

Pharmacist prescribing



Dr June Crown: supplementary prescribing by pharmacists will make things better for patients, pharmacists and the National Health Service

Views on why pharmacists should prescribe, what training they should receive, how supplementary prescribing will work in practice and what legal responsibilities prescribing brings were all presented at the seventh annual Hospital Pharmacist conference held in London on 30 October. Gareth Jones and Rachel Graham report

How we got where we are, and where we go from here, were the focus of the opening presentation, given by Dr JUNE CROWN, chair of the Royal Pharmaceutical Society's task group team that looked into extended role prescribing for pharmacists.

Dr Crown took delegates down the route to supplementary prescribing, through the reviews and legislative processes that had led first to nurse prescribing and then to pharmacist prescribing. She pointed out that the process had initially been slow. The advisory group for nurse prescribing was formed back in 1989, legislation was put in place in 1992, but national roll-out did not happen until 1998. According to Dr Crown, much of the delay was because of pilots and economic appraisals being carried out. The process then speeded up, with pharmacist prescribing being recommended in a report published as a consultation document in 1999, and legislation (Health and Social

Care Act) being enacted in 2001. Confidence had built up for pharmacist prescribing, Dr Crown said, and there was a robust approach to taking it forward.

Dr Crown also took delegates through the definitions of supplementary prescribing, supplementary prescriber and independent prescriber under the legislation (see Panel 1, p474). She pointed out that this final definition of a supplementary prescriber is wide-reaching. It has been changed from that in the consultation document issued by the Department of Health to make it clear that, for example, the supplementary prescriber (as well as the independent prescriber) has responsibilities for their prescribing. The definition could cover, for example, the situation where a doctor diagnoses a patient's condition and then hands over the management to the pharmacist. How this would work in practice (ie, whether hospital notes could constitute a clinical management plan) needs to be ironed out, Dr Crown added. But the

definition of supplementary prescriber itself is wide enough to accommodate this sort of working arrangement.

Dr Crown then went on to discuss the benefits of supplementary prescribing for patients, pharmacists and organisations. She was keen to stress that she saw the main reasons behind the recommendations to extend prescribing to pharmacists as benefiting patients and making better use of the skills of the workforce. From her point of view, "it is not about plugging the gaps of too few doctors".

Patients will benefit from supplementary prescribing in that it offers them improved access to health care staff and greater convenience, as well as increased choice, she said. "Time taken in explaining to patients about their medication ... is hugely important," she said. In particular, Dr Crown sees pharmacist prescribing as being especially useful in, for example, anticoagulant and hypertension management, where pharmacists are already essentially running clinics. She also

Panel 1: Definitions

Supplementary prescribing

A voluntary partnership between an independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement

Independent prescriber

A clinician who is responsible for the assessment of patients with an undiagnosed condition and for decisions about the clinical management required, including prescribing

Supplementary prescriber

A clinician who takes over the continuing care of a patient, which may include prescribing, after initial assessment by an independent prescriber

sees it as being invaluable in the mental health field, because it may be "tremendously important in improving ... compliance".

Pharmacists benefit from supplementary prescribing because it brings them clearer lines of responsibility and accountability, the opportunity to work more effectively in a

multidisciplinary team and recognition from team members, Dr Crown said. Organisations benefit from the better use of skills.

Pharmacist prescribing should also help the Government to reduce health care inequalities, Dr Crown added. Allowing

pharmacists to prescribe at public expense would help the vulnerable, she stressed. However, she suspected that there would be cost implications – particularly since many people with the chronic conditions that supplementary prescribing arrangements are set up to treat are over 60, and so get free prescriptions.

Despite the wide number of activities that pharmacists could perform as supplementary prescribers, Dr Crown believes there are occasions when pharmacists being able to independently prescribe would be of benefit to patients. For hospital-based practice, these included prescribing on admission and discharge, where arrangements might need to be changed. Accident and emergency pharmacists might also be well placed to prescribe independently in medicine-related emergencies, she said. Dr Crown was keen to point out that pharmacists are already independent prescribers in as much as they "prescribe" general sales list and

pharmacy-only medicines, as well as certain prescription-only medicines in an emergency, in the community.

During her speech, Dr Crown discussed the information that pharmacist prescribers (in common with all prescribers) will need to perform their role effectively. This includes timely information about the patients' clinical condition and the medicines they are already taking. How they will get this information is also crucial, she said. She urged the Government to bring about the promised and much needed improvements in NHS information technology. In the meantime, Dr Crown stressed, pharmacists will need to think for themselves about making sure safe arrangements are put in place.

She also stressed that patients and the public need information too – they need to know which professionals are authorised to prescribe, which conditions “new” prescribers can treat, and how to access services. Government and professional bodies have a

role in this. Crucially, patients also need to be aware that they have a choice – if they prefer a doctor to prescribe their medicines then they are entitled to ask for this. Similarly, patients need to know that all the options they have as to who can prescribe their medicines are safe and well regulated. Dr Crown stressed that pharmacists need to make the public aware that they are the “absolute experts in medicines” rather than just people who “take a blister pack off a shelf and hand it to them”. A recent Health Which report highlighted this.

As well as independent prescribing for pharmacists, Dr Crown saw the future of prescribing in the NHS as including health care professionals other than doctors, nurses and pharmacists. But only those professions where there is a registerable qualification and a regulatory body will be considered, Dr Crown said. There is commitment from the Government to extend prescribing beyond nurses and pharmacists

(and doctors), Dr Crown added. She is certain that by that this time next year other health care professionals will be “well on their way”.

For pharmacist prescribing, key considerations in moving forward include whether prescribing will become part of school of pharmacy curricula, how pharmacists can keep up to date with new clinical and pharmacological developments once they have done their initial training, issues about the diagnostic skills needed to prescribe independently, and how supplementary prescribing will affect their relationship with other members of the health care team. It will also be important to consider how the benefits of supplementary prescribing can be demonstrated to the Government, patients and other professionals. “Rather than waiting for the Government to make assumptions,” Dr Crown said, “it will be up to pharmacists to take the lead in deciding the answers.”

It makes good business sense

The business case for supplementary prescribing was presented by JATINDER HARCHOWAL, assistant director, clinical pharmacy services, Barts and the London NHS Trust. Mr Harchowal described the benefits that pharmacist prescribing are likely to bring to both patients and the NHS, drawing on studies and other evidence from the United Kingdom, the United States and Canada to back up his views.

The potential benefits to patients of pharmacist prescribing include increased choice and quicker access to care. There is also the potential to increase patient supervision, Mr Harchowal said. Patient safety should also improve (or will at least be maintained) and greater patient involvement should improve treatment outcomes, he added. For the organisation, supplementary prescribing by pharmacists has the potential to optimise skill mix and resources, help trusts meet national service framework targets, reduce the amount of money spent on wasted medicines and aid good clinical governance.

For these benefits to be received, and the business case to be made, pharmacists need to be effective prescribers. Mr Harchowal pointed out that there are not many controlled evaluations of how effective pharmacists are at prescribing. But those that exist are positive. For example, a US study¹ showed that pharmacists were “as effective as, if not better” than doctors at prescribing in the mental health field, he said.

Although not controlled evaluations of pharmacist prescribing, other studies^{2,3} show that pharmacists have good drug therapy management. In the UK, there is evidence of the effectiveness of pharmacists’ prescribing from situations where they are, in essence, already taking on prescribing roles, Mr Harchowal added.

In addition, an evaluation report from the Alberta College of Pharmacists (ACP) in Canada looked at some of the roles pharmacists can do, their effectiveness when doing them and how those roles were developing. It shows that pharmacists market themselves as experts in drug treatment and are capable of recognising the limits of their own competencies. It gives several examples of how chronic conditions can be managed well by pharmacists. In particular, it refers to a study showing that pharmacist prescribing in an asthma clinic improved patients’ symptoms and lung function by 50 and 11 per cent respectively. Drug-related hospital admissions also reduced by 75 per cent.⁴ This is “tangible evidence of the impact pharmacists can make” stressed Mr Harchowal. He noted that the ACP report highlighted that pharmacist prescribers operated within



Jatinder Harchowal: pharmacist prescribing can lead to improved patient safety

strict guidelines on accountability and competency profiles. This type of monitoring would be a key factor in taking pharmacist prescribing forward in the UK, Mr Harchowal added.

Another key issue brought out is that the evolution of pharmacist prescribing depends on the practice being accepted by patients, doctors, pharmacists themselves and other health care professionals. Mr Harchowal told delegates that patients basically want a safe, quick holistic service. The basic message from patients is that they did not really mind who prescribes for them, “so long as the prescriber is competent”, he said. For hospital doctors, the acceptance rate of pharmacists’ recommendations is greater than 90 per cent.⁵ But hospital doctors and other health care workers do have some issues with pharmacists prescribing, Mr Harchowal said. For example, in studies where health care workers were asked for their views on pharmacist being given prescribing rights, both doctors and nurses expressed concern that pharma-

cists would not have enough knowledge of the patient and their clinical condition, that doctors would lose the opportunity to review the patients’ drug treatment and that there would be communication problems,^{6,7} Mr Harchowal said. These issues will need to be addressed when making out a business case for supplementary prescribing. For some concerns, Mr Harchowal added, pharmacists just need to improve the understanding among others of the skills they already have and the contribution they already make.

Mr Harchowal went on to discuss an example from a trust in his own area where a successful business case was made out and a pharmacist is currently undertaking training to become a supplementary prescriber. The pharmacist concerned is working in a high-risk drug (eg, methotrexate, sulphasalazine) monitoring clinic. She takes blood, monitors drug levels, advises on alterations to doses, educates patients and communicates with primary care providers. Her involvement has improved patient safety, increased clinic capacity by 20 per cent, and reduced the total time patients took in hospital from an average of 95 to 45 minutes, Mr Harchowal added. The positive perceptions of the service as it stands from both patients and practitioners meant that she was encouraged to become a supplementary prescriber, so that she can take the final step forward in providing a “complete package of care”.

Going forward, Mr Harchowal stressed that pharmacists have to take the opportunity to make sure supplementary prescribing works. That includes making sure that there is a need for them to prescribe before undertaking training, and that their work and competencies are effectively monitored. Mr Harchowal added that it is important to ensure that the shortcomings seen now with prescribing by medical staff do not apply to pharmacist prescribing in two to three years time.

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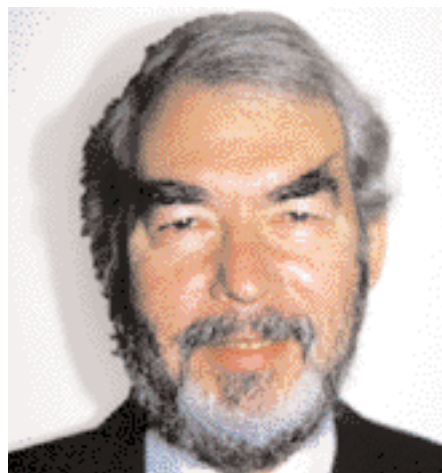
Top left: Dr June Crown (left), keynote speaker and former chair of the Royal Pharmaceutical Society's prescribing task force, in conversation with Gul Root, principal pharmaceutical officer, public health and community services, Department of Health. Top right: Keith Farrar, conference chairman and chief pharmacist, Arrowe Park Hospital, Wirral. Middle left: Charles Tugwell (left), Jatinder Harchowal (centre) and Parmjit Jagait (right), all of the Royal London Hospital. Middle right: Heather Elliston, retired hospital pharmacist, in conversation with Tony West, clinical director, Guy's and St Thomas' NHS Trust. Bottom: delegates attend one of the sessions. Further conference pictures can be found on page 486

What does the Society think?

All pharmacists should be able to train and be recognised as supplementary prescribers according to Dr PETER WILSON, a consultant to the Royal Pharmaceutical Society on continuing professional development. Until now, the focus has been on the training needs of those who are already a registered pharmacist. But part of the long-term plans include incorporating supplementary prescribing training into the pharmacy undergraduate course. Work on preparing the training for preregistration trainees and undergraduates is beginning, and this should be completed within 12-24 months.

Dr Wilson provided an update on the numbers of pharmacists who are enrolled on the first wave of courses in the United Kingdom. In England, 114 pharmacists are doing a course, and they are mainly from a hospital or primary care background. Information about pharmacists doing the courses in London shows that there is a wide spread of clinical areas (including cardiology, cancer, mental health and intensive care). In Scotland 41 pharmacists are on a course, and they are mostly community pharmacists. In Wales, the introduction of training is not yet complete. In Northern Ireland, a course was due to start in early November. There are about 25 pharmacists on the course.

The purpose of the courses is to train pharmacists in prescribing. These programmes do not exist to train pharmacists in clinical pharmacology, therapeutics and clinical pharmacy in general, said Dr Wilson. Participants on a course should develop a competence and sense of responsibility in prescribing practice. Pharmacists will train to prescribe in the clinical area where they will work once registered. In the course of their career, they may work in different areas and become competent in prescribing different drugs. It is therefore important that they learn to recognise when they are prescrib-



Peter Wilson: all pharmacists should be able to become supplementary prescribers

ing within their professional competence, and when they should refer patients to another prescriber for review. Universities must ensure that the sponsoring organisation confirm the clinical competence of trainees before the course, as it is not possible to teach this knowledge during the prescribing course.

Dr Wilson said that many different groups had been involved in the consultation on the course content. Experience of prescribing practice from pharmacists, nurses and doctors had been obtained, and pharmacists who teach prescribing to nurses had been asked to comment on how the training should be delivered. This consultation informed both the Department of Health and the Society's guidance on training of pharmacist prescribers. The programme also underwent a review by the Committee on the Safety of Medicines, the Medicines Commission and the education committee and Council of the Society.

Eight programmes are now accredited as pharmacist supplementary prescriber

courses in Britain. A further seven institutions have applied for accreditation. The programme at the Queen's University in Belfast is likely to be recognised by the Society for the purpose of registering pharmacists as supplementary prescribers, although the accreditation was provided by the Pharmaceutical Society of Northern Ireland.

Some institutions are running a uni-professional course, whereas in others there is a degree of shared learning with nurses. When accrediting the latter programmes, the Society is considering whether the differing learning needs of nurses and pharmacists are being met.

The teaching component of the prescribing courses is equivalent to 25 days learning. The courses use class contact and open learning to varying degrees, and all require the students to undertake directed private study. The other part of the training is learning in clinical practice. The minimum duration is 12 days, but this can be extended if the student requires more experience. Many of the universities have decided to use the National Prescribing Centre (NPC) competence framework to assess the competency of participants.

There are strong reflective elements in the courses. The supplementary prescribing qualification will allow pharmacists to work in different clinical areas and prescribe new drugs, so they must be reflective practitioners. Pharmacists who complete the training will be awarded a practice certificate in supplementary prescribing, which will be accepted by the Society.

The Society website (www.rpsgb.org.uk) has further information on access to the programme. Pharmacists must first establish a prescribing partnership with an independent prescriber, secure employer/primary care trust agreement, identify a practice supervisor, apply for funding and apply for the training course. They must have a prescribing role in which to work once the course is completed.

Duncan McRobbie, one of the other speakers at the conference, had criticised the requirement for experienced pharmacists to attend lectures on topics such as basic pharmacokinetics (see p480). Dr Wilson acknowledged the high level of experience of those in the first wave of the prescribing courses. It was expected that those prescribing in hospitals under local arrangements would be among the first cohort. When they have been through, other pharmacists will be going through the system and presenting different challenges to the university staff.

Designated medical practitioners

Pharmacists undertaking supplementary prescribing training must find a designated medical practitioner (DMP) to support their training, who must be experienced in the field of practice in which the pharmacist wants to work, and be experienced in training, supervision and assessment of trainees. Anne Lovejoy, from the Department of Pharmacy at King's College, outlined the role of the DMP, often known as the mentor.

The DMP must develop a learning contract with the trainee, sign-off a competency assessment for supplementary prescribing,

verify attendance at clinical practice sessions and sign the summative assessment form to indicate that the student has passed their practice placement. The National Prescribing Centre (NPC) competency framework is used at King's. The DMP is therefore asked to state, with examples, that the trainee is competent in the five main areas detailed in this framework, which are: clinical and pharmaceutical knowledge, establishing options for prescribing, communicating with patients, prescribing safely and prescribing professionally.

Prescribing courses — one size fits all?

Does “one size fit all” for the supplementary prescribing courses? This was the question posed by DUNCAN MCROBBIE, principal clinical services pharmacist at Guy’s and St Thomas’ Hospitals NHS Trust, referring to the diverse backgrounds of those being taught to be supplementary prescribers. He is currently on a training course for pharmacists and nurses at King’s College, London. He had consulted fellow pharmacists to present a reflection of the views of students enrolled on the courses.

Mr McRobbie described the course that he is undertaking. King’s College has been running independent nurse prescribing courses for 18 months, so they have previous experience in training prescribers. It is a self-directed web-based course. It requires 16 two-hour tutorials at flexible times, but a lot of pre-course work. The amount of time that this self-directed learning takes should not be underestimated. Assessment is through objective structured clinical examination (OSCE), demonstration of competence via portfolio and examination. According to Mr McRobbie, it is not clear if this methodology of assessment has yet been tested for pharmacists.

Mr McRobbie tried to get some information from other providers of the supplementary prescribing courses about their course content. He said that they had not been forthcoming and this created an impression that “we are making this up as we go along”.

Mr McRobbie said that the current students represent a “who’s who” of hospital pharmacy, with many of the leaders in the sector represented. All are highly experienced and recognised experts in their field of practice. His class has 33 pharmacists, and a similar number of nurses. The variety of practice is huge and includes neonatal nurse consultants and people specialising in care of the elderly as well as generalists (district nurses and community pharmacists). The variety of practice experience is also large. Course content is the same for everybody, which raises a number of questions about how the course can be tailored towards the individual needs of those doing them.

The course caters for both pharmacists (community and hospital practitioners) and nurses, all with different levels of experience. There would seem to be little value in a pharmacist spending time in a tutorial on the absorption, metabolism and excretion of drugs, as this is covered in the pharmacy undergraduate course. It is, however, valuable for the nurses to learn this. It is also useful for pharmacists to spend time learn-



Duncan McRobbie: a national assessment for pharmacist prescribers should be developed

ing some of monitoring skills that are second nature to nurses, eg, blood pressure monitoring and other physical assessment skills. These courses should therefore allow exemption from some aspects, so only the material of benefit would be completed, suggested Mr McRobbie. There should probably be a prior assessment to get everybody to the same level.

Mr McRobbie then asked how consistent is the delivery of training across Britain? In some courses, the trainees are being taught what drugs to prescribe in heart failure, when their area of practice might be quite different. Therefore, Mr McRobbie asked whether students are being taught the process of prescribing, or are they being taught underpinning knowledge which should be assessed before the prescribing course? He suggested that pharmacists need to develop a robust process for prescribing, in the way that medics have, and document a process for diagnosis. It is this prescribing process that should be taught on the supplementary prescribing courses.

One of the key concerns of the participants was what exactly is a clinical management plan (CMP). The law is grey about what detail is needed when they are written. Mr McRobbie believes that there is concern among pharmacists that they may face legal action if the clinical management plan is not detailed enough to cover what they are doing legally. Will a reference to hospital policy be enough for a CMP, and what if some hospitals do not have descriptive policies on managing particular groups of patients. Spending time every week working in primary care, Mr McRobbie asked also how a CMP could be imported into a GP’s database?

Mr McRobbie also questioned the transferability of the supplementary prescribing

qualification. He called on the Royal Pharmaceutical Society to create a national assessment programme, to ensure that the level of competence can be proven to be the same wherever the course takes place. He thought that if he moved hospitals, a new institution may think that his qualification was not at the required standard and therefore he would need to re-train. There needs to be consistency in both the training and the assessment. The medical training system has a consistent process for demonstrating competence. It is widely known what the minimum qualifications are for a medical consultant, for example, and this may be missing from the supplementary prescribing qualification.

There is a lack of clarity within the pharmacy profession about where prescribing is taking practitioners. Mr McRobbie is concerned that prescribing will be taught on the undergraduate course, and new graduates will therefore be in a position to prescribe. There is clear evidence to show that newly qualified pharmacists are not effective at safe use of medicines. Asking them to prescribe as well maybe slightly optimistic. The people who do most of the prescribing in hospitals are junior medical staff, who are not good at it. Should we be replacing them with junior pharmacy staff, who will not be good either? There are some real risks in this strategy.

There is also concern that some people are being sent on supplementary prescribing course to meet government targets. There have been disappointing results with nurse prescribers, with only half those that have undertaken the independent prescriber training using their skills in their jobs, he said.

There are plenty of positive points to come out of the training. Pharmacists who are training as supplementary prescribers are excited to be part of something new. The people who have put themselves forward to be at the forefront of this development in pharmacy practice are leaders within the profession. They see the opportunity to shape the training and what comes next in terms of setting some of the standards for clinical management plans.

They have received a tremendous amount of support from designated medical practitioners (DMPs). The DMPs recognise the responsibility of signing someone off as a prescriber, and have consequently provided a lot of support to help participants achieve the required standard.

A further benefit of undertaking the training is the rare opportunity to have contact with pharmacists working in different hospitals and in different specialities and nurses.

New rights bring new responsibilities

Some of the legal issues associated with prescribing were set out by CHRISTOPHER NEWDICK, barrister and reader in health care law at the University of Reading. Mr Newdick hoped to give reassurance to pharmacists about their new prescribing role by providing a legal framework, based on general aspects of the law of clinical negligence. In presenting the framework, Mr Newdick set out some of the issues for individual pharmacists associated with obtaining patient consent and performing to an acceptable standard of care. For pharmacy managers in particular, he reviewed the quality of systems and clinical governance arrangements that need to be in place to avoid potential liability.

Mr Newdick introduced the topic of informed consent by explaining that the burden on clinicians to inform patients of the pros and cons of treatments has increased markedly over the past ten years or so. Patients have a right to choose, regardless of their reasons for making a particular decision, he said. For example, it was decided in a case in 1992 that “the [competent] patient’s right of choice exists whether the reasons for making that choice are rational, irrational, unknown or even non-existent. That his choice is contrary to what is expected of the vast majority of adults is only relevant if there are other reasons for doubting his capacity to decide.”

It is in this environment that new pharmacist prescribers will be working, Mr Newdick explained. He advised pharmacists that the best way to approach the issue of how much information they need to divulge about the treatments they prescribe is to put themselves in the patient’s position and ask “knowing what [I] know, would [I] want to know about that?”. This is better than relying on statistics from case law, he said, particularly since the decisions on the point are inconsistent. For example, one case suggests that a one per cent risk of paralysis does not need to be disclosed to a patient, whereas another (an Australian case) suggests that a one in 14,000 risk of blindness does. For purely elective treatments, it will be appropriate to point out many more risks than for life saving treatments, Mr Newdick added.

Deciding whether a patient is competent to consent to treatment involves a three part test, Mr Newdick advised; whether the patient is able to (1) take in and retain treatment information; (2) to believe the information and; (3) weigh up that information, balancing risks and needs. Mr Newdick stressed that just because a patient is, for example, suffering from delusions, does not mean that he or she cannot make a decision about anything. There may be some issues (for example, whether or not they want their



Christopher Newdick: introducing new systems of working is challenging from a legal viewpoint

foot amputated) on which they are capable of withholding consent. If a patient is not competent to consent to a particular treatment, the next step is to use the “best interests” test. This is an imprecise test, Mr Newdick pointed out. If pharmacist prescribers find themselves in this situation, they are advised to consult with their independent prescribers and other professional colleagues, he added.

For children (ie, under 16s), whether or not they can give consent depends on the individual child and on the treatment proposed. Case law suggests, for example, that while children can in some circumstances decide for themselves to take the contraceptive pill, no child has the capacity to refuse a potentially life saving transplant operation.

Regarding the general standard of care to which pharmacist prescribers should operate, Mr Newdick pointed out that case law recognises the legitimacy of differences between professional opinions. The law is clear that it is not negligent to follow a course of action, for example, prescribe a particular treatment, just because the majority of professionals would not have done the same thing. But the professionals’ actions must be on spectrum of reasonable opinion – they must be “logical, defensible and reasonable”. It is not adequate for a professional to say that they did what they did because they were told to do so, or taught that way some time ago, Mr Newdick added. They must exercise independent judgement and assert their professional expertise.

During his presentation, Mr Newdick discussed the requirements for supplementary prescribing, looking at the regulations and pointing out some interesting legal aspects. For example, the regulation technically requires the supplementary prescriber to have access to just “patient records”, but to

avoid potential liability for negligence, these should be common records, Mr Newdick advised. Mr Newdick also suggested that, where patients have agreed to a clinical management plan, it would be advisable for them to be given a copy of the plan and their agreement should be recorded in the notes.

In response to a question from the audience, he pointed out that it might be difficult for supplementary prescribing to go ahead when, for example, a patient has dementia, because the regulations specifically require the patient to agree to the clinical management plan. This overrides the “common law” approach (ie, the body of law that has built up through judges’ decisions during cases) that would allow, for example, patients’ carers to make decisions in circumstances where the patient cannot. [Gul Root, from the Department of Health, noted this issue and said she would investigate.]

For pharmacy managers in particular, Mr Newdick addressed the standard of systems and clinical governance arrangements that need to be in place. When in “new territory”, managers need to be able to “show that [they] have made reasonable efforts to look into the future and try and develop systems.” As far as they can, managers need to deal with potential problems before they arise, and not just wait and see what happens.

Mr Newdick demonstrated what can go wrong when adequate systems are not in place by discussing some of the cases on system and managerial negligence in the health care service. In one case, inadequate managerial systems meant that a consultant obstetrician was physically supposed to be at more than one hospital site at the same time, and could not be available to supervise the birth of twins, one of whom was ultimately born brain-damaged. In another case, a communication breakdown meant that although clear messages were left by a staff member finishing her shift that a baby was distressed in the womb, the information was not read and was therefore not acted upon.

Ensuring effective communication is also a key factor for individual prescribers, as well as managers, in avoiding negligence, Mr Newdick said. He urged supplementary prescribers to ensure that they have the clearest lines of communication between themselves and the independent prescriber. They must not find themselves in a position where they do not have enough information on which to make a decision, he said. “There are circumstances when you must make a decision. Making no decision is a decision.”

Mr Newdick concluded his presentation by pointing out that, of the topics he discussed, ensuring safe systems and good clinical governance arrangements would be the biggest challenge.

The Department of Health's view

The Department of Health's vision of supplementary prescribing was set out by Gul Root, principal pharmaceutical officer at the DoH. Mrs Root took delegates through the principles of supplementary prescribing, paying special attention to issues of practical importance to pharmacists, patients and the NHS and setting out potential new developments.

One key principle is that supplementary prescribing must be of benefit to patients and the local NHS. Because of this, it is vital that any pharmacist who undertakes the training has a prescribing role waiting for them to perform when they complete the course, Mrs Root stressed. This is one area in which supplementary training for pharmacists can learn from the experiences of nurse prescribing - many nurses have qualified as prescribers but have not taken on prescribing roles on completion of their training. This is unsatisfactory for them, and is not cost-effective, Mrs Root pointed out.

Another key principle is that supplementary prescribing is a voluntary partnership between the supplementary prescriber, the independent prescriber and the patient. Patients' agreement with the clinical management plan and with the fact that the pharmacist will be prescribing for them must be sought. A signed consent is not necessary, but the agreement of the patient should be recorded on the clinical management plan and patient record. Without this agreement, supplementary prescribing cannot proceed. The supplementary prescriber must also be happy with what they are being asked to prescribe - it will be they who have to take clinical responsibility for their prescribing.

Patient safety is another of the key principles of supplementary prescribing. Mrs Root urged supplementary prescribers to act only within their own competencies, knowing when to refer to the independent prescriber and being aware of their own limitations. It would be helpful for pharmacists who become supplementary prescribers to review their insurance cover, she said.

Effective communication between the independent and supplementary prescriber is paramount to ensure patient safety, Mrs Root added. Supplementary prescribers should ideally record their prescribing and monitoring contemporaneously in the shared patient records. In some circumstances (for example, weekends and bank holidays) where this may not be possible, they should be recorded within 24 to 48 hours. Where possible, prescribing and dispensing functions should be separated, Mrs



Gul Root: don't make clinical management plans bureaucratic - let's keep them simple

Root added. She noted, however, that there may be exceptional circumstances where the same pharmacist would need to prescribe and dispense medicines and, following discussions with pharmacy organisations, it was agreed that within the context of supplementary prescribing, this could happen provided robust clinical governance and audit arrangements were in place to ensure patient safety.

From a practical point of view, one of the key messages is that clinical management plans should be kept simple. According to Mrs Root, it is important to remember that clinical management plans are for individuals and not for groups of patients. So they should not be prescriptive documents. Two templates are available from the DoH website, but these are there to help the NHS and are not mandatory. The only requirements are those set out in the POM order amendment (for example, patients' name, illness, reference to medicines or class of medicines to be prescribed, the arrangements that have been made for the notification of adverse drug reactions and the circumstances in which the supplementary prescriber should refer back to the independent prescriber). Clinical management plans should generally be reviewed not less than annually, she said.

Mrs Root went on to say that clinical management plans can contain either specific or general instructions. For example, when managing hypertension, they might state that drug "x" should be used if a patient's blood pressure increases above a certain level. Alternatively, they might just state that the condition should be managed according to British Hypertension Society guidelines, or the hospital protocol (ie,

national or local evidence-based guidelines). The level of delegation will depend on the relationship between the independent prescriber and the supplementary prescriber and the skills and expertise of the supplementary prescriber, she said. There is no need for clinical management plans to repeat information contained in such guidelines or in patient records shared by both prescribers. "Please don't make them too bureaucratic" Mrs Root urged, especially since medical practitioners could be dissuaded from supplementary prescribing if developing a clinical management plan is an arduous task. "Let's try and make it simple for everybody".

Regarding the education and training of pharmacist prescribers, Mrs Root stressed that some face-to-face learning is seen by the DoH as an important part of the course, particularly for learning about the physical examination of patients and the different models of consultation. However, it is also recognised that open learning for some aspects would be helpful. The DoH has commissioned a review of the minimum number of hours that need to be spent on face-to-face learning, Mrs Root said.

Recommended reading for pharmacy managers and for those thinking of training as supplementary prescribers includes the competence framework developed by the National Prescribing Centre, the clinical governance framework (for both organisations and individual supplementary prescribers) developed by the Royal Pharmaceutical Society and the supplementary prescribing section of the DoH website, she added.

Mrs Root also discussed the removal of the restrictions that prevent pharmacists prescribing controlled drugs and unlicensed medicines. For controlled drugs, she explained that the Home Office is currently preparing instructions for its lawyers to draft regulations extending the scope of supplementary prescribing to include controlled drugs. This follows on from an agreement with the Advisory Council on the Misuse of Drugs that the proposal can go ahead, and from public consultations by the Home Office, where no major objections were raised. Home Office regulations should be in place by early 2004. Mrs Root pointed out that the ability to prescribe controlled drugs are particularly important in oncology and palliative care, where supplementary prescribing would be of limited application without them.

For unlicensed medicines, the Medicines and Healthcare products Regulatory Agency (MHRA) is currently preparing a consultation letter extending the scope of

supplementary prescribing to include specials and unlicensed medicines. The aim is for this consultation to be issued by the end of the year. Currently, supplementary prescribers can prescribe only unlicensed medicines used in clinical trials. Mrs Root pointed out that pharmacists can currently prescribe "black triangle" and "off label" drugs, but urged pharmacists to make sure that they were happy to accept clinical responsibility for prescribing them. She suggested that if there was a body of opinion (for example, references in paediatric formularies) supporting their decision to use these agents, that would be helpful.

There are also likely to be developments

relating to inpatient charts, Mrs Root continued. These are needed because of uncertainty about whether supplying medicines against instructions written by non-medical prescribers on inpatient charts complies with Article 15 of the POM Order. The DoH and the MHRA have taken the opportunity to clarify the situation beyond doubt. The changes proposed would ensure the legitimacy of current practice. Supplying medicines against inpatient charts written by medical prescribers is specifically covered by Article 12 of the POM order, but Article 12 has not yet been amended to cover non-medical prescribers. Consultation on the proposal to extend Article 12 is under way, however, and a decision from ministers is

expected imminently, with changes to Article 12 expected in early 2004, Mrs Root said. [Ministers have since agreed to the proposal - see p469]. In the meantime, "the DoH and MHRA would not wish to inhibit current safe practices", Mrs Root said.

Moves towards independent prescribing were also discussed by Mrs Root. She told delegates that discussions with professions, patient organisations and the NHS to develop a framework for independent prescribing by pharmacists will begin in early 2004. She will also be talking to pharmacists informally to see how to take independent prescribing forward. "Watch this space", she concluded.

The future for pharmacist prescribing

Risks must be balanced with potential benefits as the pharmacy profession move forwards with prescribing, according to Tony West, clinical director of Guy's and St Thomas' NHS Trust. There are concerns about the acceleration in the time frame for developing new prescribers and how quickly things are happening.

The Act of Parliament to allow nurse prescribing was passed in 1992. Nurse prescribing was rolled out in 1999. It has taken 10 years to get to the start of nurse prescribing, and since then things have moved quickly. Much of this has been driven by the desire to sort out what is legal and what is not. More recently, group protocols, the third Crown report, the NHS plan and "Pharmacy in the future" have been brought out. Finally, the "Vision for pharmacy" which is raising the spectre of independent prescribing for pharmacists. This means there has been 30 years of little change, and a few years of massive change, Mr West added.

Many factors have driven the changes allowing wider prescribing status. First, the aim is to make things better for patients, and improve their access to medicines. Shortages of doctors is an increasingly significant issue, and new prescribers can alleviate this problem. Many other health professions are also looking at opportunities for prescribing. Training new prescribers increases flexibility in the workforce, and is part of the modernisation process. New prescribers may be able to ensure better value for money from the £8bn spent on drugs in the NHS: 20 per cent of drugs are not taken, and 20 per cent are taken other than as intended. Ministers may be asking why the NHS is not maximising the health gain of all this money which is being spent on drugs.

Mr West gave his thoughts about the development of the different types of prescribing models for pharmacists. The advent of supplementary and independent prescribing does not mean an end to patient group directions



Tony West: independent prescriber status may legitimise current practices

(PGDs). The "see and treat" principle of PGDs is simple, and will have a place. Supplementary prescribing is likely to be used when treating chronic conditions and is likely to be used more in primary care.

Mr West outlined the areas in which pharmacists could become independent prescribers. In the acute hospital setting, pharmacists may become independent prescribers, but work within parameters set by the hospital. This may be similar to nurses in minor ailments clinics. At hospital admission and in pre-admission clinics pharmacists often take drug histories and write the drug chart, but currently ask a doctor to sign the chart to ensure that the drugs can legally be administered. Independent prescribing would allow pharmacists to be the prescriber in this situation, where the doctor does not add value.

Mr West asked participants to consider several areas of prescribing practice where there have been questions over their legality. Examples of grey areas include substituting by protocol (swapping proton pump inhibitors), subtractive prescribing (crossing off an intravenous product), discharge pre-

scribing, and amending an electronic prescription order. The question is who is the prescriber and what is the position of the nurse who administers or the pharmacist who makes the supply, when the status of the prescriber is unclear? Mr West suggested that independent prescribing rights would legitimise this practice. There are also opportunities in the non-acute setting and pharmacists are likely to be working in the same areas as independent nurse prescribers.

We must ensure that, with the addition of supplementary prescribers to the team of people able to prescribe for a patient, we do not increase confusion for patients, said Mr West. Many patients already become confused when they have both a GP and hospital consultant prescribing. It is also known that transfer of care from one setting to another, eg, discharge from hospital, is the most risky event in terms of prescribing errors. Similar problems must be expected to occur when transferring between multiple prescribers.

Supplementary prescribing may offer more convenient supply, but can it be demonstrated that it is safe? Mr West warned that there is likely to be a situation where a mistake is made by a supplementary prescriber, whether a nurse or a pharmacist, and this reported on the front page of a national newspaper. Do we have the mechanisms to cope with that, and how do we support each other?

A concern with the new prescribing role is that pharmacists may be undervaluing the current role, which is getting the medicines right for the patient. A further problem with the increase in prescribers is how pharmacists know on what basis any given prescriber signs a prescription. Mr West asked participants how comfortable they felt with all the new prescribers.

Mr West concluded by saying the pharmacists can take on the new prescribing roles, but should make sure that they are well prepared for it, and do a good job.



Top left: Mary-Beth Peddell, Novartis Pharmaceuticals (left) and Maria Christou, University of East Anglia. Top right: Natasha King (left), Dorset Healthcare Trust and Suky Bhogal, Horton District General Hospital. Middle and bottom: delegates visit stands during the lunch interval.