches agreed recommendations from the prescriber.'

Concordance is a relatively recent term, predominantly used in the United Kingdom (UK). Its definition has changed over time from one which focused on the consultation process, in which doctor and patient agree therapeutic decisions that incorporate their respective views, to a wider concept which stretches from prescribing communication to patient support in medicine taking.

The concept of compliance describes the extent to which patients will follow instructions given by health care professional and has raised concerns about the authoritarian and judgemental approaches often adopted by prescribers (Marinker and Shaw 2003). Medicines concordance was originally defined as 'an agreement reached after negotiation between a patient and a health care professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken' (Marinker *et al* 1997). It is seen as a potential way of increasing adherence with medication regimens. Adherence reflects the extent to which a person's behaviour in terms of taking medication coincides with medical advice and is intended to be a non-judgemental measure (Horne *et al* 2005). Patients do not comply with medication for several reasons which may be intentional or involuntary. As mentioned in the previous section it may not accord with their beliefs or priorities. It may also relate to the quality of information given, the impact of the regimen on daily life, the physical or mental incapacity of patients, or their social isolation (Marinker and Shaw 2003). Thus, in order to address this element of prescribing quality, many different approaches need to be adopted.

Some have argued that the concept of medicines concordance has been accepted in clinical practice without a theoretical framework for

understanding whether, when and how medicines concordance is best employed in clinical practice (de Almeida 2008). There has been some recognition of this need for greater knowledge about medicines concordance, with a critical appraisal of the evidence on shared decision-making (Horne *et al* 2005).

NICE has reviewed the evidence and produced a clinical guideline on medicines adherence (Nunes *et al* 2009, NICE 2009). This guideline states that it is believed that between one-third and a half of all medicines prescribed for long-term conditions are not taken as recommended. It says that if a prescription is inappropriate, then this may represent a loss to patients, the health care system and society. The guideline asserts that non-adherence should not be seen as the patient's problem. It represents a fundamental limitation in the delivery of health care, often because of a failure to fully agree the prescription in the first place or to identify and provide the support that patients need later on.

Possibly the most important aspect of this guideline is the explicit recognition that we should be more frank and open about the reality of non-adherence; it should be recognised that non-adherence may be the norm (or is at least very common) and to take a no-blame approach, actively encouraging patients to discuss non-adherence and any doubts or concerns they have about treatment (NICE 2009). This 'patient-centred' guideline recommends identification of specific perceptual and practical barriers to adherence for each individual, both at the time of prescribing and during regular review, because perceptions, practical problems and adherence may change over time. It gives advice on how best to communicate with patients and the issues to be addressed at medication review.

Some people have argued against concordance being applied to all patients, or patients as a whole, as sometimes an explicit and directive communication style may have a place in advising on medication and it may convey to the patient clear messages on what to do, leaving little room for ambiguity (de Almeida 2008). It is argued that research on behaviour change in other domains of medical practice, such as problem drinking and smoking, suggests that straightforward advice from a medical practitioner can be effective in influencing behaviour. This view is supported by research showing that not every patient agrees with the concept of shared decision-making in clinical care. For example, in a study of 344 patients living with rheumatoid arthritis, 50 per cent reported the view that patients should go along with doctor's decisions even if they did not agree with such decisions (Neame *et al* 2005).

For this reason it is suggested that practitioners would benefit from practical communication tools that would enable them to assess individual responses and attitude to concordance during the consultation process, allowing medication counselling to be tailored accordingly. By this means medicines concordance can be tailored to circumstances when the practitioner detects that it can be accepted and is most likely to be fruitful.

Patient decision aids and patient information

Definition of patient decision aid (PDAs)

'Decision aids are intended to prepare patients to participate with their health care professionals in making deliberated, personalised choices about health care options. They supplement counselling by providing information on options. The aim is that patients are better able to judge the value of the benefits versus the harms.' (O'Connor and Edwards 2001)

As stated in the previous section, the values and perceptions of individual patients may be different from those of health care professionals. This also extends to their attitudes to risk. There are many influences on individual perceptions of medical interventions, including previous experience, media reporting and culture.

A patient decision aid (PDA) is a tool that presents evidence-based estimates of the benefits and risks of the available treatment options in sufficient detail so that patients are better able to judge their value. In contrast to health education materials, which simply provide broad background information, PDAs are tailored to patients' health status and help them to make specific, personal choices about their treatment. PDAs can be available in various formats such as leaflets, interactive media, video/DVD or audio tape. Importantly, they are not intended to replace the patient-practitioner interaction, rather to supplement it (National Prescribing Centre 2008a).

The Cochrane Systematic Review Group maintains the Cochrane Inventory, a register of PDAs for researchers, and the A to Z Inventory, a registry of decision aids for patients (see http://decisionaid.ohri.ca/cochinvent.php). However, many of the PDAs are American, which may limit their use in the UK. Since 2007 the National Prescribing Centre has been developing PDAs (www.npci.org.uk/pda) based on evidence in a range of therapeutic areas.

It is important to distinguish PDAs from the kind of informed consent materials often provided to potential participants in clinical trials, general educational interventions not dealing with a specific decision, or materials designed to promote a particular option or support compliance with such an option (O'Connor and Edwards 2001). Decision aids may prepare patients for decision-making by increasing their knowledge about expected outcomes and helping them to relate these to their personal values.

The role of PDAs may be particularly important in helping people understand the value of interventions in preventing disease. Modern chronic disease management often involves patients taking medicines long-term which may not have any effect on the patient's symptoms, for example taking statins for primary or secondary prevention of cardiovascular disease. In these cases patients need to weigh up the likely benefits against the inconvenience of daily medication and the risk of side-effects.

A Cochrane review of 55 randomised controlled trials (RCTs) identified 38 PDAs that provided information meeting their main effectiveness criteria (O'Connor *et al* 2009). They placed the context of the review in allowing choice between different medically supported interventions, rather than guiding choice over a particular intervention compared with the risks of no intervention (which may not be supported by health care professionals).

That is, the authors see that the place of PDAs is to guide choice when there is more than one medically reasonable option where no option has a clear advantage in terms of health outcomes and each has benefits and harms that people value differently. The review of the trials found evidence that decision aids can improve people's knowledge of the options, create accurate risk perceptions of their benefits and harms, reduce difficulty with decision making, and increase participation in the process (O'Connor *et al* 2009).

There is also a Cochrane review on the subject of systems or strategies to support medication adherence (Haynes *et al* 2008). Many of the interventions were complex, including combinations of more convenient care, information, reminders, self-monitoring, reinforcement, counselling, family therapy, psychological therapy, crisis intervention, manual telephone follow-up, and supportive care. In this review a qualitative approach was adopted as studies could not be directly compared quantitatively. For short-term studies, all involving antibiotic use, four of ten interventions reported in nine RCTs showed an effect on both adherence and at least one clinical outcome, while one intervention reported in one RCT significantly improved patient adherence, but did not enhance the clinical outcome. For long-term treatments (eg, hypertension, hyperlipidaemia, COPD, schizophrenia), 36 of 83 interventions reported in 70 RCTs were associated with improvements in adherence, but only 25 interventions led to improvement in at least one treatment outcome. Even the most effective interventions did not lead to large improvements in adherence and treatment outcomes. For short-term drug treatments, counselling, written information and personal phone calls helped. For long-term treatments, no simple intervention, and only some complex ones, led to improvements in health outcomes and even with the most effective methods, improvements in drug use or health were not large. Several studies showed that telling people about adverse effects of their medications did not affect their use of the medications.

Another way to aid patient decision-making is to use computer-based programmes, sometimes called interactive health communication applications (IHCAs). A Cochrane review has looked at their value in helping people who have chronic disease (Murray *et al* 2005). This identified 24 RCTs (involving 3,739 participants) which were included in the review. The authors state that people with chronic disease have multiple needs, including information about their illness and the various treatment options; social support; support with making decisions; and help with achieving behaviour change, for example, changes in diet or exercise. They assert that computer-based programmes that combine health information with online peer support, decision support, or help with behaviour change may be one way of meeting these needs, and of helping people to achieve better health. The review authors found that IHCAs improved users' knowledge, social support, health behaviours and clinical outcomes (Murray *et a*l 2005). They also concluded that it is also more likely than not that IHCAs improve users' self-efficacy (a person's belief in their capacity to carry out a specific action) but it was not possible to determine whether IHCAs had any effect on emotional and economic outcomes. However they say that the included studies involved different IHCAs, with different characteristics, for a wide range of chronic diseases and there was variability in several of the outcomes, and the results should therefore be treated with some caution. They also concluded that there is a need for larger, high-quality studies to confirm these preliminary

findings, to determine the best type and best way to deliver IHCAs, and to establish how IHCAs affect different groups of people with chronic illness.

Another strategy is to provide information that 'arms' patients for the consultation by improving understanding and use of medicines before consulting. The rationale for this is that patients often report that they want more information from their health care providers or that the information they do receive does not address their needs, and that generally the amount of information given is small. People have differing needs for information, which also varies with the specific illness, but providing information is important as it helps patients recall, understand and follow treatment advice and be more satisfied. Clinicians may underestimate or undervalue the information needs of patients and may also lack the skills to give information effectively (Kinnersley *et al* 2007). A Cochrane review looked at how systems could be employed to try to direct patients to ask pertinent questions in their consultations to help them decide on treatment choices (Kinnersley *et al* 2007). This can be done by various methods such as question prompt sheets (which encourage patients to write down their questions) or coaching (when someone helps the patient to think of the questions they want to ask). The review evaluated studies of these types of interventions. It identified 33 RCTs involving 8,244 patients from six countries, mainly the USA, in a range of clinical settings. This may make the translation into UK practice problematic. Most interventions, which included written materials (for example, question prompt sheets) and coaching sessions, were delivered in the waiting room immediately before the consultation. They were compared to dummy interventions or usual care. Health issues included primary care and family medicine, cancer, diabetes, heart problems, women's issues, peptic ulcer and mental illness. The reviewers found small increases in question asking and patient satisfaction and a possible reduction in patient anxiety before and after consultations. However they also found a possible *reduction* in patient knowledge and a possible small increase in consultation length. Both coaching and written materials produced similar effects on asking questions but coaching had a larger benefit in terms of patient satisfaction. The interventions seem to help patients ask more questions in consultations, but did not have other clear benefits. The authors concluded that doctors and nurses need to continue to try to help their patients ask questions in consultations and question prompt sheets or coaching may help in some circumstances (Kinnersley *et al* 2007).

There has been considerable interest in the provision of patient information sheets and how this can improve patient care; in particular this may have a role in improving adherence to medication and patient satisfaction. People taking medicines need good-quality information: to enable them to take and use the medicines effectively, to understand the potential harms and benefits, and to allow them to make an informed decision about taking them. A Cochrane review examined if written information about individual medicines can improve knowledge or attitudes, or change behaviours relating to taking a medicine (Nicolson *et al* 2009). It included 25 RCTs involving 4,788 participants. Six of twelve trials showed that written information significantly improved knowledge about a medicine, compared with no written information. The results for attitudinal and behavioural outcomes were mixed. No studies showed an adverse effect of medicines information. However the authors of the review felt that it was inconclusive for a number of reasons. First, because the included trials measured

different outcomes in different ways, they were unable to combine their results. Second, these trials presented the written information for patients in different ways, and most did not design the leaflets in a way that made them easy to read. Third, in many cases trials were not clearly reported, so they do not know if they were carried out correctly. Despite these limitations the finding that written information improved knowledge and was not harmful is encouraging for people who want to learn about their medicines from leaflets. The authors remark that it is important that medicines information is well written and designed to maximise the possibility of improving knowledge (Nicolson *et al* 2009).

The Cochrane review considering provision of written information also looked at the role of internet information as there is evidence that people increasingly seek out health information, including information about medicines, on the internet, but they found no trials examining whether internet-based medicines information changed people's knowledge, attitudes, or behaviour (Nicolson *et al* 2009).

NHS Direct has started to develop, pilot and implement online patient decision aids (PDAs) (NHS Direct 2010). They state that these are to be used when there is no clinical evidence that one treatment is better than another and patients aren't sure which option will be best for them. They have developed and piloted three PDAs: one for patients with an enlarged prostate (benign prostatic hyperplasia); another one for patients newly diagnosed with localised prostate cancer; and the third for patients with osteoarthritis of the knee.

It seems reasonable to propose that the considered and appropriate use of PDAs in the consultation, and the provision of information leaflets, can be regarded as a marker of quality in prescribing in general practice.

Patient decision aid resources for the NHS

National Prescribing Centre training materials plus database of patient decision aids – www.npci.org.uk/iPDAs.php

Review looking at the place of PDAs in the NHS:

- Elwyn G, Laitner S, Coulter A, et al. Implementing shared decision making in the NHS. BMJ 2010; 341:c5146

www.bmj.com/content/341/bmj.c5146.full

There are two important UK university research centres working collaboratively on patient decision aids:

- Cardiff University – hosts International Patient Decision Aids Standards Collaboration (IPDAS), headed by Professor Glyn Elwyn www.decisionlaboratory.com
- Newcastle University – Risk Communication and Decision Making, headed by Professor Richard Thomson www.ncl.ac.uk/ihs/research/risk

Medicines use in older people and in care homes

The involvement of patients or their carers in decision-making relevant to prescribing is a particular challenge in a frail older population. Evidence suggests that the use of drugs in elderly people is often inappropriate partly

because of the complexities of prescribing as well as other patient, provider, and health-system factors (Spinewine *et al* 2007). Inappropriate prescribing can cause substantial morbidity, and represents a clinical and economic burden to patients and society (Spinewine *et al* 2007). Inappropriate prescribing in elderly people has therefore become an important public health issue in the UK.

As discussed in previous sections, evidence suggests that a patient's decision to take or not to take drugs might be part of a negotiation process rather than a final stance, and that people are more likely to adhere to treatment if they are helped to make decisions for themselves rather than being told what to do. Encouraging adherence in this population for whom multiple drug therapy is common will need particular care in prescribing, assessment of benefit, and avoidance of adverse effects. It is also likely that changes in the attitudes of prescribers towards sharing prescribing decisions are needed, in addition to the improvements in communication that could arise from information technology.

Drug therapy is essential when caring for elderly patients, but older people are at higher risk of having drug interactions. Several types of interactions exist: between drugs or between the drug and herbal or over the counter preparations, for example. Factors such as age-related changes in pharmacokinetics and pharmacodynamics, frailty, inter-individual variability, reduced homoeostatic mechanisms, and psychosocial issues need to be considered when drug interactions are assessed. Computer software may help clinicians to detect drug interactions and this is discussed in another section of this report.

Physicians may not be aware of all the drugs their older patients are taking. Frank and colleagues reported that, in 37 per cent of cases, patients were taking drugs without their physician's knowledge, and 6 per cent of patients were not taking medications that were on their physician's lists. Incomplete documentation of past medical history and active drug profile means that doctors may not consider interactions as a possible cause of the presenting complaints of elderly patients (Frank *et al* 2001). Furthermore, atypical presentation of disease or vague presenting complaints such as confusion, falls, urinary incontinence, and weakness could mask or confuse the detection of drug interactions (Gaeta *et al* 2002).

Elderly patients might receive prescriptions from several physicians and take them to be filled at many pharmacies. Tamblyn and co-workers have shown that the risk of receiving an inappropriate drug combination is directly related to the number of physicians prescribing drugs for that elderly patient (Tamblyn *et al* 1996).

In the UK a recent research article has highlighted some important lessons in the use of medicines in care homes. The article describes a research project into medication errors using both qualitative and quantitative analysis and makes some carefully reasoned recommendations for improving care. The researchers examined the experience of 256 residents in England from 55 care homes (residential, nursing and mixed), with a mean age of 85 years. The residents were taking an average of eight medicines each; a sign of the complexity of their clinical conditions. Errors were identified by experienced clinical pharmacists who interviewed patients, looked at medical records, observed care and examined the dispensing pathway. Of these 256 residents, 178 (69 per cent) had one or more medication error (mean 1.9). The most

common prescribing errors were no strength or route being stated on a prescription or chart when there was more than one option (38 per cent), an unnecessary drug being prescribed (24 per cent), the wrong dose or strength being prescribed (14 per cent), and not prescribing a drug (12 per cent) when it should have been prescribed. Administration errors are probably of greater consequence and 57 residents were given the wrong drug or dose, or not given a drug (116 errors). A drug that needed monitoring was prescribed to 147 residents and 27 (18 per cent) of these had an error, the most common one being failure to monitor by blood tests.

It is important to understand the reasons why this might have occurred and develop remedies to improve the situation. The type of problems identified included doctors who were called in to deal with problems, but did not know the patients and had limited access to relevant clinical information. The staff themselves were often overworked, were interrupted when handing out medicines (drug round) and had unmet training needs. The authors highlighted other systems failures where there was limited team work with community pharmacies, general practices and care homes all working in their different silos. They rarely got together to resolve problems in a co-ordinated fashion. There was a concern that nobody took responsibility for the whole system. The authors reiterate that safety is a systems issue.

One issue that was striking was the analysis of the 86 per cent of residents on monitored dose systems (MDS), using blister packs or cassettes, which although intended to improve medication use often appeared to compound the problem. The authors point out that more research is urgently needed in this area. These problems arise because to prepare MDS, many tablets need to be repackaged, which immediately introduces the chance of mixing up tablets removed from their original container and the loss of specific instructions required for administration. If an acute treatment is added, or a change made in the four-week cycle, the MDS system reveals rigidity and can add confusion.

The role of packaging of medications with reminder systems for the day and/or time of the week in an attempt to help people take long-term medications has been explored by a Cochrane review (Heneghan *et al* 2006). This assessed eight studies involving 1,137 participants who were taking self-administered medications for at least one month. The studies involved different types of packaging, and different medications for a variety of health problems. It found that reminder packaging increased the proportion of people taking their medications when measured by pill count; however, this effect was not large. There was insufficient information to say whether reminder packaging had an effect on improving health outcomes. The conclusion is that reminder packing for certain individuals may represent a simple method for improving the taking of medications but further research is needed to improve the design and targeting of these devices.

Suggestions made to improve prescribing for nursing homes include utilisation of better systems for recording and communicating information via electronic records and prescribing systems. Other suggestions include having nominated lead general practitioners for individual homes who call in to regularly do 'ward rounds' and improve continuity of care. Many practices in the UK are adopting such approaches. Each home should have an individual with overall responsibility for medicines use and co-ordination so that reviews of medication and monitoring of drugs is planned and it might be that

suitably trained pharmacists would be suitable in this context. These are all suggestions that could improve the quality of GP prescribing.

Repeat prescribing, medication review

Repeat prescribing plays a significant part in the delivery of medicines to patients in primary care in the UK. More than two-thirds of prescriptions generated in primary care are for patients who have requested a repeat supply of medicines they regularly take. It is estimated that more than two million prescriptions are issued each day in England, meaning that more than 1.5 million prescriptions are issued each day for repeat items. It is therefore important, not just for general practice staff, but also for patients, that an efficient and effective repeat prescribing process is in place.

A poorly designed system, or one that is not well-managed, can cause frustration to patients, practice staff and other health care professionals. It can waste precious time, as well as leading to an increase in the likelihood that mistakes could be made, thus putting patients' health at risk.

Benefits of a well-managed system include:

- improved quality of prescribing
- improved patient convenience and access to the medicines they need
- improved patient safety.

The new General Medical Services contract emphasises the importance of timely access for patients by awarding quality and outcomes framework (QOF) points for 24-hour and 48-hour turnaround.

The place of medication review alongside repeat prescription systems also needs examining. The National Prescribing Centre guide to medication review looked at this area and produced a guide outlining good practice (National Prescribing Centre 2008b). The guide describes three types of medication review: prescription review, compliance and concordance review, and clinical medication review. These are summarised below.

- A prescription review addresses technical aspects of prescribing, for example cost-effectiveness, possible interactions, prescription anomalies (medication which is still being prescribed even though it was only intended for short-term use), checking that necessary blood monitoring has been done, etc. The patient does not have to be present. This type of review should improve patient safety and potentially cut costs.
- A compliance and concordance review aims to check that the patient is taking their medication as intended by the prescribing doctor (in terms of dosage, time of day, etc) and to explore their feelings about taking regular medication. You should give your patient the opportunity to ask questions and also explain what to do if symptoms persist or change. You should also ask about their use of over the counter (OTC) and complementary medications.
- A clinical medication review addresses issues relating to the patient's use of medications in the context of their clinical condition. Again, it should include use of OTC and complementary medications. You should ask your patient about side-effects they are experiencing and how

these weigh up against the benefits of the medication(s). You should also discuss prognosis and how the treatments prescribed may affect this. You should adjust treatments according to symptoms and in light of clinical indicators, if appropriate. You should also enable your patient to have an active role in managing their condition if they want to. No changes should be made to a patient's medications without first informing them of the change and obtaining consent.

Quality and outcomes framework: Medication review components

Success in the quality and outcomes framework for 2009/10 requires that the practice meets the primary care organisation prescribing adviser at least annually, and agrees up to three actions related to prescribing, and subsequently provided evidence of change (*Medicines 10)*. Often the agreed actions relate to enhancing medication review or improving management of the repeat prescribing system.

There are also specific targets related to medication review (Quality and Outcomes Framework 2009). These are:

- *Medicines 11.* A medication review is recorded in the notes in the preceding 15 months for all patients being prescribed four or more repeat medicines. (Standard 80 per cent or more).
- *Medicines 12.* A medication review is recorded in the notes in the preceding 15 months for all patients being prescribed repeat medicines. (Standard 80 per cent or more).

Role of community pharmacy and practice-based pharmacists

It is believed that community pharmacy in the UK has a big part to play in helping to ensure the quality of prescribing by general practice in the UK and as a checking mechanism or 'backstop' to reduce patient harm associated with errors ('error trapping'). For example, it is a condition of the professional allowance received by pharmacies in the UK that patient medication records (PMRs) are held. Most pharmacies keep an electronic record of the medication that a patient has previously had dispensed. The PMR allows the pharmacist to carry out a more complete clinical check for drug interactions and contra-indications when a prescription is presented for dispensing and also when a patient purchases medicines from the pharmacy. There is, however, no guarantee that the PMR shows all a patient's medication, as some may have been dispensed elsewhere. Once satisfied that the prescription is legal and there are no clinical issues that need to be resolved with the prescriber, the item(s) will be dispensed. Currently all prescriptions must be dispensed (and handed out) under the direct supervision of a pharmacist.

The new pharmacy contract introduced in 2005 recognised that pharmacists' clinical skills may be under-utilised by the NHS and that continuing a system of remuneration that was almost entirely driven by dispensing volume added little value. The new contract also encouraged community pharmacists to take on more clinical work. These roles are necessary as developments in electronic prescribing and robotic dispensing could reduce the need for their traditional dispensing work.

The contract introduced in 2005 contained some important changes affecting medicines use. One of these was the potential for repeat dispensing: This is a development whereby a GP can generate one repeatable prescription backed by a number of batch issues for selected patients. This allows the pharmacist to re-dispense the original prescription without the patient having to go back to the GP. The aim of the service is to improve patient access and convenience, improve the monitoring of repeat medication so improving concordance and reducing waste and to reduce GPs' workload. It also enabled the process of medicines use review (MUR) which is a form of medication review carried out by pharmacists with patients who are on long-term medication. It is designed to identify any problems the patient has. The pharmacist is required to try to find a solution to any problems identified and provide a report to the GP.

Since pharmacists have acquired the capacity to recommend or prescribe more medicines without reference to a doctor and have other new roles, their effectiveness has come under some scrutiny (Bradley 2009). Recent reviews that have sought to quantify the benefit of medication reviews conducted in primary care by pharmacists or others, in terms of adverse effects, hospital admission, and deaths, have shown mixed results. Royal *et al* looked at studies in primary care aimed at reducing medication-related adverse events that result in morbidity, hospital admissions, and/or mortality (Royal *et al* 2006). While they found that pharmacist-led interventions in a meta-analysis of 17 studies appeared to be effective in reducing hospital admissions (OR = 0.64, CI = 0.43 to 0.96), this perception disappeared when analysis was restricted to the nine randomised controlled trials involving more than 10,000 patients (OR = 0.92, CI = 0.81 to 1.05). Holland *et al* looked at pharmacist-led medication reviews in older people only, and found no significant benefit in terms of emergency hospital admission or mortality (Holland *et al* 2008). However, they did note a possible decrease in the numbers of drugs prescribed and positive effects on other intermediate outcomes, such as drug knowledge, adherence, and drug storage.

An example of one of the studies included in these reviews is that by Zermansky *et al* (Zermansky *et al* 2001). This looked at whether a pharmacist can effectively review repeat prescriptions through consultations with elderly patients in general practice and was a randomised controlled trial comparing clinical medication review by a pharmacist against normal general practice review in four general practices. 1,188 patients aged 65 or over were invited to a consultation at which the pharmacist reviewed their medical conditions and current treatment. The results showed that 590 (97 per cent) patients in the intervention group were reviewed compared with 233 (44 per cent) in the control group. Patients seen by the pharmacist were more likely to have changes made to their repeat prescriptions (mean number of changes per patient 2.2 v 1.9; difference=0.31, 95 per cent confidence interval 0.06 to 0.57; P=0.02). Monthly drug costs rose in both groups over the year, but the rise was less in the intervention group. There was no evidence that review of treatment by the pharmacist affected practice consultation rates, outpatient consultations, hospital admissions, or death rate. The conclusion was that a clinical pharmacist can conduct effective consultations with elderly patients in general practice to review their drugs and such a review results in significant changes in patients' drugs without affecting the workload of general practitioners.

Another example is the MEDMAN study (The Community Pharmacy Medicines Management Project Evaluation Team 2007), which was an RCT of community pharmacy-led medicines management for patients with coronary heart disease across nine sites in England. Patients with coronary heart disease were identified from general practice computer systems, recruited and randomised (2:1) to intervention or control. The 12-month intervention comprised an initial consultation with a community pharmacist to review appropriateness of therapy, compliance, lifestyle, social and support issues. Control patients received standard care. The primary outcome measures were appropriate treatment (derived from the National Service Framework, health status (SF-36, EQ-5D) and an economic evaluation. Secondary outcome measures were patient risk of cardiovascular death and satisfaction. It involved 1,493 patients (980 intervention and 513 control), 62 pharmacists and 164 GPs. No statistically significant differences between intervention and control groups were shown at follow-up for any of the primary outcome measures such as numbers on aspirin or lifestyle measures. However, there were few differences in quality of life (SF-36) between the intervention and control groups at baseline or follow-up or with overall EQ-5D score over time. The total NHS cost increased between baseline and at 12 months in both groups but to a greater extent in the intervention group. Significant improvements were found in the satisfaction score for patients' most recent pharmacy visit for prescription medicines among the intervention group, compared with the control group. Self-reported compliance was good for both groups at baseline and no significant differences were shown at follow-up. The study concluded that there was no change in the proportion of patients receiving appropriate medication as defined by the NSF and that this pharmacist-led service was more expensive than standard care.

The trial was conducted before the inception of the new pharmacy contract, which introduced medicines utilisation reviews, ahead of pharmacists achieving independent prescribing status and before electronic prescribing initiatives which might be expected to have a more positive effect on the cost-effectiveness of prescribing services. This and other studies of collaboration between community pharmacists and family practitioners demonstrate a need for clarification of the community pharmacist and physician roles. The extent to which GPs and community pharmacists worked together in this study is unclear. The importance of a systematic approach when changing professional practice, with careful planning, resourcing, implementation and monitoring has been emphasised. All of these may not have been sufficiently addressed in this study.

The recently published RESPECT study (Randomised Evaluation of Shared Prescribing for Elderly people in the Community over Time) set out to estimate the effectiveness of pharmaceutical care for older people, shared between GPs and community pharmacists in the UK, relative to usual care. This was a relatively large and complicated study which implemented pharmaceutical care at two-month intervals in random order. Patients acted as their own controls, and were followed over three years including their 12 months' participation in pharmaceutical care. It involved 760 patients, aged ≥75 years, recruited from 24 general practices in east and north Yorkshire. Sixty-two community pharmacies also took part. A total of 551 participants completed the study. Pharmaceutical care was undertaken by community pharmacists who interviewed patients, developed and

implemented pharmaceutical care plans together with patients' GPs, and thereafter undertook monthly medication reviews. Pharmacists and GPs attended training before the intervention. Outcome measures were the UK Medication Appropriateness Index, the Short Form-36 Health Survey (SF-36) which is a measure of quality of life, and serious adverse events. However the intervention did not lead to any statistically significant change in the appropriateness of prescribing or health outcomes. Although the mental component of the SF-36 decreased as study participants became older, this trend was not affected by pharmaceutical care. The authors concluded that this model of medicines management shared between community pharmacists and GPs did not significantly change the appropriateness of prescribing or quality of life in older patients.

Work of practice-based pharmacists

What does a practice pharmacist do? (derived from Stott 2004)

- Communicate with local retail pharmacists to ensure repeat prescribing is efficient and well-managed.
- Structured medication reviews – face-to-face consultations with individual patients (known colloquially as brown bag reviews) to which patients bring all their prescribed and OTC medications, health foods and nutraceuticals.
- Provide patient education materials related to prescribed medication.
- Define and create protocols, formularies and programmes of medication review.
- Create practice-based systems to achieve success in prescribing incentive schemes.
- Work with difficult patients – medication reviews and falls prevention work in care homes and for housebound patients.
- Deal with day-to-day prescribing problems and contacting patients after drug alerts.
- Work as a clinical co-ordinator to ensure success in gaining quality initiative points; as qualified health care professionals, pharmacists are able to relate to patients and to direct them in a way that less-qualified staff might find difficult.
- Practice audit, flagging up areas where improvement can be made.
- Repeat prescribing management.
- Future role as independent prescriber – authorising repeats.

Support for 'obligatory' polypharmacy

There is no exact definition but polypharmacy refers to the use of multiple medications by a patient. In the past it was frowned upon but in recent years it has been recognised that polypharmacy is in many cases obligatory or a 'necessary evil' and it has become much more common. For example, in the past decade, the average number of items prescribed to people aged 60 or over has almost doubled from 21.2 to 40.8 items for each person per year

(Information Centre 2007). Part of the reason for this is the move to treat asymptomatic people to reduce their future risk of chronic disease and for this reason many 'well' people are being prescribed complicated preventive drug regimens, but also, as a result, they are being put at risk of adverse events and drug interactions (Payne and Avery 2011). Since 2004, the GP quality and outcomes framework in the UK may have fuelled this increase.

This can only increase further in the future as with changing demographics the population is ageing and the prevalence of chronic disease is likely to increase alongside this. Many patients have several co-morbidities. If each one of these is treated according to national guidelines, patients may end up taking a complicated cocktail of drugs. However, it has also been argued that the effects of complexity and co-morbidity are systematically excluded from practice guidelines (May *et al* 2009) and that more effort should be made to explicitly address the problems of managing multiple chronic conditions. For example, guidelines could be developed to cover chronic conditions that commonly co-exist, such as diabetes, coronary heart disease, heart failure, and chronic obstructive pulmonary disease.

Another important issue is that the patient with complex conditions may have several people prescribing for them and this can result in adverse drug events, such as missed drug interactions or duplication, unless communication is very good (Green 2007).

Practical management tips on polypharmacy (Derived from Duerden 2009, Milton *et al* 2008)

- Never assume your patient is taking what you think they are taking. Regular review is essential. Brown bag reviews (ask the patient to bring all the medicines they are taking to the surgery) or reviews in the patient's home can be illuminating.
- Keep medication regimens as simple as possible – ideally with once- or twice-daily dosages. The number of pills or 'pill burden' should be kept to a minimum.
- Provide clear written instructions and a dosing schedule.
- Try to ensure that the directions on each prescription item identify the problem it is intended to treat.
- Be aware of the known pitfalls with specific drugs, and recognised drug interactions (for example, ACE inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs)). You should carefully consider and avoid these where possible.
- Consider the use of compliance aids such as monitored dosage boxes or 'pill organisers.
- Discuss complex regimes with community pharmacy colleagues.
- Prescribing unequal quantities of different medications so that prescriptions are 'out of sync' is a bad idea, as is using the term 'as directed' rather than specific dosage instructions on prescriptions.

- Always ask your patient if they are using home remedies, for example, herbal products or OTC products. Also, could the patient be using somebody else's treatment?

Other important messages

- Try to keep the number of prescribers to a minimum.
- Polypharmacy should never be thoughtless.
- Within reason, establish the diagnosis rather than treat symptoms.
- Promote patient and carer understanding of prescribed drugs. Establish concordance.
- Try to substitute rather than add to medication regimens.
- Think of introduced drugs as a trial: do not forget to stop treatment that is unnecessary or ineffective.
- Combination products may seem like a good idea but can add to the complexity with little room for titration of individual constituents.
- Anticipate interactions and be alert to side effects.
- Remember to harness the four Ps: prompts, plans, partners, pharmacists.

10 How can prescribing be better supported by information?

Information support for prescribing

As highlighted in the previous section on prescribing safety, there is a wide variety of sources of information to support prescribing in general practice, including:

- paper-base information
- clinical computer systems
- the internet
- services offering expert advice, such as drug information centres.

Information supports the prescribing of specific drugs and devices in a large number of ways:

- by helping decision-making:
  - whether to prescribe a drug or not
  - what to prescribe in terms of effectiveness, risk of harm, comparative effectiveness with other treatments, and cost-effectiveness
  - which formulation is most appropriate for the patient
  - what dosage (dose and frequency of administration) to prescribe and when the dosage should be modified
  - how long to prescribe the drug for.
- by informing the prescriber about:
  - what formulations the drug is available in
  - adverse effects of the drug and the frequency that these occur
  - whether other diseases or patient states (eg, pregnancy) mean the drug is contra-indicated
  - what monitoring is required
  - whether the drug is licensed for the condition it is being prescribed for
  - whether the drug is new and under enhanced surveillance by the licensing authority (black triangle drugs)
  - the cost of that drug
  - whether the drug is available through the NHS
  - whether the drug is on the local formulary
  - whether the drug is available over the counter or is a prescription-only medicine.
- by informing patients:
  - how to take or use the drug (eg, eye drops, insecticides to treat scabies)
  - about the drug – its indications, contraindications, and adverse effects.

General information is also required about the principles of prescribing, about for example:

- prescribing controlled drugs
- prescribing for oneself, family, and close friends
- how to write a prescription
- prescribing unlicensed drugs and drugs off-label
- adverse drug reaction reporting
- remote prescribing eg, by telephone
- repeat dispensing
- mixing drugs eg, in syringe drivers
- keeping up-to-date.

Information sources currently available to support prescribing in general practice. How are they accessed/delivered?

General information about the principles of prescribing

This information is provided through the following:

- The General Medical Council (GMC) sets out the principles that doctors must follow when prescribing medicines in *Good Medical Practice* (2006). This is freely available from the GMC website and printed pamphlets are sent to all doctors through the post.
- *Good Practice in Prescribing Medicines* guidance issued in 2008 (See Appendix B).
- British National Formulary (BNF). This is freely available to all prescribers in the NHS through a website and in a printed book delivered to the workplace every six months.
- Medicines and Healthcare Products Regulatory Agency (MHRA) for information on the safety of medicines and the reporting of suspected adverse drug reactions.
- Medicines and pharmacy section of the Department of Health website.
- Undergraduate training.

Specific information to support evidence-based prescribing in primary care is available from a wide variety of resources (see the table *Initial information sources cited by GPs as influence on prescribing new drugs* below).

- Reference books (such as Martindale's *The Extra Pharmacopoeia* which provides detailed information on drugs).
- Drug compendia – provide a comprehensive list of drugs available on the market and usually include generic and brand names for drugs, clinical contra-indications and precautions, drug interactions, adverse effects, and dosage recommendations. Examples include the Monthly Index of Medical Specialties (MIMS) and the electronic Medicines Compendium that provides the Summaries of Product Characteristics (SPCs) and Patient Information Leaflets (PILs) for UK medicines.

- Formularies – restricted lists of drugs approved for use at national, regional or institutional (practice) level, to which prescribers are encouraged to adhere. The British National Formulary is provided free of charge to all prescribers in the UK.
- Clinical guidelines – 'systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and well-being'. They can be national (for example, guidelines from the National Institute for Health and Clinical Excellence) or local. They can also be targeted specifically at primary health care professionals (for example the NHS clinical knowledge summaries).
- Bulletins and newsletters/summary publications – provide regular, usually concise, updates on drugs and the management of conditions.
- Medical journals – provide reports on individual clinical trials, systematic reviews of trials, and expert review articles on a topic.
- Stockley's Drug Interactions, an online source of information on drug interactions.
- Other health care professionals – colleagues, consultants and other secondary care specialists.
- Local opinion leaders – health care professionals who are credible, likeable, and trustworthy, and are considered by colleagues to be educationally influential. They may provide informal one-to-one teaching, educational outreach visits, small group teaching, or provide feedback.
- Educational outreach visits – personalised visits from a trained person to a health care professional in their own setting with the aim of changing their behaviour and improving performance. The information provided may include feedback on the health care professional's performance and may also be tailored to overcome obstacles to change. An example is a visit from a pharmaceutical adviser.
- Drug information centres – at a regional level provide an enquiry answering service on all aspects of drug treatment and provide critically appraised information on recently launched drugs. National information services answer enquiries on the use of drugs in pregnancy, in breastfeeding, in renal failure, in liver disease, in psychiatry, and in HIV and AIDS although health care professionals may be advised to contact their regional medicine information centre initially.
- The pharmaceutical industry – through pharmaceutical representatives, stands at professional meetings, journal articles and supplements supporting use of a company's drug, direct advertising in journals and magazines, and direct mailing.
- Continuing education meetings – including activities such as conferences, lectures, workshops, seminars, symposia, and courses.
- Audit and feedback – defined as any summary of clinical performance over a specified period of time. Prescribing analyses and cost (PACT) data are derived from prescriptions issued by primary health care

professionals. PACT includes information on prescribing costs, the number of items prescribed, and generic prescribing and is one way for health care professionals to audit their prescribing.

These information sources are available in a variety of formats including print (such as textbooks, magazines, flyers, journals, newsletters, summary publications), electronic (emails and websites), and verbal communication (ie, in person).

What information resources do GPs use?

As part of the National Audit Office investigation into how to support doctors and other prescribers in making prescribing decisions, a survey of 1,000 GPs was undertaken which indicates that the BNF, summary publications (such as the Drugs and Therapeutic Bulletin and Bandolier), and other GPs are the preferred information resources to support prescribing (NAO 2007a).

Also as part of the National Audit Office's investigation, the RAND Corporation undertook a qualitative study which aimed to understand what influences GPs' prescribing choices and how these might be changed (Scoggins *et al* 2006). Interviews with senior managers, focus groups with GPs, and workshops involving senior managers and GPs were undertaken in two PCTs. Many factors were reported to influence GP prescribing and those that relate to information resources are summarised here. Interestingly the BNF was not discussed by the participants in this study but the Audit Commission's own survey of GPs showed that the BNF was ranked as the most useful and objective information resource.

At a national and international level (macro-level):

- **Journals** Clear evidence on treatments published in authoritative journals (such as the British Medical Journal) was reported to be a 'significant' influence on prescribing by GPs. The quality of the evidence was considered to be very important. This is consistent with much of the literature on the self-reported information seeking behaviour (Astrom *et al* 002, Dawes and Sampson 2003, NAO 2007a) but is inconsistent with actual practice.
- **Guidelines** Guidelines produced by the National Institute for Health and Clinical Excellence (NICE) were also reported to influence prescribing practice but GPs stated that they were too 'vague' and needed to be 'interpreted' in a local context to be useful for prescribing.
- **National media** This was considered to raise awareness of certain diseases and treatments and increase patient demand. GPs reported that this increased demand 'was generally easy to manage'.
- **Conferences.**
- **Pharmaceutical industry** (discussed in more detail below).

At a PCT level (meso-level):

- **Local formularies** This finding is consistent with a questionnaire survey in which most (86 per cent) GPs reported that their prescribing behaviour was influenced by a joint formulary (Heal *et al* 2006).

- **Consultants and other specialists in secondary health care** This finding is consistent with a study that showed between 16 and 20 per cent of GP prescribing is initiated in hospital and 40 per cent is strongly influenced by hospitals (probably because GPs are guided by the prescribing behaviour of the local consultants) (Audit Commission 1994). It is also consistent with other GP surveys (Astrom *et al* 2002, Carthy *et al* 2000, National Audit Office 2007a).
- **Benchmarking exercises** such as comparing PACT data from across GP practices or PCTs. The Audit Commission's own survey showed that prescribing advisers ranked this as a useful way of influencing GP prescribing and 70 per cent of GPs said this influenced their prescribing (National Audit Office 2007a).
- **Local websites** that make relevant and locality-specific information easily accessible.
- **Personalised visits by prescribing advisers** to practices. The National Audit Office's own survey of prescribing advisers indicated that greater contact time with GPs was the most effective way of influencing GPs' prescribing behaviour (NAO 2007a).The prescribing advisers also reported that they had less influence on the prescribing behaviour of nurse prescribers than the pharmaceutical industry. Two-thirds of GPs surveyed said that prescribing advisers have more influence on their prescribing behaviour than pharmaceutical representatives.
- **Drug-company sponsored events** PCT managers had differing views on the influence of drug companies on GP prescribing behaviour.
- **GP forums** Senior managers considered that 'getting GPs in the same room' was a useful way of influencing prescribing behaviour. In these meetings findings from prescribing reports and prescribing action plans are discussed.
- **Local networks of the prescribing community** (including consultants, specialists, pharmacy advisers, and GPs).
- **Local guidelines** from the PCT (including PCT adaptations of NICE guidance) were considered to be more useful but less objective (because of the influences of budgetary issues) than national guidance. GPs stated that they found short and clear information in a standardised format very useful.

At a practice level (micro-level):

Knowledge and professional experience were stated by GPs to be key influences on prescribing. Training was also considered to be important. In one study of modifiable factors associated with GP prescribing, GPs described using a head-held formulary which was established as an undergraduate and modified by colleagues, patients, policy, and experience (Carthy *et al* 2000). An ethnographic study also showed that GPs based health care decisions on head-held guidelines ('mindlines') that were established early in training and updated by brief reading, interactions with each other and with opinion leaders, patients, pharmaceutical representatives, and experience (Gabbay and le May 2004).

- **Pharmaceutical representatives** Many GPs stated that they collected information from pharmaceutical representatives and acknowledged this helped them keep up-to-date. Most GPs (87 per cent) report seeing pharmaceutical representatives (usually between once a week and once every three months): 21 per cent report they see a pharmaceutical representative at least once a week (National Audit Office 2007a). The GPs were confident that they were not unduly influenced by the representatives and were aware that they were provided with selective information. This is in line with a number of other studies that show most physicians believe that they are immune to undue influence from the pharmaceutical industry (either from visits from representatives or promotional items and gifts) (Reeder *et al* 1993; Sergeant *et al* 1996; Hopper *et al* 1997; Gibbons *et al* 1998; Carthy *et al* 2000, Steinman *et al* 2001, Astrom *et al* 2002, Grande *et al* 2009).
- **Formal and informal networks** within each practice (for example, weekly or monthly practice meetings and conversations over tea breaks) were reported to influence prescribing behaviour.

There is evidence that there is a difference between the information resources that doctors rate as important or report they use, and the information resources they actually use (Covell and Uman 1985; McGettigan *et al* 2001; Gabbay and le May 2004). Doctors rate as important or believe they use print resources (journals, summary publications, and the BNF) but in fact they were most likely to seek information from other people (doctors and pharmaceutical representatives).

The usefulness of the available literature about the information-seeking behaviour of primary health care professionals is therefore limited by the fact that much reliance has been given to self-reported behaviour rather than directly observed activity and little is specifically focused on primary health care professionals working in the UK. In addition the landscape is constantly changing with the introduction of better access to the internet, increasing availability of clinical information on the internet, and the development of federated search engines specifically for health-related topics – making the evidence we do have potentially out of date.

A systematic review that assessed the information-seeking behaviour of health care professionals showed that health care professionals most frequently seek information from text sources (books, papers, and desk reference) and from colleagues (Dawes and Sampson 2003). Most of the 19 studies considered in this systematic review involved primary health care professionals. However, most used questionnaires or interviews to collect data. Four studies collected data by interview after a clinical session but only one study was observational in nature.

We are aware of only a few observational studies of the information-seeking behaviour of primary health care professionals.

A primary care based study in New Zealand in which the information-seeking activity of physicians was observed, showed that high access to computers did not relate to high usage of internet resources to answer clinical questions, and that books and colleagues were the two most commonly used information sources (Arroll *et al* 2002).

A primary care based study undertaken in England observed the ways in which GPs and practice nurses used evidence to inform their clinical decisions both on an individual basis and on a collective basis when discussing best practice (Gabbay and le May 2004). This study showed that health care professionals rarely used evidence from research and other formal sources (such as electronic or printed guidelines). Instead they relied upon 'mindlines – collectively reinforced , internalised tacit guidelines, which were informed by brief reading, but mainly by their interaction with each other and with opinion leaders, patients, pharmaceutical representatives and other sources of largely tacit knowledge that built in their own and their colleagues experience'.

An observational study of primary health care professionals in the United States showed that text books, colleagues, and desktop computer applications were the most commonly used resources to answer clinical questions (Ely *et al* 2005).

A study undertaken in the United States and Canada observed the information-seeking behaviour of primary health care professionals when answering simulated clinical questions with the information resource of their choice (McKibbon and Fridsma 2006). All apart from one participant (1/25) chose to use the internet to answer the questions. The resources which were collations or summaries (Cochrane Database of Systematic Reviews and Clinical Evidence) were used most frequently, followed by MEDLINE.

We did not identify any reliable evidence about the variation in information-seeking behaviour between individual health care professionals in primary care in the UK.

It is highly probable that with new technology this situation has changed and will evolve further. GPs are much more likely to use computerised information and decision support. The advent of personal digital devices, such as iPhones and iPads, with app-based technology, is poised to fundamentally alter the approach of the next generation of GPs.

What is the evidence that information resources change practice?

Guidelines

A systematic review that assessed the effect of guidelines on medical practice showed guidelines improve patient care (Grimshaw *et al* 2004). It also showed that:

- dissemination of educational materials may have a modest effect on guideline implementation which may be short-lived
- audit and feedback may have a modest effect on guideline implementation.
- reminders may have a modest effect on guideline implementation. Multifaceted implementation interventions did not appear to be more effective than single interventions
- educational meetings may have a small effect on guideline implementation.

Educational meetings

A Cochrane systematic review found that educational meetings can result in small-to-moderate improvements in professional practice and smaller improvements in patient outcomes (Forsetlund *et al* 2009). Mixed interactive and didactic education was more effective than didactic education alone, and interactive education alone was the least effective. There was no difference between multi-faceted interventions that included education meetings compared with educational meetings alone. Educational meetings about topics that health care professionals perceive to have serious consequences for patients were found to be more effective than educational meetings about topics that were not considered to have a serious outcome for patients.

Educational outreach visits

A Cochrane systematic review found that educational outreach visits resulted in small but consistent changes to prescribing behaviour (O'Brien *et al* 2007). The effects on other types of professional behaviour were small-to-moderate and the results were variable for reasons that are not clear. It is uncertain if multifaceted interventions that included educational outreach visits are more effective than educational outreach visits alone. It is not known whether any improvement to performance is maintained over time.

A more recently published update of two other systematic reviews of prescribing interventions found that educational outreach visits are generally effective in improving appropriate care and prescribing compared with no intervention (Ostini *et al* 2009).

Audit and feedback

A Cochrane systematic review found that audit and feedback, although widely used, is not consistently effective in changing professional behaviour (Jamtvedt *et al* 2006). When it is effective, the effects are small-to-moderate. Audit and feedback is more likely to be effective as an intervention when baseline adherence to recommended practice is low and when feedback is delivered more intensively. There was no significant difference between multi-faceted interventions that included audit and feedback and audit and feedback alone.

Formularies

There is evidence (from controlled and uncontrolled studies) that introducing formularies in general practice changes prescribing behaviour and reduces costs (Beardon *et al* 1987, Grant *et al* 1985, Field 1989, Dowel *et al* 1995; Hill-Smith 1996, Avery *et al* 1997).

Mass media interventions

A Cochrane systematic review found there was weak evidence to suggest that mass media communications (planned campaigns and unplanned coverage) increases health service utilisation (Grilli *et al* 2002). However it is not clear to what extent this effect is attributable to changes in the behaviour of health care professionals.

Pharmaceutical industry

The pharmaceutical industry spends more than £850 million every year on marketing and promotional activities in the UK and there are 8,000 pharmaceutical representatives (about one representative for every four GPs). The pharmaceutical industry sponsors more than half of postgraduate education and training in the UK.

A House of Commons Health Select Committee undertook an enquiry into the influence of the pharmaceutical industry and reported 'the industry is hugely influential, affecting every aspect of the medical world, including prescribers, patients, academics, the media, and even the institutions designed to regulate it' (House of Commons Health Committee 2005).

The available trial evidence does not help quantify the effect that the pharmaceutical industry has on the behaviour of primary care prescribers. A national cross-sectional survey found that frequent contact between general practitioners and pharmaceutical representatives was associated with higher prescribing costs (Watkins *et al* 2003). An Australian study indicated that pharmaceutical advertisements embedded in clinical software did not change the prescribing practice of general practitioners (Henderson *et al* 2008).

In one study in the north west of England 107 GPs were interviewed to determine what had influenced them to prescribe a predefined basket of new drugs (Prosser *et al* 2003). Pharmaceutical representatives were the most commonly cited influence. Hospital consultants and observation of hospital prescribing was cited next most frequently. Patient request for a drug, and patient convenience and acceptability were also likely to influence new drug uptake. Perhaps surprisingly written information was of limited importance except for local guidelines. GPs were largely reactive and opportunistic recipients of new drug information, rarely reporting an active information search. The researchers concluded that the decision to initiate a new drug is heavily influenced by 'who says what', in particular the pharmaceutical industry, hospital consultants and patients, and that the decision to 'adopt' a new drug is clinched by subsequent personal clinical experience. Evaluation of the scientific merit or evidence base for the treatment did not appear to be a strong influence (see the table *Implementation strategies for guidelines from the Scottish Intercollegiate Guideline Network* below).

Collaborative working between the NHS and the pharmaceutical industry in which pharmaceutical marketing activity is supported and encouraged by a health authority, although feasible, does not appear to change the prescribing practice of general practitioners (Freemantle *et al* 2000).

Opinion leaders

A Cochrane systematic review found that using local opinion leaders can result in moderate changes in professional practice (Doumit *et al* 2007). The effects of opinion leaders varied across trials and between trials where multiple outcomes were assessed. The intervention was directed at primary health care professionals in only four of the twelve trials and no studies were undertaken in the UK. A subsequent study of the effectiveness of opinion leaders directed at primary health care professionals has also shown modest improvements in practice (Majumdar *et al* 2007).

Computerised decision support systems

Computerised clinical decision support systems (CDDSs) are information systems designed to improve clinical decision-making and offer 'an automated process for comparing patient-specific characteristics against a computerised knowledge base with resulting recommendations and reminders presented to the provider (health care professional) at the time of clinical decision-making (Hunt *et al* 1998). CDSSs can support decision-making in a number of ways including one or more of the following:

- alerts of critical values
- reminders of overdue preventative health task
- advice for diagnosis, disease management, and drug dosing and prescribing
- critiques of patient care indicating potential non-compliance with desired practice.

Systematic reviews show that many CDSSs improve health care professional performance but the evidence that they improve patient outcomes is less convincing (Garg *et al* 2005, Bryan and Boren 2008, Mollon *et al* 2009). A systematic review that focused on CDSSs for prescribing showed that providing advice to fine-tune existing drug treatment was more effective than providing advice before a drug was selected (Pearson *et al* 2009). The most effective approaches were to make recommendations to improve patient safety; to adjust the dose, duration, or formulation of the drug prescribed; and to increase laboratory monitoring. Information systems that are automatically initiated appeared more effective than those that were user initiated.

A systematic review that assessed the effectiveness of CDSSs in ambulatory or primary care settings showed that many, but not all, CDSSs improve outcomes (mostly health care professional performance) (Bryan and Boren 2008). A further systematic review assessed the features associated with a successful CDSS – a CDSS was considered successful if it was utilised by clinical staff and improved health care professional behaviour and/or patient outcomes. The features that were present in all successful CDSSs and not in most unsuccessful CDSSs were provision of a recommendation rather than just an assessment; justification of the decision support by providing the underpinning evidence; and data standards that supported integration (for example with the electronic health record) (Mollon *et al* 2009).

Some research shows that GPs may ignore computerised drug alerts or information on drug interactions and simply override them (Magnus *et al* 2002). There are several reasons why this might occur. Perhaps a common reason is that the messages are too frequent and a degree of 'alert fatigue' creeps in (Baker 2009). Some medication is particularly hazardous, and for these possibly the answer is to have very clear flagging of hazard, as now happens with methotrexate, on GP computer systems in the UK.

Bulletins and newsletters/summary publications

There is a lack of evidence on bulletins and newsletters/summary publications and changes in prescribing behaviour. Evidence from one small

randomised controlled trial in the Netherlands showed that drug bulletins had a variable effect on self-reported prescribing behaviour (Denig *et al* 1990).

Printed educational materials

A Cochrane systematic review found that printed educational materials have a small effect on professional practice (Farmer *et al* 2008). It is not known whether printed educational materials change patient outcomes. No studies were identified that compared a multifaceted intervention that included printed educational materials with a multifaceted intervention that did not. See previous section on patient decision aids for more information.

GP forums and networks

There is limited evidence from a retrospective analysis of a non-randomised controlled trial that peer-led small group education can improve the prescribing behaviour of GPs (Richards *et al* 2003). This positive effect reduces over time but remained statistically significant for 24 months.

Other information resources

We are unaware of controlled studies that assessed the effect journals, consultants and other specialists in secondary care, text books, and reference books have on the prescribing behaviour of primary health care professionals.

Initial information sources cited by GPs as influence on prescribing new drugs (Prosser *et al* 2003)

Information source	***n (%)***
Pharmaceutical industry	49%
Advertising/mailshots/promotional literature	94 (15%)
Pharmaceutical representative	202 (33%)
Pharmaceutical industry-sponsored meeting	7 (1%)
Professional	13%
Hospital doctors–discharge letters/patients	49 (8%)
Hospital doctors–meetings	9 (2%)
GP colleagues	9 (1%)
Nurse colleagues	12 (2%)
Pharmacist	1
Health Authority/PCG	1
Professional/post-graduate meetings/conferences	5
Local prescribing meeting	1

Academic and professional literature	17%
Medical peer-reviewed journals	5 (1%)
Non-peer-reviewed medical literature, e.g. *Pulse*, *GP*,	97 (16%)
BNF, *MIMS*	1
Therapeutics literature (national and local), e.g. HA newsletters, MEREC, Drug and Therapeutics Bulletin	0
Media	101 (16%)
Patient	18 (3%)

Implementation strategies for guidelines from the Scottish Intercollegiate Guideline Network (SIGN 2008)

Method	*Effectiveness*	*Local considerations*
Written materials	Variable findings; at best, small effect	Whilst impact is small, could be used to raise awareness of the guideline through materials or through medical journals or local publications. Useful in combination with other strategies.
Audit and feedback	Sometime effective; small to moderate effect but potentially important	This could be a valuable starting point to provide baseline information from which to develop an implementation strategy.
Education (group)	Variable effects which improve when the influence of peers is included	Identify a local multi-professional group who can be supported with education from experts or by attending workshops or conferences. Facilitation at practice/ unit level is helpful.
Education (individual)	More effective than other educational initiatives	Targeting stakeholders through individual education centred on the topic, or more general implementation issues. Consideration needs to be given to cost.
Opinion leaders	Mixed effects	Identify local and national opinion leaders and consider how they might be involved.
Product champions	No conclusive evidence	Identifying product champions might highlight innovative methods for implementation.

Method	*Effectiveness*	*Local considerations*
Academic detailing/ educational outreach	Effects are small to moderate but of potential importance	Could be incorporated with individual education approach and written materials.
Mass media	May have a positive influence on how health services are used	Take advantage of mass media coverage and additionally local media sources.
Patient-mediated interventions	No conclusive research evidence	Consider local patients, consumer and pressure groups so that involvement is part of strategy at the outset
Continuous quality improvement	No conclusive research evidence	Local audit/clinical governance/ effectiveness departments should always be included in any implementation strategy.
Financial incentives	Some appear to influence practice, but not all	This may only be available for some professional groups and would depend on the nature of the guideline, eg financial support for audit, prescribing incentives.
Policy/ regulation	No conclusive research evidence	National standards drawn up by NHS QIS are supported by clinical guidelines and can be influential in supporting local implementation
Reminder systems	Computerised records have supported the implementation of guidelines. Manual reminder systems were effective in many, but not all studies	Implementation may prompt a review of the record keeping system and may initiate developments such as multi-professional integrated care pathways. Computerised decision support is being developed.
Internet / online databases	No conclusive research evidence	If local services are networked this could form a useful medium for communication and information sources
Combinations of methods	Appear to be more effective than any one intervention on its own	Importantly, a local strategy needs to consider which of the above and in what combination such strategies may be helpful

What does high-quality information to support primary care prescribing look like?

Our review of the literature suggests that high-quality information is likely to involve a number of factors.

The best information sources will provide relevant, valid material that can be accessed quickly with minimal effort (Smith 1996), otherwise described as the '3 Rs' of evidence-based communication – reliability, relevance, and readability (Straus and Haynes 2009).

Ely *et al* have developed a number of specific recommendations for information authors based on interviews with 48 generalist physicians who wanted 'rapid access to concise answers that were easy to find and told them what to do in specific term' (Ely *et al* 2005). These provide some indication of what 'high-quality' means to health care professionals.

Reliable

The methods used to develop information should be rigorous and explicit to minimise the risk of bias. The best available evidence should be interpreted and formulated into recommendations wherever possible. It is unrealistic to expect busy health care professionals to identify the best research evidence and then integrate this with clinical expertise and patient values in order to practice evidence-based medicine for all the decisions they have to make. Studies and systematic reviews simply take too long to find, read, appraise, interpret, and to implement. Synopses and summaries of the evidence, although quick to read, are often not orientated to the problems seen in day-to-day practice and are therefore difficult to implement. Problem-orientated, high-quality guidance is the best tool we have at present to support busy health care professionals to practice in a safe and evidence-based way (Dartnell *et al* 2007).

Clear links to the underpinning evidence

A rationale should be provided for recommendations which is separate from the clinical recommendations (Ely *et al* 2005; Vidal *et al* 2005).

Up-to-date

The information should be updated frequently (Ely *et al* 2005).

Comprehensive

Information resources should answer the clinical questions that occur in clinical practice (Ely *et al* 2005). Information or recommendations should be provided even where there is a lack of trial data (Ely *et al* 2005). There should be sufficient detail to allow the health care professional to put the information into practice (Ely *et al* 2005).

Relevant

To be relevant information needs to be tailored to the specific needs of primary care (Straus and Haynes 2009). The information needs to be

problem-orientated and reflect the scenarios that primary health care professionals see in day-to-day practice (Dartnell *et al* 2007, Ely *et al* 2007). Information resources should reflect clinical experience and expertise as well as practical considerations (Ely *et al* 2005, Dartnell *et al* 2007).

Readable

The information should be easy to read, free of unnecessary jargon and abbreviations, and as short and concise as possible.

Clear

The information should be unambiguous. Recommendations should be clear, directive, and focus on what to do and by whom (Michie and Johnston 2004; Ely *et al* 2005).

Accessible

The information should be quick to access – the information resource should be easily found and the content structured and formatted appropriately so that the relevant information can easily be identified (eg, with lists, tables, bullets, bold subheadings) (Ely *et al* 2005). Lengthy uninterrupted prose should be avoided. The information should be structured using a step-wise approach that is aligned with clinical workflow (Ely *et al* 2005). Information resources should also have a user-friendly search function (Ely *et al* 2005).

Accreditation of information

Ideally all information to support prescribing within the NHS should be accredited as fit-for-purpose. NHS Evidence has developed standardised criteria and assessment processes, based on the recognised quality standard Appraisal of Guideline Research and Evaluation (AGREE), to evaluate the process used to develop guidance. Using these criteria, the NHS Evidence Accreditation Scheme recognises organisations that achieve high standards in producing guidance and allows accredited resources to be kitemarked. In the longer term standardised criteria to evaluate the processes used to develop other sources of information will be developed.

Based on the NHS Evidence evaluation criteria high-quality guidance should:

- have a defined scope and purpose
- represent the views of its intended users and those affected by the information by involving stakeholders in its development
- have a rigorous development process to gather and synthesise information, develop recommendations, and keep the guidance up-to-date
- be clear and well presented.

In addition the guidance producer should:

- consider issues of implementation (such as support tools), barriers to applying recommendations (financial and organisational), and review criteria for monitoring and/or audit purposes

- ensure editorial independence of the recommendations, that competing interests are acknowledged, and that the guidance is credible.

Full details of the assessment criteria for the NHS Evidence Accreditation Scheme can be found at: www.evidence.nhs.uk/Accreditation/Documents/NHSEvidenceAccredManual.pdf (accessed on 5 February 2011).

The current quality of information to support prescribing

There are many reliable resources to support prescribing in general practice but too few that can be considered reliable *and* relevant *and* readable (where the information source is text) *and* quickly accessible. It is likely that this causes or encourages primary health care professionals to either not look for answers to their clinical questions or to take shortcuts to the information they require (for example by asking colleagues, or reading summary information in magazines, or asking pharmaceutical representatives). These shortcuts may or may not provide reliable information.

There is some evidence that colleagues and experts provide incorrect answers. A small study in The Netherlands showed that when occupational health doctors asked peers for advice, an incorrect answer (ie, differed from the best available evidence) was given 53 per cent of the time (Schaafsma *et al* 2005).

There is evidence to suggest that primary health care professionals do not always seek information to answer their clinical questions, often because they doubt that information resources will provide an answer.

An observational study in the United States showed that general physicians during ambulatory care (ie, not hospital based patients) only pursued 55 per cent of the clinical questions that arose during the consultation (Ely *et al* 2005). Of the questions that were pursued, 72 per cent were answered (31 per cent with difficulty). The most common reason for not pursuing an answer was the belief that no useful information would be found. Other reasons were time pressures and that referral was more likely to benefit the patient than pursuing the answer. If the health care professional decided to try and answer a question, the most common obstacle to finding the answer was the lack of the *needed* information within the selected resource.

There is evidence that primary health care professionals do not always find the correct answer when they search for information.

One study in Australia examined the effectiveness of using an online information resource for doctors (including primary health care professionals) and nurses to answer clinical questions (Westbrook *et al* 2005). The online resource provided access to six resources (most provided summarised information). On average 29 per cent of answers were answered correctly before using the online information resource and 50 per cent were answered correctly after using the information resource. Despite there being significant differences between the 'pre-test' scores of hospital doctors, primary care health care professionals, and nurses, there was no difference in the number of questions answered correctly after using the online information resource. Only 7 per cent of answers changed from correct to incorrect after using the online information resource.

Another study, based in the United States and Canada, directly observed the information resources that primary health care professionals used to answer two simulated clinical questions and assessed whether searching for information improved their ability to answer the questions using the electronic information resource of their choice. Before searching 39.1 per cent of questions were answered correctly and after searching the number of correct answers increased only slightly to 42.1 per cent (McKibbon and Fridsma 2006). Around 10 per cent of answers went from correct to incorrect after searching. Using Google and searching the Cochrane Database of Systematic Reviews appeared to be associated with the correct answer about half the time. Use of MEDLINE was more often associated with an incorrect answer than a correct answer.

Why the health care professionals found incorrect answers to the clinical questions is not clear. A number of reasons have been suggested including: inappropriate choice of resource; inefficient use of resource; incorrect or out-of-date resource; the inability of the health care professional to analyse and apply the information; and automation bias (McKibbon and Fridsma 2006).

Improving the quality of information resources to support prescribing in primary care

Improve the content of information resources to support prescribing

Resource providers should provide information that is useful in a clinical setting. The information should be problem-orientated and offer guidance that is clear and specific (ie, specifies what, when, where, and how) with transparent links to a rationale and the underpinning evidence.

Improve the access to high-quality information resources to support prescribing

There is a need for better information tools to ensure that when seeking information primary health care professionals can quickly access high-quality guidance and information resources that are accredited for use in the NHS in preference to accessing unappraised evidence. As these tools are likely to be web-based, high speed connections to the internet and adequate bandwidth are essential for general practice but unfortunately are not yet universal.

The website NHS Evidence, launched in April 2009, provides access to high-quality clinical and non-clinical information about health care. It also awards an accreditation mark to organisations who meet high-quality standards in developing health information. See www.evidence.nhs.uk.

Provide concise information

Although there is a lack of evidence on the effectiveness of summary information in changing prescribing behaviour or on patient outcomes, primary health care professionals consistently rate as important and actually use this type of information.

Support 'in-person' information

Health care professionals are most likely to seek advice from other health care professionals and it would seem sensible to foster these networks, both formal and informal, to promote evidence-based practice. An example where this has occurred is the practical advice for pharmaceutical advisers on how to make the most of every visit to health care professionals provided by the National Audit Office (National Audit Office 2007b).

We need to ensure that opinion leaders' knowledge is based as far as possible on critically appraised research evidence rather than anecdote and the influence of the pharmaceutical industry. It would also seem sensible when teaching evidence-based practice to highlight the potential problems that are inherent in relying on the advice of colleagues.

Provide computerised clinical decision support tools

Computerised clinical decision support tools that draw on valid and up-to-date knowledge bases should be developed, evaluated, and implemented.

Support appraisal and revalidation

The Royal College of General Practitioners has advised that GPs will be 'expected to record their educational activity and award themselves credits based upon the hours involved and the impact of the education on themselves, their patients or the service in which they work' for revalidation purposes (Royal College of General Practitioners 2010).

Finally, online information resources should support appraisal and revalidation of GPs by logging or tracking information resources that have been accessed; facilitating notes about learning outcome; and by having the functionality to be easily uploaded into electronic revalidation tools.

Useful online sources of drug information for doctors and patients (accessed on 5 February 2011)

For doctors

- British National Formulary (which also gives websites and telephone numbers for other important sources of drug information): www.bnf.org
- Clinical Knowledge Service: http://cks.library.nhs.uk
- Drug datasheets: http://emc.medicines.org.uk
- Drug safety updates from the MHRA: www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm
- Medication monitoring advice is available from: www.ukmi.nhs.uk/Newmaterial/html/docs/21100201.pdf
- National Electronic Library for Medicines: www.nelm.nhs.uk
- National Prescribing Centre (advice on quality prescribing, medication review and repeat prescribing): www.npc.co.uk/prescribers/mp.htm

- NHS Connecting for Health projects (including the Electronic Prescriptions Service and the Summary Care Record): http://connectingforhealth.nhs.uk/systemsand services
- National Patient Safety Agency: www.npsa.nhs.uk
- Stockley's Drug Interactions, 8th ed (Also available as a pocket guide): www.pharmpress.com
- The whole range of drug information products from the pharmaceutical press available at: www.medicinescomplete.com

For patients

- Drug information leaflets for patients are available from: http://emc.medicines.org.uk
- Information leaflet on medical conditions and their treatment are available from various sites including: http://cks.library.nhs.uk
- Medicines for Children. Specific information for children and carers/patients: www.medicinesforchildren.org.uk/

The A*sk about Medicines* website has useful information and links to other gateways and websites: www.askaboutmedicines.org

11 Ensuring value for money

National Audit Office (NAO)

In 1994 the Audit Commission reviewed the cost-effectiveness of prescribing in primary care in an influential report *A Prescription for Improvement* (Audit Commission 1994). They saw that cost-effectiveness was an important driver of quality and gave clear guidance to health authorities on how savings in prescribing could be achieved by using generic drugs or cheaper types of treatment. As a result of this influential report and many other initiatives, the UK now has one of the highest rates of generic prescribing in the world (83 per cent in England in 2008). Other main drivers for this in the NHS may be the historic belief in generic prescribing in medical schools and hospitals and the fact that generic drugs are generally cheaper than their branded counterparts.

The themes from *A Prescription for Improvement* still persist and remain valid. In December 2007 a report from the House of Commons Committee of Public Accounts criticised GPs for continuing to prescribe branded, premium-cost products when they could be saving the NHS millions of pounds by switching to generic alternatives (House of Commons Committee of Public Accounts 2007). The report saw GPs as being too susceptible to drug company marketing and implied that secondary care physicians are not so susceptible and are also more restricted by hospital formularies. It is fair to say that many GPs would disagree with this as they see the pressure to prescribe high-cost newer drugs often comes from consultants. They also see that postgraduate education sessions are largely sponsored by the drug industry, and local specialists, as key opinion leaders, inform GPs about new expensive products. Also, on occasion it appears that specialists themselves get upset when GPs switch patients to cheaper equivalent products.

In 2007 the NAO review of *Prescribing Costs in Primary Care* stated that £200 million could be saved if all PCTs in England used statins and a number of other drugs in the same way, or at the same standard, as the 25 per cent most efficient PCTs (National Audit Office 2007a). In particular this highlighted the use of generic simvastatin rather than other brand statins and aspirin as an alternative to clopidogrel (although a generic clopidogrel has subsequently emerged). The clear message was that all PCTs should be influencing and advising GPs to substitute statins to save money. The use of low-cost statins has become one of the *better care, better value* indicators of the Institute of Innovation and Improvement in England (Institute for Innovation and Improvement 2010). This advises that GPs can switch patients to low-cost statins provided there are no clinical reasons for them to remain on the more expensive drug, and increases pressure on NHS bodies to be seen to actively pursue productivity gains. The NAO published a follow-up report in May 2009 saying their recommendations had been successful based on an estimate of the savings that PCTs had achieved through changing prescribing patterns in four therapeutic areas (statins, proton pump inhibitors, rennin-angiotensin drugs and clopidogrel) (National Audit Office 2009). According to their calculations the total saving in 2008, across all PCTs in England, was £394 million.

In the UK there remains considerable pressure from commissioners and providers of medicines in their various guises (general practices, primary

care organisations, practice based commissioning groups etc) to make efficiency savings. This is felt much more keenly at a time when there is economic hardship and growth in allocations for health budgets are expected to be minimal. However, clinicians may be opposed to these moves if they believe that generic or therapeutic equivalence is unproven and patients may believe they are getting cheaper, inferior drugs. The drug companies are opposed and put up barriers to these initiatives as they see this as a means to deny them a free market and as a threat to their profits. One way to encourage clinicians to be more enthusiastic about these approaches is to pay them for taking part through prescribing incentive schemes.

The Association of the British Pharmaceutical Industry (ABPI) has been resistant to the NHS using incentive schemes to stimulate switching by financial reward and started a legal challenge. In June 2007, the Department of Health, obviously keen to promote money-saving schemes, but wary about upsetting the drug industry and the legal implications, issued guidance for primary care trusts in England on strategies to achieve cost-effective prescribing. This guide specifically looks at prescribing incentive schemes and was said to be interim pending the outcome of the ABPI legal challenge (Department of Health 2007). It advised the use of standard operating procedures and gave case examples of incentives for statin switches. An interim determination appeared to have come out in favour of the ABPI and supported the UK pharmaceutical industry's view that prescribing incentive schemes are illegal under European law as they breach rules on promotion of medicinal products (Pharmaceutical Times 2010). The European Court of Justice has since ruled that the prohibition could not apply to national public health authorities who have the responsibility of controlling public expenditure (Dyer 2010). However, primary care organisations must make the schemes public and give the industry and health care professionals the evaluations showing therapeutic equivalence between cheaper products and the more expensive ones.

Generic substitution

This challenge does not directly square with the ABPI's response to the consultation to proposals to implement direct generic substitution by pharmacists in the UK which has been negotiated as part of the Pharmaceutical Price Regulation Scheme (PPRS) from 2009 (Department of Health 2009). This proposes that *'subject to discussion with affected parties, the Department of Health will introduce generic substitution in primary care. This will enable pharmacists and other dispensers to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine. Provision will be made to allow the prescriber to opt out of substitution where, in his clinical judgment, it is appropriate for the patient to receive a specific branded medicine. In these circumstances, the named brand must be dispensed. Provision may also be made to exclude certain categories of medicines for clinical reasons in the interests of patient safety'* (Department of Health 2010). The ABPI has supported this initiative but with exclusions from substitution in certain areas based on their view of patient welfare and international best practice (ABPI 2010). Their suggested exclusions include: modified or sustained release preparations, medicines with a narrow therapeutic index/window where there is evidence regarding the risk of adverse patient reactions or inadequate efficacy; vaccines, biosimilars, and controlled drugs (ABPI 2010).

However, in October 2010 the government (speaking for the whole of the UK) decided against the plans for pharmacist-led generic substitution of medicines in primary care. Following a consultation process, the Department of Health was swayed in its decision by the 'strong perception (by consultees) that generic substitution poses a threat to patient safety' (Department of Health 2010). Despite this assertion, looking at the responses, it seems that many were in favour of these plans. It appears that concerns expressed by a minority have seemingly influenced a decision that would have saved the NHS millions of pounds annually, and this does appear to have been a political decision. Moreover, in anticipation of the efficiencies achieved from generic substitution which the drug companies involved had agreed to, the PPRS has made provisions for a 0.5 per cent compensatory increase in the price of branded medicines (which account for around 80 per cent of the NHS drugs bill) over the next three years. Thus while the proposal for generic substitution has been shelved, the costs of branded medicines to the NHS in the UK are allowed to rise. This decision seems particularly perverse at a time of financial austerity.

Generic prescribing is almost universally acknowledged as desirable and representing high-quality prescribing in the UK and has several benefits; it reduces the risk of error as each drug has only one international chemical name rather than many brand names and, in time, usually the cost of prescribing is reduced. There is little evidence that it detracts from patient care, in most cases. Recently European laws have meant that there has been a move from using British Approved Names (BAN) to Recommended International Non-proprietary Names (rINN), which has strengthened the safety argument and also ensures that drugs of the same class have similar names and helps reduce confusion. Thus the name bendrofluazide (BAN) has been changed to bendroflumethiazide (rINN) making it more obvious that it is a thiazide diuretic. In the UK, hospital practice has been to use the generic name for most drugs, and increasingly in general practice, the generic name is used as well.

After a drug is first marketed, it is given approximately 10 years of patent protection to enable the manufacturer to recoup the research investment. Once the patent has expired any manufacturer can apply for a product licence and, if granted, manufacture and market a generic product. As generic manufacturers normally submit applications based upon the safety and efficacy data of the equivalent branded product they have to make a product that has essentially the same pharmacokinetic properties (ie, same dose and dispersal characteristics as the original brand). This proof of bio-equivalence is an important issue affecting both generic formulations and different brands of a particular drug.

The evidence overall appears to support the concept of clinical equivalence. For example a systematic review and meta-analysis of clinical equivalence of generic and brand-name drugs used in cardiovascular disease identified 47 articles providing evidence on this topic of which 38 were randomised controlled trials (Kesselheim *et al* 2008). Overall there was no evidence of superiority of brand-name compared with generic drugs. The same review looked at editorials on this subject and examined whether authors were positive, negative or neutral in the field of cardiovascular prescribing. More than 50 per cent of these counselled against interchanging generic drugs (Kesselheim *et al* 2008).

Prescribers can on the whole assume that generic products are bio-equivalent to a branded alternative. However, there are specific examples where effectiveness and safety may not be assured, even for products that meet regulatory standards. Also, although most generic manufacturers endeavour to adhere to an agreed code of conduct that recommends similarity to the proprietary product, there is no binding requirement for different formulations of a drug to have a similar appearance. For this reason, generic drugs often differ from the originator brand and, likewise, brands from one another, as is the case for packaging. Unless warned that the appearance of their medicine has changed, this may cause patients alarm and raise fears that a prescribing or dispensing error has been made.

In one comparison of generic and branded salbutamol inhalers, 45 per cent of patients claimed to have been able to detect some difference between their usual Ventolin® inhaler and the blinded Ventolin® used in the study (Williamson *et al* 1997). A survey in Germany found that 37 per cent of patients expressed scepticism about generics because of their lower price and these patients were more likely to consider generic drugs inferior to branded products (Himmel *et al* 2005). On the other hand, many people in the UK have now grown accustomed to, and accept, their medication in generic form and as stated previously around 83 per cent of all items in general practice were prescribed by their generic name in England in 2008. Despite this only 65 per cent of prescriptions in England were dispensed as generic products in 2008 either because only a brand product was available as the drugs are not 'off patent' or because no generic alternative was available (Prescribing Support Unit 2009a).

Therapeutic substitution

The recommendations of the National Audit Office and the concept of 'better care, better value' indicators has been met with some concern in certain quarters. In late 2007 an observational study conducted by Pfizer, and authored by Pfizer employees, was published in an attempt to provide evidence for potential problems with switching statins (Phillips *et al* 2007) This study was an analysis of GP computer records using The Health Improvement Network (THIN) database which looked at people who had been on atorvastatin for more than six months between 1997 and 2005. They compared outcomes between those that were switched to simvastatin on the database to matched controls of those who remained on atorvastatin. They estimated that the risk of death or first major cardiovascular death was 30 per cent higher in the switch group (hazard ratio 1.3, 95 per cent confidence interval 1.02–1.64). They also estimated that discontinuation of therapy was at least twice as high in the switch group (21 per cent per year v. 8 per cent $p<0.001$). In a sub-group of people who had cholesterol levels available for analysis, the lipid-lowering effects of the treatments appeared similar. Paradoxically the authors stated that more patients who remained on atorvastatin achieved the quality and outcome framework (QOF) target of <5mmol/litre total cholesterol – 65 per cent of the switch patients achieving this one year after the switch versus 72 per cent of those who remained on atorvastatin (Phillips *et al* 2007). This study has major limitations in that the reasons for switching were not available for analysis, nor were the reasons for discontinuation of therapy. In these people it might be expected that outcome is worse. It is also highly likely that people were switched for a good reason rather than in a planned approach to save money. There is also a clear

suggestion that the groups were unequal at the time of switching – 60 per cent of the switch patients were achieving QOF target at time of the switch versus 74 per cent of those who remained on atorvastatin (Phillips *et al* 2007).

Another relevant study is that of a practice-based audit in Hertfordshire in which patients were switched from atorvastatin to simvastatin. Although rather small, the study was very carefully conducted and each patient was individually assessed to see if it was appropriate. The two-year follow up to this study was published in January 2008 (Usher Smith 2008) Of the 69 patients switched from atorvastatin to simvastatin, 65 were still registered at the practice. Of these, 61 (94 per cent) were still on simvastatin and 58 (89 per cent) on the same dose. There was no significant change in mean total cholesterol over the two-year period (4.04±0.52mmol/litre prior to the switch and 3.90±0.63mmol/litre two-years follow-up; p=0.06). There was no evidence of increased adverse events. Of note, is that a questionnaire survey of participant's views (though with a limited response rate) suggested that they were quite happy to change treatment and saw benefit in terms of cost-savings for the NHS (Usher-Smith *et al* 2008). This supports anecdotal evidence that patients are willing to switch medication if the reasons are carefully explained.

The remaining arguments against statin switching seem to rest on the concept that the newer statins are more potent and therefore must be better. A counter-view might be that even if older products are marginally less effective, their greater affordability to the health economy can benefit the wider population. However, for standard-dose therapy (simvastatin 40mg, atorvastatin 10mg) this argument is largely irrelevant as the evidence demonstrates that they are equally effective at lipid-lowering and equally well tolerated. The UK-based Heart Protection Study, the largest study on statins involving more than 20,000 participants, clearly demonstrated that simvastatin given at a dose of 40mg daily was safe and highly effective for people with a range of risks, and very well tolerated (Heart Protection Study Collaborative Group 2002). This has been the approach adopted by the NICE Guideline on Lipid Modification (NICE CG67) for England and Wales which recommends a dose of simvastatin 40mg for most people without the need to pursue targets for cholesterol reduction (NICE 2008).

As part of our inquiry we held a a stakeholder meeting in Chester in July 2009. At that meeting of 12 individuals (including GPs, hospital and community pharmacists, a community matron, patient representatives and a PCT public health/patient safety physician) patient priorities around 'value for money' were identified as access to medicines that should be equitable, reflecting patients needs, not restricted by geographical, ethnic or social factors (ie, postcode prescribing) and reflecting individual therapeutic need while avoiding waste. In general, the view was that patients are receptive to switching from branded to generic medicines and between different generic brands where therapeutic equivalence can be guaranteed, and these provide genuine savings for the NHS. There was a strong view that where generic or brand substitution occurred, patients preferred the intervention to be explained face-to-face by either a doctor or pharmacist, as opposed to a written communication from the PCT or practice.

The overall conclusion for this section is that in many instances generic and therapeutic substitution is appropriate and accepted by patients. However,

there are cases where generic prescribing may not be appropriate, and in these cases drugs should be prescribed by brand-name to ensure continuity of supply of a particular product and to avoid potential lack of effect, adverse effects due to toxicity or poor patient understanding, co-operation and compliance. There are also considerable cost gains to be made by therapeutic substitution by switching to a cheaper apparently equivalent product, usually within the drug class. There is little evidence to show that harm arises from such switches but the drug substituted may be less convenient and can conflict with patient-centred care and patient choice.

Medicines for which prescribing by brand might be safer, more effective or reduce the risk of medication error (Duerden and Hughes 2010)

Reason not to substitute	*Examples (BNF 2010)*
Where there is a difference in bio-availability between brands of the same medicine, particularly if the medicine has a low therapeutic index	Ciclosporin, lithium, CFC-free beclometasone metered dose inhalers (Qvar® and Clenil Modulite®), carbamazepine,
Where modified release preparations are not interchangeable	Prolonged release preparations of carbamazepine, theophylline, diltiazem, aminophylline, mesalazine, nifedipine, morphine and oxycodone
Where pharmacokinetic differences may be evident	Phenytoin
Where there are important differences in formulation between brands of the same medicine	Adrenaline pre-filled syringes; transdermal formulations of fentanyl, buprenorphine
Where products contain multiple ingredients and brand-name prescribing aids identification	Combination topical preparations, hormone replacement therapy, oral contraceptives, pancreatin supplements, antacids preparations containing simeticone
Where there is a significant danger of medication error	Tacrolimus
Where administration devices (eg, inhaler or self-injection) have different instructions for use and patient familiarity with the same product is important	Dry power inhaler devices, insulin, apomorphine, estradiol transdermal patches, somatropin injection cartridges, alprostadil injection, interferons
Where different preparations of the same medicine have different licensed indications	Cyproterone (Androcur® or Cyprostat®), silfenafil (Viagra® or Revatio®), duloxetine (Cymbalta® or Yentreve®), bisoprolol (Cardicor® or Emcor®), buprenorphine (Temgesic® or Subutex®)
Where the product is a biological rather than chemical entity	Biosimilars, vaccine products

Prescription Pricing Regulatory Scheme (PPRS)

The Prescription Pricing Regulatory Scheme (PPRS) is an instrument that aims to balance the needs to secure value for money for the NHS while providing pharmaceutical companies with the right incentives to invest in new and useful drugs for the future and support the work of the drug industry in the UK. It was first introduced in 1957 and will continue until 2014 when the coalition government has stated its intention to replace it with value-based pricing.

In broad terms the PPRS comprises two main components:

- **Profit controls** which set a maximum level for the profits that a company may earn from the supply of branded drugs to the NHS. Exceeding this level will require a repayment of excess profits to the Department of Health. The profit control also enables companies to increase prices if their profits fall below a given minimum.
- **Price controls** which give companies freedom to set the initial price of new active substances but impose restrictions on subsequent price increases. They also comprise **price cuts,** which are agreed at the time of scheme renegotiations. Companies are also given some flexibility in deciding which products to target in cutting prices, a system known as **price modulation.**

The PPRS effectively allows new medicines to be launched in the UK without a limit on price. This means that the UK, along with Germany and Scandinavian countries, are often targeted by pharmaceutical companies to establish a higher initial launch price and a 'basket of prices' which can then be used to barter with France, Italy and other European countries where reference prices are mandated prior to product launch, often in comparison to lower-priced generic reference products with equivalent efficacy. While this scheme allows drugs to come onto the UK market rapidly without the need for lengthy up-front price negotiations there is evidence that uptake of new drugs by UK prescribers is low by international standards. Companies are also free to discount one dosage form of a product while the maintenance dose remains at a premium price. This could be construed as manipulation of the market place. Also, the current pricing arrangements allow drugs with very similar effects to have widely divergent prices so that price differences of 500 per cent or more are observed for very close substitutes.

The 2007 PPRS review conducted by the Office of Fair Trading (OFT) questioned the role of the PPRS (OFT 2007):

> *Despite its name, we do not consider the scheme to be a regulatory mechanism in the true sense of the word. It is best thought of as an attempt to exercise buyer power in the purchase of prescription pharmaceuticals by the NHS across the UK.*

OFT concludes that *'as it is currently designed: neither the profit cap nor the price cut helps secure prices that reflect the therapeutic value of the drugs companies are supplying to the NHS' and* stated:

> *…under current arrangements, there are high levels of prescribing for some products that cost much more than available substitutes but deliver very similar benefits to patients. This raises a major question as to whether value for money is being secured'. It also went on to comment that 'neither are patients price-sensitive: they contribute*

through prescription charges to less than five per cent of expenditure on prescription pharmaceuticals – a lower rate than in almost all other countries in the world…

The move to value-based pricing

The OFT report advocated a move to a value-based pricing system for the NHS. It argued that the PPRS should be reformed and that drug prices should be set in the UK on the basis of an explicit assessment of the value they represent to the NHS. The drug industry has favoured the PPRS because it allows them to set high prices for certain drugs in the UK, and these prices may be reflected in the global marketplace, particularly as many health systems around the world use 'reference pricing', which is based on how much is paid in other countries. It also helps the drug company to predict the future commercial value of their drug because clinical data are often lacking when the drug is launched, particularly for cancer drugs.

It is not yet clear how a value-based system would operate (at the time of writing a consultation on this is in progress), but a reformed NICE is likely to be involved in the process and a formal cost-effectiveness appraisal carried out. One proposal is that the price could be set at launch (the Office of Fair Trading report used the term '*ex ante*') at the level that NICE or other drug appraisal bodies deem cost-effective. This means that an incremental cost-effectiveness ratio per quality-adjusted life year (QALY) threshold could be agreed – for example, at a specific point between the £20,000 and £30,000 per QALY threshold currently set as the conventional upper limit of cost-effectiveness, and the price of the drug calculated from this point.

Whether a different threshold should be set for pricing cancer drugs and assessing their value compared with other treatment areas is controversial. The use of end-of-life criteria by NICE and the setting up of a cancer drug fund indicates that the two recent governments think that it should (Duerden 2010b). This does suggest that other disease areas are valued less, for example should palliative care be considered less important?

Considerable problems can be envisaged with the value-based pricing proposal (Duerden 2010b):

- it undermines the role of NICE – the intent is that funding for the recommendations of NICE technology appraisals will no longer be mandatory in 2014
- it may delay the availability of the drug while wrangling over the price takes place
- it will require more robust trial data than is usually available when a drug is launched, although it could be argued that this requirement is no bad thing
- the true value of the drug may change over time as more information on effectiveness and safety becomes available; for example, if the need to monitor the drug or an adverse effect becomes evident after launch, these costs should be factored in. Revisiting the decision on price over time will be a complicated process

- it is unclear how drugs currently available on the market will be assessed and valued, and this process could be time- and labour-intensive
- the drug industry may not be supportive and may be more interested in setting prices that are relevant to a global market
- prices set for an England NHS economy by a central government, which are then applied across the UK, may not be appropriate for the devolved NHS systems of Scotland, Wales and Northern Ireland.

Value-based pricing and GP commissioning consortia

Therefore, as a result of these proposals NICE will no longer advise on which treatments should or should not be funded by the NHS from 2014. Instead, in England, this will be the decision of the new GP commissioning consortia. This means that GPs may have to directly advise patients that they cannot have a treatment because their consortium will not or cannot afford to pay for it. There is a concern that decisions will vary from one consortium to another undermining recent efforts to remove 'postcode prescribing' and create equity in the NHS. With the removal of practice boundaries described in the White Paper *Equity and Excellence: Liberating the NHS* (Department of Health 2010b), patients will now be free to move practices to seek funding from other consortia. The pressures in the system will be even more intense given the unprecedented major restrictions on funding due to cuts in public spending.

There are many other concerns and it is difficult to see how the proposals for value-based drug pricing, as proposed, will add value within the NHS. As described, drug companies are multinational and usually set prices based on the global economy so they may not be too worried about engaging in complex negotiations with the NHS, which only represents 3.5 per cent of the total global market. In the future they may simply decide not to engage or market in the UK. They may also decide to no longer invest in research and development in the UK, as has been seen with Pfizer's closure of their Sandwich research facilities (BBC 2011). It is possible that faced with such prospects and in order to make the UK more drug-company friendly the government bows to pressure and the new system results in an overall increase in drug prices to the NHS. The GP consortia will have an unenviable task of both the gatekeeper role and holding the purse strings.

Generic drug pricing

Until April 2005 generic manufacturers set their own price for a generic product; usually a competitive price, relative to prices set by other companies. The drug tariff, which is a tariff outlining what will be paid to contractors (pharmacists or dispensing GPs) for medicines or products supplied on an NHS prescription, then sets a price for reimbursing the likely costs spent on these products. This was previously solely based on a basket of average prices from a range of manufacturers (prices are listed as category A products). In April 2005 new arrangements for calculating the drug tariff for many commonly used generics came into force in England and Wales. The changes were introduced as a part of the process of implementing the new pharmacy contract for 2005/06 which sought

to more clearly separate how pharmacists were paid from the profit they could generate from purchasing drugs at a discount and then subsequently getting full reimbursement. On a quarterly basis some drugs go into the category M basket while others are removed, and also some drugs within the basket had their price adjusted. This may have the beneficial effect for the NHS of more rapidly reducing drug prices shortly after patent expiry, if a generic product is available. However a knock-on effect is that it difficult for planning and budgetary control in primary care organisations and in general practice; for example, formulary choices based on cost-effectiveness may vary substantially from one quarter to the next (Duerden 2006). A further complexity is that the pricing for 'branded generics' may undercut the category M price for an equivalent generic drug. Branded generics are off-patent drug sold under a brand name (not the original). Branded generics priced below Drug Tariff price for the generic equivalent are an attractive option for PCOs and practices trying to keep drug prices down but such savings may be transient as the manufacturer can increase the price at relatively short notice (Duerden 2006). It is also important to reflect that prescribing by brand in such cases, even if as a branded generic, where there is a generic product available, runs counter to years of effort in the NHS to promote generic prescribing. It can be argued that the pricing system for drugs set by the Department of Health now creates anomalies that contradict best practice in the NHS (Duerden 2010a).

The UK now has one of the highest rates of generic prescribing in the world. As previously stated, the main drivers for this in the NHS may be the historic belief in generic prescribing in medical schools and hospitals and that generic drugs are generally cheaper than their branded counterparts. Because of this cost benefit there are proposals to introduce generic substitution by pharmacists dispensing prescriptions. However, there are cases where generic prescribing may not be appropriate, and in these cases drugs should be prescribed by brand-name to ensure continuity of supply of a particular product and to avoid potential lack of effect, adverse effects due to toxicity or poor patient understanding, co-operation and compliance (Ferner *et al* 2010). There are also considerable cost gains to be made by therapeutic substitution by switching to a cheaper apparently equivalent product, usually within the drug class. There is little evidence to show that harm arises from such switches but the drug substituted may be less convenient and can conflict with patient-centred care and patient choice.

Better care better value drugs

Are prescribers more cost-sensitive than patients? There is some evidence to suggest that in the UK, GPs and hospital doctors may be unaware of most of the costs associated with routinely prescribed medicines that they prescribe, unless there has been recent publicity surrounding high-cost drugs such as Herceptin®. This may be less of an issue in general practice where GP computer systems flag up the cost for most items available for selection when making a prescribing decision. The latest version of the British National Formulary lists, but does not stratify, the costs of medicines (as did previous editions). This may be a missed opportunity to influence prescribing, by drawing attention to those medications with similar effectiveness but with higher acquisition costs.

The *Quality Indicators in Prescribing* (QUIP) project hosted by the NPC in Sept 2009 aimed to 'generate a validated list of options for maximising efficient use of NHS spend on primary care prescribing in the context of a challenging medium-term financial position'. The project used a modified nominal group technique that focused on producing evidence and consensus-based recommendations that would involve quality improvement and sustainable change and not 'quick fixes' or wholesale 'switching'. While the outputs from this meeting are confidential and may not be published in full due to potential commercial considerations, the essence of the recommendations were to identify topics:

(a) that the NHS can implement immediately with limited enabling support or further systems changes eg, implementing NICE guidance to use the least expensive proton pump inhibitor (PPI) when initiating treatment for dyspepsia and to use better care better value (BCBV) focus on the lowest cost acquisition PPIs omeprazole and lansoprazole in chronic therapy.

or

(b) which actions might be taken or mandated nationally eg, removal of perverse incentives for pharmacists which might encourage dispensing of 'specials' for which no standard national tariff exists, and to inform prescribers that this constitutes off-licence use with no guaranteed stability or quality. There appears to be a need to address the needs of patients who cannot swallow conventional medications and require 'special' liquid preparations, such as stroke patients with percutaneous gastrostomy requiring percutaneous endoscopic gastrostomy (PEG) feeding.

Following the introduction of NICE in 1999 with the remit to advise the NHS on the use of new technologies largely, but not exclusively on the basis of clinical and cost-effectiveness, a number of neuropsychiatric therapies have seen increased usage eg, riluzole for motor neurone disease, atypical antipsychotics and cholinesterase inhibitors for dementia. NICE rejected interferon-beta and other products for multiple sclerosis on the grounds of clinical uncertainty about long-term benefits and poor cost-effectiveness. This was unpalatable for the government at the time and a risk-sharing scheme was set up to enable access to these drugs and collect further information on their long-term effectiveness (Boggild *et al* 2009). The idea was that the drug companies should reimburse the costs of the drugs if they proved ineffective. Recent reviews have criticised this approach and questioned whether the data collected was robust enough to allow such an assessment (Raftery 2010).

Further to this the UK government has created patient access schemes, in collaboration with the sponsoring companies, to make these drugs available at a cost that is more acceptable to the NHS, usually by reimbursement if the drug is ineffective or provision of several months' treatment at no cost. This enables provision of drugs which would not otherwise reach acceptable thresholds of cost-effectiveness based on assessment of incremental cost-effectiveness compared with other available interventions. The area which this has most affected is cancer treatment which has little relevance to general practice.

The feasibility and applicability of the patient access schemes is as yet unclear. For example, is it practical for hospitals to claim the costs back in a consistent manner? There is some evidence that the complexity of

these schemes means that the intended 'refunds' are not being claimed (Williamson 2010). The schemes are examples where patient advocacy has played an important role in encouraging acceptance of therapies where the evidence base was weak or the incremental cost-effectiveness ratio was unfavourable.

The principles behind the activities of NICE attract wide support within the NHS, but the need to implement NICE guidance is often ahead of funding being made available and this has been unpopular with NHS management who have to deliver this. The delay in assessment or approval by NICE of new, usually more 'expensive', medications has led in some areas to 'NICE blight' and the perception that UK patients are delayed in receiving new medicines until endorsed by NICE (Burke 2002).

12 The future of prescribing in the NHS in England

As is evident in this report, prescribing is increasing at a relentless rate, with items prescribed increasing by about 7 per cent year-on-year, alongside similar growth in costs. The demographics of the UK population are changing so we can expect the number of older people to steadily grow. Older people consume more medicines but also the evidence for using drugs as preventative therapy steadily mounts up and complex polypharmacy has become the norm. The need to supervise these treatments and undertake detailed drug reviews increases at the same pace.

Political change is also rapid: GPs have mixed views about the move to GP commissioning consortia. Some embrace this change and look forward to the challenge. Others do not want the responsibility and want simply to get on with their day job and manage their individual patients. Significant reservations about the viability of these health care reforms have been raised by the BMA, the RCGP and others, such as the NHS Confederation. The main concern is that this is a major change in the NHS which is untried and untested. This experiment has major financial risks, including the costs of reconfiguration, alongside considerable overall reductions in public funding.

The proposed health care reforms also have significant implications for the future of GP prescribing. GP commissioning consortia will take over from PCTs in setting prescribing budgets and providing prescribing support for their GP practices. This has significant strengths, for example formulary choices made by the consortium are more likely to be accepted and respected by GPs and adherence is likely to be greater. It can be argued that the choices made for inclusion on the formulary will more closely reflect the needs of the practice populations.

There are weaknesses as well; the advice to the consortia might not be as well-informed as that provided by experienced PCT advisers, although the consortia will have the potential to buy in this expertise, if they see the value of this support and can afford it. There is a risk they might buy in support with a particular commercial bias, rather than the ethos of the NHS. Because there are likely to be many more consortia than there were PCTs, variations in care are likely to be more pronounced. This may increase inequity of care and as patients will have greater choice in where they register for primary care services they may shop around for the treatments they prefer. Practices may be torn between making themselves popular to patients seeking the treatments they want and ensuring they provide adequately for overall need, given the increasing financial restraints.

These differences in provision will not be helped by the downgrading of the role of NICE. The requirement to implement and fund NICE technology appraisals will be removed by 2014 and at this point each consortium will be required to decide which drugs they wish to use based on drug prices set by the new value-based pricing arrangements. This becomes a major threat as the costs of reorganisation are likely to be high, alongside the possibility that funding could be so constrained that rationing decisions become painful to general practitioners. Patients may not want to see their caring GP as the person that rations their care and GPs may not want to be so close to such uncomfortable decisions. GPs will not only be the gatekeeper for their patients but will also have to hold the purse strings. However, NICE will in

future have a role for 'standard setting' and the consortia will need to have robust systems showing adherence to these standards.

Another one of the main concerns expressed by critics of the changes is the likely increase in privatisation of the NHS. This may apply to the Consortia which could potentially be more open to working closely with drug companies; for example, a company helping them to manage medicines use or even giving them preferential deals or discounts. This may not be truly cost-effective – generic prescribing may not be the preferred approach.

What will happen if GP practices within the consortia disagree over the place of a commercial enterprise, commissioning arrangement or over formulary choices? There may be dissent and who will be responsible for managing this? The other issue that may be uncomfortable is the concern about who will regulate adherence to treatments agreed as consortium policy. Can GPs be responsible for making these decisions and then policing their peers as well?

Another move that has unsettled GPs is the proposal that it saves money if hospital outpatient specialists simply tell primary care what medication to initiate, and let them get on with it. This is one of the 50 'top tips' on prescribing in the Quality, Innovation, Productivity and Prevention (QIPP) initiative (Department of Health 2010c). This suggestion can apply to complex drugs that might have been considered 'hospital only' or 'hospital initiated' in the past. Does this fit with General Medical Council Guidance on appropriate prescribing (see Appendix B)? The new GP consortia might be prepared to supply drugs in this way as community supplied drugs are exempt from the 20 per cent VAT which is applied in hospital purchase. Do GPs have the expertise to manage these drugs or could the consortium act to supply the necessary specialist supervision? They can certainly arrange to buy in such expertise and this suits concepts of the shift to community care, but it may not be as economical as envisaged. For example, expertise costs money and hospitals can bulk purchase medicines at discounts that might be considerably less than the VAT saving.

A further consideration is that our repeat prescription systems are now antiquated and it is very difficult for busy GPs to give meaningful thought to every single repeat prescription when they sign several hundred a day. The role of practice pharmacists and prescribing technicians in managing repeat systems is becoming critical, but is this enhanced workforce affordable? The future of repeat prescribing must also lie in electronic prescribing and repeat dispensing systems. It is likely that in the near future all repeat prescriptions will be managed following pharmacist checks through repeat dispensing; this must be more efficient, safer and more appropriate than the current processes still used by many practices. The enhanced role of the pharmacist also has great potential to improve concordance and reduce wasted medicines.

Information technology (IT) can further revolutionise the prescribing process. Computer prompts are becoming more sophisticated at flagging up the appropriate formulary choice, potential for adverse effects and drug interactions, in a way that prescribers cannot ignore. Primary care is way ahead of hospitals in the use of IT for prescribing; hospitals rarely have electronic prescribing systems which is astonishing in this day and age. At some stage we need primary care and hospital systems that talk to each other so that all health care professionals know what has been prescribed in

whatever setting and therapy information is readily available at GP clinics, outpatients, and on admission and discharge. Maybe with GPs in the driving seat, in the guise of GP commissioning consortia, they can drive through these changes by only commissioning with hospital services that have the capability to exchange and share prescribing information in this way.

13 Conclusions

Prescribing is a fundamental part of the work of a GP. Our use of drugs and appliances 'on prescription' is increasing rapidly in our ageing population and where more and more preventative treatments are being encouraged by evidence-based guidelines. There is further encouragement to ensure that everyone who may benefit gets these treatments, according to best practice, as part of the GP quality and outcomes framework. This brings with it the attendant problems of increasing complexity, with polypharmacy, co-morbidity, risk of medication errors, adverse drug reactions and drug interactions all being more common. Also of importance is that prescribing costs in primary care amount to a significant proportion of all costs in the NHS and these are rising.

This review highlights the need to improve knowledge about pharmacology and therapeutics, enhance our prescribing support systems, drug monitoring, prescription reviews, communication with patients and achieving concordance, and many other elements of the prescribing process. We have tried in this review to outline how the process of prescribing can be enhanced and developed and how an understanding of measuring the quality and safety of prescribing can help us in the future.

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Appendix A
Case studies

Multi-systems approach for antipsychotic use in dementia

The recent independent Banerjee Report to the Department of Health into antipsychotic use in people with dementia is a review of the dangers of antipsychotic prescribing in confused, older patients (Banerjee 2009). It examines the problem and suggests how systems need to be altered to improve care and reduce the hazard of these drugs. The report states that a third of people with dementia live in care homes.

In particular, it recognises there will be a continued need to use antipsychotics in dementia but advises that their use should be kept to a minimum, where other methods have been tried, and the person remains a risk to themselves or others. It says that any such use should be short-term, for no more than three months, and that every effort should be made to put an alternative care plan that avoids drug use in place.

Professor Banerjee, an expert in old age psychiatry at King's College London, conducted the review in recognition of widespread concern about the over-prescription of antipsychotic drugs and as part of the priority being given to improving care for people with dementia. The evidence has indicated that antipsychotic drugs are only partially successful at reducing agitation and behavioural problems in people with dementia, but for the last five years there has been clear evidence that antipsychotic drugs can increase stroke and cardiovascular risk in these patients (Anon 2007).

Based on a calculation that six per cent of over 65-year-old people have dementia, and using prescribing data, the report persuasively estimates that 180,000 people with dementia are treated with antipsychotic medication in England for an episode of 6 –12 weeks per year (25 per cent of all people with dementia at any one time). Having reviewed the evidence on benefit and harm it is estimated that if treated for an episode of 6 –12 weeks, 36,000 of these may derive some benefit from treatment, but an additional 1,800 may die and an additional 1,620 suffer a cerebro-vascular adverse event (around half of which may be severe) per year.

If treatment episodes are longer than this then this estimated harm may be even more. Most of this prescribing is by GPs. The report suggests that if support was available to provide alternative methods of managing behavioural problems, prescribing of antipsychotics could be reduced by two-thirds in people with dementia. The report proposes that this as an achievable target over a 36-month period.

A 'whole systems' approach is described to address this problem and includes a list of recommendations for prioritisation which include: improvements in leadership, audit, training of staff and improvements in the services offered to people with dementia. The government has accepted these and has responded with a series of actions for England.

These include appointing a new national clinical director for dementia. It advises providing measures to ensure people with dementia and their carers have access to psychological therapies to tackle the root of agitation and aggression. This will require better provision of psychology services, which

is a major challenge for commissioners. Further actions include enhanced governance between health and social care and audits to establish current prescribing information, with clear local targets to cut antipsychotics use as a result of the audit. It also directs better regulation alongside collaboration with the GMC and royal colleges to ensure all health and social care staff have specialist training in dementia.

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Medication error leading to hospital admission

Mrs Brown was admitted to hospital with bradycardia and unstable angina. She was taking a combination of drugs to control her hypertension (verapamil and atenolol), which are known to cause bradycardia (a very slow heart rate). This combination is only used in special circumstances, such as difficult to control arrhythmias, where patients are known to have good cardiac function. In addition, she was not prescribed aspirin as thromboprophylaxis, despite this being indicated.

Mrs Brown was started on atenolol 18 months before her hospital admission to help control her hypertension. Verapamil and irbesartan had been added; a number of other anti-hypertensives had been tried in the past which Mrs Brown had been unable to tolerate. The electronic prescribing system should have alerted the GP to the interaction between atenolol and verapamil. The GP placed a lot of faith in the interaction alerts and, despite knowing the

risks of the combination, may have relied on the system to alert him to any problems; it is unclear if this occurred.

Mrs Brown's pharmacy first dispensed the atenolol as a lone prescription, reducing the chances of the interaction being recognised. Atenolol was not presented on the same prescription as verapamil until five months later. There was no record of an intervention having been attempted by the pharmacy. The pharmacy's computer system would have alerted to the interaction, but the clinical importance of the interaction would not have been highlighted, no additional information would have been given, and the alert would have been in the middle of a list of alerts printed on dispensing labels. The pharmacist thought that time pressures would have contributed to the interaction either not being noted, or not being adequately checked. However, the pharmacist was unconvinced of the significance of the interaction even after she had looked it up.

Mrs Brown's GP performed six-monthly medication reviews, but admitted these were unlikely to identify existing drug interactions (although the surgery policy stated that these should be looked for). Mrs Brown had a diabetic check up every three months. One month before her admission, the practice nurse recorded an unusually low blood pressure for her (112/62mmHg). This was not noted as remarkable and an appointment was made with the GP for eight weeks time. She was admitted to hospital before she was followed up by her GP. On the day of admission, she developed chest pain and hypoglycaemia. When reviewed by a locum GP she was found to have profound bradycardia and was admitted to hospital with unstable angina.

Complex factors leading to hospital admission

Miss Weir was admitted to hospital with an exacerbation of her asthma. She had stopped taking her preventative medication four days before hospital admission because of vomiting. It seems likely that her sickness was due to oesophageal irritation from alendronate (it was relieved by Gaviscon®). Alendronate is known to cause this problem, and patients should remain sitting or standing upright for 30 minutes after taking. However, Miss Weir was unaware of this and sometimes lay down after taking it.

Miss Weir had severe asthma which was poorly controlled (she was admitted to hospital every one to two months and became short of breath after walking fast). Her GP and pharmacist both assumed that Miss Weir had a good understanding of her medication and how to take it. However, Miss Weir was confused by why some of her medication was stopped and started when she came in and out of hospital. Despite this, she believed she knew all she needed to about her medication. Miss Weir's GP did feel that she had a poor understanding of the severity of her asthma.

Miss Weir displayed some ambivalence about her asthma and the impact it had on her life, at times saying it was OK, and at others expressing frustration and annoyance. This meant that there were times when she did not want to take her medication, but said her mum always made sure she did.

Miss Weir's local pharmacy was staffed by two part-time pharmacists. She reported having a good relationship with the first, but not the second. The second pharmacist said she rarely had contact with Miss Weir because a

representative usually collected her prescriptions. This pharmacist believed that Miss Weir should have received counselling about her medication from the hospital, GP or asthma nurse. She appeared reluctant to provide counselling to patients herself because she could spend up to 10 minutes talking to patients if she did so.

When Miss Weir began vomiting, four days before her hospital admission, she did not seek medical help until her asthma had deteriorated (despite using her nebuliser). She explained that this was because she was reluctant to be admitted to hospital again.

References

Howard R (2006). *The underlying causes of preventable drug-related admissions to hospital.* PhD thesis. University of Nottingham.

Appendix B
GMC: Good practice in prescribing medicines

General Medical Council: Guidance for doctors, September 2008

The GMC expects doctors to comply with the standards of good practice set out in this guidance.

You must be prepared to explain and justify any decision not to follow this advice on good practice in prescribing.

Principles of prescribing (1–45)

(www.gmc-uk.org/guidance/ethical_guidance/prescriptions_faqs.asp)

1. Doctors with full registration who hold a licence to practise may prescribe all medicines, but not those drugs in Schedule 1 of the Misuse of Drugs Regulations 2001. If you have provisional registration and hold a licence to practise you may prescribe medicines in line with the supervisory conditions of your employment.
2. For information about the relevant legislation, including the Medicines Act 1968 and the Misuse of Drugs Act 1971, see the Home Office website: www.homeoffice.gov.uk/ and the British National Formulary: www.bnf.org/. Medicines legislation applies throughout the UK.
3. You should only prescribe drugs to meet identified needs of patients and never for your own convenience or simply because patients demand them.

Avoid treating yourself and those close to you

4. Objectivity is essential in providing good care; independent medical care should be sought whenever you or someone with whom you have a close personal relationship requires prescription medicines.

Keeping up-to-date and prescribing in patients' best interests

5. When prescribing medicines you must ensure that your prescribing is appropriate and responsible and in the patient's best interests. To do this you must:
    a. Ensure you are familiar with current guidance published in the British National Formulary and BNF for Children, including the use, side effects and contraindications of the medicines that you prescribe. You should be aware of the guidance about the clinical and cost-effectiveness of interventions published by the National Institute for Health and Clinical Excellence (NICE) in England & Wales; in Wales by the All-Wales Medicines Strategy Group; in Northern Ireland by Department of Health, Social Services and Public Safety; and in Scotland by the Scottish Medicines Consortium and NHS Quality Improvement Scotland (including Scottish Intercollegiate Guidelines Network). In addition the Department of Health has published a

report Building a Safer NHS: Improving Medication Safety on the safe use and administration of medicines.

b. Be in possession of, or take, an adequate history from the patient, including: any previous adverse reactions to medicines; current medical conditions; and concurrent or recent use of medicines, including non-prescription medicines.

c. Reach agreement with the patient on the use of any proposed medication, and the management of the condition by exchanging information and clarifying any concerns. The amount of information you should give each patient will vary according to factors such as the nature of the patient's condition, risks and side effects of the medicine and the patient's wishes. Bearing these issues in mind, you should, where appropriate:

i. Establish the patient's priorities, preferences and concerns and encourage the patient to ask questions about medicine taking and the proposed treatment

ii. Discuss other treatment options with the patient

iii. Satisfy yourself that your patient has been given appropriate information, in a way they can understand, about: any common adverse side effects; potentially serious side effects; what to do in the event of a side-effect; interactions with other medicines; and the dosage and administration of the medicine; (see Consent: patients and doctors making decisions together)

iv. Satisfy yourself that the patient understands how to take the medicine as prescribed

v. Satisfy yourself that the patient is able to take the medicine as prescribed.

6. When prescribing for a patient you should:

a. Prescribe dosages appropriate for the patient and their condition.

b. Agree with the patient arrangements for appropriate follow-up and monitoring where relevant. This may include: further consultations; blood tests or other investigations; processes for adjusting the dosage of medicines, changing medicines and issuing repeat prescriptions.

c. You should inform the Committee on the Safety of Medicines of adverse reactions to medicines reported by your patients in accordance with the Yellow Card Scheme. You should provide patients with information about how to report suspected adverse reactions through the patient Yellow Card Scheme.

d. Make a clear, accurate, legible and contemporaneous record of all medicines prescribed.

7. If you prescribe at the recommendation of a nurse or other health care professional who does not have prescribing rights, you must be satisfied that the prescription is appropriate for the patient concerned and that the professional is competent to have recommended the treatment.

Keeping patients' general practitioners informed

8. If you are not the patient's general practitioner and you accept a patient for treatment without a referral from the patient's general practitioner, then you must:
    a. Explain to the patient the importance and benefits of keeping their general practitioner informed.
    b. Inform the patient's general practitioner unless the patient objects.
    c. Where possible inform the patient's general practitioner before any treatment is started, unless the patient objects to this disclosure.
9. If the patient does not want their general practitioner to be informed, or has no general practitioner, then you must:
    a. Take steps to ensure that the patient is not suffering from any medical condition or receiving any other treatment that would make the prescription of any medicines unsuitable or dangerous.
    b. Take responsibility for providing all necessary aftercare for the patient until another doctor agrees to take over.

Doctors' interests in pharmacies

10. You should ensure that your patients have access to information about your own and (where known) your employers' financial or commercial interests in any pharmacy they are likely to use.
11. Patients should be free to choose from which pharmacy to have their prescribed medicines dispensed. Advice about specialist pharmacies or those that offer collection and delivery services, for example, can be helpful. It might not be practical or clinically appropriate for patients to use alternative pharmacies when in hospital or visiting clinics at which medicines are dispensed free of charge.
12. You must not allow your own or your employers' financial or commercial interests in a pharmacy to influence the way you advise patients. You should not accept any inducement which may affect or be seen to affect the advice you give patients. You must not pressurise patients to use a particular pharmacy in any event, either personally or through an agent, nor should you disparage or otherwise undermine patients' trust in a pharmacy or pharmacist by making malicious or unfounded criticisms.

Prescribing situations requiring special consideration

Prescribing controlled drugs for yourself or someone close to you

13. Doctors should, wherever possible, avoid treating themselves or anyone with whom they have a close personal relationship and should be registered with a GP outside their family. Controlled drugs can present particular problems, occasionally resulting in a loss of objectivity leading to drug misuse and misconduct.
14. You should not prescribe a controlled drug for yourself or someone close to you unless:

a. No other person with the legal right to prescribe is available to assess the patient's clinical condition and to prescribe without a delay which would put the patient's life or health at risk, or cause the patient unacceptable pain, and

b. That treatment is immediately necessary to:

i. Save life

ii. Avoid serious deterioration in the patient's health, or

iii. Alleviate otherwise uncontrollable pain.

15. You must be able to justify your actions and must record your relationship and the emergency circumstances that necessitated your prescribing a controlled drug for yourself or someone close to you.

16. The National Prescribing Centre has published A guide to good practice in the Management of Controlled Drugs in Primary Care (England).

Prescribing for patients to whom you also dispense

17. Your primary duty is to act in your patient's best interests; you must also make efficient use of the resources available to you; you should not prescribe in a manner that conflicts with either of these duties. You should respect patients' freedom to choose where to have their prescribed medicines dispensed. You should not prescribe differently for patients to whom you also dispense for your own or your employers' commercial or financial benefit.

Prescribing unlicensed medicines

18. You can prescribe unlicensed medicines but, if you decide to do so, you must:

a. Be satisfied that an alternative, licensed medicine would not meet the patient's needs

b. Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy.

c. Take responsibility for prescribing the unlicensed medicine and for overseeing the patient's care, including monitoring and any follow up treatment (see also paragraphs 25–27 on prescribing for hospital outpatients).

d. Record the medicine prescribed and, where you are not following common practice, the reasons for choosing this medicine in the patient's notes.

Prescribing medicines for use outside the terms of their licence (off-label)

19. You may prescribe medicines for purposes for which they are not licensed. Although there are a number of circumstances in which this may arise, it is likely to occur most frequently in prescribing for children. Currently pharmaceutical companies do not usually test their medicines on children and as a consequence, cannot apply to license their

medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary in paediatric practice.

20. When prescribing a medicine for use outside the terms of its licence you must:

    a. Be satisfied that it would better serve the patient's needs than an appropriately licensed alternative.

    b. Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. The manufacturer's information may be of limited help in which case the necessary information must be sought from other sources.

    c. Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or arrange for another doctor to do so (see also paragraphs 25–27 on prescribing for hospital outpatients).

    d. Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing the medicine.

Information for patients about the licence for their medicines

21. You must give patients, or those authorising treatment on their behalf, sufficient information about the proposed course of treatment including any known serious or common side effects or adverse reactions. This is to enable them to make an informed decision (for further advice, see Consent: patients and doctors making decisions together).

22. Some medicines are routinely used outside the scope of their licence, for example in treating children. Where current practice supports the use of a medicine in this way it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients, or those authorising treatment on their behalf, require or which they may see as significant. Where patients, or their carers express concern you should also explain, in broad terms, the reasons why medicines are not licensed for their proposed use. Such explanations may be supported by written information, including the leaflets on the use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice produced by the Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines.

23. However, you must explain the reasons for prescribing a medicine that is unlicensed or being used outside the scope of its licence where there is little research or other evidence of current practice to support its use, or the use of the medicine is innovative.

24. For specific information on prescribing medicines for children see the websites of the Royal College of Paediatrics and Child Health and the British National Formulary for Children.

Responsibility for prescribing medicines for hospital outpatients

25. Where a patient's care is shared between clinicians, the doctor with the responsibility for the continuing management of the patient must be fully competent to exercise their share of clinical responsibility. They also have a duty to keep themselves informed about the medicines that are prescribed for their patient. They should take account of appropriateness, effectiveness and cost when prescribing any medicine. They should also keep up-to-date with any relevant guidance on the use of the medicine and on the management of the patient's condition.
26. If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine should they occur.
27. There should be full consultation and agreement between general practitioners and hospital doctors about the indications and need for particular therapies. The decision about who should take responsibility for continuing care or treatment after initial diagnosis or assessment should be based on the patient's best interests rather than on the health care professional's convenience or the cost of the medicine.

Patient group directions

28. The majority of clinical care should continue to be provided on an individual, patient-specific basis. The use of Patient Group Directions (PGDs) should be reserved for those limited situations where this offers a distinct advantage for patient care and where it is consistent with appropriate professional relationships and accountability.
29. Patient Group Directions may be suitable for the supply and administration of some injectable medicines. However, the administration of medicines (such as Botox®, Vistabel® or Dysport®) to paralyse muscles which cause wrinkles requires assessment of individual patients' suitability and (in the event that administration is delegated to a nurse or other person) patient specific directions; general directions which would apply to any patient with an appointment on a particular day are not sufficient.

Procedures to simplify the work involved in issuing repeat prescriptions

30. Getting repeat prescriptions prepared by other members of the general practice health care team/staff or generated by computer can be an efficient way of meeting patients' needs, while reducing demands on doctors' time.
31. It is important that any system for issuing repeat prescriptions takes full account of the obligations to prescribe responsibly and safely and that the doctor who signs the prescription takes responsibility for it. Before signing a repeat prescription you must be satisfied that it is safe and appropriate to do so and that secure procedures are in place to ensure that:

a. The patient is issued with the correct prescription.

b. Each prescription is regularly reviewed so that it is not issued for a medicine that is no longer required.

c. The correct dose is prescribed for medicines where the dose varies during the course of the treatment.

32. Arrangements for issuing repeat prescriptions should include suitable provision for monitoring each patient's condition and for ensuring that patients who need a further examination or assessment do not receive repeat prescriptions without being seen by a doctor. This is particularly important in the case of medicines with potentially serious side effects.

Repeat dispensing

33. Repeat dispensing can relieve pressure on doctors' time and make better use of pharmacists' professional skills, as well as being more convenient for patients.

34. You should offer repeat dispensing only to patients for whom it is appropriate, such as those with chronic conditions who are likely to remain stable for the duration of the dispensing period and who take stable, long term medication. Patients on a large number of medicines or who are likely to be hospitalised may be less suited to inclusion in a repeat dispensing scheme.

35. Patients must give consent to be included in a repeat dispensing scheme. You should satisfy yourself that patients understand the implications for confidentiality as well as the clinical and practical effects of inclusion.

36. You should make a record of the dispenser holding the original repeatable prescription form, when you know who they are, so that you can contact them as necessary.

37. As with repeat prescribing, you should ensure that secure procedures are in place to regularly review the prescription, monitor the patient's condition and for further examination or assessment of the patient as necessary.

38. The National Prescribing Centre in England has published Saving time, helping patients: A good practice guide to quality repeat prescribing, Repeat Prescribing Service Improvement Guide, and Dispensing with repeats.

Remote prescribing via telephone, email, fax, video link or a website

39. From time to time it may be appropriate to use a telephone or other non face-to-face medium to prescribe medicines and treatment for patients. Such situations may occur where:

a. You have responsibility for the care of the patient.

b. You are deputising for another doctor who is responsible for the continuing care of a patient or

c. You have prior knowledge and understanding of the patient's condition/s and medical history and you have authority to access the patient's records.

40. In all circumstances, you must ensure that you have an appropriate dialogue with the patient to:

    a. Establish the patient's current medical conditions and history and concurrent or recent use of other medications including non-prescription medicines.

    b. Carry out an adequate assessment of the patient's condition.

    c. Identify the likely cause of the patient's condition.

    d. Ensure that there is sufficient justification to prescribe the medicines/ treatment proposed. Where appropriate you should discuss other treatment options with the patient.

    e. Ensure that the treatment and/or medicine/s are not contra-indicated for the patient

    Make a clear, accurate and legible record of all medicines prescribed.

41. If you are not providing continuing care for the patient, do not have access to the patient's medical records, or are not deputising for another doctor, you must follow the advice above and, additionally you must:

    a. Give an explanation to the patient of the processes involved in remote consultations and give your name and GMC number to the patient.

    b. Establish a dialogue with the patient, using a questionnaire, to ensure that you have sufficient information about the patient to ensure you are prescribing safely.

    c. Make appropriate arrangements to follow the progress of the patient.

    d. Monitor the effectiveness of the treatment and/or review the diagnosis.

    e. Inform the patient's general practitioner or follow the advice in paragraph 9 if the patient objects to the general practitioner being informed.

42. Where you cannot satisfy all of these conditions you should not use remote means to prescribe medicine for a patient.

43. If you prescribe for patients who are overseas, you should also have regard to differences in a product's licensed name, indications and recommended dosage regimen. The Medicines and Healthcare products Regulatory Agency issues guidance on import/export requirements and safety of delivery, which you might also need to consider. You should ensure that you have adequate indemnity cover for such practice. You may need to be registered with a local regulatory body in the country in which the prescribed medicines are to be dispensed.

Obesity and private slimming clinics

44. The prescription of anti-obesity medicines should be considered only as part of an overall management plan that includes dietetic assessment and lifestyle management. Specific guidance on medicines used in the treatment of obesity is available in the British National Formulary, from

the Royal College of Physicians of London, the National Institute for Health and Clinical Excellence and the Scottish Intercollegiate Guidelines Network, among others.

45. You should note that:

    a. In England private clinics and doctors who practise solely in the independent sector must be registered with the Care Quality Commission. Failure to register is a criminal offence.

    b. The Regulation and Quality Improvement Authority is responsible for registering and inspecting independent hospitals, clinics and other care services in Northern Ireland.

    c. The Scottish Commission for the Regulation of Care (also known as the Care Commission) regulates independent specialist clinics and health care services in Scotland.

    d. Healthcare Inspectorate Wales is the regulator of independent health care in Wales.

Appendix C
Statement from the Dispensing Doctors Association

There are around 6,000 dispensing doctors working in the 1,300 dispensing practices in the UK. They care for nearly 9 million patients and provide dispensing services to more than 3.5 million of them.

Doctor dispensing is only available in rural areas and only to patients who live more than a mile (1.6 km) from their nearest pharmacy – a distance criterion that has been unchanged (apart from metrication) for a century.

The integration of medical and pharmaceutical services under one roof and under single management as a 'one-stop shop' has the potential to improve patient care. Since the same computer system is used for prescribing and dispensing, there is no chance of transcribing errors occurring.

The service dispensing practices provide is hugely appreciated by their patients, as witnessed by the overwhelming support they gave to the campaign to prevent the service being inadvertently lost through a proposed change in the law in 2008. (More than 6,200 patients responded to the Department of Health consultation).

The perception of some that drug provision is more expensive for the Exchequer when prescribing and dispensing are combined is not borne out by the figures. Once all costs are taken into consideration there is little to choose between doctor-led or pharmacist-led dispensing services. Over many years the average net ingredient cost of NHS items has been less for dispensing patients, although more items per patient have been dispensed than for their prescribing counterparts.

Various explanations have been posited for the differences, among which are: better adherence by dispensing practices to a 28-day repeat prescribing interval; contractual restrictions on the sale of over-the-counter (OTC) items to patients; less possibility of 'leakage' (non-presentation of a prescription) and the fact that GPs are not permitted to prescribe except through the medium of prescription (ie, no OTC substitution is allowed).

Appendix D
Prescribing Indicators used in Australia

National Prescribing Service indicators of quality prescribing for Australian general practice

Examples:

- **Antibiotic guidelines:** Do you have access to a copy of Therapeutic Guidelines: Antibiotic that is 3 years old or less?
- **Product information:** Do you have access to up-to-date product information for prescription drugs?
- **Drugs of addiction:** Does the practice have a policy on prescription of benzodiazepines and opioids?
- **Disseminating information:** Does the practice have a mechanism for disseminating information about medicine withdrawals, recalls and significant events?
- **Medicine misadventure:** Does the practice or GP have a system for identifying and managing patients at high risk of medicine misadventure?
- **Antibiotics:** Percentage of patients prescribed an antibiotic for a non-specific upper respiratory tract infection (URTI)
- **Diabetes:** Percentage of patients with type 2 diabetes and hypertension and macroalbuminuria or proteinuria who have not been prescribed an ACE inhibitor or an ARB
- **Benzodiazepine, long-term use:** Percentage of patients aged over 65 years prescribed regular benzodiazepines for more than 4 weeks
- **Triple whammy:** Number of patients receiving a combination of ACE inhibitors (or ARB), diuretics and NSAIDs (including COX-2 selective NSAIDs)

Quality Prescribing Indicators in Australian General Practice are available at: www.nps.org.au/health_professionals/tools/quality_prescribing_indicators_in_australian_general_practice (accessed on 5 February 2011).