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Systematic approaches to strategic medicines management

The use of medicines in a health community is a complex activity. There are many thousands of prescribing and ‘administering or taking’ events each day. Choices are made with respect to dose, route, form, product, chemical entity, timing and so on. There are hundreds of prescribers, purchasers and thousands of recipients of medicines. There are also many influences on those taking decisions – not only advertising, evidence, anecdote, experience, consumer pressure but also national guidance and, it is hoped, the influence of local strategic medicines management. In this complex system it is hard to establish what changes result from intervening in a particular way. Previous chapters examine the core activities of strategic medicines management – the formulary, horizon scanning, critical appraisal and guideline development; this chapter looks at how these activities can be put together to approach medicine use in a systematic way. It examines how synthesis of the various elements might produce an impact that is bigger than the sum of its parts. In addition, the place of policies restricting access are considered, and the role of shared care guidelines. The approach that two organisations have taken to the overall medicines management system will be discussed. The two are chosen as ‘case studies’ because they have been described in the literature, not because they have shown to be the best performers.

A systematic approach

Taking a systematic approach to strategic medicines management is when an organisation or health community seeks to arrange structures, policies and practice in a deliberate attempt to make a real difference to the way medicines are used. Individual interventions such as formularies and guidelines play a part of this whole package. Most organisations probably set out to have systems that interlink and thus deliver the vision, but occasionally taking a step back and considering how well elements interlink can highlight the need for review and change. Various

documents have, over the years, given prompts for this stocktaking process. *A Prescription for Improvement*, health circular HC (88) 54 and, for hospitals, *A Spoonful of Sugar* could each fall into this description.¹⁻³

For there to be a well-organised, systematic approach, there should be a clear vision. ‘Vision’ tends to be a word that falls into disrepute; George Bush Senior dismissed it in a throwaway comment: ‘the vision thing’, when challenged over the need to look at the longer term, and it may be considered to be an excuse for substance.⁴ However, in discussing effective organisations, Handy provides evidence that the success of organisations is in part dependent on the vision of their leaders, the ability to see the big picture.⁵ For strategic medicines management, this means being clear about the purpose of activity. If it is about making the most of medicines, then the policies and practices need to support that. There are several contributing elements. These include: gaining resources for effective medicines to be accessible, investing in medicines that give the biggest benefits (assuming not everything is affordable), basing decisions and guidelines on evidence, then implementing these decisions and policies. These elements will support the overall vision.

Seeking to get the most from medicines may entail restricting access to some medicines in some circumstances. Failure to apply decisions can undermine the purpose and reduce credibility in the system used. Although achieving financial balance is a requirement of NHS organisations, it is not the sole purpose of medicines management. Delivering more benefits to patients should be the aim, not controlling spend, but failure to live within available resources will ultimately put patients at risk. The drive simply to control spend has often provided reason to examine an organisation’s overall approach to strategic medicines management.

Examples from the literature

Although cited in Chapter 3 as a confounding factor while investigating the effect of a formulary on spend, the work Baker *et al.* reported as the broad approach to controlling spend could be seen as an early example of a systematised approach to strategic medicines management.⁶ They reported changes of policy for outpatient supplies, reducing waste and improvements in purchasing practice alongside their revised formulary system. Several activities were initiated with the single aim of controlling spending on medicines.

The health circulars of 1988 also suggested a multifaceted

approach to good medicines use.² Hospital clinical pharmacy services, involvement of pharmacists in priority care groups in the community, DTC development, formularies and medicine use review were each included in the circular as important aspects of pharmaceutical services. The circulars gave an opportunity for pharmacy services to be reviewed and investment sought. Taken as a package, there was the basis of a systematic approach to medicines management.

In 1998, Fitzpatrick and Coker discussed the various aspects of strategic medicines management in their description of prescribing controls.⁷ They listed the elements of these controls but pointed to the need for a whole system approach. Getting each element right was deemed essential, but the implication made was that this alone was not enough. Integration of the elements into a total package was proposed.

For secondary care the medicines management framework provided an assessment tool for these activities.⁸ It drew out seven areas for action that, together, could be taken as a systematic approach to medicines management. The Audit Commission supported this systematic methodology, asking trusts to compare their own performance against the 19 recommendations for action included in *A Spoonful of Sugar* and proposing action plans be developed to bring performance to that of the best.³

The idea of a systematic approach to medicines management sounds laudable and the examples and documents mentioned so far put some flesh on the bones of the idea, but what does this approach mean in practice? To illustrate this, two examples of hospital trusts that have presented their approaches in the literature will be examined as case studies.

Southampton

Southampton University Hospitals NHS Trust reported work that they described as the optimising drug value project.⁹ Their work began in 1997 and came as a response to financial pressures, in particular the problem of approving medicines on a 'scientific basis' but then having no funding to support their use. A report was developed, based on a series of interviews with clinicians and managers, aimed at identifying the perceived strengths and weaknesses in medicines management systems. Then an action plan to build on strengths was produced and investment made.

To increase the effectiveness of the already established clinical pharmacy service, therapeutic substitution was introduced. Pharmacists were empowered to make changes to inpatient medicine charts without

the prospective agreement of the individual clinician. These were within agreed guidelines and undertaken by experienced members of the team. The changes each related to specific DTC decisions regarding choice of therapy. A second change for pharmacists was described as the advanced dispensing of discharge medicines; this was a system that allowed pharmacists to write up a discharge request based on the inpatient chart. Southampton reported that this change considerably reduced the time required to contact doctors regarding problems with discharge prescriptions. Both developments sought to use pharmacists' skills while controlling costs and improving safety.

A further change that fits into the description of medication management given in this book's introduction was made. A patients' own medicine scheme was established – using medicines brought into hospital by patients instead of dispensing new supplies, along the lines of other schemes already in the literature at that time. Waste was avoided and hospital costs were reduced, without an adverse impact on primary care.

Committee structures were reviewed, the trust DTC given a stronger role in monitoring finances and a new subcommittee was set up, called the drug finance group. This subgroup was given funds to administer on behalf of the DTC, seeking to invest in items given support on the basis of evidence and the expected health benefits. The DTC also had increased support from the medicines information department (a regional and local centre combined) who provided horizon scanning and trend analysis.

Another action included was a review of purchasing, embracing a parallel import partner and benchmarking on prices. Additional training for junior doctors on prescribing was developed. The hospital also set up a system of recording representative visits to the site. Additional pharmacists were appointed to lead the directorate pharmacist service and to provide support for junior clinical pharmacy staff.

Southampton made this series of changes in staffing, structures and policies to address medicines management issues. They reported a multi-faceted attempt to shift the organisation's culture to one where only affordable, evidence-based developments took place. Their report in *Hospital Pharmacist* claimed some success based on a slowing in growth of spending. They reported the difference in activity growth (measured in finished consultant episodes) and medicine spend growth. In the three years prior to the project, growth in spend on medicines was 8%, 13% and 8% above the growth in activity. In the first and second years of implementation, growth was 2.5% below activity and then 2.3% above activity, respectively. It is, however, very difficult to be certain of the

impact that optimising drug value had on these figures. Case mix changes, outpatient activity changes and fortuitous price reductions may each have had an important effect. These years were also before NICE appraisals. Now, simply measuring growth in spend compared with growth in activity would have even less meaning – failing to increase expenditure could mean that NICE guidance is not being implemented.

Southampton reported that they had reasonable medicines management and clinical pharmacy systems in place, but they sought this multifaceted change to improve controls. The concept of making a number of small, specific changes together, to cause a significant shift, is one worth considering for medicines management and other change management projects.

North Staffordshire

The year following Southampton's description of their project to improve medicines management, work undertaken at the North Staffordshire hospital was shared in the *Pharmaceutical Journal*.¹⁰ As at Southampton, the authors reported a long history of formulary use and other medicines management initiatives but they also noted four areas of concern that motivated them to initiate change. The four were:

- the ability for consultants to request non-formulary medicines for individual patients, leading to creeping developments
- the DTC having no means to fund the decisions that they took to permit new medicines
- senior management not aware of the cost pressures on the medicines budget
- no budget management system at directorate level.

It is interesting, although not surprising, that the same issue facing the DTC in Southampton emerged as a problem in North Staffordshire – no funds to back DTC decisions. No doubt this was common throughout the country. Pressure on primary and secondary care budgets has been continuous; the NICE technology appraisals have dealt with the funding issues in part, but not all medicines are covered and there still needs to be 'planning and managing'.

The overall response to North Staffordshire's four areas of concern was to revise the medicines management system. Four streams of work were developed:

- managed entry of new medicines
- pharmaceutical advice
- senior management information and attention
- purchasing pharmaceuticals.

As discussed in Chapter 3, formularies are often implemented as binding for junior staff but as guidance for consultants – or perhaps even as suggestions. North Staffordshire took this approach with a consultant signature required on non-formulary prescriptions. In 1997 an additional step was added: consultants were still permitted to request non-formulary medicines but had to seek support of their clinical director – the lead clinician for a directorate. A proforma was developed that was completed before the supply of the non-formulary medicine.

A DTC of sorts was developed as a group accountable to the executive board. It was called the Medicines Management Group and it supplemented other DTCs in the trust. It also had the remit of considering new, high-cost medicines. Unlike Southampton's drug finance group, it was not reported as having a delegated budget. However, it did approve medicines for use in two ways: where the trust had funds to support and where a business case seeking further funding was required. In the latter case the group assisted the development of that case. North Staffordshire reported rejecting 60% of the requests made for new, high-cost medicines, supporting 13% and seeking business cases for funds from the health authority for 25%. All cases in this final category were funded alongside the development of guidelines for use. This seems to be a successful approach to the controlled, self-managed introduction of new medicines. Importantly, the use of a guideline or protocol restricting or guiding access at the start of introduction can give confidence to the funders and prevent the overspill into usage that is either less cost-effective or has a weak evidence base. The NICE guidelines have this element, approved for use in *x* circumstance, not for use in *y*.

North Staffordshire had the benefit of working closely with a single health authority. Working with large numbers of commissioning organisations could be more problematic. The full impact of new funding streams in the NHS might deal with developments in a more standard way.

North Staffordshire also saw additional clinical pharmacy input to extend coverage to all medical wards. Delivering strategic medicines management without clinical pharmacy is likely to be frustrating and even could put patients at risk. Pharmacists working at an individual patient level can interpret and use the strategic medicines management framework without losing sight of the patient's individual needs. Pharmacists working at the next level up, with directorate teams, were used to support prescribing audit, cost-saving initiatives and guidelines. Clinical pharmacologist support for the directorate teams and work

with the formulary pharmacist enabled structured reports on prescribing to be fed back to the clinical teams. Use of budget reports, reports on developing trends, and on individual prescribers' divergence from the agreed prescribing patterns have an important role. They can help the general and clinical managers in a directorate support the medicines management efforts. Feedback to individual prescribers can encourage reflective practice and even help apply peer pressure.

Board attention was brought to medicines issues by preparing quarterly reports, with figures and commentary so that an overview could be given. Financial and quality issues were included. Purchasing was improved by a closer working relationship between directorate pharmacists and the procurement team. The results of this multifaceted review were reported as a reduction in spending in year 1 and a slower growth than historically in place during year 2. The figures given were a fall in overall spend in 1998–99 of £0.5 million and a growth of only 5.6% in 1999–2000. This was a similar pattern to that reported by Southampton, although they had not claimed an absolute fall in expenditure. The results in each case are similar to the figures mentioned in Chapter 3 on the introduction of formularies – an initial impact then a slowed growth that suggests the benefits are retained.

The North Staffordshire authors argued that the success was dependent on the systematic approach taken. A raft of measures was used to build on an already reasonable system. Whether the Southampton, North Staffordshire or other models are used, organisations can reflect on the weaknesses of their current systems and develop action plans to improve their medicines management systems. The two models described here are secondary care based, but a parallel, multifaceted approach could be used across a health community or within a primary care organisation.

Shared care arrangements

It was difficult to decide where shared care guidelines fit in the structure of this book. They tend to support the 'traffic light' systems mentioned in the discussion of DTCs – indeed, they were recommended as part of the Midland Therapeutic Review and Advisory Committee (MTRAC) decisions. They have also been suggested within NICE guidance: riluzole, for example.¹¹ For convenience, shared care guidelines have found a home in this chapter on systematic approaches to medicines management, as they do support the move, in a controlled way, of complex or problematic medicines from secondary or tertiary care, to

primary care. Shared care guidelines have also been described as shared care protocols. The former name will be used here.

In 2001, Duggan *et al.* reported their work evaluating shared care guidelines in the UK.¹² They noted the development of such guidelines from 1991, with cost shifting as a major motivator. As described in the opening chapter, until financial flows were unified, there was the opportunity to move prescribing costs to general practice to protect secondary care budgets. Developing shared care for financial reasons may have been expedient, but that does not seem to be a good basis for developing care.

In 1994, the executive letter on purchasing and prescribing highlighted the need for the provider units to ensure that local arrangements existed, on which hospital-led medicines ought not to be passed to GPs.¹³ The letter also asked that arrangements be made for those medicines requiring special arrangements before being passed to GPs. A checklist also asked that these arrangements gave GPs appropriate information and support that enabled them to prescribe for and monitor patients. Following this, MTRAC was set up in 1995 in the West Midlands region to give advice and guidance on which medicines should be supported by shared care arrangements. Tacrolimus was one medicine included in this category.¹⁴

Although potentially helpful, shared care guidelines have been problematic. Reaching agreement at a local DTC on a shared care guideline, although important, is only one step in the process. Individual GPs may still not remain comfortable to take on the prescribing of specialist medicines where they lack the skills to take responsibility. Monitoring response and side-effects, and adjusting dosage may require knowledge seemingly straightforward to the specialist but beyond the usual experience of a GP. Biochemical results of tests undertaken in secondary care have not always been readily available to GPs when it is time to prescribe, although they retain professional responsibility and should only prescribe when they are assured it is safe to do so. Shared care guidelines do not replace the need for good communications between the specialist and the GP. Problems are guaranteed if they are used in this way.

Ashcroft *et al.* reported experiences of shared care arrangements for erythropoietin.¹⁵ This was an early example of shared care, as the availability of this agent for renal units coincided with particular financial pressure on the NHS. They noted that 11 patients within their survey (total 119, 72% response) stated their GP had not been aware of the dose required at the point of prescribing, as dosage adjustments had been

made in secondary care. However, they did comment that the shared care approach seemed to work.

The work by Duggan *et al.*, mentioned earlier, was a little more critical.¹² They undertook a survey and used content analysis to examine shared care guidelines. They noted that GPs were often excluded from the production of shared care guidelines and that the perception of their use as a cost-shifting device was described as a significant barrier to their use.

The area DTC could be an appropriate place to identify the need for a shared care guideline. Their use should be to support GPs to prescribe more complex therapies, where the patient can benefit from access to the medicine in primary care. This patient-centred rather than financed-focused approach is important. Placing prescribing in primary care can mean that additional trips to an acute hospital, possibly at some distance, are avoided. It can also mean that the GP has a better understanding of the healthcare for their patient. The approach also fits with the general principle of moving care from a tertiary/secondary setting to primary care, where this is safe and appropriate.

Shared care arrangements may be requested at the stage of appraising how a new medicine fits in to practice or later in a medicine's life cycle. General practitioner, specialist doctor, pharmacist and patient input into the shared care guideline can ensure that an appropriate document is developed. A clear statement of the responsibilities of each professional involved in the care is essential. Details of monitoring requirements and arrangements need to be included. There needs to be local agreement on how use of shared care guidelines fits in with the general medical service contract; some items needing particular monitoring are mentioned but others are not.

Once a suitable shared care guideline is in place it becomes the responsibility of the prescriber initiating therapy to ensure that the aspects of care taken up by the GP are handed over in a mutually acceptable way. Issuing a copy of the shared care guideline to support a letter requesting that care is shared may be the best approach. This may occur immediately when the patient commences therapy or after a period of stabilisation.

Figure 7.1 summarises the approach that can be taken in developing and using shared care guidelines. Reviewing individual arrangements and the general application of a guideline can allow modification or confirmation that it is working. The overriding principle should be what is best for the patient, although use of resources must not be overlooked. If this aspect of strategic medicines management is undertaken effectively,

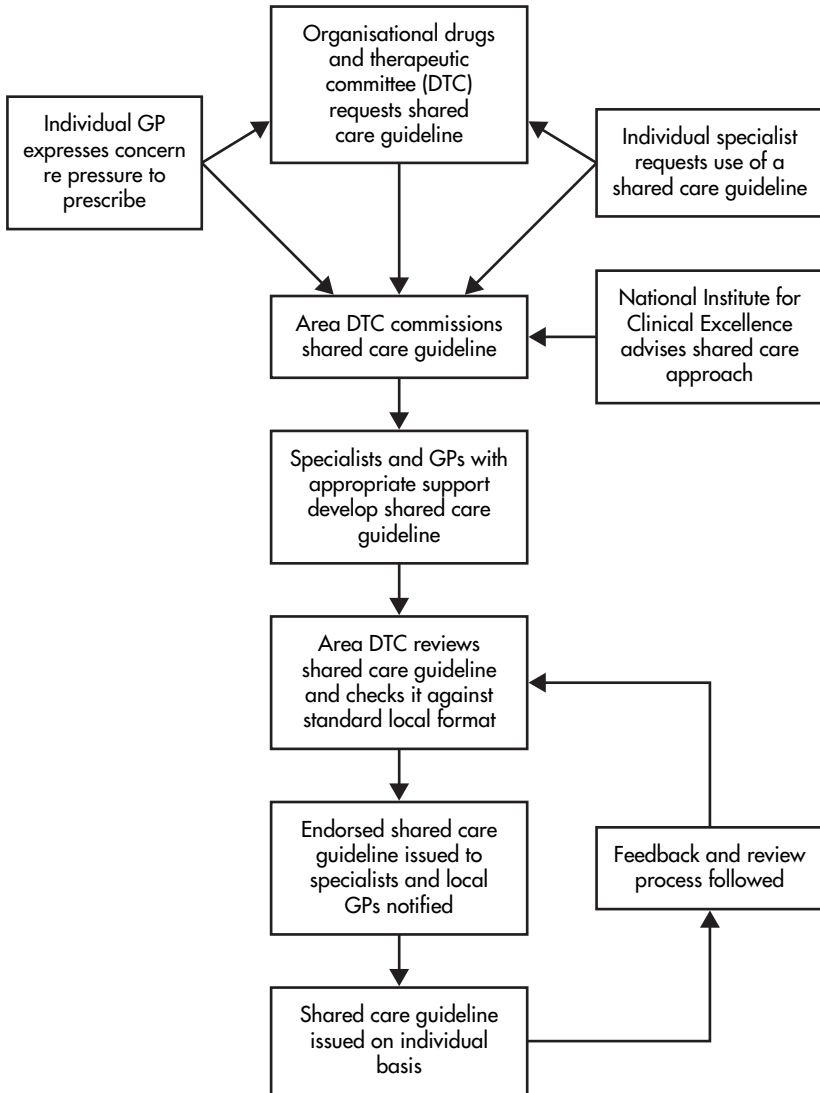


Figure 7.1 Developing and using shared care guidelines.

the risk of such arrangements being ‘dumped prescribing orders’ can be minimised and shared care guidelines can live up to their name.

Influencing prescribers

It could be argued that much of the work described by the term ‘strategic medicines management’ is about influencing those taking prescribing

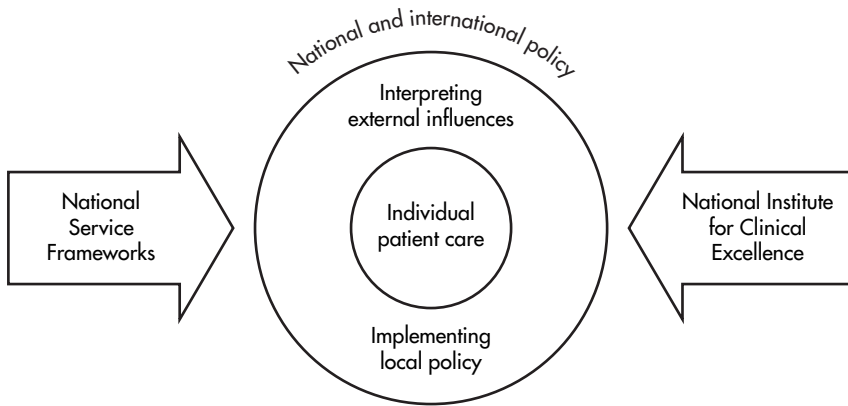


Figure 7.2 The place of strategic medicines management.

decisions. Figure 7.2 repeats Fig. I.3; it reminds us of the multilayered description of medicines management described in the introduction. Direct influence on prescribers in hospital is delivered by the clinical pharmacy team (clinical pharmacy is of course more than an influence on prescribers; direct care and support for patients, among other tasks, are covered by that term). Strategic medicines management is the next layer, and can be described as the indirect influence. Figure 7.3 attempts to identify the various layers. It describes a hospital system, but for primary care there are parallels, particularly if, in an extended team, an active part is played by the pharmacist providing the dispensed medicines.

Medicines information

Medicines information services play an important part in supporting medicines management at the individual and strategic level. The national network role played by UKMi is described in Chapter 4, leading on horizon scanning and preparing documents on emerging products. The UKMi website (www.ukmi.nhs.uk) and DrugInfoZone (www.druginfzone.org) are important sources of information and gateways to a range of resources that support strategic medicines management. Regional and local centres are the source of information and of critical appraisal skills, and can provide support by issuing various active medicines information bulletins. Primary care pharmacy teams may use medicines information support in preparing their own bulletins and documents.

This is just a mention of a few aspects of a vital service for strategic medicines managers. Prescribers, primary care lead pharmacists,

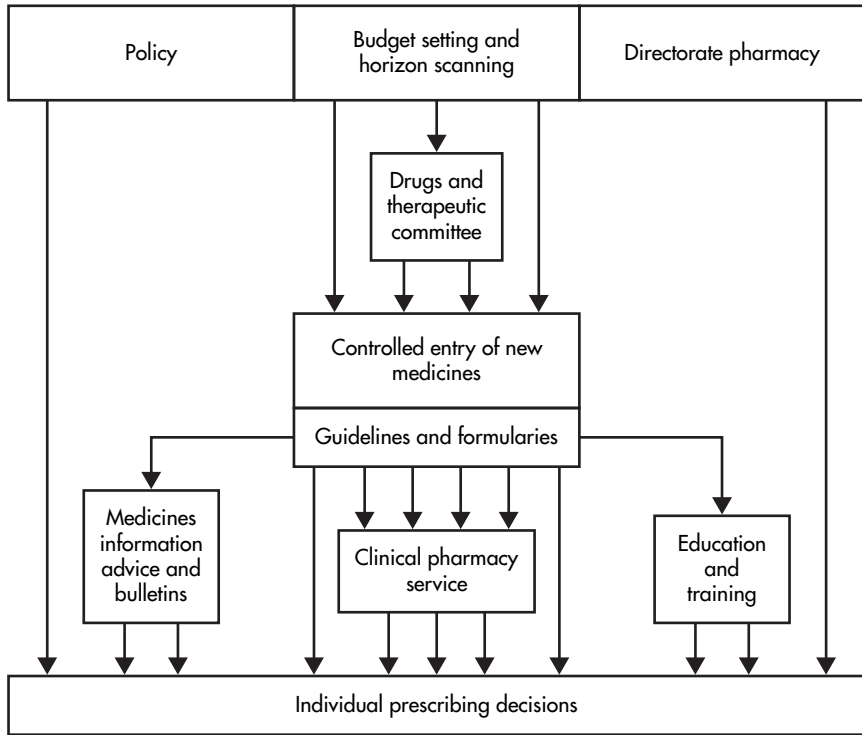


Figure 7.3 The multilayered nature of strategic medicines management.

hospital directorate and chief pharmacists and DTCs should all understand what medicines information can offer and use the resources to make the most of medicines.

Education and training

The medicines management framework for hospitals includes a section on influencing prescribers.¹⁶ The emphasis is around the point of prescribing and this is important. Better to discuss the appropriate decision than to ring a junior doctor later to try to improve or correct the prescription. However, induction, education and training, and continuous professional development for prescribers provide important opportunities to influence. Induction for junior doctors should address safety as well as systems of strategic medicines management. Often there is little time in formal induction sessions to do more than point out where the pharmacy is and remind doctors how controlled drugs should

be prescribed. Use of electronic learning packages and regular early contact in practice at ward level may be more effective in explaining how the local arrangements work. Consultants too require information on DTCs, formulary systems and the approach taken to guideline development. After induction, junior staff can be provided with advice and feedback on prescribing, and multiprofessional teams can learn from audit and clinical meetings. The possibly helpful, possibly disruptive learning that can form part of semi-promotional educational meetings for junior medical staff provided by the pharmaceutical industry are problematic. They will take place and a realistic approach is needed. Understanding the messages being given, and dealing with any changes in prescribing that result is the pragmatic way to respond.

The arrival of pharmacists as prescribers may be a positive influence on junior medical staff. Electronic prescribing systems can provide on-the-spot influence and serve as an educational tool.

In primary care, practice meetings, feedback to individuals on prescribing patterns and the process of developing guidelines can serve as educational tools. Meetings involving secondary care specialists and GPs provide educational and relationship building opportunities. Such meetings should support DTC-agreed practice and can be used to launch guidelines developed locally.

Directorate and practice pharmacists

In primary care, the practice is a natural unit for review of prescribing and other issues. In acute hospitals, directorates and divisions have been developed since the reforms in structure during the 1990s. The involvement of clinicians alongside general managers in running sections of a trust was the driver. Typically a directorate would encompass a group of wards of the same speciality: general surgery or elderly care medicine, plus the medical staff associated with the speciality. Divisions tend to be larger, grouping all medical specialities; all surgical specialities into single divisions would be the norm. The management team might include a nurse, a doctor and a general manager. In mental health trusts there may be similar management groupings: old-age psychiatry and adult psychiatry, for example, or care may be organised on a locality basis.

Whatever the specific nature of the arrangements, senior pharmacist advice focusing on medicines usage would be an important influence supplementing the clinical pharmacy service. Many have developed these arrangements with reports in the literature from the early 1990s.^{17,18} The development of the role is a natural progression from

that of the specialised clinical pharmacist, but not all specialised pharmacists wish to take on the broader semi-management role the directorate requires. A continued, direct patient-care role is a perfectly reasonable alternative. It will be interesting to see how this develops as the consultant pharmacist emerges.

Skills needed include an ability to work with prescribing data, whether hospital-computer generated or prescribing analysis and cost data (PACT) in primary care. An ability to present and persuade, using information, to negotiate and to plan is also essential. Clearly, a solid understanding of the medicines used and the clinical issues as well as aspects of policy will be needed. Personal credibility and interpersonal skills will enable the directorate or locality pharmacist to use their knowledge and medicines management skills to best effect.

Directorate, and other 'organisational unit', pharmacists can undertake audit, lead on or support guideline development, provide feedback on prescribing, help tailor horizon scanning, support the development of business cases for investment, assist in budget management and provide educational programmes. They may also take on broader roles in the directorate and continue with their underpinning clinical pharmacy work – whether running a clinic in general practice or involvement at ward level. These are potentially challenging and rewarding roles, vital in the delivery of high-quality, strategic medicines management.

Clinical audit

Clinical audit can be described as where the multiprofessional team examines clinical practice against pre-determined standards, with a view to learning lessons and implementing change. A detailed description of the way audit in healthcare has developed and how it can be implemented will not be addressed here, but audit has an important part to play in strategic medicines management systems. Examining if clinical guidelines are being implemented, including NICE guidelines, is a vital way for an organisation to check and improve performance. Feedback to prescribers and to those assisting good medicines use should help inform and educate.

Restricting access and saying 'no'

The formulary has been used in hospitals for many years to guide prescribing choices along pre-agreed, restricted paths. As discussed, the

formulary is often binding for junior doctors but consultant staff are permitted to move outside the formulary, possible after some additional step, such as the North Staffordshire proforma. Others apply the document for all prescribers. The approach taken to restrict access to medicines tends to be by influence and negotiation rather than by application of policy – although there may be a set process to follow. Individual review and discussion of a non-formulary or new medicine may take place, and there is audit and expenditure monitoring. Where prescribing appears to be atypical it may be raised as a matter of performance under the remit of clinical governance. What about circumstances where prescribing moves or seeks to move outside the range of medicines supported by the local DTC when (a) the medicine is seen to offer no additional benefits at extra cost compared with a formulary medicine and (b) the medicine is newly available and has not been supported on the grounds of evidence or cost-effectiveness or affordability? These are situations, along with occasions where NICE has proposed restrictions on the use of medicines, where an organisation may wish to bind all prescribers to the DTC decision, not just junior hospital doctors.

The subject of restricting access to particular medicines is difficult – there are legal and ethical issues involved. A full discussion of all legal matters and the examples from case law goes beyond the scope of this book and this author, but a few key issues will be mentioned. The arrival of the blacklist and greylist in the 1980s restricted the prescribing of a range of branded medicines and of certain products seen as less beneficial, but generally GPs are seen as allowed to prescribe what they believe necessary for their patients. Newdick argues that paragraph 43 of the Terms of Service of GPs makes clear that 'any drugs . . . which are needed' shall be prescribed and that all necessary services should be provided.¹⁹ Newdick was writing before the new general medical services contract, but a very similar paragraph (number 39 in part 3) to that quoted, regarding prescribing, is found in the revised document.²⁰ It could be argued that the thrust of the paragraph is to discuss how prescribing takes place rather than a statute dealing with access to all medicines but, taken with other aspects of the provision of service, Newdick presents a strong case to support a GP's duty to prescribe any medicines needed by their patient. (Paragraph 39 of the GMS contract states: 'Subject to paragraphs 42 and 43, a prescriber shall order any drugs, medicines or appliances which are needed for treatment of any patient who is receiving treatment under the contract by issuing to that patient a prescription form or a repeatable prescription and such a

prescription for or repeatable prescription shall not be used in any other circumstances.')

In terms of the controls on spending in primary care prescribing during the 1990s, he argues that seeking to discipline a doctor for prescribing required medicines that cause indicative prescribing limits to be exceeded would have been unlawful and quotes the government's own words at the time: 'It remains committed to ensuring that patients get the drugs that their doctors judge appropriate to their clinical needs.'²¹ Newdick re-examined the issues in an article in 1998, following the NHS changes announced in 1997.²² He noted the move to increase the involvement of GPs in the allocation of resources but restated the views on the duty to prescribe, although acknowledging there is an argument that restricting access to treatments may be inevitable.

Discussion and influence and a shared approach to rational prescribing, including involving patients in decision making, seem to be the necessary approach in primary care. Where spending exceeds funding owing to a few prescribers using more costly or non-approved medicines, peer challenge and sharing information, rather than issuing edicts, is the way forward.

What is the situation in secondary care? It is worth reflecting on the cases and comment drawn together by Ham and McIver as part of a series on policy dilemmas.²³ They explore five cases where decisions not to treat or to make a therapy available were contested. This was a continuation of the discussion that emerged from the Child B case where a decision not to treat was disputed.^{24,25} Not all the five cases Ham and McIver discuss relate to medicines, but a case of access to Taxol (paclitaxel) and another regarding interferon beta for multiple sclerosis are included. In these two cases the patients' doctors did wish treatment to proceed (in a further case that was challenged, this was not so). These two are therefore pertinent to the discussion on restricting access; both cases related to funding restrictions. The interferon beta case was, however, complicated by the fact that government guidance had been issued; a failure of the health authority to take note of this guidance was an important factor in the decision not to fund being overturned at judicial review. The Taxol case did not get as far as judicial review. The public health advice of the health authority was to decline support for the therapy on the basis of newness and uncertainty of the evidence. This was challenged publicly, as the patient approached the local press. The opinion of a second oncologist was sought. On reviewing the case he commented that the patient was likely to respond to treatment and that toxicity was not a problem. Treatment was therefore funded.

One of the cases regarding medicines and other cases discussed by Ham and McIver involved judicial review.²³ Newdick comments that the courts are very careful about overruling the decisions made by health service managers regarding the use of resources.¹⁹ He quotes Balcombe who ruled at appeal regarding access of a child to treatment, who stated the 'absolute undesirability of the court' to compel doctors or a health authority to make scarce resources available to one particular individual when others might gain more. However, Newdick also states that the courts will consider whether the decision maker allocating resources, refusing to support a treatment perhaps, has acted reasonably. Ham and McIver state that there is a well-established reluctance in English courts to rule against authorities who have decided not to fund a particular service or therapy.²³ However, where guidance has been ignored or a blanket decision taken that ignores the specifics of a case, a court will do so. The onus is on the decision maker to have a robust process of reaching a decision, then to have a mechanism for dealing with cases that may challenge that decision.

For strategic medicines management, the evidence-based appraisal process, supported by good horizon scanning and budget planning, must be the starting point for consideration of a policy that binds all prescribers and means that patients do not normally have access to a particular medicine. If these elements are not in place, then how could a trust claim to have a reasonable prioritisation process? Taking the line that no new medicine should be prescribed until NICE has supported it, is simply not good enough. If these elements are in place and a decision to refuse to support a medicine on the basis of cost-effectiveness or affordability is taken, albeit reluctantly, then a challenge via the courts may not be successful. A general policy of 'medicine x is not available' would also need an appeal or review mechanism for cases where the clinician or patient feels there is particular merit in the treatment in the specific circumstances. Hospital DTCs should consider preparation of explicit policies that have board understanding and backing. Policies should describe how access is restricted, the decision-making process and methods of appeal. Ideally, as has been described in earlier chapters, decisions should be jointly taken across the health community. These are not easy matters and run contrary to the way most healthcare staff wish to work, but as demand exceeds ability to respond, they must be faced. There has often been a focus on access to medicines – indeed, NICE was established in part to prevent variable access across England and Wales but, throughout the health service, decisions are taken each day that prioritise one service or intervention over another. Allowing all patients

to have access to every conceivable medicine that may provide even a diminishingly small benefit, means that there is less resource for nursing staff numbers or wards, access to therapies or even the provision of counselling on how to make best use of the medicines prescribed.

Conclusion

The chapter considers the way in which a number of features of strategic medicines management can be put together to deliver rational, affordable and effective use of medicines. Health communities should seek to work together to achieve this systematic approach. Work evolving in Glasgow was reported in the *British Medical Journal* in 1998.²⁶ Beard *et al.* described their four-pronged approach: encouraging cost-effective prescribing, investing only in 'proved worth' medicines in hospitals, educating the public and joint working across the community. They sought to establish a drug evaluation unit to oversee this programme. These strands and the approaches discussed earlier can form the basis of a coherent local system.

Structures need to be in place – the DTCs. Policies and processes on how decisions will be taken, what restrictions can be placed, rights of appeal and so on should be established. These processes should gain the support of the executives and boards of individual organisations. Rapid, high-quality critical appraisal of evidence to inform decision making should be available, although use of national documents where available can avoid duplication of effort. Systems of induction, education and communication should be in place to support the medicines management process. Expert advice, supported by timely information should be available to the appropriate level of the organisation – practice, locality or directorate. A multiprofessional approach with public and patient involvement is required. The realities of financial constraints should be openly discussed and decisions taken to prioritise use of resources. Regular review of how the systems are working is advisable – North Staffordshire and Southampton felt they had reasonable medicines management, but both reported improvements following their reviews.

An aspect not addressed by either organisation was around risk to patients. Good use of medicines, advice to prescribers, guidelines and so on inevitably have elements related to risk reduction, but a systematic approach should also be considered, which addresses the risks of medicines as well as managing spend. *Building a Safer NHS* addresses a range of aspects relating to the risks of medicines; organisations need to use

this as a tool to inform their medicines management processes.²⁷ Reporting systems, risk assessments, assessing the risks relating to new products, training and education, learning why things go wrong and building safer systems are just some of the building blocks for a safer service.

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