Development and Evaluation of a Primary Care Drug Formulary

MD Thesis 2000
Ian Hill-Smith

PLEASE CHECK CD-ROM IN POCKET
Abstract

Aim
This study asks if practices can collaborate to create a shared formulary, which influences prescribing.

Secondary questions
If so, how long does the effect last? To what degree can such a formulary influence volume of prescribing, choice of treatment and cost? Is there a limit to the number of practices involved before the effect is lost? Are doctors more influenced by the formulary if they are closely involved with its creation?

Method
Controlled trial in two stages. 100 general practitioners from 20 urban and semi-rural practices and 50 community nurses worked with a small team of facilitators to create a formulary. Between 1991 and 1999, prescribing by the participating doctors was compared with the prescribing by all other general practitioners in the county.

Results
Collaborative work resulted in a countywide formulary for primary care. The use of information to support prescribing changed from a few practices using their own formularies, to an evidence-based formulary supported by all five Primary Care Groups in the county. Choice of treatment changed in seven out of thirteen therapeutic groups. Volume of prescribing reduced in three groups. Cost reduced by £3000 per doctor per annum.

Conclusions
Sharing resources between practices to create a primary care formulary can lead to modest changes in prescribing, sustained over three years, and lower overall costs. The largest observed changes were a 14% change in the choice of drugs for musculoskeletal conditions, and a saving of £5000 per practice per year on antibiotics. Such changes, attributed to the development of a formulary, also occur in practices that have no direct involvement, but later by several years. The greatest change in prescribing is seen immediately after a formulary is created and in those involved with its development. The funding
for the work is estimated to amount to 17% of the saving on prescribing. Doctors and nurses from 32 practices can work together on such an intervention.
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Introduction

The Main Question

Can practices collaborate to create a shared formulary that influences prescribing?

This is the main question of this thesis. The hypothesis, that the statistical tests employed attempt to refute, is: Practices can collaborate to create a shared formulary that influences prescribing.

Elements of this question are not original, but their combination and the scale on which the study has been conducted are. Formularies have been fairly extensively studied as one way to change prescribing. The question implies a formulary suitable for primary care but does not exclude recognition of local prescribing policies in secondary care. Collaboration is a key aspect. This is not a study into a practice-based formulary, but one founded on agreement between practices. What is being shared is the research ability needed to create such a formulary. Sharing too, in the decisions that need to be made and in the use of the final formulary. The process and the output must come from inter-practice co-operation, not from external directives or strong leadership within the group. Given this, will it be possible to create a successful formulary, one that is used and one that influences prescribing.

Why it is important

Historical perspective

"It is an absolute obligation on doctors to use only drugs about which they have troubled to inform themselves."

William Withering 1785
After an unknown traveller had revealed the remarkable properties of a herbal tea containing foxglove leaves to William Withering, the use of the plant extract we now call digitalis rapidly became widespread. Many newcomers lacked Withering's skill in titrating the dose of this potent poison and as a result many patients died. Their physicians at the time blamed Withering for introducing such a substance, causing him to conclude

"..shall we wonder then that patients refuse to repeat such a medicine, and that practitioners tremble to prescribe it"¹

One hundred and fifty years passed before the drug became accepted once again. Despite its long history, doctors could not agree about its use.

"I owe my reputation to the fact that I use digitalis in doses the text books say are dangerous and in cases that the text books say are unsuitable." Karel Frederik Wenckebach²

In the times of these quotes, the problem was one of lack of knowledge; nowadays one of the main challenges facing primary care is how to navigate through the plethora of detailed information available to arrive at a point which is of benefit to a particular patient.³⁴ Making information available may not be enough to make it useful. Independent practitioners will continue to echo the distrust of dictum expressed by Wenckebach. This is one aspect of why the question as to whether practices can share resources to create a joint policy is important. Subject matter too large for any one practice to tackle may either be taken on by a larger organisation, or examined by the co-operation of those practices that will be the users of the information. The two approaches can be combined to some extent, by a lead organisation involving end users in development. One example is PRODIGY.⁵ Getting the balance right between central and local support for practitioners is critical for success. The background review in this thesis illustrates many attempts to improve prescribing which have depended for their success or failure on this balance.

Students often prefer their own hand-written notes to textbooks. They may not be as complete or as accurate, but they are personal. The points that were important to the student are stressed, even if they seemed a minor detail to the lecturer or author. Medical education has evolved from passive attendance
at lectures and demonstrations, to early interaction between students and patients with real problems. Life long learning starts earlier and finishes much later than the 5 or 6 years spent at university. Personal learning plans are seen as key to continuing the professional development of doctors and nurses. Information sources need to fit into this educational environment if they are to be effective.

In 1990 the Department of Health recommended that formularies were locally developed and owned, preferably at practice level, and that participation and compliance with them should be entirely voluntary. Creating a local formulary provides a chance for participating doctors to update their knowledge on the pharmacology, use and acceptability to patients of commonly prescribed drugs, and provides a starting point for later discussions of management policies.

Wide variations in prescribing

There is wide variation in prescribing choices. It has always been so, but from time to time it becomes the focus of attention, giving the press ample opportunity to offer the public an image of general practitioners prescribing haphazardly whatever medication happens to be in vogue. When the British National Formulary included a symbol to identify drugs 'less suitable for prescribing' the headline from the Health Correspondent of the Guardian appeared as "£100m BILL FOR WRONG NHS DRUGS". It is not simply a matter of unnecessary expense. Professionals as well as the public find it difficult to understand why there can be so much variation between practices. There is a tendency to assume that all variation results from irrational prescribing, that a practice serving thousands of patients should on average prescribe much the same as any other practice of the same size. This would be an oversimplification of the reasons for variation. There may be good clinical reasons why one practice prescribes differently from another. Even within my own town, the practice running the student health centre would need to prescribe differently from the practice serving residents in local nursing homes, differently again from my own practice, which has twice the national average of pregnancies and children aged under five. Variation in prescribing
between hospitals has been shown to reflect case-mix more than illogical prescribing. Nevertheless, the degree of variation and the choice of some drugs known to be of doubtful value must represent areas where prescribing could be improved.

The Prescription Pricing Authority provides feedback to all general practitioners on levels of prescribing and cost. Although this is useful (indeed this research thesis could hardly have been done without it), feedback based on overall levels of prescribing takes limited account of case-mix and therefore cannot reliably assess what really matters, which is whether prescribing is appropriate or not. I will return to this in the discussion section, but for now the point to note is that variation in prescribing is one indicator that the question as to whether prescribing can be influenced by an inter-practice formulary is important.

The link between rational prescribing and lower costs

In 1994 the Audit Commission reported that more rational prescribing by general practitioners would lead both to better quality care for patients and save £425 million a year, but purely financial pressure to change prescribing, such as through incentive schemes, may prove to be a false economy if treatment is less effective.

Primary Care Groups and Trusts are obliged to have prescribing incentive schemes aimed at improving prescribing and reducing costs. Offering prescribers a financial incentive is just one of the ways to change prescribing. The section reviewing the various methods tried so far goes into this in more depth, but the relevance to the importance of my research question is that currently large funds are allocated to changing prescribing. Luton Primary Care Group has allocated just under £400,000 for the prescribing incentive scheme for the town this year. If better prescribing can result from helping practices to develop their own quality agenda, then money currently used for the incentive schemes nationally might be better used elsewhere.
Clinical governance

While prescribing may be an unusual activity in that improvement in quality may be linked with reduction in cost, the main political and moral objective is to provide every patient with the treatment they need, when they need it, and to avoid harm caused by unnecessary prescribing. Whereas Prescribing Incentive Schemes are inherently financial, other methods of influencing prescribing may offer quality improvements first, with cost savings coming as a bonus.

"The Government will require every NHS Trust to embrace the concept of 'clinical governance' so that quality is at the core."\(^{20}\)

The British Medical Association commented on the above by pointing out the moral dimension.

"Clinical Governance will not introduce radically new or different proposals for doctors. Virtually every duty listed is already covered in the GMC's Duties of a Doctor."

Although Primary Care Groups were set up partly in response to the criticism that the NHS was providing 'care by postcode', this did not at first seem logical, given that they were local organisations. Locally created formularies could be seen as part of the problem, not the way forward. National bodies, such as the National Institute for Clinical Excellence would seem to be the way to ensure quality in prescribing amongst other treatments. However, later government papers gave insight into the balance of national and local clinical governance, which it described as:

"...a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."\(^{21}\)
Far from replacing local initiatives, clinical governance was to depend on such activities to draw upon nationally available information in such a way that it could be integrated with clinical practice:

"We need consistent action locally to ensure that national standards and guidance are reflected in the delivery of services."\textsuperscript{21}

Creating a primary care formulary is one example of this, but does it achieve the aim of clinical governance? This question needs answering if we are to get the balance right between national, local and practice-based information.\textsuperscript{22}
Secondary Questions

1. If the formulary does influence prescribing, how long does the effect last?
2. To what degree can such a formulary influence the volume of prescribing, choice of treatment and cost?
3. Is there a limit to the number of practices involved before the effect is lost?
4. Are doctors more influenced by the formulary if they are closely involved with its creation?

Each of these questions can be stated as hypotheses by setting limits to the degree of change that would be considered of interest and then attempting to refute each hypothesis using statistical methods. While this would be a valid approach it would be less useful than considering these question in a more qualitative way. For example, it would be helpful to know if a shift in the choice of drugs prescribed in a therapeutic group took effect immediately after a formulary event, and then decayed over a certain time. Whereas it would be less helpful to know the result of a test against a hypothesis that such a change in prescribing lasted for a particular and arbitrary length of time.

These secondary questions are formulated to help future planning of formulary events, either in Bedfordshire or elsewhere. There can be no certainty that the answers obtained from the process adopted in Bedfordshire will apply elsewhere to a process that will have variations or major differences. In the discussion section I shall deal with this issue of how generalisable the findings are. If some degree of generalisable knowledge can be extracted from the results, then questions that face others in setting up a primary care formulary using shared resources might be easier to answer. Practical issues gave rise to the secondary questions listed above. Examples are:

- Will review meetings be required to maintain an effect on prescribing?
- If so, how often will they be needed?
- Is it reasonably likely that a formulary could improve care to a degree that could be assessed by firm end-points?
- How long after the formulary creation could such end-points be measured?
- Is it worth assessing volume of prescribing, or is a formulary only likely to change choice of treatment?
- How much time and money can be spent creating such a formulary without making a loss?
- Would it be better to limit the creation of the formulary to one Primary Care Group / Trust area, or to share it across several?
- Is there an advantage in involving doctors in the process of creating the formulary?

The last question in each of the above lists is restricted to doctors because so is the prescribing data in this study. It would be an assumption to extend any finding on this to the nurses who took part in the formulary creation and use.

**Limitations of the questions**

Certain aspects to these questions could be interpreted as very wide ranging, but all studies must limit the scope of their aim. My main boundary in this thesis is that I am not considering why doctors and nurses change their prescribing. This would be a major study in itself. All I have attempted to do is to test one method of creating a formulary to see if it does change prescribing. While feedback and comments from participants has helped to define the methods used to drive the process, this is not presented as data nor evaluated. It is included in sections on methods and discussion to illustrate how the process was fine-tuned to maximise its potential.

A second limitation to the questions is included in the phrasing. The main question asks 'can practices collaborate..?' Demonstrating one example of practices collaborating successfully would provide an answer: yes, it is possible. If the study were to show no effect on prescribing, then this would not discount the possibility, but simply fail to answer it. Quite a different question would be required to say whether any group of practices could collaborate to create an effective formulary. The difference is important. Showing that a particular group of practices can collaborate would suggest that running the process to create a formulary in a similar way could also be productive. Whereas different process, which selected practices instead of giving them the opportunity to volunteer, might or might not result in productive co-operation. This study cannot inform such a process.
Unlike randomised controlled trials in which questions or hypotheses are designed to maximize the general application of the results across all cases, this study on the creation of a formulary asks a more limited question. However, I believe the limited question to be more important. Adult education, including life-long learning for nurses and doctors, offers a wide range of different methods of learning and can be more effective if the method is matched to both the learner's requirements and the subject\textsuperscript{9,23-26}. Systematic practice-based interventions and outreach visits are seldom used by CME providers, but there is evidence that such methods are more effective educational tools than traditional lectures\textsuperscript{27-30}. The formulary process made use of small group discussions and feedback to individuals and practices on their prescribing. Under these circumstances it is the limited question which is relevant. Asking a more general question might miss any effect that would naturally occur in a non-experimental setting with volunteer practices, and pre-selection of practices could, in theory, invalidate the findings on a random selection of practices, which would by chance be more diverse.

There are limitations to the secondary questions too. If any effect lasts longer than the total duration of the study, nine years, then it will not be possible to say how much longer such an effect might last. Similarly a limitation to the number of practices involved can only be found if it is below the twenty taking part in this study at its close. Further information may be available later because the formulary is now countywide, but this would require collection of data comparing this county with another.

The degree to which the formulary affects costs is limited to prescribing costs. So if a doctor opts for fewer prescriptions for non-steroidal anti-inflammatory drugs after discussing potential side-effects in one of the formulary meetings, and his volume of prescribing drops in comparison with control levels, then this will be shown as a saving in costs. What is hidden from this limited view is the possibility that the doctor opts for more referrals to a physiotherapist or osteopath. Overall costs to the health service or to the patient are not included in the question. Nor is the choice of treatment other than drug treatment. The only aspects that are included in the study are whether the formulary causes prescriptions to be written for different drugs or none at all.
Finally, the question whether close involvement with the formulary process is associated with a greater effect on prescribing is limited to asking if partners within a practice who attended meetings changed their prescribing more than partners who received copies of the formulary and gave consent for their prescribing to be monitored, but who did not attend meetings. Such a question is limited to doctors, not nurses for whom no prescribing data is yet available.
Background

**Reasons for attempting to influence prescribing**

There is plenty of evidence for room for improvement in prescribing\(^\text{17, 18, 31-35}\). There are issues of quality in prescribing\(^\text{21, 36-39}\) and cost-effectiveness\(^\text{11, 16, 40-44}\). Much has been made of the wide variation in volume and cost of prescribing between practices from the prescribing data available to Health Authorities and Primary Care Groups and through national audit\(^\text{18}\). But many criticisms have failed to take adequate case-mix and other practice-specific factors\(^\text{45-48}\), which have been estimated to account for 51%\(^\text{49}\), 81%\(^\text{50}\), or even 97%\(^\text{43}\) of the variation. Similar findings have been found in the secondary sector\(^\text{17}\). Now that Primary Care Groups (PCGs) have responsibility for clinical governance and prescribing budgets, interventions which are known to have an influence are likely to be used within the geographical area of a PCG\(^\text{51}\).

**Methods of influencing prescribing**

Prescribing has been shown to respond to a variety of interventions, including the development of local formularies and contact with other health professionals, notably pharmacists. A formulary can be seen as occupying the middle ground between a set of guidelines in therapeutics and a limited list of recommended drugs aimed at reducing prescribing costs. If it can achieve both an improvement in quality and a reduction in prescribing costs, all to the good. However it is only one of many methods of influencing prescribing and the following sections put it into the perspective of what is known in more general terms about the options for education and guidance.

This is the point at which to note that although it may seem inefficient for many different groups to be working on primary care formularies, education, discussion and contact with colleagues from other disciplines during the development of a formulary is an important and intrinsic part of the process, likely to play a major part in any effect of the formulary. The National Institute...
for Clinical Excellence has recognized that for central guidance to be effectively implemented it will need the support of local initiatives.

Before considering specific interventions that might influence prescribing, I would like to sketch the backdrop against which extra influences play. There are many continuing influences on doctors' prescribing decisions. The presence of these emphasises the need for baseline comparisons and control data when evaluating any method of changing prescribing. Natural fluctuations in the background influences can obscure, reverse or apparently enhance changes resulting from an intervention. I was therefore surprised to find a large number of uncontrolled, short-term before and after studies on prescribing interventions both in the literature and at a conference on this subject at the Royal Pharmaceutical Society of Great Britain.

The backdrop of continuing influences is summarised in the Tables 1 - 3, which are based on a focus group discussion of GPs, researchers and health economists held at the Department of Health on June 8 2000. I have omitted some of the outdated or particularly minor influences, and attempted to rank the influences roughly into the order of relative importance. Some tables I have combined to give an impression of where national and local work corresponds. Some items appear in more than one table, and even those that are listed just once have some influences in other areas.
<table>
<thead>
<tr>
<th>Guidance</th>
<th>National</th>
<th>Local</th>
</tr>
</thead>
<tbody>
<tr>
<td>British National Formulary</td>
<td>Formularies - District, Primary Care Group / Trust, Practice, Hospital</td>
<td></td>
</tr>
<tr>
<td>National prescribing centre and MRec bulletins*</td>
<td></td>
<td></td>
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<tr>
<td>Drug and Therapeutics Bulletin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription Pricing Authority Bulletins and data*</td>
<td>Primary Care Group / Trust Pharmaceutical Advisor - Newsletter, contacts, prescribing feedback, practice budget</td>
<td></td>
</tr>
<tr>
<td>National Institute for Clinical Excellence Guidelines and product appraisals*</td>
<td>Health Authority / Regional Prescribing advice</td>
<td></td>
</tr>
<tr>
<td>Scotland SIGN - used in England</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Evaluation Committees*</td>
<td>Joint sector prescribing committee</td>
<td></td>
</tr>
<tr>
<td>International and national guidelines*</td>
<td>Local disease / referral guidelines*</td>
<td></td>
</tr>
<tr>
<td>Committee on Safety of Medicines Bulletins</td>
<td>Independent pharmaceutical advisors</td>
<td></td>
</tr>
<tr>
<td>PRODIGY*</td>
<td></td>
<td></td>
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<tr>
<td>National Performance Framework</td>
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<tr>
<td>Nation Service Framework</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public Health / Immunisation targets</td>
<td>Health Improvement Programme</td>
<td></td>
</tr>
</tbody>
</table>

* = Now closely linked to National Institute for Clinical Excellence  
e = also available in electronic form

Table 1. Sources of guidance on prescribing
<table>
<thead>
<tr>
<th>Drug Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Independent</strong></td>
</tr>
</tbody>
</table>
| British National Formulary  
Independent research in peer-reviewed journals  
Cochrane Database  
Bandolier  
Drug and Therapeutic Bulletins  
Primary Care Group Pharmaceutical Advisors  
Prescribing data (PACT)  
National prescribing centre and MRec bulletins*  
Continuing Medical Education  
Drug Information Bureau  
Textbooks  
Courses on pharmacology  
Clinical Audit Projects / MIQUEST | Monthly Index of Medical Specialities  
Data on file  
Data sheet compendium  
Trade press and Advertising  
Company representatives  
Sponsored Medical Education  
Company information centre  
Sponsored audit |

* = Now closely linked to National Institute for Clinical Excellence  
e = also available in electronic form  

**Table 2. Sources of information on drugs**
<table>
<thead>
<tr>
<th>Drivers external to the practice</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Quality Drivers</strong></td>
<td><strong>Incentives</strong></td>
</tr>
<tr>
<td>Primary Care Group: Peer pressures,</td>
<td>Prescribing Incentive Scheme</td>
</tr>
<tr>
<td>prescribing monitoring,</td>
<td>Generic prescribing targets</td>
</tr>
<tr>
<td>pharmaceutical advisor contacts,</td>
<td>Repeat prescribing protocols</td>
</tr>
<tr>
<td>Health Improvement Programme</td>
<td>Doctor awareness of prices</td>
</tr>
<tr>
<td>Clinical Governance 'Quality is statutory'</td>
<td>Less risk of litigation and</td>
</tr>
<tr>
<td></td>
<td>'defensive medicine'</td>
</tr>
<tr>
<td>National Institute for Clinical Excellence</td>
<td></td>
</tr>
<tr>
<td>Evidence-based healthcare</td>
<td>Practice prescribing budget</td>
</tr>
<tr>
<td>Red book rules</td>
<td>Profits from vaccine purchase,</td>
</tr>
<tr>
<td></td>
<td>administered drugs and dispensing</td>
</tr>
<tr>
<td>National Service Framework</td>
<td></td>
</tr>
<tr>
<td>Commission for Health Improvement</td>
<td>Revalidation</td>
</tr>
<tr>
<td>Clinical Audit Programme</td>
<td>Prescribing data feedback</td>
</tr>
<tr>
<td>National Patient and User Survey</td>
<td>Media and better informed, more</td>
</tr>
<tr>
<td></td>
<td>demanding patients</td>
</tr>
<tr>
<td>University Education</td>
<td>Postgraduate qualifications</td>
</tr>
</tbody>
</table>

**Table 3. Sources of influence on prescribing external to practices**
Systematic Review

The next section includes a systematic review of trials on interventions aimed at changing prescribing in primary care. Criteria for inclusion in the review were as follows:

- influence on primary care prescribing - direct or indirect
- intervention targeted at prescriber - doctor or nurse - direct or indirect
- type of intervention as described by Gill et al\textsuperscript{52}

"That is distribution of educational materials; conferences or educational meetings; interventions that involve locally deriving consensus recommendations; educational outreach visits that take place in the participants' location; the influence of local opinion leaders (educational influentials); patient mediated interventions in which information given to or received from patients is intended to influence professional practice; audit and feedback where physicians receive summary information on their practice over time; reminder systems where physicians receive specific reminders at the time of intervention to enhance particular strategy or behaviour; marketing, in which physicians are targeted by interventions similar to those used to market commercially specific desired practices." \textsuperscript{52}

Although Gill cited criteria from a review in the Cochrane Library, which has since been updated\textsuperscript{53}, the criteria I have used are based on the above criteria plus interventions where no written education materials were mentioned.

Non-randomised studies on doctor behaviour

I chose not to specify a study design criterion. Most systematic reviews look at randomised controlled trials. The great advantage of this design is that the results are more easily applied in general. Non-randomised studies may show an effect which only applies under the particular circumstances of the study. Despite this, to exclude non-randomised studies misses important information. Prescribing behaviour will inevitably depend on the characteristics of the person prescribing. Randomisation of people into a trial will misalign some
people into groups in which their preferred behaviour will be thwarted, for example an enthusiast for pharmacology audit being allocated to a control group receiving no support for changing prescribing, and vice versa. If randomised controlled trials show no cost-effective outcome from educational intervention\textsuperscript{53}, the natural conclusion would be to avoid wasting time on such interventions on a wider scale. However, such interventions could be effective when applied in a non-random way, and in practice this is what happens. The recipient largely determines choice of continuing education. If only those who choose to take part change their prescribing as a result, then the information gained from randomised studies is misleading.

There is a need to balance the interests of research, development and practice\textsuperscript{54}. The development of the formulary in Bedfordshire provided the ground for a 'natural' experiment to test the effect of collaboration and sharing of resources. Randomising practices to participate or not would have excluded some interested practices from a major educational event. Practices selected as participants, but less interested in developing a formulary, might have had problems collaborating with others.

**Search Strategy**

A variety of search strategies were used. Electronic searches were most useful for recent literature. Reviews and meta-analyses were targeted first and those found provided many more references to original research. A broad search was used to capture a variety of interventions aimed at influencing prescribing, not just formulary development. Articles on both primary and secondary care were accepted initially. Some centred on secondary care had influences on primary care prescribing, but those of little relevance to primary care were excluded from further review. The specific strategies, given in Table 4, aimed at finding articles that evaluated an intervention in terms of prescribing either numerically – number of items, cost, degree of acceptance of guidelines or formulary – or qualitatively, based on opinions, acceptability, impact on clinical freedom, and perceived usefulness. The quantitative research papers had a more direct influence on the evaluation methods adopted for the Bedfordshire formulary. The qualitative papers were relevant
to the methods we used for the intervention. Only minor details of how the Bedfordshire formulary is developing have changed in the past nine years. The core activities of providing and a forum for discussion, literature research and feedback on prescribing for the development group, have been constant.

**Electronic sources**

The electronic searches were done using

- Medline 1966 - 2000
- EMBASE 1988 - 2000
- Cochrane Library 2000 Issue 2 from 1966
- British Medical Association library database from 1966

**Human sources**

Further assistance was forthcoming from librarians at Luton & Dunstable Hospital and the British Medical Association. People working in the field and supervisors of the work on this thesis, suggested other articles. Older references, unpublished work and obscure publications were obtained from personal contact with academic departments of general practice, the national prescribing centre, personal contacts at national conferences, focus groups and reviewers of papers submitted as part of the formulary work.
The right-hand column in Table 4 is the number of useful references obtained after assessing all 401 found by the strategy.

<table>
<thead>
<tr>
<th>Search Strategy</th>
<th>Number Meeting Review Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 journal of medical education AND prescriptions, drug</td>
<td>15</td>
</tr>
<tr>
<td>2 prescriptions, drug (exploded) limited to review</td>
<td>18</td>
</tr>
<tr>
<td>3 BMA standard search for all reviews, meta-analyses and systematic reviews AND prescriptions, drug</td>
<td>24</td>
</tr>
<tr>
<td>4 BMA standard search for Randomised Controlled trials AND prescriptions, drug</td>
<td>32</td>
</tr>
<tr>
<td>5 education, medical, continuing AND prescriptions, drug</td>
<td>42</td>
</tr>
</tbody>
</table>

Table 4. Search strategy for the systematic review

Review

The review reference list includes those studies that support the background to this thesis and meet the criteria given above. The scoring system in Table 5 is based on that proposed by Johnson et al\textsuperscript{55}. I added two extra parameters: S for sample size and D for duration as these are features which affect the power of studies on interventions to affect prescribing. An original parameter for follow-up rate was removed as it would be inappropriate in this context. The zero score for unit of sample was originally 'patient or family'. This was changed to 'unspecified'. Maximum score is 12.
<table>
<thead>
<tr>
<th>Symbol</th>
<th>Parameter</th>
<th>Scoring criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Sample size</td>
<td>0 = one unit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = 2 - 5 units</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = &gt;5 units</td>
</tr>
<tr>
<td>U</td>
<td>Unit of sample</td>
<td>0 = unspecified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = doctor or nurse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = practice, clinic, district</td>
</tr>
<tr>
<td>R</td>
<td>Randomisation</td>
<td>0 = selected / concurrent / historical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = quasi-random</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = randomised</td>
</tr>
<tr>
<td>B</td>
<td>Baseline</td>
<td>0 = no statement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = differences unadjusted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = none / adjusted</td>
</tr>
<tr>
<td>O</td>
<td>Outcome</td>
<td>0 = no explicit criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = subjective / not blind</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = objective / blind</td>
</tr>
<tr>
<td>D</td>
<td>Duration</td>
<td>0 = &lt;1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = 1 - 2 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = &gt;2 years</td>
</tr>
</tbody>
</table>

Table 5. Scoring of papers in the systematic review

The first two parameters give a weight to the size of the sample studied. At least 6 practices would need to be included for a study to score the maximum of 4 on these two parameters. Randomisation increases the general applicability of the results and is scored 2 for formal randomisation, 1 for methods which include some degree of randomisation. All non-randomised studies score zero. Baseline scores reflect whether the effect studied is compared with non-intervention activity, either on a historical basis or a simultaneous comparator. Outcome in the case of educational interventions was not studied blind, so the score for this parameter depended on whether the outcome had been clearly defined, such as a change in the choice of drugs prescribed or the cost of medication. Duration is important in this field because of the effect of season variation in prescribing and the chance that an intervention may give rise to immediate but short-lived effects. Studies under
one year in length could not adequately take account of these difficulties and score zero.

The results of the review are in the **Review References** section, near the end of the thesis, just before the Main References section.

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**What is known from previous research**

**Education**

Randomised studies have not shown a clear effect of written material in influencing prescribing\(^52,53\). Strategies that rely primarily on dissemination of advice, particularly if unsolicited, show no effect\(^56-59\). There are exceptions to this when information concerns a narrow range of drugs with a particular prescribing problem, such as over-prescribing of antibiotics\(^60-62\), under-prescribing of antidepressants\(^63\) or tranexamic acid\(^64\), or a particular problem in the public interest\(^60,65\). There are studies that show no effect of newsletters even under these circumstances\(^66\).

Curiously the same intervention of an educational bulletin on the same group of GPs influenced knowledge and intentions to prescribe for renal colic but not irritable bowel syndrome\(^67\). This may have been because the content of the advice on renal colic was perceived as being more evidence-based. Targeted guidance, such as writing to the doctors of patients receiving drugs less suitable for prescribing, can reduce inappropriate prescribing\(^68\).

Formularies are educational if the prescribers are involved in development or maintenance. Under these circumstances prescribing changes in participants\(^69-73\). The studies on formularies developed in this way find a shift toward prescribing drugs within the formulary and a reduction in drug costs. Sometimes this was an inevitable finding because the formulary was based on existing prescribing of a practice or small group, reinforcing behaviour rather than presenting any challenge to reconsider the evidence and change\(^74-76\).

Recommendations to start creating a formulary in this way\(^76,77\) are misguided. Evidence for formularies influencing prescribing when the users are not the
developers is much less strong. The adherence to a formulary will depend on the area of coverage. A narrow formulary of first line drugs will show much lower levels of adherence than a broader formulary offering more choices. Special function formularies, such as for emergency drugs or out-of-hours cover, may show high levels of adherence if the demand for alternative treatment is low, or low levels of adherence if the formulary is bypassed by alternative sources of drugs, such as samples supplied to deputising services.

Visits by pharmacists and clinical pharmacologists to provide general advice and education are not effective unless linked to prescribing feedback, or a specific problem, such as dose adjustment of allopurinol, or the overuse of antibiotics for viral illnesses, or use of drugs less suitable for prescribing. The strongest effects have been detected when a colleague from the same profession visits. Small group discussions and 1- or 2-day workshops are effective, in contrast to didactic style, or conventional lecture type education. This may depend on cultural background and what is expected of education.

Involvement of prescribers can be done through mailed questionnaires and nowadays via the Internet. This is more likely to achieve a change than simple distribution of advice, particularly in younger GPs. This is necessary because doctors are slow at implementing change following publication of evidence based research. The use of prophylactic aspirin is unquestionably valuable, and yet in 2000 only 78% of patients in Luton who should be taking aspirin are doing so. Similarly the use of beta-adrenoceptor blocking drugs after myocardial infarction has been 20 years in gaining acceptance despite good clinical trials.

Continuing education is influential if sufficiently structured. Doctors will usually choose this education for themselves, so this may miss those less interested in prescribing matters who have most to gain.

Publicity campaigns may be more effective if aimed at both professionals and the public simultaneously, thereby increasing demand and perceived demand at the time information is provided to support prescribing.
Health Authorities can utilise the work of pharmaceutical company representatives, but no changes in prescribing result.

Feedback

Feedback influences prescribing if it is specific to a prescriber, especially if it identifies a specific problem of that individual's prescribing, or if presented by a pharmacist personally. The effect is lost after 2 years when doctors have become tolerant to receiving feedback in the same format.

Critical events provide an opportunity for education through review. This is practical only within a culture of shared information on prescribing, where it can achieve a change in about half the doctors who declare they intend to change prescribing as a result of feedback about a particular event. Shared prescribing data within Primary Care Groups may make this easier in Britain, but the public image of a profession organising education on the basis of failures may not be easy to sustain. A more proactive approach would need to be used in parallel.

Suggesting simple generic substitution to reduce costs has been effective, more complex unsolicited advice is ignored.

The evidence for feedback on prescribing producing change in subsequent prescribing towards higher quality indicates that there is willingness on behalf of professionals to improve given a guide as to where to make the improvements. This is important for the future of financial incentive schemes, which risk undermining the professional ethos of continuing professional development to achieve high quality care for non-financial rewards. The cost of the schemes to the Health Service may be seen as a poor way to use money, even by the people who receive it. Some GPs expressed this view at the Department of Health focus group on 8 June 2000.
Prescribing support

Providing information intended for use at the time of prescribing is a method dependent on reference material rather than education which aims to prepare a prescriber with knowledge to make informed decisions. Until recently, such reference material has been printed, but increasingly it is becoming available electronically. This brings the usual advantages of fast searching through electronic forms of indexes and scanning software, instant updating, together with the important advantage that prescribers can access information 'just-in-time'. Information can be presented automatically by cross-referencing to diagnostic or prescribing data at the time of entry on to a clinical computer system. Simulated cases have shown such methods to affect prescribing decisions. The use of a computer to prescribe is associated with lower costs.

Financial

Every Primary Care Group / Trust is required to support a prescribing incentive scheme. Thus the prevalence of such schemes is not evidence for their effectiveness, as is sometimes stated.

Financial savings as a result of lower prescribing costs can accrue to the practice. Formularies have achieved this in the past both before and after the introduction of fundholding. Stepped formularies where cheaper drugs are tried first before more expensive drugs may be effective in reducing costs; even when there is no effect on the volume of prescribing. In general, those formularies which influence prescribing choices will reduce costs.

Knowledge of costs influences prescribing decisions. GPs are becoming more aware of the cost of drugs and this is playing an increasing part in prescribing decisions.

The way in which doctors are paid alters the likelihood that an intervention will change prescribing. A variety of methods, which have been successful.
elsewhere, failed to change prescribing within a prepaid group practice in Canada\textsuperscript{117}. Private primary care doctors in the United States were unaffected by an educational feedback intervention that did change the prescribing of the health maintenance organisation in the same area\textsuperscript{118}.

**Health**

There are relatively few studies assessing the health of patients following an intervention to improve prescribing. Mostly surrogate measures have been used as endpoints, but May et al showed both a 28% reduction in the prescribing of non-steroidal anti-inflammatory drugs and a 70% reduction in the rate of admission for drug associated gastro-intestinal disorders\textsuperscript{119}.

**Regulation**

Statutory regulation can have a large and rapid effect on prescribing; for example the introduction of the 'black list' of drugs not available from the NHS. Less formal advice can have a major impact. Recent examples include central advice on treatment for sexual dysfunction in men and prescribing for influenza. The National Institute for Clinical Excellence has a major role in future recommendations, but controversies over the legal and political issues of market regulation may be a stumbling block. The Prescription Price Regulation Scheme was renegotiated in 1999 with a reduction in the cost of branded medicines of just over 4%, but the pharmaceutical industry were free to adjust relative prices of drugs. This resulted in some odd pricing structures; for example only one dose of the metered dose inhaler of Flixotide was reduced while the other retained at a premium price. The sudden increase in cost of generic products swallowed up funds intended for modernisation of the health service. These swings will influence prescribing choices. Interventions aimed at reducing costs will need to take account of such changes. If prices fluctuate on a shorter time-scale than most interventions, then recommendations based on value for money become unsustainable. Over the next four years until the next regulation scheme review, the Department of Health is considering the assertion coming from industry that competition and
a free-market are now sufficient to control the NHS drug bill, as it does in some other European countries.

**Review summary**

Table 6 summarises the findings from the systematic review. Various methods of influencing prescribing are listed in the left hand column. In the middle column are the review scores of the papers supporting the method having an influence on prescribing. In the right hand column are the review scores of the papers showing no effect. The order of the rows starts with the method with the most evidence for influencing prescribing at the top, going down to the least at the bottom. The order is only a guide based on the score totals. Some methods have scores in both columns, which reflects the method being effective only under certain circumstances, or inconclusive evidence as to whether there is any influence on prescribing or not.
<table>
<thead>
<tr>
<th>Method</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Influence</td>
</tr>
<tr>
<td>Formulary development by prescriber</td>
<td>10\textsuperscript{59}, 9\textsuperscript{62}, 8\textsuperscript{70}, 8\textsuperscript{12}, 7\textsuperscript{74}, 7\textsuperscript{73}, 6\textsuperscript{115}, 5\textsuperscript{41}, 4\textsuperscript{78}, 3\textsuperscript{75}</td>
</tr>
<tr>
<td>Continuing professional education</td>
<td>11\textsuperscript{61}, 11\textsuperscript{100}, 10\textsuperscript{96}, 10\textsuperscript{83}, 8\textsuperscript{65}, 8\textsuperscript{61}, 4\textsuperscript{120}</td>
</tr>
<tr>
<td>Feedback on prescribing</td>
<td>12\textsuperscript{104}, 11\textsuperscript{118}, 10\textsuperscript{99}, 10\textsuperscript{103}, 10\textsuperscript{82}, 9\textsuperscript{101}, 9\textsuperscript{68}, 9\textsuperscript{62}</td>
</tr>
<tr>
<td>Drug educator visit to prescriber</td>
<td>11\textsuperscript{83}, 10\textsuperscript{64}, 10\textsuperscript{119}, 8\textsuperscript{66}, 8\textsuperscript{85}</td>
</tr>
<tr>
<td>Pharmacist visit to prescriber</td>
<td>11\textsuperscript{58}, 10\textsuperscript{36}, 9\textsuperscript{80}, 9\textsuperscript{101}, 7\textsuperscript{61}, 4\textsuperscript{84}</td>
</tr>
<tr>
<td>Computer support</td>
<td>8\textsuperscript{113}, 8\textsuperscript{84}, 7\textsuperscript{114}</td>
</tr>
<tr>
<td>Individualised teaching using critical events</td>
<td>10\textsuperscript{86}, 9\textsuperscript{105}</td>
</tr>
<tr>
<td>Therapeutics discussion group</td>
<td>10\textsuperscript{88}, 5\textsuperscript{71}</td>
</tr>
<tr>
<td>Information campaign</td>
<td>10\textsuperscript{60}, 5\textsuperscript{97}</td>
</tr>
<tr>
<td>Problem-based learning</td>
<td>10\textsuperscript{95}, 5\textsuperscript{92}</td>
</tr>
<tr>
<td>Providing doctors with information on drug costs</td>
<td>7\textsuperscript{116}, 7\textsuperscript{106}</td>
</tr>
<tr>
<td>Doctor - patient discussion group</td>
<td>10\textsuperscript{89}</td>
</tr>
<tr>
<td>Doctor visit to prescriber</td>
<td>8\textsuperscript{66}</td>
</tr>
<tr>
<td>Media attention (slow change)</td>
<td>7\textsuperscript{93}</td>
</tr>
<tr>
<td>Pharmacist review of medication</td>
<td>5\textsuperscript{102}</td>
</tr>
<tr>
<td>Health Authority - Industry partnership</td>
<td>10\textsuperscript{98}</td>
</tr>
<tr>
<td>Drug bulletin</td>
<td>11\textsuperscript{118}, 10\textsuperscript{90}, 10\textsuperscript{67}, 7\textsuperscript{93}, 6\textsuperscript{57}, 8\textsuperscript{66}</td>
</tr>
</tbody>
</table>

Table 6. Summary of findings of the systematic review
Method

Developing the formulary

Participants

South Bedfordshire GPs
The first cohort of participating practices was invited. At least one partner from each practice was a member of the South Bedfordshire Practitioners' Group, a collaboration of GPs with a ten year history of research, developing out of a young practitioners' group originally set up to offer mutual support.

Out of 300 general practitioners in Bedfordshire, 50 participated and the remaining 250 formed the control group. The participating doctors were from 11 urban and semi-rural practices. Twenty-seven general practitioners attended at least one of the formulary meetings and every practice had at least one participating partner. Everyone received copies of the formulary. All practices agreed to participate, to help create the formulary, and all but one partner gave signed consent to allow analysis of prescribing data. The practice with a dissenting partner could not be included in the analysis. Two practices dispensed a minority of their prescriptions.

North Bedfordshire GPs
The second cohort, from a different area of the county, had no formal contact with the development that had been occurring in the South. By 1995 the formulary in the South had been established, but it had been achieved by a group of practices that were accustomed to collaborative work. Could the same be achieved in a different part of the county where no such prior group co-operation existed? To find out, an initial presentation at the postgraduate institute in Bedford launched an invitation to practices in the area. Nine responded as being willing to participate in developing a primary care formulary along the lines of the South.
Whereas the South's formulary had used 3 previously published formularies to seed the shortlist of drugs to be considered, the most up-to-date formulary was now the South Bedfordshire Primary Care Formulary, which was adopted as the shortlist source. In all other respects the process was the same for both cohorts.

**Nurses**

Nurses started coming to the formulary meetings in 1996, when wound care items were included. Over the following four years a total of 50 nurses attended at least one meeting. They were either district nurses or practice nurses. Most worked with one of the subject practices. As the wound care section enlarged and became more widely known in the nursing community, nurses from non-participating practices joined. By February 2000 nurses had attended from 12 practices not in the above cohorts. Thus in total 32 practices have contributed to the formulary to date.

**Timing**

Formularies were distributed to all participants and their partners automatically on New Year's Day for each year. In the initial years for each cohort, when only part of the range of therapeutic groups had been considered, partial formularies were distributed. Prescribing data for the therapeutic groups covered was collected for analysis with the exception of wound care products, which were a later addition to the formulary. The first quarter of every year was used throughout to avoid seasonal variations. The first data set January - March 1991 was prior to any development work on the formulary.
<table>
<thead>
<tr>
<th>Year</th>
<th>South Cohort</th>
<th>North Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>Baseline prescribing data obtained. Development of formulary for therapeutic groups: 2 Cardiovascular 3 Respiratory 10 Musculoskeletal</td>
<td></td>
</tr>
<tr>
<td>1992</td>
<td>1 Gastrointestinal 4 Nervous 5 Infections 6 Endocrine 7 Obs &amp; Gynae 8 Nutrition &amp; Blood</td>
<td></td>
</tr>
<tr>
<td>1993</td>
<td>11 Eye 12 ENT 13 Skin 15 Anaesthesia Development of South formulary complete.</td>
<td></td>
</tr>
<tr>
<td>1994</td>
<td>Update</td>
<td></td>
</tr>
<tr>
<td>1995</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1996</td>
<td>A8 Wound Care Publication of results Update - drugs</td>
<td>Baseline prescribing data obtained. Development of formulary for therapeutic groups: 1 Gastrointestinal 2 Cardiovascular 3 Respiratory 10 Musculoskeletal</td>
</tr>
<tr>
<td>1997</td>
<td>4 Nervous 5 Infections 6 Endocrine 7 Obs &amp; Gynae 8 Nutrition &amp; Blood 11 Eye 12 ENT 13 Skin 15 Anaesthesia A8 Wound Care Development of North formulary complete.</td>
<td></td>
</tr>
<tr>
<td>1998</td>
<td>Prescribing data collected to assess effect on North cohort.</td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td>Process to combine formularies</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>New formats developed</td>
<td>Update - drugs Process to combine Wound Care section with county education programme Update - Wound care</td>
</tr>
</tbody>
</table>

Table 7. Formulary development 1991 - 2000
Aim of formulary

The aim was to include drugs that would be first-line treatment for 80% of all conditions seen in primary care. So if a doctor entirely agreed with the formulary, 80% of the prescriptions that doctor issued would be for drugs in the formulary. Such an aim is arbitrary, but necessary to define the intended scope of the formulary. The structure of the formulary was to be a list of drugs indexed according to the classification used by the British National Formulary, with notes explaining the reasons for the selection. Page numbers were avoided to allow for easy replacement of updated pages. The latest version of the formulary is on the CDROM included as part of this thesis. Instructions for use are in Appendix A.

Preparation prior to meeting

Drugs in any of three published primary care formularies13, 14, 15 seeded a short-list for inclusion in the new formulary. A single sheet summarising information on each drug was sent to every participant prior to each meeting. Information was drawn from the British National Formulary, the drug data sheet, primary care and local hospital formularies. Participants reviewed this information before sending proposals for additional drugs or recommendations to exclude drugs on the short-list. Reasons were invited on single page, structured questionnaires, which were sent to the pharmacist, who then researched the corresponding evidence. The forms are in Appendix B, with electronic versions forming part of the formulary on the enclosed CDROM and recommendations can be made online at www.wlhc.demon.co.uk. This system targeted the time of the pharmacist to searching for the information relevant to the issues that would be raised by the participants at the meeting. At the meeting, the literature research findings were discussed, and a vote was taken on each proposal. A drug was included in the formulary if it achieved a simple majority.
Schedule of events

The timing of events needed to take account of the following:

- doctors and nurses needed to be introduced to a vision of the final primary care formulary so they could make appropriate proposals.

- they also needed to decide on the process by which such a formulary could be achieved at the outset.

- new participants would join the group who would need to be aware of the above, so the information had to be re-iterated or made apparent through clear correspondence allowing sufficient time for them to catch up.

- proposals and exclusions had to be received by the pharmacists sufficiently in advance of each meeting to allow time to research the evidence.

- meetings had to be held at a time and place convenient to doctors and nurses who were likely to have a full clinical commitment.

- the amount of time available to the participants limited the coverage of any one meeting to discussion of a single major therapeutic group such as cardiovascular drugs or wound care.

- smaller chapters of the British National Formulary, for example those dealing with conditions of the ear and eye, could be covered in one meeting.

- to allow comparison of prescribing influences with minimal influence of seasonal variations in disease, formularies had to be distributed at the same time of year.

- any possible advantages of the formulary would be delivered earlier if therapeutic groups more likely to permit a change in prescribing, such as those covering medication for common, acute, short-term conditions, were tackled first, and this could also encourage interest.
Table 8 shows the initial schedule for events in the South of the county.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 September 1991</td>
<td>Introductory Meeting</td>
</tr>
<tr>
<td>3 October 1991</td>
<td>Deadline for receiving proposal and exclusion forms</td>
</tr>
<tr>
<td>17 October 1991</td>
<td>Musculoskeletal drug meeting</td>
</tr>
<tr>
<td></td>
<td>8pm Wigmore Lane Health Centre</td>
</tr>
<tr>
<td>5 November 1991</td>
<td>Deadline for receiving proposal and exclusion forms</td>
</tr>
<tr>
<td>19 November 1991</td>
<td>Cardiovascular drug meeting</td>
</tr>
<tr>
<td></td>
<td>8pm Wigmore Lane Health Centre</td>
</tr>
<tr>
<td>4 December 1991</td>
<td>Deadline for receiving proposal and exclusion forms</td>
</tr>
<tr>
<td>18 December 1991</td>
<td>Respiratory drug meeting</td>
</tr>
<tr>
<td></td>
<td>8pm Wigmore Lane Health Centre</td>
</tr>
<tr>
<td>1 January 1992</td>
<td>Formulary distribution</td>
</tr>
<tr>
<td>January 1992</td>
<td>Amendments meeting</td>
</tr>
<tr>
<td>June 1992</td>
<td>Results feedback meeting</td>
</tr>
</tbody>
</table>

Table 8. Timetable for the South Bedfordshire cohort.

From this initial timetable we learned what worked well and what could be improved for future arrangements.

*Where the timetable failed*

The most important lesson was that the single pharmacist found it difficult to undertake the necessary information research in the two-week gap between receiving the suggestions from doctors and the meetings to discuss the drugs and the information in question. This was despite the pharmacist having been seconded to the work on the formulary twenty hours per week, including weeks before the deadline for proposals and exclusion, and the fact that she is a highly experienced senior pharmacist operating with all the resources of a drug information bureau. It was a demonstration of how difficult it would be for any one practice to undertake such work itself or bear the cost of employing such professional help. For the next batch of therapeutic groups considered in the following autumn in 1992, the deadline was moved to 1 month before the discussion meeting. This had an apparent advantage that proposal and exclusion forms could be delivered by hand at one meeting for drugs to be
discussed in the next. In fact, this confused some participants and I would not recommend it. It was difficult to spend time considering suggestions for drugs in one therapeutic category, fill out the forms, then attend a meeting that discussed a different therapeutic group. The small saving in postage for the participants was not worthwhile.

Since 1992, the time allowed for researching the information has lengthened further: participants are now required to submit proposals and exclusions a full two months ahead of the meeting in September 2000. This is despite the fact there are now five full-time primary care group pharmacists dividing the proposals and researching one fifth of them each. In addition, three other pharmacists are available for backup: Janet Clarbour the original pharmacist who still runs the hospital-based drug information bureau, Karen Homan and Jacqueline Clayton, pharmaceutical advisors to the Health Authority. Furthermore access to information has become dramatically easier over the past nine years. I suspect it is this that has enabled more information to be available for assessment and therefore increased the time taken to research the questions raised by the proposals. Perhaps there has also been an increase resulting from a cultural shift demanding more detailed and formalised appraisal of evidence.

The idea behind the amendments meeting was to ensure that the formulary had correctly reported the outcome of discussion (similar to ratifying the minutes of a meeting), but as there were no amendments required by the participants, the meeting was cancelled.

June was optimistic for a feedback meeting. Prescribing data for the first quarter of 1992 was not received until mid May. The requirements of the Prescription Pricing Authority regarding confidentiality meant that all the data were printed and delivered in boxes by post. They had to be transferred to computer before any analysis could be done. Even with only three therapeutic groups, it was a tight schedule to provide every participant with feedback on their individual and practice prescribing by October, which is when the first feedback meeting actually took place. Electronic formats of data now available would certainly speed up this process, but pre-designed analysis methods cannot be employed to assess the impact of any one particular formulary, so such targeted analysis is still time-consuming.
Where the timetable succeeded

The meetings were well attended. Twenty-six general practitioners from the South of the county attended the first meeting. It would be expected that numbers would fall with time, but this did not happen. Fifty-six professionals including general practitioners, nurses and pharmacists and two pharmaceutical advisors from another county attended the latest meeting on 17 February 2000. I have no evidence as to why the meetings have sustained popularity, but aspects that I believe have helped include

- the right time - 8pm - allows general practitioners to reach the meeting after surgery
- the right day - never a Monday or Friday
- good food provided from 7.30pm because participants will not have had time to eat after clinical commitments
- finish by 10pm usually, or at the very latest 10.30pm
- choice of venue size according to the size of group, more intimate rooms for smaller groups, lecture hall size for large groups
- choice of venue local to participants - now that the formulary is county-wide the venue is in the centre of the county

When the formulary meetings were moved to the North of the county, the lessons learned in the South were taken into account and the successes were kept. So the timetable copied that which had developed in the South, with local evening meetings and a four-week slot for research to be undertaken after the receipt of proposals and exclusion.
Who attended the meetings

Meetings were attended by general practitioners and community-based nurses including practice nurses, district nurses and specialists in wound care. Pharmacists presented evidence. Initially this work was undertaken by the local hospital formulary pharmacist, who was employed half time, with money from the project grants, to support the primary care formulary development. This had several bonuses:

- experience of formulary evidence research
- detailed knowledge of the local hospital formulary
- resources of a drug information bureau

As the formulary has become county-wide and with the emergence of primary care groups, the work of researching the data for the meetings and presenting the evidence to the participants has been taken over by the primary care group pharmaceutical advisors. Further pharmacy support is provided by an ongoing link with the hospital pharmacists and the Health Authority pharmaceutical advisors.

A consultant in Gerontology with a special interest in clinical pharmacology provided independent advice on the use of drugs. Modest honoraria were originally funded from the project grants, but more recently this has been funded directly by the primary care groups. There was a specific request from the participating GPs to continue to support the input from this member of the support team. Advice on clinical pharmacology is seen as particularly useful by the generalist clinicians attending the meetings. This may be because it is free of speciality bias.

Particular therapeutic groups of drugs required input from other support personnel. Consultant microbiologists from both hospitals in the county attended the meeting on antibiotics. Their knowledge of local sensitivities was seen as crucial to the selection process. The general practitioner adviser to the Royal College of Obstetricians and Gynaecologists attended the meeting that included contraceptives.
Two nurse specialists on wound care, one from the North and one from the South of the county supported the meetings on wound care products in their respective localities. This year, the educational course on wound care has been integrated with the formulary with assistance from the nurse tutors.

Structure of the meetings

Meetings started at 8pm after half an hour for food. The aim was to finish by 10pm, but approximately one third of the meetings continued up to half an hour longer. All meetings were approved for two hours of post-graduate education allowance. One main therapeutic group of drugs, using the British National Formulary classification, was discussed at each meeting. Towards the completion of the formulary smaller therapeutic groups were combined, such as drugs acting on the eye and ear.

Initial meetings needed time to discuss the aim of the formulary process and the way in which the discussions could be structured, but as participants became familiar with the process and fewer people were attending for the first time, this became unnecessary.

This was followed by a presentation on one therapeutic subgroup of drugs by the pharmacist. The number included in the presentation before discussion depended on the nature of the drugs. The aim was to include all the information found by the pharmacist that was relevant to an informed choice of drug(s) within the therapeutic subgroup. Usually this would be 3 - 5 drugs, but sometimes 2 or up to 10 for groups of emollients or contraceptive drugs. Overhead projection was used to show the data. A photocopy provided for the chairman helped form the notes to the formulary.

Each presentation was followed by open discussion amongst the GPs and nurses. The content fell into these forms:
- reflection of experience in the light of the evidence
- opinion in support of or in contrast to evidence
- extra information not discovered by the pharmacist, including unpublished observations
- review of the evidence from the patient's point of view; issues of acceptability
- review of the evidence from the practice point of view; practical issues of prescribing interacting with general problem management

The pharmacist's role was to find evidence to help prescribers make an informed decision about inclusion of a drug or product in the formulary, with sufficient comparative data to support the corresponding notes. This required a variety of sources. The drug information bureau provided the infrastructure for access to published material in journals, conference abstracts, books, datasheets, case studies, bulletins and correspondence with drug evaluation committees both local and national. In addition, the contact with the drug manufacturers provided further data, but this often had to be evaluated in the light of data from other manufacturers and published research data. Opinion was not sought at this stage. This was left to the discussion.

Although it might seem that decisions would be most reliable if only the evidence was considered, such an exclusive approach would have been neither practical nor helpful. Many areas of primary care still lack a research base. Only 1% of the research that is done concerns acute illness\textsuperscript{121}, an important area for formulary influence when chronic, especially stable, conditions are not so amenable to change of medication. Furthermore, perspectives from the patients' and prescribers' viewpoints are under-reported in the literature. For example, at the meetings about drugs applied to the skin, samples were provided so that the participants could literally assess the feel of the product as no suitable data was found. Our sample of participants was not large enough for statistical validity, nor were the products used to cure any disease present. The test was a single smear, not a period of use. Overall, hardly a good assessment, but better than ignoring the issue of acceptability to patients.

It was also interesting to hear views from the experience of prescribers on how medications should be seen in the context of the social circumstances in which they are used. One young GP puzzled the group by blandly stating that it was unwise to prescribe lemon and lime Dioralyte, as though it was self-apparent. When others asked why, she explained that parents commonly believe that green vomit signifies a more serious illness in a young child or
baby than other colours. Furthermore, they are correct because the BabyCheck system supports this by scoring green colour higher. Lemon and lime Dioralyte colours the stomach contents green and therefore prescribing this flavour can cause unnecessary concern and a repeat contact for medical help. This is one example of the invaluable added value that came from the discussions which would never have been found among the published literature. Pure evidence-based formularies would have a publication bias, which would not be so helpful to prescribers.

A second example illustrates how professional tips in prescribing can be shared. Quinine bisulphate is included in the formulary not for any particular therapeutic advantage of this salt of quinine over any other, but because there is no quinidine bisulphate, only sulphates of both quinine and quinidine are available. Habitually prescribing the bisulphate for nocturnal cramp reduces the risk of the wrong drug being prescribed or dispensed.

Following the discussion on a therapeutic subgroup the chairman summarised the conclusions and asked participants to decide which drugs should be included in the formulary. An item was included if either:

- it had been short-listed and no-one had recommended exclusion
- it had been proposed and achieved a simple majority vote at the meeting

Recording the discussion

I chaired all the meetings. Neither the resource people nor I voted. My main task was to record the reasons for the decisions made by the group at the meeting in order to transfer this information into the formulary notes. An independent record was kept by the project administrator to verify that the formulary correctly reflected the decisions.
Dissemination

Notes from the meetings were formalised and transcribed to a word-processed document. To allow for pages to be inserted from future upgrades, simple 2-hole loose-leaf A4 binders were used. Indexing was according to the classification of drugs in the British National Formulary, with a thumb tab at the start of each chapter. Page numbers were avoided. Formularies were delivered by hand to each participating practice on, or near, 1st January each year, one copy for each partner. Additional copies were available on request.

When the nurses created the first draft of the section on wound care, additional copies of the full formulary were made available to community based nurses. All doctors and nurses working with practices that had contributed to the development of the formulary were provided with free copies automatically. A few practices within Bedfordshire, and a few in other counties, purchased copies. No copies were purchased by practices in the North of the county, which formed the second cohort. The price in 1994 was £6, which covered the materials used only.

Towards the end of 1997, a floppy disc was included with the paper version. One hundred extra formularies were purchased by the Dunstable and Houghton Regis Locality Commissioning Pilot. The cost basis then changed to a yearly subscription, which included updates. Previously this had been unnecessary because updates would have been automatically distributed to participating practices. The cost differential encouraged the uptake of electronic formats, which were easier to keep up-to-date: £10 for a printed copy, £2.50 for a disc.

In 1999, a GP in the North, who had no previous involvement with the formulary, transferred it into WAX, the electronic medical library developed by the Cambridge Informatics Group. From here it was a short step to the first Hyperlink Text Markup Language (HTML) version. Three upgrades later, the current formulary is available in a variety of formats: paper, floppy disc document, WAX book, HTML on CD ROM and online. The HTML version is the easiest to maintain and is likely to be the format preferred by users because of the ease of accessing information on specific drugs or therapeutic
groups by a few clicks. The online version offers the latest news, can be updated continuously instead of periodically, and has virtually no overheads in terms of materials required to maintain it. Much wider access is possible, although the research presented in this thesis is limited to effect on prescribing within the county. No data are available on prescribing effects further afield, but in the past year over 1000 visits have been made to the online version and the update meetings for the formulary in 2000 have been attended by uninvited (but welcome) pharmaceutical advisors to other Health Authorities and Primary Care Groups.

Feedback on prescribing

Every general practitioner who contributed to the formulary in either the South or the North cohort received annual feedback on prescribing during the development period, but not subsequently when the formulary was being maintained by update meetings. This was largely a matter of necessity. Continuing to provide regular feedback for all the doctors and practices in the South cohort while preparing and later facilitating the North cohort would have overwhelmed the resources of the project. PACT data were not available electronically so every item down to the detail of individual prescriptions had to be entered on to a computer database even before analysis could begin. Both the delegate's individual and practice prescribing were included so that partners could have a copy relevant to the practice as a whole, while the delegate could see which changes were individual. A sample of the feedback is given in Appendix C.

Combining the formularies

By 1998, each of the two cohorts had produced and distributed a district formulary. The aim of the second cohort in the North had been to see if practices with no history of collaborative work would achieve the same effect as the first cohort, which had a long history of collaboration. Having completed two distinct formularies for primary care, doctors in both cohorts suggested
combining the formularies to form the basis for a countywide primary care formulary, developed by doctors and nurses over a wide area of Bedfordshire. Work on this started in 1999, after the conclusion of the evaluation of prescribing which relied on using non-participating practices in the county as controls.

**Process**

The process to combine the formularies involved two extra steps, before we continued with the same format of formulary development. Step one was a focus group of five GPs and one nurse from the South cohort discussing the differences between the two formularies, comparing the more up-to-date North formulary with the older South formulary. Data on this are presented in the results section. Items that had been included by the North cohort that were very similar to items previously included by the South cohort were briefly discussed with a view to the North's choice being adopted by the South. Often there was a clear answer, for example a product that had come off patent and available generically. This process resolved minor differences. All others were deferred to a meeting conducted in the style of the normal formulary development meetings, but one with the specific aim of combining the two formularies.

**Special meeting**

Drugs were not proposed or recommended for exclusion prior to this special meeting; the proposals consisted of any drug or wound care product that appeared in only one of the two formularies. The logistics of holding this meeting changed the nature of all subsequent meetings. Suddenly there were twice as many practices involved, and the higher profile of the formularies had attracted more doctors and nurses to help with ongoing development. Instead of 20-25 people attending, there were 75. The list of items to be considered was also bigger for this special combining meeting. The research posed little problem because it had largely been done. The South cohort items required some updating of information. It would have been impractical to present information to the whole group within one evening meeting. Instead, several pharmacists were recruited to facilitate smaller group discussions, each group taking a few therapeutic groups. There was an initial presentation for
newcomers about the history and aim of the formulary and an explanation of the group work. Most of the evening was taken up with the group work, followed by a brief drawing together of what had been decided by each group facilitator. All notes were collated to form the changes that needed to be made to the formulary notes regarding reasons for inclusion of selected items.

Four pharmacists and one nurse were the facilitators. I chaired the meeting, visited the small groups in turn, recorded the decisions, collected the facilitators' notes and created the first combined county formulary from these. The meeting was held in the large postgraduate medical centre at Luton.
Measurement of prescribing

Full prescribing data were obtained with consent from all partners in the 20 subject practices for the relevant first quarters of the years 1991 – 1998. This includes one year’s data prior to the formulary development for each therapeutic group. The longest series was for 8 years, in the case of the first three therapeutic groups considered by the South cohort: cardiovascular, respiratory and musculoskeletal. One practice had to be excluded from analysis because one of the partners did not consent to release of prescribing data. The delegate from this practice continues to play an active role in the formulary development. The Health Authority pharmaceutical advisor gave consent to release the aggregated county prescribing data. The project administrator transferred data for analysis on to computer. Cross-checking for accuracy was done by comparing totals of the entered data with totals listed in the PACT data summary.

Details of the method by which practices were compared with control levels are fully described in Appendix D, recently submitted to the British Journal of General Practice for publication as a paper entitled ‘Measuring changes in primary care prescribing - traps for the unwary and how to avoid them’. In summary, control data was obtained by subtracting the subject practices’ data from the county total to give aggregated data for all non-participating practices in Bedfordshire. This control data was used to create demand factors for each therapeutic group, for formulary drugs and non-formulary drugs. For example, the North cohort, who developed a formulary for drugs in 12 chapters of the British National Formulary plus Wound Care products in the appendix, would have 26 (2x13) demand factors. Another factor was needed to adjust for differences in list size. These factors were applied to the prescribing data of each practice, in order to estimate the expected prescribing of each practice the following year. Match-pairs were compared for each year, a subject practice compared with the same practice’s expected prescribing in the same quarter year and for the same therapeutic group, divided into formulary item group and a non-formulary item group. Only after these matched pair comparisons were made, were the data totalled to show the overall picture. This provides a better use of control data to match practices’ existing prescribing with expected prescribing, than comparisons the with Health Authority equivalent practices before and after the formulary. Full details and a worked example using real data can be found in appendix D.
Units of prescribing and list size

Under the subtitle of ‘The Difficulties’ in Appendix D, the particular problems of items and list size are covered. These are important enough to make it worth inserting the text here.

What are we counting?
The item can be any size.
A prescription for one item can be anything from a single tablet to a six-month supply. The difficulties in using such a variable unit have been the subject of entire papers. Defined daily doses offer an alternative. The choice depends on the question being asked. If volume of prescribing and cost analysis are central to the study, defined daily doses may be better. If it is the activity of prescribing that is central – the choice of drug, the decision to prescribe – rather than how much, then the item may be a more appropriate unit.

List size.
Notorious for causing difficulties. This is the denominator for all the fractions often quoted where a parameter is expressed relative to the list size of a practice. Rather than simply using the number of patients, a formula to calculate prescribing units (PUs or ASTROPU or STARPUs) is usually used in an attempt to compensate for the fact that certain groups of patients require more medication than others. Despite these improvements, list size remains one of the biggest jokers in the data pack. Prescribing is not simply related to the number of patients in a linear way, but influenced by the demand for treatment and the availability of doctors to prescribe. A partner retiring and not being replaced for several months could have a major impact on prescribing despite a steady list size. Such events happen often enough to disrupt studies involving a small sample of practices. Bizarre swings in the supposed prescribing are usually found to be an artefact of a sudden change in list size, such as a practice taking over the list of a closing practice.

Despite these problems, the units of prescribing used in this study were ‘items’, as explained above, and the units of list size were prescribing units, 1 unit for every registered patient or temporary resident under the age of 65, 3 units for anyone older. These are the reasons why.
- no standardised daily defined doses exist for the wide range of drugs in the formulary
- formularies are selective lists, primarily aimed at informing the choice of drug, not the amount prescribed
- prescribing units are still used in PACT reports, the source of all the data
- ASTROPUs and STARPUUs were not available for practices at the start of the study
- changing units mid way through the study was undesirable

Statistical method

Sample size

It would be normal to set a sample size at the very start of a project. The sample size for each cohort was checked as soon as the 12 practices of the South Bedfordshire Practitioners' Group had agreed to take part and all but one doctor had signed consent to allow access to prescribing data. The initial data in 1991, prior to the formulary intervention, allowed calculation of the variance in the numbers of items prescribed and costs, for the samples of 11 practices. This sample size would detect a 4% change in the subject practices relative to control in volume of prescribing, and a 4.4% change in the cost at a significance of p<0.05. These were considered acceptable levels. If they had been higher, more practices would need to have been invited.

In the North, the aim was to enrol 13 practices to bring the detection of cost difference down to 4%. When only 9 joined despite a presentation at the medical institute in Bedford, a close decision was made to continue with the development of a formulary for the North of the county despite the small sample size. Shifts of 4.4% for prescribing and 4.8% for cost would be detected. Even if no significant effects were observed, the practices might later co-operate with the South cohort to enlarge the sample.
Tests of significance

One advantage of the method described in Appendix D is that it facilitates the use of matched-pair t-tests, generally considered to be a robust test of significance applicable to data that has an approximately normal distribution. Support for the tests of significance was obtained by displaying 95% confidence intervals on the graphs, corresponding to the p values from the matched-pair t-tests. The non-parametric but less powerful Wilcoxon signed rank test was also used on a sample of the South cohort data in case some distributions deviated from normal sufficiently to interfere with the t-test but no discrepancies were found.

Limitations

Are the results generally applicable?

The main limitation of this study is that it was conducted in one location, had an enthusiastic leader and a team of dedicated supporters. There is no evidence presented here that effects of developing a formulary elsewhere would be similar.

Multi-faceted intervention

The method cannot show what it is about formulary development that has any effect on prescribing. This intervention has many facets: educational, social, peer-review, evidence-based medicine, multiprofessional input, academic links, documented prescribing advice, online access, integration with practice computer systems. Any of these could have an impact on prescribing.

Assumption in use of control data

Using control data assumes that the subject practices respond to demands for medication similarly to other practices in the county that were not involved in the formulary project. This is perhaps the best estimate that can be made, but the control data cannot be an excellent match for the subject because the practices were self-
selected, and therefore more likely to have an interest in prescribing issues than others.

The two cohorts were treated as independent projects in obtaining control data. In other words, the control for the North cohort was simply the totals for the county minus the subject practices in the North cohort. No adjustment was made for the 11 practices in the South cohort. An adjustment could have been made by subtracting all 20 subject practice’s data from the county data of 93 practices, to give a control level for all 73 non-participating practices. This would have answered the point that the second cohort was likely to adopt much of the South’s formulary because it was used to create the shortlist of initial proposals. However, it was not known if this would happen or not. Furthermore, it would exacerbate the degree of mismatch between the controls and the subjects because even fewer practices with a particular interest in therapeutics would be left in the control group. The choice was made on the grounds that by treating the cohorts independently, any differences between the subjects and control would be slightly less than if both cohorts were excluded from the control group. Thus any positive result suggesting an effect of the formulary would be slightly more robust, but a negative result of no effect slightly less robust. This was the preferred way round.

Limitations of prescribing data

Many of the limitations are described in Appendix D. The most important one is that aggregated data on prescribing is a poor indicator of whether prescribing is appropriate. For this, clinical information must be matched to prescribing information.\textsuperscript{17, 94}
**Originality**

Many previous studies on ways to influence prescribing have been reported. This one follows the standard method of using prescribing data to assess the impact of an intervention. Some features are somewhat unusual:

- wide involvement of local general practitioners and community nurses
- follow-up of up to 8 years prescribing
- a formulary section on wound care
- electronic formats and online access

Some of these aspects may have been why the project was awarded an NHS Beacon Award in 1999 and 2000.

**Funding**

Overall income was £40,000 in grants and £1,500 in sales.

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**Table 9. Funding of the project**

Funding has come entirely from grants for research and development, with a smaller contribution from the proceeds of formulary sales. There was no sponsorship of the
formulary development by the pharmaceutical industry. Sponsorship of medical meetings can weaken the message of independent drug information\textsuperscript{128}. Furthermore, participants were asked not to see representatives about drugs that were to be discussed at the next formulary meeting, for fear of introducing bias into the discussions.

Since the formulary has become countywide there have been a few incidents relating to the influence of the pharmaceutical industry which may be of help to future formulary developers. The method used to propose items to be included in the formulary is robust in that it is limited to NHS staff, that evidence behind proposals is sought by pharmacists independent of both the industry and of profits resulting from the sale of items, and that I as the chairman take a leading but non-voting role. Despite this, one enterprising representative, on learning that the prescribing lead of one large Primary Care Group in Bedfordshire was no more able than anyone else to influence the content of the formulary, visited seven single-handed GPs in the area and supported their proposal forms for one particular drug by suggesting how the form could be filled in and offering to deliver it. Thus we received seven very similar proposals for one drug, all from GPs who may not have been aware of their colleagues’ proposals. The process survived the attack without intervention. The evidence was researched as usual by the pharmacists, presented at the meeting, and there was not a single vote to include the drug from the 50 people in attendance.

It took some persuasion before the Primary Care Group pharmacists would accept that the formulary could be online available over the Internet. Their preferred option was to wait until NHSnet limited access. Their concern rested on precedents in the United States where information provided by pharmacists about drugs has resulted in libel actions. The pharmacists in Bedfordshire have somewhat reluctantly accepted the need to use the Internet after being reassured that

- no individual pharmacist can be identified as the source of the information
- the formulary represents a record of meetings, not a statement of fact
- a disclaimer to this effect is included on the website

They were the only group of support people who asked for their names not to be included in the acknowledgements online.
Results

South Cohort 1991 - 1998

Participants

Out of 300 general practitioners in Bedfordshire, 50 participated and the remaining 250 formed the control group. The participating doctors were from 11 urban and semi-rural practices, covering Luton, Dunstable and the surrounding rural areas and villages. Twenty-six general practitioners attended at least one of the formulary meetings and every practice had at least one participating partner. Everyone received copies of the formulary and all but one provided their level-3 PACT data for analysis. The practice with a dissenting partner could not be included in the analysis. Two practices dispensed a minority of their prescriptions.

There was only one change in the age/sex profile of the subject practices when one took on a university health commitment. During the study 2 (18%) of the 11 subject practices became fundholding (both in April 1993), as did 12 (13%) out of the 95 practices in the county.

Data nearest to the time when practices were invited, is for 1st January 1992, when the prescribing list sizes ranged from 6,366 to 16,056 prescribing units, with a mean of 11,063 and a total of 121,697. A list of prescribing list sizes is given in Table 10.

Formulary

Initial results from the project were published in 1996 Appendix E, when the formulary consisted of brief notes on the selection of 179 drugs and drug delivery devices, 72% of which were specified by generic name. Only two formats were available: a printed, loose-leaf, thumb-tabbed document and a disc of the word-processed document. After the first full review meeting, a new section was added, which formed an appendix, listing all the entries that had been deleted from the formulary and the reasons why.
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Table 10.
List sizes in prescribing units.
11 practices in South Bedfordshire.
Prescribing

Volume

Figure 1 shows the volume of prescribing of the 11 subject practices relative to the expected level derived from control data. A negative result means the subject practice reduced the number of items prescribed relative to control. The only comparison to reach significance was an 11% reduction in the number of items prescribed in the musculoskeletal group in 1994. All but three of the comparisons show the subject practices reduced their prescribing across all therapeutic groups, but the shifts are small relative to the confidence intervals. This is confirmed by Figure 2, showing the overall number of items prescribed.

Choice of drug

Significant changes in the choice of drug occurred in three out of twelve therapeutic groups: cardiovascular, musculoskeletal and, for 1993 only, obstetrics and gynaecology. The greatest change occurred in 1992, when the prescribing in the musculoskeletal therapeutic group shifted towards drugs in the formulary by 13.9% more in subject practices than in controls. All changes occurred immediately after the development and distribution of the formulary. Generic prescribing in the subject practices increased from 44% in 1991 to 51% in 1994, similar to the control practices, which increased from 40% to 48%. Figure 3 gives proportion of formulary items prescribed to total number of items prescribed for the first quarter of each of the study years, with means, 95% confidence intervals and the result of the matched-pair t-tests. A positive result represents a shift towards use of formulary drugs.

Figure 4 is a simpler representation of the data without statistical information being presented. For the three therapeutic groups considered in autumn 1991, that is cardiovascular, respiratory and musculoskeletal, each graph charts the proportion of prescribing that was for an item in the formulary. Red circles represent the subject practices, blue triangles the controls.

Figure 5 and 6 show the results for the therapeutic groups covered in autumn 1992 and included in the formulary distributed on 1st January 1993. Figure 7 gives the results for the next year, ending in distribution of the first complete formulary on 1st January 1994.
Figure 1.
Volume of prescribing by 11 practices in South Bedfordshire relative to expected level derived from control data. Mean and 95% confidence interval for first quarter of each year.
Figure 2.

Volume of prescribing by 11 practices in South Bedfordshire in all therapeutic groups relative to expected level derived from control data. Mean and 95% confidence interval for first quarter of each year.
Figure 3.
Proportion of prescribing by 11 practices in South Bedfordshire for items in the formulary, relative to expected level derived from control data. Mean and 95% confidence interval for first quarter of each year.
Figure 4.
Proportion of prescribing for items in the formulary by 11 practices in South Bedfordshire. Control data from the rest of the county. Therapeutic groups covered by the formulary distributed on 1st January 1992. Mean for first quarter of each year.
Figure 5.
Proportion of prescribing for items in the formulary by 11 practices in South Bedfordshire. Control data from the rest of the county. Therapeutic groups covered by the formulary distributed on 1st January 1993. Mean for first quarter of each year.
Figure 6.
Proportion of prescribing for items in the formulary by 11 practices in South Bedfordshire. Control data from the rest of the county. Therapeutic groups covered by the formulary distributed on 1st January 1993. Mean for first quarter of each year.
Figure 7.
Proportion of prescribing for items in the formulary by 11 practices in South Bedfordshire. Control data from the rest of the county. Therapeutic groups covered by the formulary distributed on 1st January 1994. Mean for first quarter of each year.
Overall changes in prescribing choices across all therapeutic groups show a shift in the subject practices, relative to controls, towards using items in the formulary between 1992 - 1995. The first two years reach significance on a one-tailed t-test at p<0.01. Thereafter no significant differences are seen. Figure 8 displays these results.

**Cost**

Savings occurred in subject practices relative to the prescribing cost of control practices. Significant levels were reached in four therapeutic groups. Three correspond to the groups where there was a shift in the choice of drug, cardiovascular, musculoskeletal and obstetrics and gynaecology. Changes in cost coincide with changes in choice, with the exception of the single change in obstetrics and gynaecology where the choice shifts immediately after the formulary in 1993, but costs remained unchanged until 1996. Figure 9 shows the changes in total drug costs for all 11 subject practices relative to controls, in thousands of pounds Sterling, for the first quarter of each year. Mean, 95% confidence intervals and the results of the matched-pair t-tests are shown.

Overall changes in prescribing costs across all therapeutic groups shows a saving by the subject practices, relative to controls, between 1992 - 1995, the same years as the change in choice of item. The first two years reach significance on a one-tailed t-test at p<0.01 for 1992 and p<0.05 for 1993. Thereafter no significant differences are seen. Figure 10 displays these results.

Data for Figure 10 are in the row labelled 'Practices' in Table 11. The total saving in the January - March quarters only, over seven years 1992 - 1998 inclusive, is £49,307. This equates to a mean saving of £519 per practice per quarter year.

Mean costs of formulary and non-formulary items are shown in Figure 11. The data for the graph are in Table 12. A rule of halves applies. Items in the formulary cost half that of non-formulary items at the start of the project in 1991, £4 per item as opposed to £8. Over the course of the project, the price of formulary items increased at half the rate of the non-formulary ones, rising 25% as opposed to 50%.
Figure 8.

Proportion of prescribing by 11 practices in South Bedfordshire for items in the formulary in all therapeutic groups, relative to expected level derived from control data. Mean and 95% confidence interval for first quarter of each year.
Figure 9.

Prescribing costs of 11 practices in South Bedfordshire relative to expected level derived from control data. Mean cost for first quarter of each year.
Figure 10.
Quarterly prescribing costs of 11 practices in South Bedfordshire relative to expected level derived from control data. Totals and 95% confidence interval for first quarter of each year.
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<thead>
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Table 11. Quarterly prescribing costs of 11 practices in South Bedfordshire in pounds sterling relative to expected level derived from control data. Negative values are savings.
Figure 11. Mean cost of formulary and non-formulary items.
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Table 12.
Mean cost of formulary and non-formulary items at the beginning of each year. £ Sterling per item.
Who was affected

Doctors who attended any of the meetings to help develop the formulary changed their prescribing more than their partners, who in turn changed their prescribing more than the control group in the therapeutic groups where the formulary had an effect. Figure 12 shows this for the choice of drug, the proportion of formulary items prescribed to total number of items prescribed. Higher levels indicate greater acceptance of the formulary.

North Cohort 1996 - 1998

Participants

Nine practices with a total of 43 partners responded and took part in a series of workshops in 1996 and 1997, using the same format as previously used in the South. Thirteen general practitioners attended at least one of the formulary meetings and every practice had at least one participating partner. In 1997, their prescribing list sizes ranged from 4929 to 16043 prescribing units, with a mean of 11431 and a total of 103373, covering areas within the county town of Bedford and the surrounding more rural towns and villages. Unlike the South Bedfordshire Practitioners' Group, these practices did not have a history of collaborative work. A full list of prescribing list sizes is given in Table 13.

The prescribing of the 9 subject practices was similar to the control group prior to the formulary. For the therapeutic groups considered in 1996 the average number of items per prescribing unit was 0.66 for both the subject practices and the control practices, and the cost per prescribing unit per quarter year was £6.73 for the subject practices and £6.67 for the control practices.

Formulary

The first complete formulary included 245 entries, similar in style to the South version with notes on each entry to explain the reason for the inclusion. A section on wound care was included, accounting for some of the increased size over the first complete formulary for the South, which contained only 179 drugs and drug delivery devices.
Figure 12.
Proportion of prescribing for items in the formulary by 26 delegates who developed the formulary and 24 of their partners from 11 practices in South Bedfordshire. Control data from the rest of the county. Therapeutic groups covered by the formulary distributed on 1st January 1992. Mean for first quarter of each year.
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<td>Total of Partners (Practices-Delegates)</td>
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Table 13.
List sizes in prescribing units. 13 delegates who developed the formulary from 9 practices in North Bedfordshire.
Formats were initially the same, printed copy and disc document, but work on other electronic versions started as soon as the formulary was finalised.

Prescribing

Volume

Only small changes were observed, of which the largest two reductions and the largest two increases were as follows. Relative to control levels, subject practices prescribed 1.1% fewer items per prescribing unit for infections, and 0.3% fewer for neurological items. Increases were seen of 1% in the endocrine group, and 0.5% in the obstetrics and gynaecology group. There was no apparent overall tendency for subject practices to prescribe either more or less than controls.

Choice of drug

Significant changes in the choice of drug occurred in five out of thirteen therapeutic groups: respiratory, infection, musculoskeletal, ear nose and throat, and skin. The greatest change occurred in 1997, when the prescribing in the musculoskeletal therapeutic group shifted towards drugs in the formulary by 13.5% more in subject practices than in controls. All changes occurred immediately after the development and distribution of the formulary. Figure 13 gives proportion of formulary items prescribed to total number of items prescribed for the first quarter of each of the study years, with means, 95% confidence intervals and the result of the matched-pair t-tests. A positive result represents a shift towards use of formulary drugs.

Cost

Savings occurred in subject practices relative to the prescribing cost of control practices. Significant levels were reached in three therapeutic groups: respiratory, infection and musculoskeletal. Changes in cost coincide with changes in choice. Figure 14 shows the changes in total drug costs for all 11 subject practices relative to controls, in thousands of pounds Sterling, for the first quarter of each year. Results of the matched-pair t-tests are shown.
Figure 13.

Proportion of prescribing by 9 practices in North Bedfordshire for items in the formulary, relative to expected level derived from control data. Mean and 95% confidence interval for first quarter of each year.
Figure 14.

Prescribing costs of 9 practices in North Bedfordshire relative to expected level derived from control data. Mean cost for first quarter of each year.
Total prescribing costs for the 9 subject practices were £13,000 lower than expected costs derived from controls in the first quarter of 1997, when only 4 therapeutic groups had been considered, including two of those that showed savings: respiratory and musculoskeletal. Subject practices costs were £27,000 lower in the first quarter of 1999, when all therapeutic groups had been discussed.

**Combining the formularies**

**North and South**

Overall the take-up of the formulary was 21 (23%) out of 93 practices and 93 (31%) out of 300 general practitioners, of which 39 helped develop the formulary. Approximately 50 community nurses were involved.

Practices in the North adopted 79% of the formulary chosen by the practices in the South defined as exact or near matches, declined 21%, and added 100 different items. The South formulary was used as the shortlist of initial proposals for the North formulary. Table 14 and Figure 15 show more details of the comparison. A full list of the entries in each formulary in March 1998 is given in appendix F. Differences between the two formularies are underlined.

**Integration with wound care education**

While the formularies were being combined, a countywide education programme was set up to improve the skills of district nurses in the management of wound care. Many products require specialist training in their use. Nurses who were helping to develop the formulary included 25 entries, but more items were recommended by the education programme, which needed to be more inclusive than the formulary aim of 80% prescribing. In April 2000, the educational formulary was combined with the county formulary by the addition of 22 items and the deletion of 4 items out of the original 25. Details of this are given on the CDROM accessed from the home page under "Wound Care Section revised 25th April 2000", click on "What's new". All the changes were considered minor and undertaken by a focus group, consisting mainly
Table 14. Comparison of entries in the two formularies

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<td>Exact matches</td>
<td>132 (54%)</td>
<td>132 (72%)</td>
</tr>
<tr>
<td>Near matches</td>
<td>13 (5%)</td>
<td>13 (7%)</td>
</tr>
<tr>
<td>Unmatched entries</td>
<td>100 (41%)</td>
<td>38 (21%)</td>
</tr>
</tbody>
</table>

Total No of entries 245 (100%) 183 (100%)
Figure 15. Correspondence of items in the North and South formularies.
The darker the columns, the more the agreement between the two formularies.
of nurses with specialist knowledge of wound care and pharmacists from the Primary Care Groups.

Some new items were included to broaden the range of choices. New subsections, such as which dressing pack to use, had been overlooked by the county formulary. More controversial differences have been listed as proposals and exclusions for the forthcoming formulary wound care review meeting in October 2000. The section has enlarged to the point where it needs its own review meeting. Previously it had been managed within the general formulary review.

Data sources

Formulary

The complete Bedfordshire Primary Care Formulary is enclosed in the envelope bound with this thesis. See appendix A for instructions. It was last updated on 25th April 2000. The latest version is online at www.wlhcdemon.co.uk.

Prescribing data

Data required for the graphical representation of the results are needed down to the level of details for individual items prescribed by individual doctors. One of the spreadsheets to hold the data contains 12,880 cells, and this only covers one therapeutic group, for one cohort, for half the duration of the project. It would therefore be impractical to include all the data in this thesis, but for anyone who would like to make use of the data in re-analysis or for comparison purposes, I can provide it. Contact me at Wigmore Lane Health Centre, Luton, Beds LU2 8BG. Example tables are given in Appendix G.
Discussion

Participants

Practices

One quarter of practices and one third of general practitioners in the county accepted the invitation to develop the formulary. Thus there was a bias towards larger practices. The mean prescribing list sizes for the two cohorts were 11,063 for the South and 11,431 for the North compared with the county mean of 7800. Twenty-six doctors in the South and thirteen in the North contributed personally to the process by making recommendations and contributing to the discussions. Most delegates came to all the meetings, one for each of 12 or 13 therapeutic groups, plus update meetings, each of at least two and a half hours. Thus a substantial proportion of the doctors in Bedfordshire were prepared to make a substantial commitment to develop a formulary.

Formularies are known to be more effective if the prescribers are involved with the development. The Audit Commission recommended that formularies should be developed locally by users. New national formularies still need local implementation. The collaboration of the participating doctors and nurses in the development of the Bedfordshire formulary was broad-based and continues after eight years.

Nurses

Fifty nurses contributed to the meetings on wound care. No analysis of their prescribing was possible prior to recent developments in nurse prescribing. About 40 were district nurses, the other 10 were practice nurses. The push to include a section on wound care came from the nurses who heard about the formulary for drugs. Nurses expert in wound care facilitated meetings. Personally I discovered the greatest gap in my knowledge of prescribing at these fascinating meetings. Many of the delegates commented on this. They had become accustomed to attending formulary meetings, so the turn out for meetings on dressings and related products was well attended by the doctors, something which I know from my experience as
GP tutor would not have happened if such events had been arranged independently of the formulary project.

If the transfer of knowledge and ideas at these meetings on wound care was fertile educational ground for the doctors, so too were the general formulary update meetings attended by both nurses and doctors. Each came for a primary interest in either therapeutics or wound care, but the nurses soon started contributing to our discussions on the use of drugs. It was interesting to note when doing the systematic review that virtually no research has been done on the nursing aspects of prescribing. This must surely change with the advent of nurses signing their own prescriptions and the increasing role of their profession within primary care.

With the increasing size of the group interested in maintaining the formulary, sadly the joint update meetings are no longer practical, either in terms of the number of items needing to be discussed in one evening, or the number of delegates who need to be involved in the discussion.

**Formulary**

The formulary itself forms part of this thesis and is included on the CDROM enclosed in the envelope. This electronic format in Hyperlinked Text Markup Language, the language of the World Wide Web, has proved to be the most popular this year. Updates are planned for twice every year and anyone working in the National Health Service is welcome to contribute. Dates of the next update meeting can be found at www.wlhc.demon.co.uk, where proposals and exclusion recommendations can be made online.

The formularies that were found to influence prescribing in the systematic review have changed in format over the past fifteen years. Early formularies focused on providing guidance for common conditions seen in primary care, but this role was taken over by more general advice on management in the increasing number of guidelines being produced in the 1990s. Formularies became more pharmacological in their approach, concentrating on drugs not diseases. The great advantage of using an electronic format is that the same information can
be navigated as a set of management guidelines or as a pharmacological reference source. So far, the Bedfordshire On-line Formulary is indexed according to the pharmacological classification of drugs. The next step in its development is to encourage the formulary groups to consider the information from a clinical angle, while the pharmacists continue to support the drug information. This will no doubt identify many aspects of the use of drugs which have not so far appeared in the text of the formulary. The aim will be to keep each section as short as possible, but improve access to each section by smart indexing with hyperlinks.

**Prescribing**

**Volume**

The formulary developed by the South cohort appears to reduce the volume of prescribing slightly. The number of items prescribed per prescribing unit by the subject practices goes down relative to control levels for almost all therapeutic groups. Only one change showed any significance, and this is likely to be because of the number of tests done. No significant effect on volume is found on the overall volume either. No bias towards a reduction in volume was seen in the North.

Formularies are selected lists of drugs. Their main aim is to inform prescribing decisions, particularly to fill the gap which cannot easily be covered in basic medical training when the choice of which angiotensin converting enzyme inhibitor to use is considerably less important than knowing when to use one and why. Volume of prescribing is less of an issue than choice of drug when a formulary is used, although formularies, especially those limited to one group of drugs such as antibiotics, have been used in an attempt to reduce overall prescribing and costs\textsuperscript{12, 90, 115, 135}. No recommendations about repeat prescribing are included in the Bedfordshire formulary because it is primarily a pharmacological information source, not a management tool. It is possible that the discussions on the formulary would influence doctors to avoid prescribing a drug because of lack of efficacy or side effects. A non-pharmacological alternative treatment might be tried instead, or no treatment at all.

One feature of the results on prescribing shown in Figure 1 is worth noting. There is a sudden reduction in the confidence interval between 1992 and 1993. This is the
group that showed the greatest shift in the choice of drug. The partial formulary was
distributed on 1st January 1992, so the first bar represented the confidence interval
for the three-months immediately after the formulary was received. Delegates would
have known what was going to be in the formulary, but partners probably would not.
Perhaps the wide confidence interval in 1992 is because smaller practices, with
most, or one with all, partners being developers, shifted their prescribing straight
away. In larger practices, where only one or two partners were developers, little
change would occur until the partners had read the formulary or talked with the
developer partner. This could explain an enhanced divergence of prescribing
volumes, followed by a contraction the following year.

The conclusion from the data must be that there is no significant effect of the
formulary intervention on prescribing volume.

Choice of drug

Therapeutic groups affected

A shift towards using drugs listed in the formulary was seen in the South in the
cardiovascular, musculoskeletal and obstetrics and gynaecology groups. The largest
change was seen in the musculoskeletal group in both cohorts. This short chapter of
the formulary, contains five non-steroidal anti-inflammatory drugs and four other
drugs: prednisolone, Depo-Medrone, allopurinol and quinine bisulphate.
Prednisolone can be discounted from the changes seen in the musculoskeletal group
because it also appears in the endocrine group. To avoid counting the same items
twice, all prescribing for prednisolone was measured under the endocrine section.
The main drugs of the musculoskeletal group in the formulary are the non-steroidal
anti-inflammatory drugs. These are commonly prescribed in primary care, both for
acute muscle or joint inflammation, and chronic conditions such as arthritis. The
acute conditions are short in duration and provide an opportunity for doctors to
prescribe from a wide range of agents listed in the British National Formulary without
presenting problems for the patient by way of any change from a previous drug.
Non-steroidal anti-inflammatory drugs

The pharmacists described the well-known ladder of increasing potency and increasing side-effect risk, but for any particular level of potency there is little evidence to say that one drug has a significant advantage over the others available. (The recent advent of drugs that selectively inhibit cyclooxygenase-2 may change this.) The five that were selected gave an adequate range of potencies at reasonable cost. This clarity of evidence gave an opportunity for doctors to change their preferred drug to one in the formulary, without presenting problems to the patient by way of a change in their usual medication. Many doctors were surprised and interested to learn that after application of a transdermal anti-inflammatory drug to one knee, the concentration of drug in the synovial fluid of each knee was very low and much the same on the two sides. Transdermal application may occasionally be useful for superficial inflammation, but there is no deep penetration. This may have caused a shift away from transdermal formulations, none of which were included in the formulary. The effect would be to show a swing to favour drugs in the formulary and a reduction in total costs. Other researchers have found it possible to influence the choice of non-steroidal anti-inflammatory drugs, even if the volume of prescribing remains largely unaffected.

Oral contraceptives

The shift towards the formulary items in the obstetric and gynaecology group probably occurred for different reasons. Here the dominant subgroup of commonly prescribed drugs is the oral contraceptive section. Prescriptions are usually issued for 3 months' supply initially and 6 months' supply thereafter. Patients who required a repeat prescription would be seen once every six months, so the chance of a doctor seeing a patient in the first quarter of the year when the prescribing data were collected is only 50%. Against this is the high number of women who take the oral contraceptive. Many patients would have been seen during the three months, although only a proportion of them would have required a change in their normal contraceptive. The large number of consultations involved increase the chance than we would see an early shift towards use of contraceptives listed in the formulary than if the opportunities for change had been fewer. A slight shift towards the formulary in this therapeutic group is seen in the North too, but the cohort was smaller in size, and no significance is attached.
The sudden increase in the use of oral contraceptives in the formulary between 1995 and 1996 by both the subjects and controls is probably as a result of the media announcement on 19th October 1995 linking third generation combined oral contraceptives with thrombosis. The formulary was updated at a review meeting after the announcement. In 1995 the combined oral contraceptives in the formulary were Femodene, Minulet, Marvelon and Logynon. At the review meeting in late autumn that year, Microgynon 30 and Cilest (the only third generation pill not tested in the study on risk of thrombosis) were added. The professionals who attended that review meeting decided not to remove any of the previous selection. To do so was considered an over-reaction to a media scare and that many women already taking one of the named pills would wish to continue.

By the time the North cohort considered the issue, they decided to invite an expert on contraception to facilitate the discussion on what they saw as an important issue for the formulary: guiding prescribing decisions from the evidence while accepting that the pill users views were important and would be coloured by the media attention. The North’s decisions were later to be adopted by the South cohort. The latest edition of the formulary reflects this history of changes in its current selection: Loestrin 20, Mercilon, Brevinor, Microgynon 30, Marvelon, and Cilest.

**Choices in other therapeutic groups**

Cardiovascular drugs were prescribed more in accord with the formulary in the South cohort only. In The Netherlands, many cardiovascular drugs are initiated by specialists and continued by GPs, but conventions of prescribing may be somewhat different in Britain. The shift towards the formulary drugs was modest compared with some other groups such as musculoskeletal and ENT, but the tight confidence intervals show a significant effect. The effect is less marked immediately after the formulary, increasing over the next two years, before gradually subsiding. This may correspond to drugs in this group being used long term for conditions such as hypertension and ischaemic heart disease.

Changes in the North towards the use of formulary drugs coincided with those in the South for the musculoskeletal group only. The other groups that showed a significant shift in prescribing choices in the North were respiratory, infection, ENT and skin. This represents 5 out of the 13 groups considered. The length of the study period was shorter. Some of these changes may be transient, particularly the groups for
which there is only one comparative year: infection, ENT and skin. Both the infection group and the skin group changes only just reached significant levels. This was a smaller cohort and with only nine practices it is not surprising that confidence intervals are fairly wide.

**Therapeutic group most amenable to rapid change**

The message from comparing the changes that occurred in different therapeutic groups is that to see an immediate effect of a formulary, the best therapeutic group to target is the musculoskeletal group. Groups that contain drugs commonly used, or particularly useful for acute conditions, are more likely to show an early change. Choices of drugs used for chronic disease may change, but more gradually. This implies that studies shorter than about two years may miss an effect that did occur.

**Time course of changes**

The shifts in choice of drug relative to control disappear after two or three years. A clear example is seen in the musculoskeletal group in the South. Here the 14% swing towards using formulary drugs, which occurred immediately after it had been developed, drops to 4% by 1998. The fall is linear at a rate of 1.6% per year, with the exception of 1996 when a dip occurred (see Figure 3). The same rate of decline is seen in the respiratory group between 1995 - 1998. It is not possible to make any judgement about changes over time for the North cohort.

Turning to Figure 4, we see that the decline is due to a convergence between the control group and subjects. Doctors increasingly prefer drugs in the formulary in both the subjects and the controls. This is echoed in some of the therapeutic groups that showed no shift in prescribing choices relative to controls, such as the gastrointestinal group. The reason for the erosion of the influence of the formulary is not that the subjects turn to alternative drugs, but that the changes adopted by the subject practices are followed by other practices in the county.

There are a number of possible explanations for this. The one I would favour is that where the formulary has an effect, it is to advance a change in practice that would have occurred eventually in any case. The process of developing a formulary, with its evidence-based approach, its educational content and multiprofessional collaboration, can be seen as a way of getting research findings into practice.
Although the Primary Care Group pharmacists have now taken over the role of researching the evidence and presenting it at the meetings, up to 1999 this work was undertaken by one pharmacist, seconded half time to assist the development of the formulary, while her main occupation continued at the local hospital pharmacy. She had no contact with other practices. It was not the person who persuaded the control practices to follow suit in any way, although up to 12 may have been influenced by a nurse attending some of the meetings. More likely it was the weight of evidence that control practices would become aware of and accept more gradually than the subject practices, who had been informed by developing the formulary and perhaps convinced of the validity of the evidence in the course of discussion with colleagues.

There are other explanations. There could have been a diffusion of knowledge from the delegates, to their partners, to other colleagues. Prescribing incentive schemes started in Bedfordshire in 1995. These were not detailed enough to recommend specific treatments until recently, but instead required practices to reduce overall spending. Drugs were selected for the formulary if they were equally effective, safe and acceptable as alternatives but cheaper. So a scheme to encourage cost reductions may have driven practice towards using the drugs listed in a formulary they had never seen. Over the same time period, there was more awareness for the need to reduce costs. Practices were being faced with allocations for number of referrals, longer waiting times, and a greater public awareness of how the health service was dependent on finance and could not meet all demands from cradle to grave. It was a time of a great many changes. Doctors who previously felt comfortable defending their prescribing of expensive branded drugs on the grounds of quality over generics, may have had to think again. The formulary process had no prior intention of favouring generics, but the evidence for cost-effectiveness and equivalent quality carried through. Delegates attending meetings in 1992 hotly debated the issue, but as time passed, it seemed to matter less and less. By the time the cohort in the North started, objecting to generics on the grounds that they were substandard imports had changed from being a common concern to a quaint notion.

Some of the charts in Figures 4 - 6 show prescribing choices have changed considerably over the 1991-1998 period, with no apparent effect of the formulary. The bottom chart in Figure 5 shows an increase in the proportion of drugs used to treat infection that are in the formulary from just under 50% in 1992 to 75% in 1998, nearly reaching the formulary target level. Guidelines on antibiotic treatment,
addressing known local sensitivities, were developed in Bedfordshire and first
distributed to practices in 1994. Although this was done independently of the
formulary development, the evidence used to support the recommendations was
from the same microbiology laboratories. The guidelines may have influenced
practices across the county to adopt similar prescribing to the ones participating in
the formulary development, but no sudden increase in the use of formulary antibiotics
is seen between 1994 and 1995. The rate of increase is fairly constant from 1992 to
1997, only tailing off in 1998.

The South cohort data show that there was an overall difference in prescribing
choices between the subject and controls for two years after the development of the
formulary. This is shown in Figure 8. What this hides is that the changes that
occurred did not fade, but were followed by the control practices. Thus it would be
fair to say that the formulary produced a change in prescribing choices with a
measurable difference between participating and non-participating practices
sustained over three years. Thereafter the effect of the formulary remains, but non-
participating practices adopt similar prescribing.

Baseline differences
Figures 4 -7 show that the subject practices were prescribing a higher proportion of
drugs in the formulary before the project started in 1991. This could be because
practices motivated to volunteer to help develop a formulary might have more interest
in the evidence supporting good prescribing. Another possibility is that the formulary
items were chosen to some extent on the basis of what the doctors were used to
prescribing. The aim of sharing facilitators to research and present the evidence was
to minimise this effect.

Appropriate prescribing
The above discussion is based on the results of the evaluation of the formulary
intervention, which used data on prescribing separated from clinical context. It has
been suggested that the variation in prescribing between practices\textsuperscript{16,18,141} is largely
accounted for by differences in the needs of the patients\textsuperscript{35,46}. Between European
countries there is also variation cause by differences in regulation, marketing, and
distribution of drugs\textsuperscript{48}. Caution is needed in interpreting the results of studies on the
appropriateness of prescribing when it is judged by the clinicians who are doing the
prescribing. Cockburn and Sabrina found that although patients brought expectations to the consultation regarding medication, the doctors' opinions about their expectations were the strongest determinants of prescribing. It is difficult to see any justification for the wide variation in the level of prescribing of drugs noted in the British National Formulary to be 'less suitable for prescribing'. Nor can there be rational reason for using excessive doses of thiazides in the treatment of hypertension. When doctors are asked why they prescribe drugs of doubtful value, the reasons given are:

- patient demand (perceived)
- use as a placebo
- opinion/experience over-riding evidence

However doctors appear to be more aware of the pressure to prescribe than of the preference for self care.

Evaluation of interventions in future would be more sensitive to the area where prescribing can and should change if prescriptions were linked to clinical need and assessed by evidence-based algorithms. Expert opinion would be a poor substitute. Two studied from Peru and Pakistan suggest that specialists may be less willing to accept practical restraints on "good" prescribing and less likely to follow guidelines based on their own recommendations than the doctors for whom the guidelines were intended.

**Cost**

A shift in prescribing drugs in the formulary would be expected to reduce overall costs because the average price of formulary drugs is lower than non-formulary drugs. High quality prescribing for asthma increases costs, but overall the results for the respiratory group in the South showed that the greatest saving occurred in 1995, the year when there was a large swing towards the use of drugs in the formulary. This is probably because the shift from expensive inhalers to cheaper equivalents saved more money than the cost of any increase in the overall use of inhaled corticosteroids.

Figure 11 shows the rule of halves for formulary drug costs, including the rate of increase in price being half that of non-formulary drugs. Many drugs in the formulary...
are well established, off patent and listed by generic name, such as amoxicillin and ibuprofen, for which the need to recoup the cost of research and development has passed.

The best estimate on cost effects comes from the South cohort where the data can be assessed over a longer period of time. Practices saved just under £50,000 in total during the January to March quarter over seven years between 1992 -1998 inclusive. However 57% of this was accounted for by savings on the prescription of antibiotics, with most of the rest of the saving being from the musculoskeletal group. To estimate the overall saving a correction must be made for the reduced requirement for anti-infective agents in the other quarters of the year. Correction factors have been published, but they are ten years old and the factors were calculated from prescribing data 1983-1987. No factor was found necessary for the musculoskeletal group. Compared with the preceding quarter year, factors for preparations acting on systemic infections in Bedfordshire were:

- January-March 8%
- April-June -18%
- July-September -9%
- October-December 26%

The factors refer to the number of items, not cost. They were not designed for sequential use, but simply to compare one quarter with the next in order that short duration audits could be done. All these difficulties mean it would be wise to err on the side on a conservative estimate of cost savings related to the formulary over the full years 1992 - 1998. Accepting the factors directly would suggest that for the infection group, a saving of £100 in the first quarter of a year would result in a saving of about £350 over the 12 months. I prefer to reduce the estimate, assuming a £100 saving in the first quarter would save £300 over a year. If this is applied to the South cohort data on costs, then the estimated saving would be £117,000.

In the North, total prescribing costs for the 9 subject practices were £13,000 lower than expected costs derived from controls in the first quarter of 1997, when only 4 therapeutic groups had been considered, including two of those that showed savings: respiratory and musculoskeletal. Subject practices' costs were £27,000 lower in the first quarter of 1999, when all therapeutic groups had been discussed. Thus £40,000 had been saved in just two quarters. Again, seasonal variations mean that it would
be inappropriate to assume this will be maintained throughout the year. The savings by the North cohort exceed those of the South, which saved £27,000 in the first two January-March quarters, but such savings may not persist. The South cohort has reduced costs over a period of three years, but this may not happen in the North.

The savings by the North cohort are less affected by seasonal variation than the South. Most of the savings were made in the respiratory, infection and musculoskeletal groups. Factors for preparations acting on the respiratory system are as follows:

- January-March 1%
- April-June -13%
- July-September -1%
- October-December 12%

However there is an 80% increase in the use of antihistamines in the spring, April-June, compared with the previous quarter. These drugs are included in the respiratory section of the British National and Bedfordshire Formularies. Applying the same conservative estimate to the infection savings, and using the factors above for the respiratory section, accepting the saving in musculoskeletal drugs as being consistent throughout the year, and ignoring other savings as being small in comparison, gives an estimate of £118,000 saved in the two years of the North's formulary 1997 and 1998.

The total estimated saving from both cohorts is £235,000 over the seven years 1992-1998 inclusive. The grants to support all the formulary work totalled £40,000, which is 17%.

Who was affected

It is no surprise that the delegates who helped develop the formulary were the doctors who changed prescribing the most. What is more interesting is that the partners changed more than the controls, as shown in Figure 12. This may be confounded by the problem that some practices have a repeat prescription policy which uses a duty doctor's prescription pad for all the repeat prescribing on the day that doctor is on duty. The prescribing data is attributed to the doctor's pad rather
than the signature. It is possible for a doctor who developed the formulary to be writing some prescriptions on partners' pads. This is not likely to be the whole explanation for the effect seen in Figure 12. Most repeat prescriptions would not be changed without seeing the patient, so no change would be reflected in the partners' data on this account. Many prescriptions are produced by computer, which automatically prints the correct doctor's details on the prescription.

There does seem to be a practice effect. Some practices are known to have had clinical review meetings, after one partner had been to a formulary meeting, in order to discuss the outcome of the meeting. This may have been encouraged by the feedback provided, which included information about the whole practice prescribing, not just the delegate's prescribing. More recently, since the end of the prescribing analysis in 1998, the formulary has been integrated into some practice computer systems. This would imply a general acceptance of the formulary amongst the partners. No estimate of the effect on partners has been made for the North cohort.

It would be reasonable to conclude that not all partners need to contribute to a formulary actively for it to have an effect on the whole practice.

Combining the formularies

The acceptance by the North cohort of 72% of the South formulary would suggest that most new formularies could be started with a group of common, uncontroversial drugs. These are listed as the drugs without underlining in Appendix F.

The focus group identified a further 7% of the differences as near matches, but also proposed new items in response to the inclusions in the North formulary which had not been considered by the South cohort. Many were new drugs or concerned new uses for older drugs. The result was a list of 95 items that needed to be considered, but 41 of these were simple decisions that did not rest on therapeutic information. It was possible to reach agreement on all the differences in one large evening meeting, functioning as five small groups of 15-20 people each. It was popular. Approximately 70 doctors and nurses contributed and were interested and accepting of other small groups' decisions. Perhaps this will be how centralised guidance can be locally
owned, although there may be less scope for discussion and adjustment in some guidelines.

**Future formulary development**

**Signposts**

The systematic review revealed that the three methods with the most evidence for influencing prescribing are: formulary development by prescribers, continuing professional education and feedback on prescribing. All three were used in the development of the primary care formularies in Bedfordshire, so it is in keeping with previous research that we find the intervention did affect prescribing. This does not mean that that developing a formulary is the best or only way to influence prescribing, because other methods may be quicker or cheaper. A systematic review of 102 trials of interventions to improve professional practice found no magic bullets but recommended a mixture of methods\(^5\).

The degree of influence of various methods has been assessed in a meta-analysis of 26 studies conducted between 1979 - 1991, which shows that methods targeted at the individual's needs work best\(^5\). There is evidence to support group work in this field over individual education\(^2\), and that education and contact with colleagues account for about half the changes that are initiated in practice\(^1\). We also know that doctors change their prescribing habits for a wide range of reasons\(^3\). Horder, Bosanquet and Stocking's paper\(^4\) on 'Ways of influencing the behaviour of general practitioners' can be summarised as follows:

> If a formulary is to be widely adopted, the participating GPs need to be sure that it is necessary. Personal contact with doctors, nurses, other colleagues, and to a lesser extent patients, is effective. Financial incentives and unsolicited feedback about performance is of doubtful efficacy. The most successful approach uses a combination of different methods.

A decade later, the World Health Organisation, in its review of promoting rational prescribing, recommended using a wider variety of methods to influence change\(^4\).

- prescribing protocols
- consensus
- feedback
- face-to-face education
- focused, structured forms
- educational campaigns

Future development of prescribing support is likely to take advantage of information technology. Some, but probably not all, visits from a drug educator or pharmacist could be replaced by distant support via the clinical desktop computer. The Bedfordshire Formulary CDROM offers advice in this way, but does not yet take full advantage of integration with the clinical system. Information appearing at a time when it is most relevant and most needed would be the aim. This would combine aspects of the method of problem-based learning, critical event education, personal reflection, with specialist support. It could answer the needs of GPs who prefer to use one or two sources of information for all questions relating to drugs, while satisfying the needs of those who prefer multiple sources by providing links to the relevant information, local or distance. Such a method would powerfully combine many of the methods of influencing prescribing identified in the systematic review.

**Influence of the pharmaceutical industry**

Sponsorship by the pharmaceutical industry can weaken the message of independent drug information. Many doctors continue to receive much of their continuing education on drugs directly or indirectly from companies that profit from increased prescribing of their products. Information provided by representatives is generally accurate, but is a selection of evidence in support of a particular product. Although the industry follow guidelines agreed with the medical profession, promotion of high quality prescribing is difficult when the industry is involved. Independent educators have successfully adopted some of the methods used by representatives to achieve a change in prescribing. Attracting doctors away from the convenience of a visit by a company representative, who is offering free advice and other gifts, is a challenge for the future. Reaccreditation may encourage more doctors to seek independent information. If that information can be presented in a convenient way, doctors may be in a stronger position to challenge some of the bias in the information they receive from other sources.
**Education or Information**

There has been a gradual shift in the terms used to describe methods of changing professional behaviour from passive absorption of information selected by a teacher, towards active learning by the student. 'Training' and 'post-graduate education' gave way to 'continuing professional development' and 'life-long learning'. The problem with the newer terms is that they sound more like a burden than an opportunity. I see a further shift away from 'education' as the core to professional development towards terms that reflect the ability of practitioners to access information when and where it is needed. Learning has an association with memory, but with the huge body of knowledge available to those who seek it out, memory is not the key skill it once was. The challenge for the next batch of primary care formularies is to take over and improve upon the prescriber's memory by being more reliable, more knowledgeable, more up-to-date, and nearly as easy to access.

**Incentives**

Fundholding allowed practices control over money saved on drugs. This did limit the rise in costs of the fundholders in the early 1990s more than non-fundholders, but the effect was modest, explaining less than 10% of the variation in cost per item and even less of the variation in total costs between practices. The uptake of fundholding was low in Bedfordshire and occurred at similar rates in the subject and control groups.

Prescribing incentive schemes reward doctors for prescribing according to certain criteria. These schemes are mandatory for Primary Care Groups throughout England and Wales. While they do affect prescribing, the majority aim at limiting expenditure on drugs, rather than encouraging appropriate prescribing. Very few include clinical information on the needs of the patients. The development of Primary Care Trusts gives us the opportunity to link incentive schemes with clinical audit and governance to encourage and reward appropriate prescribing. The scheme in Luton this year includes a target based on the appropriate use of aspirin to prevent strokes.
and infarcts. A cheap, effective drug, with room for wider use, it is seen as an innovative part of the incentive scheme, aiming to improve care for patients and not a need to save money on the drug bill.

**Doctors' knowledge of the cost of drugs**

Prescribing is influenced by the doctor's knowledge of the cost of the drug, but often that knowledge is either lacking or inaccurate. Only one third of estimates of cost by Scottish GPs were accurate to within 25%. Errors tended towards mean drug costs. At a focus group discussion of GPs with a particular interest in prescribing, researchers and health economists, held at the department of health in June 2000, none of the 20 delegates knew of the differential cost of anti-viral drugs for shingles as mentioned in the formulary:

"A shingles treatment pack of Valaciclovir costs £98.50, in sharp contrast to £15.99 for the equivalent pack of Aciclovir (of which it is a pro-drug)."

There is a such a large body of information in constant flux that it is hardly surprising that doctors will not know when a product comes off patent, or that the maximum dose of a course of colchicine recommended by the British National Formulary has dropped by 40%, or that the costs of providing apomorphine in pre-filled syringes instead of ampoules would pay for a full-time personal nurse to give each injection. Lack of time to keep up-to-date with developments in therapeutics has been identified by GPs as a major factor in explaining the variation in prescribing between practices. Formularies are seen an important solution to this, and one that is not as restrictive as some doctors imagine.

Automatically providing information on costs through a practice computer system may be a useful way to warn prescribers of an unusually high cost for an item compared with similar drugs in the same therapeutic group. This may not be welcomed by doctors with high prescribing costs, who are known to have more concern than their cost-conscious colleagues do over financial restraints. The article referenced puts forward the suggestion that high prescribers may be using prescriptions to cope with clinical workload and their perception of demanding patients.
Repeat prescribing

The Bedfordshire Primary Care formulary offers guidance on selecting and initiating medication. It gives no advice on repeat prescribing policy. The only influence the formulary may have would occur when a doctor or nurse reviews the need for a repeat prescription. Yet Zermansky found that 66% of repeat drugs show no evidence of authorisation by a doctor; and 72% show no evidence of having been reviewed by a doctor in the previous 15 months. The problem is that it takes time to review medication; time that many GPs do not have available. Zermansky goes on to suggest imaginative use of nurses and pharmacists may help to solve this major problem. This adds more weight to continuing the formulary as a multi-professional tool. GPs have a positive attitude towards community pharmacists, their inclusion into the primary health care team and extension of their role in relation to medicines, but there is less support for the idea of pharmacists undertaking screening and running therapeutic monitoring clinics. Where such roles for pharmacists do occur, they are usually to be found in large training practices.

The patient’s view

We had no patient representatives at the formulary discussion meetings, although professionals often discussed acceptability, the burden of taking medication, and tried out harmless products provided for this purpose at the meeting, such as creams, ointments, sprays and dressings. The difficulty with inviting the public is that this would affect the discussion among professionals. However, exclusion is not a good option either. Patients are affected by the decisions taken on prescribing. The chance that a person treated for depression with a selective serotonin re-uptake inhibitor will complete an adequate course is affect by restriction on the choice of drug. A formulary can save money at the expense of patient satisfaction, for example the substitution of lansoprazole for omeprazole. Patients’ view may have to be sought separately from the meetings on therapeutics.
Conclusion

Main conclusion
Practices can collaborate to create a shared formulary, which influences prescribing.

Secondary conclusions
Sharing resources between practices to create a primary care formulary can lead to modest changes in prescribing, sustained over three years, and lower overall costs. The largest observed changes were a 14% change in the choice of drugs for musculoskeletal conditions, and a saving of £5000 per practice per year on antibiotics. Such changes, attributed to the development of a formulary, also occur in practices that have no direct involvement, but later by three years. The greatest change in prescribing is seen immediately after a formulary is created and in those involved with its development. The funding for the work is estimated to amount to 17% of the saving on prescribing. Doctors and nurses from 32 practices can work together on such an intervention.
Acknowledgements

Please see the acknowledgements in the formulary for the people who have helped create and evaluate the formulary. Without their good will this thesis would not have been possible. Those who helped with the evaluation and this thesis are listed in Appendix H.
Appendices

Appendix A Bedfordshire Primary Care Formulary

The formulary is provided on the CDROM to be found in the envelope bound with this thesis. It was last updated on 25th April 2000. The latest version can be found at www.wlhc.demon.co.uk/formulary

Three formats are available, as provided to practices. The easiest one to navigate is the HTML version.

<table>
<thead>
<tr>
<th>Directory</th>
<th>Files</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Word</td>
<td>Formulary</td>
<td>The main formulary document</td>
</tr>
<tr>
<td></td>
<td>Appendix A</td>
<td>Details of items previously deleted from the formulary</td>
</tr>
<tr>
<td></td>
<td>Appendix B</td>
<td>Forms to propose new items or exclude ones from the formulary</td>
</tr>
<tr>
<td></td>
<td>Revision 170200</td>
<td>Changes made on 17 Feb 2000</td>
</tr>
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<td>Read Me</td>
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<tr>
<td>HTML</td>
<td>index</td>
<td>Start by clicking on this file</td>
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<td>Other files</td>
<td>Resources for the web site</td>
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<td>Wax / books / Formular files for loading into Wax</td>
<td>Set of 4 Formular files</td>
<td>Wax book</td>
</tr>
<tr>
<td>A:\</td>
<td>Read Me</td>
<td>This page in plain text</td>
</tr>
</tbody>
</table>

The files can be accessed directly from the CDROM. Practices usually load the files on to the hard drive on a practice computer system, or have the formulary integrated into the clinical software program for the practice by one of the Primary Care Group pharmacists. So far this is only available for EMIS and Torex systems.
These are the instructions to practices:

To load files simply copy them from the CDROM to a suitable location on your hard disk.

Typical locations:

Word files in My Documents/Formulary/Word/

HTML in My Documents/Formulary/Webpages/

Wax copy the whole Formulary directory into Wax/books/

For quick access to the formulary you may like to put a shortcut icon on your desktop to either the word version "Formulary" file or the HTML version "index" file. To do this, first copy the files to your hard disk. Then locate the file you want to create a shortcut to by using Windows Explorer. Click with the right button on the file. On the drop down menu, click with the left button on "Create Shortcut". A new file will appear called "Shortcut to..." If you want to change the name to something shorter, press the function key F2 and type in whatever name you like, followed by return. Then make the Explorer window smaller by clicking on the middle of the three icons at the top right corner. Finally drag your newly created shortcut file to the desktop background. If this alters the pattern of icons on the desktop, you can line them up by clicking using the right button anywhere on the desktop and selecting "Line up icons".
Appendix B  Proposal and Exclusion forms
PROPOSAL FORM  Your name & contact

1. Date:

2. Name of drug:

3. Is this a proprietary name?
   No  Yes

4. Formulations proposed?
   All  Some

5. Does this item replace one in the formulary?
   No  Yes

6. What is the main indication?

7. Please comment on the reason for the proposal:

8. Do you have any conflict of interest affecting this proposal?
   No  Yes

Return to Lorraine Dakin, Wigmore Lane Health Centre, Luton LU2 8BG. Fax 01582 456 259
EXCLUSION FORM  Your name & contact
If a drug is to be replace by a newly proposed drug, use the DRUG PROPOSAL FORM

1. Date:

2. Name of drug:

3. Formulations excluded (tick one):
   - All
   - Some
   List those to be excluded

4. Reason for exclusion (tick as many as apply):
   - Ineffective
   - Duplication
   - Rarely required
   - Unacceptable side-effects
   - Poor value
   - Unacceptable to patients

   With what?
   What side-effects?
   Why?

5. Please comment on the reason for the exclusion:

6. Do you have any conflict of interest affecting this exclusion?
   - No
   - Yes

Return to Lorraine Dakin, Wigmore Lane Health Centre, Luton LU2 8BG. Fax 01582 456 259
Dr Anonymous

**Ten most commonly prescribed drugs**

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<th>No of Rx</th>
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<th>In</th>
<th>No of Rx</th>
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<td>Ventolin Inh</td>
<td>Y</td>
<td>43</td>
</tr>
<tr>
<td>Becotide</td>
<td>N</td>
<td>35</td>
<td>Bendrofluazide</td>
<td>Y</td>
<td>39</td>
</tr>
<tr>
<td>Sudafed</td>
<td>N</td>
<td>29</td>
<td>Atenolol</td>
<td>Y</td>
<td>33</td>
</tr>
<tr>
<td>Bendrofluazide</td>
<td>Y</td>
<td>28</td>
<td>Ibuprofen</td>
<td>Y</td>
<td>29</td>
</tr>
<tr>
<td>Atenolol</td>
<td>Y</td>
<td>27</td>
<td>Terbutaline inh,turbo</td>
<td>Y</td>
<td>25</td>
</tr>
<tr>
<td>Co-Amilozide</td>
<td>N</td>
<td>20</td>
<td>Nifedipine</td>
<td>Y</td>
<td>22</td>
</tr>
<tr>
<td>Ventolin</td>
<td>N</td>
<td>20</td>
<td>Becotide</td>
<td>N</td>
<td>22</td>
</tr>
<tr>
<td>Nifedipine</td>
<td>Y</td>
<td>17</td>
<td>Frumil</td>
<td>Y</td>
<td>19</td>
</tr>
<tr>
<td>Tiaprofenic Acid</td>
<td>N</td>
<td>15</td>
<td>Pseudoephed HCL</td>
<td>Y</td>
<td>18</td>
</tr>
<tr>
<td>Frumil</td>
<td>Y</td>
<td>14</td>
<td>Budesonide inh, turbo</td>
<td>Y</td>
<td>16</td>
</tr>
</tbody>
</table>

**Ten drugs which cost the most**

<table>
<thead>
<tr>
<th>Jan-March 1991</th>
<th>In £</th>
<th>Jan-March 1992</th>
<th>In £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Becotide</td>
<td>N 575.89</td>
<td>Nifedipine</td>
<td>Y 541.83</td>
</tr>
<tr>
<td>Tiaprofenic Acid</td>
<td>N 334.16</td>
<td>Becotide</td>
<td>N 487.86</td>
</tr>
<tr>
<td>Atenolol</td>
<td>Y 321.14</td>
<td>Atenolol</td>
<td>Y 388.23</td>
</tr>
<tr>
<td>Nifedipine</td>
<td>Y 311.02</td>
<td>Captopril</td>
<td>N 357.24</td>
</tr>
<tr>
<td>Captopril</td>
<td>N 226.78</td>
<td>Budesonide inh, turbo</td>
<td>Y 315.50</td>
</tr>
<tr>
<td>Ventolin</td>
<td>N 225.00</td>
<td>Terbutaline inh,turbo</td>
<td>Y 205.25</td>
</tr>
<tr>
<td>Ventolin Inh</td>
<td>Y 212.22</td>
<td>Ventolin Inh</td>
<td>Y 201.74</td>
</tr>
<tr>
<td>Fenbufen</td>
<td>N 206.99</td>
<td>Tiaprofenic Acid</td>
<td>N 196.36</td>
</tr>
<tr>
<td>Frumil</td>
<td>Y 137.84</td>
<td>Ventolin</td>
<td>N 183.10</td>
</tr>
<tr>
<td>Pulmicort</td>
<td>N 131.00</td>
<td>Ketoprofen</td>
<td>Y 174.00</td>
</tr>
</tbody>
</table>
Percentage of prescriptions within the formulary, expected (E) and actual (A), for Jan-March 1993.
BNF groups 1-7, 9 & 10. Grey section of column shows 95% confidence interval.
Table of number and cost of prescriptions, with proportion (%) in the formulary

<table>
<thead>
<tr>
<th>BNF Group</th>
<th>In/Out</th>
<th>JAN-MAR '91</th>
<th>JAN-MAR '92</th>
<th>JAN-MAR '93</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Rx</td>
<td>£</td>
<td>Rx</td>
</tr>
<tr>
<td>1 (Gut)</td>
<td>In</td>
<td>210 (45%)</td>
<td>1452 (40%)</td>
<td>245 (46%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>258</td>
<td>2187</td>
<td>288</td>
</tr>
<tr>
<td>2 (CVS)</td>
<td>In</td>
<td>360 (47%)</td>
<td>1549 (25%)</td>
<td>428 (55%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>400</td>
<td>4623</td>
<td>345</td>
</tr>
<tr>
<td>3 (RS)</td>
<td>In</td>
<td>230 (28%)</td>
<td>817 (23%)</td>
<td>227 (26%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>587</td>
<td>2745</td>
<td>656</td>
</tr>
<tr>
<td>4 (CNS)</td>
<td>In</td>
<td>476 (58%)</td>
<td>998 (30%)</td>
<td>584 (58%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>350</td>
<td>2288</td>
<td>472</td>
</tr>
<tr>
<td>5 (AntiB)</td>
<td>In</td>
<td>508 (67%)</td>
<td>1023 (44%)</td>
<td>733 (62%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>251</td>
<td>1295</td>
<td>443</td>
</tr>
<tr>
<td>6 (Endo)</td>
<td>In</td>
<td>123 (65%)</td>
<td>554 (37%)</td>
<td>176 (72%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>65</td>
<td>926</td>
<td>69</td>
</tr>
<tr>
<td>7 (Obs/G)</td>
<td>In</td>
<td>80 (50%)</td>
<td>431 (57%)</td>
<td>122 (52%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>81</td>
<td>331</td>
<td>111</td>
</tr>
<tr>
<td>9 (Nut/Bld)</td>
<td>In</td>
<td>79 (48%)</td>
<td>247 (28%)</td>
<td>49 (39%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>84</td>
<td>635</td>
<td>78</td>
</tr>
<tr>
<td>10 (MSk)</td>
<td>In</td>
<td>111 (20%)</td>
<td>383 (8%)</td>
<td>150 (37%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>449</td>
<td>4498</td>
<td>253</td>
</tr>
<tr>
<td>All</td>
<td>In</td>
<td>701 (33%)</td>
<td>2749 (19%)</td>
<td>2281 (49%)</td>
</tr>
<tr>
<td></td>
<td>Out</td>
<td>1436</td>
<td>11866</td>
<td>2346</td>
</tr>
</tbody>
</table>
### Table of cost implications

This table shows the effect of the formulary on the cost of prescriptions Jan-March 93. The second column shows the expected cost if the proportion of prescriptions for drugs in the formulary before the meetings had been continued into 1993. Subtracting the actual cost gives the saving. Negatives value represent an increased in cost.

<table>
<thead>
<tr>
<th>Dr X</th>
<th>BNF Group</th>
<th>Expected</th>
<th>Actual</th>
<th>Saving</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Gut)</td>
<td>3873</td>
<td>3875</td>
<td>-2</td>
<td></td>
</tr>
<tr>
<td>2 (CVS)</td>
<td>9116</td>
<td>8116</td>
<td>1000</td>
<td></td>
</tr>
<tr>
<td>3 (RS)</td>
<td>5731</td>
<td>5852</td>
<td>-121</td>
<td></td>
</tr>
<tr>
<td>4 (CNS)</td>
<td>4154</td>
<td>4143</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>5 (AntiB)</td>
<td>3310</td>
<td>3898</td>
<td>-588</td>
<td></td>
</tr>
<tr>
<td>6 (Endo)</td>
<td>1491</td>
<td>1375</td>
<td>116</td>
<td></td>
</tr>
<tr>
<td>7 (Obs/G)</td>
<td>1240</td>
<td>1245</td>
<td>-5</td>
<td></td>
</tr>
<tr>
<td>9 (Nut/Bld)</td>
<td>476</td>
<td>494</td>
<td>-18</td>
<td></td>
</tr>
<tr>
<td>10 (MSk)</td>
<td>4439</td>
<td>3943</td>
<td>496</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>33829</td>
<td>32941</td>
<td>888</td>
<td></td>
</tr>
</tbody>
</table>
Appendix D  Measuring changes in primary care prescribing -
traps for the unwary and how to avoid them

This paper has been submitted to the British Journal of General Practice.
Measuring changes in primary care prescribing - traps for the unwary and how to avoid them
Summary

The principles of how to use and interpret prescribing data are readily available from the Prescription Pricing Authority, but there are many traps in converting the principles into practice. Described here is a simple tool to assess prescribing. It removes the effects of many confounding variables. It may be helpful to anyone wishing to assess the impact of local initiatives on prescribing in primary care.

Introduction

Now that Primary Care Groups are responsible for drug budgets, many more people across the United Kingdom will be involved in analysis of prescribing. Of particular importance is the strong link between the clinical governance agenda to improve quality and the new ability of primary care group prescribing advisors to support good prescribing practice. Interventions to improve prescribing are often evaluated using data from the Prescribing Analysis and Cost (PACT) data (PPD in Scotland), but the sheer volume of data and the complexity of the activity underlying the figures mean that it is no easy task to reach firm conclusions. Standard analysis can be done using the electronic version online ePACT, although access is restricted to preserve confidentiality.

This article addresses problems that face anyone trying to answer a specific non-standard question using primary care prescribing data, and presents a method which enables the effect of an intervention to be assessed while minimising the effect of confounding variables. Standard methods are often designed for national or research covering a large area, but local initiatives in primary care, such as the evaluation of a formulary or educational programme, require analysis of prescribing relating more specifically to the intervention. Some of the pitfalls are well known, some more obscure. Whilst it is not
possible to offer a complete solution for each one, being aware of the difficulty is half the battle. More realistic conclusions can be reached once it is appreciated that they rely on certain assumptions, which will not always be valid. Small or moderate changes resulting from interventions to improve prescribing need to be carefully extracted from substantial background variation, intrinsic to prescribing data.² ³

As a general example, assume we wish to evaluate the effect of an intervention to improve prescribing. It may be a prescribing incentive scheme, or a new formulary, or a series of practice visits by a pharmacist, or anything that happens to some practices within a given time. The type of parameters of interest include volume of prescribing, choice of drug, and cost.

The Difficulties

1. What are we counting?

*The item can be any size.*

A prescription for one item can be anything from a single tablet to a six month supply. The difficulties in using such a variable unit have been the subject of entire papers. Defined daily doses offer an alternative. The choice depends on the question being asked. If volume of prescribing and cost analysis are central to the study, defined daily doses may be better; if it is the activity of prescribing that is central, the choice of drug, the decision to prescribe, rather than how much, then the item may be a more appropriate unit.

*List size.*

Notorious for causing difficulties. This is the denominator for all the fractions often
quoted where a parameter is expressed relative to the list size of a practice. Rather than simply using the number of patients, a formula to calculate prescribing units (PUs or ASTROPUs or STARPUs) is usually used in an attempt to compensate for the fact that certain groups of patients require more medication than others. Despite these improvements, list size remains one of the biggest jokers in the data pack. Prescribing is not simply related to the number of patients in a linear way, but influenced by the demand for treatment, and the availability of doctors to prescribe. A partner retiring and not being replaced for several months could have a major impact on prescribing despite a steady list size. Such events happen often enough to disrupt studies involving a small sample of practices. Bizarre swings in the supposed prescribing are usually found to be an artefact of a sudden change in list size, such as a practice taking over the list of a closing practice.

2. Collecting the data.

Access to PACT data is restricted.

Unless you have implied consent by virtue of your post as an NHS prescribing advisor or researcher, full detail PACT data are only available with signed consent of all partners in a practice. This applies to GP board members of Primary Care Groups, even though they are subcommittees of Health Authorities and accountable for the drug budget. In fact, very few practices withhold consent. Between 1991 - 1998 I analysed PACT data to assess the impact of developing a primary care formulary for Bedfordshire, with full signed consent from all doctors in 20 practices. PACT data were delivered in boxes full of paper, requiring painstaking effort to re-enter the data on to a computer database so that it could be analysed. The development of ePACT and the possibility to download this information is most welcome. There may be difficulties in permitting access to a non-standard set of data, such as only 20 out of 100 practices spread across the county.

Appendix D. Measuring changes in primary care prescribing
It is not time to question the assumption that doctors want tight security about this information, particularly as it concerns public money?

PACT data changes occasionally

In 1994, list sizes were included in the full catalogue PACT data, what was then called level-3 data, but from 1995 onwards they only appeared in the summary level-1.

Unexpectedly, signed consent for level-3 data did not entitle a researcher to the simpler level-1 printout. This disappearance of the list size halted research until a complete new set of signature could be obtained. More recently the way in which the proportion of generic items is calculated was changed to exclude dressings. Vigilance is needed to spot these changes, otherwise there can be an unexplained shift in prescribing or a big hole in the data.

3. Finding the ripple of evidence amongst the ocean waves.

Wide variation in prescribing between practices.

Simple comparisons between small groups of practices using average levels of prescribing will be unlikely to detect the effect of the intervention, even if there is one. The inter-practice variation will mask differences in prescribing caused by the intervention. The standard PACT summary compares a practice with a Health Authority or National equivalent practice, an imaginary practice with the same number of prescribing units. This is an unmatched comparison. Two practices with the same number of prescribing units may have quite different prescribing to meet the needs of their population of patients. The standard statistical method to deal with this problem is to use matched pairs of subject and control practices, but well-matched practices are difficult to find. A compromise which goes some way towards this ideal is to apply shifts in the

Appendix D. Measuring changes in primary care prescribing
demand, as seen in other nearby practices, for prescribing of a particular drug or small therapeutic groups of medication (e.g., 3 commonly used beta-blockers, 2 particular antihistamines). Then an imaginary practice can be created by applying these demand factors to the actual prescribing of a real subject practice in year 1 to predict how that practice would prescribe in year 2 in response to local demands. Such an imaginary practice is a better match for the subject practice than a Health Authority or National equivalent practice.

Seasonal variation.

This invalidates any study which looks at prescribing immediately before and after an intervention, when prescribing levels in different months may be wildly different, particularly in the case of antibiotics. Attempts have been made to allow such comparisons \(^{13}\), by applying average adjustments to compensate for the seasonal variation, but such adjustments cannot take into account local epidemics, media releases, new drugs or newly discovered problems with old ones. Furthermore, the source of these adjustment factors is now 10 years old.

Price changes are unpredictable.

The price of a particular drug can change suddenly as a result of market forces or Government price negotiation. Even the average price of drugs cannot be expected to follow the general inflation rate of any one country \(^{14}\).

Individual doctor's data are unreliable when prescribing is a team activity

List size problems are amplified when it comes to looking at the prescribing of a single doctor. Junior partners will often have small lists but actually prescribe for a full partners' share of the patients in a practice. Computerised repeat prescriptions do not
always bear the name of the responsible doctor. Locums, registrars and deputising services confuse the picture further. Unless a practice operates a strict individual list system which also includes a formal repeat prescription policy, analysis of an individual doctor's prescribing cannot reliably reflect that doctor's prescribing.


Absolute proportions are invalid.

For example, if a control practice increases a proportion parameter, such as generic prescribing, by 17%, it would be invalid to expect a subject practice to change by 17%. The control practice might have shifted from 40% to 57%, whereas if the subject practice were already at 86% it could hardly increase to 103%. More on this later.

Regression towards the mean. 15.

Primary Care Groups may target practices where prescribing is unusual, the outliers on the bar charts. After an intervention, a shift towards the mean could easily be misinterpreted as a sign that the intervention had an effect, but in fact such a shift would be expected from the natural tendency of a sample of outliers to become more average. This is a statistical, not a prescribing phenomenon.

5. Interpreting the data.

PACT is amalgamated data unlinked to either the patient or their illness.

Quality of prescribing cannot be assessed by using PACT data alone16,17, except for drugs with high risk to benefit ratio which should not be prescribed at all.

Lack of validated prescribing indicators for primary care.

Indicators that are used in general practice are based on opinion as to what should
represent good prescribing\textsuperscript{18,19}. Even the best known of these, the brown to blue (corticosteroid : bronchodilator) ratio of inhalers for asthma has been shown to be unreliable in assessing quality of prescribing\textsuperscript{20,21}. What we need are evidence-based indicators, such as those used in secondary care\textsuperscript{22}.
A Suggested Method

General principles

Aim to apply standard principles of research to any study on prescribing. Units have to be defined and used consistently throughout, even if they are not perfect in themselves. On a shifting background, a control group is essential. Comparisons have to be made between groups that are as closely matched as possible, so use the same months of the year and the same practices. A decision has to be made about what represents the smallest unit in the sample, is it a doctor, a practice, a Primary Care Group, or a still larger group? The smaller the unit the bigger the apparent sample size, but also the bigger the natural variation in the data for each unit. Analysis by practice is usually a good balance.

A compromise which goes some way towards the ideal of using matched practices as controls is to apply shifts in the demand for medication, as seen in other nearby practices, to prescribing of a particular drug or small therapeutic groups of medication (e.g. 3 commonly used beta-blockers, 2 particular antihistamines). Then an imaginary practice can be created by applying these demand factors to the actual prescribing of a real subject practice in one year, to predict how that practice would prescribe the following year, in response to local demands. Such an imaginary practice is a better match for the subject practice than a Health Authority or National equivalent practice. At first sight, it may seem that the two methods are the same. The reason for the difference and slight improvement in matching is the application of demand factors to small therapeutic groups before totalling, instead of an averaged demand factor applied to total prescribing in a larger therapeutic group. For example, the number of items of three small therapeutic groups of drugs prescribed by a subject practice January-March 1999 is A, B and C. Other nearby practices show that demand for prescribing changes thus: A changed by a factor

Appendix D. Measuring changes in primary care prescribing
$d_A, B$ changed by $d_B$, and $C$ changed by a factor $d_C$. Mostly these demand factors are in the range 0.9 - 1.1. After an intervention in September 1999, we wish to see if the subject practice is prescribing differently in January-March 2000. A Health Authority equivalent practice as shown on a PACT standard report would give an expected level of prescribing of $(A+B+C)$ multiplied by the average change in demand $(d_A+d_B+d_C)/3$. This is does not give the same result as applying the demand factors individually before totally, which would be $(A.d_A+B.d_B+C.d_C)$. This result more closely matches what the subject would have prescribed without the intervention because it takes into account the levels of prescribing of the small therapeutic groups, reflecting the population needs that practice is serving.

The rest of this article describes a method which overcomes some of the difficulties outlined above. The mathematical pitfalls are avoided, the inter-practice variation and powerful external influences are accommodated, and the list size problem disappears in the section 2.

Appendix D. Measuring changes in primary care prescribing
A Suggested Method

Visualising the comparison with vectors

The term is borrowed from mechanics, where two independent forces can be analysed to find out the direction and strength of the combined force. When applied to prescribing, one force is the effect of an intervention and the other is the effect of every other influence. The aim is to enable a comparison of a practice (or group of practices) before and after an intervention. In order to do this we need to minimize the effect of the many external influences. To see the effect of the intervention, we need to look at the difference between the practice prescribing after the intervention and what it would have been if the intervention had not happened.

A dinghy that hoists a sail will end up in a different place to one that drifts with the tide. The difference in the final positions is the effect of the sail. See Figure 1.

To estimate how practices would have prescribed without intervention, the following information is needed:

1. the initial prescribing of the practices before the intervention, equivalent to the starting position of the dinghy
2. the external influences on prescribing:
   a) the list size factor, which adjusts for changes in the number of people registered with the practices
   b) the demand factor, which adjusts for changes in the need for prescriptions for a group of drugs

These external influences are equivalent to the tide in the marine analogy. The factors are

Appendix D. Measuring changes in primary care prescribing 125
derived from control data from a large number of practices in the same locality. Suitable control data can be obtained by subtracting all subject practices’ data from county or Primary Care Group data, leaving amalgamated data on all practices not involved in an intervention. With these three pieces of information, an \textbf{expected value} can be calculated for the practices, which can be compared with the \textbf{observed value} using standard statistical tests, in order to measure the effect of the intervention.

\textbf{Calculating the vectors}

Simple arithmetic using nothing more than $+ - \times \div$ is all that is required, but the method described below carefully avoids the pitfall which arises from summing proportions. For example, the correct way to apply control data to a practice’s initial prescribing in order to estimate what change in generic prescribing would have occurred without intervention, is to calculate the effect on generic and non-generic prescribing separately and then find the predicted proportion of generic prescribing. Following the method given will ensure such calculations are done in the right order.

\textbf{Parameters of prescribing}

The method gives information on three aspects of prescribing: volume, choice of drug, and cost. It is independent of the units used, but the units must be the same throughout. For simplicity, I refer to items as the unit of prescribing. The most reliable measure of the impact of an intervention is when the choice of drug is influenced. This is because it is independent of list size. The way to assess it is given in section 2.

\textbf{Maximising the power of the method}

Results will be more reliable if the control data is a good match for the subject data, for example if all the data used applies to the same group of drugs. If the aim is to measure
the impact of a pharmacist visiting practices to discuss drugs for musculoskeletal conditions, those in chapter 10 of the British National Formulary, then the control data should apply to exactly the same group of drugs. For overall assessment of the influence of an intervention on cost, it is best to analyse groups of drugs separately and add together the cost changes afterwards. Amalgamating the data first would result in a poorer match between the control and subject data. For example, a general inflation in the cost of certain expensive cardiovascular drugs should not be allowed to mask a significant change in the prescribing of analgesics just because they are cheaper. In fact the smaller the group of drugs analysed, the more powerful the method, but the price to pay for this is the need to subdivide the prescribing data down to individual drug level. There must be a limit to focusing down on a very small group of drugs, especially rarely used ones, beyond which the number of items prescribed in the time studied becomes low enough to impair the statistical power. Pragmatically the usual limitation is not the number of items prescribed but the number of practices in the sample. A formal estimation of the number of practices required to represent a sample size sufficient to detect a certain degree of change requires knowledge of historical variability in local prescribing. This data is held by Health Authority pharmaceutical advisors. In my experience, a sample of ten practices, such as might be found within smaller primary care group areas, will be sensitive to changes in prescribing over about 5%.

Appendix D. Measuring changes in primary care prescribing
Vectors applied to prescribing

The idea of drawing the vectors is simply to make the method that follows easier to visualise. Each parameter of prescribing activity can be plotted vertically against time horizontally. See Figure 2.

To simplify the calculations and avoid the problems of seasonal variations, we can keep the right hand vector vertical by finding the expected prescribing for the same time period for which we have data about actual prescribing. The next section gives the method of finding the position of the expected prescribing point for each of three parameters: volume, choice of drug and cost. Subtracting the expected from the observed point gives the estimated influence of the intervention.

Finally, a worked example using real data is included.

1. Influence on the volume of prescribing

for example, number of items per quarter year.

1. Factor 1. Change in list size (more patients will require more prescriptions)

\[
lsf_s = \frac{ls(y)}{ls(0)}
\]

\[ls(y)\] list size of subject in year y, using the same date in each year

(year 0 is prior to the intervention)
2. Factor 2. Change in the demand for prescriptions

Change in demand is estimated by change in the frequency of prescribing, for example an 
epidemic increasing antibiotic prescribing.

\[ \text{df}_c = \frac{i_c(y)}{l_{sc}(y)} \]

\[ \text{df}_c = \frac{i_c(0)}{l_{sc}(0)} \]

3. The expected volume of prescribing of a subject can be found using the factors

\[ \text{expected } i_s(y) = i_s(0) \cdot \text{lsf}_s \cdot \text{df}_c \]

This is the volume prescribed at baseline, adjusted for changes in list sizes and demand. 
This can be compared with the observed volume of prescribing of the subject in a quarter 
of year y. The difference between the observed and expected volume of prescribing is the 
intervention vector.

Statistical tests:

1. mean and confidence intervals can be calculated for the changes in volume of 
prescribing by a group of subjects

2. p values can be calculated by using matched paired t-tests, with each pair being 
observed \( i_s(y) \), expected \( i_s(y) \). This is a robust test which is valid if the 
sample data is drawn from a population which is approximately normally distributed.

3. Wilcoxon matched-pairs signed-rank test can be used to test a null hypothesis that the 
subject practices changed randomly, but this in itself gives no indication as to the degree 
of change.
2. Influence on the choice between drugs in and drugs out of a formulary

*A formulary could be any list of drugs within an intervention programme aimed at changing prescribing.*

1. Defining proportions.

*In a quarter of year y:*

\[ p_{ins}(y) \] proportion of items prescribed by subject s which are in the formulary
\[ i_{ins}(y) \] number of items prescribed by subject s which are in the formulary
\[ i_{outs}(y) \] number of items prescribed by subject s which are outside the formulary

\[
p_{ins}(y) = \frac{i_{ins}(y)}{i_s(y)} = \frac{i_{ins}(y)}{i_{ins}(y) + i_{outs}(y)}
\]

2. Expected volumes in and out of the formulary.

Expected levels of prescribing of drugs in the formulary can be calculated by using the equation on volume:

\[ df_{inc} \] demand factor for drugs in the formulary (*calculated from control data*)

\[
\text{expected } i_{ins}(y) = i_{ins}(0) \cdot lsf_s \cdot df_{inc}
\]

This is the number of formulary items prescribed at baseline, adjusted for change in list sizes and demand.

Similarly, for drugs outside the formulary:

\[ df_{outc} \] demand factor for drugs out of the formulary (*calculated from control data*)

\[
\text{expected } i_{outs}(y) = i_{outs}(0) \cdot lsf_s \cdot df_{outc}
\]
3. Expected proportions

The expected proportion of items prescribed by subject $s$ which are in the formulary

$$\text{expected } p_{\text{in}_s}(y) = \frac{(i_{\text{in}_s}(0) \cdot lsf_s \cdot df_{\text{in}_c})}{(i_{\text{in}_s}(0) \cdot lsf_s \cdot df_{\text{in}_c}) + (i_{\text{out}_s}(0) \cdot lsf_s \cdot df_{\text{out}_c})}$$

which simplifies to:

$$\frac{(i_{\text{in}_s}(0) \cdot df_{\text{in}_c})}{(i_{\text{in}_s}(0) \cdot df_{\text{in}_c}) + (i_{\text{out}_s}(0) \cdot df_{\text{out}_c})}$$

(The list size factor cancels out because it affects the prescribing of drugs in and outside the formulary equally, and thus has no influence on the proportion.)

This can be compared with the observed proportion $p_{\text{in}_s}(y)$. See statistical methods in section 1 on volume above.

Influence of the formulary on the choice between two drugs which are either both in the formulary, or both outside it, will not be reflected in this comparison. However, if there is a great difference in the cost of the two alternative drugs, then it would be possible for the formulary to influence prescribing costs without any apparent change in either volume of prescribing, or the proportion of drugs prescribed from within the formulary.
3. Influence on the cost of prescribing

*this will depend on changes both in the volume of prescribing and the choice of drug*

1. Expected cost of prescribing by a subject s.

*In a quarter of year y:*

\[
c_s(y) \quad \text{total cost of items prescribed by subject s}
\]

\[
c_{\text{in}}(y) \quad \text{cost of items prescribed by subject s which are in the formulary}
\]

\[
c_{\text{out}}(y) \quad \text{cost of items prescribed by subject s which are outside the formulary}
\]

For drugs in the formulary, the expected costs can be calculated by multiplying the average cost of formulary items

\[
\text{expected } c_{\text{in}}(y) = \frac{\text{expected } i_{\text{in}}(y) \cdot c_{\text{in}}(y)}{i_{\text{in}}(y)}
\]

Similarly, for drugs outside the formulary:

\[
\text{expected } c_{\text{out}}(y) = \frac{\text{expected } i_{\text{out}}(y) \cdot c_{\text{out}}(y)}{i_{\text{out}}(y)}
\]

2. Expected total costs

\[
\text{expected } c_s(y) \quad \text{Total expected cost of items prescribed by subject s}
\]

\[
\text{expected } c_s(y) = \text{expected } c_{\text{in}}(y) + \text{expected } c_{\text{out}}(y)
\]

This is simply the sum of costs for items in and out of the formulary. It can be compared with the observed cost of items prescribed in a quarter of year y by subject s. If the observed costs are lower than expected, then the intervention reduced costs.
1. Drifting on the tide

2. What happens with the sail up

3. Working out the effect of the sail

Figure 1. Marine analogy
Figure 2. Prescribing vectors

Appendix D. Measuring changes in primary care prescribing
Key messages

- Compare prescribing in the same months of different years
- Sample practice data, not individual doctor's data
- Compare expected and observed prescribing after an intervention
- Calculate means with confidence intervals or use a matched-pair statistical test
References

1. Available with prescriber's consent from Prescription Pricing Authority. Newcastle NE2 1DB. Help Desk telephone 0191 203 5050


8. See any PACT standard report document (source in reference 1)


*Appendix D. Measuring changes in primary care prescribing*


Worked Example

In 1997, the dermatology section of a primary care drug formulary was developed in one part of Bedfordshire. It was distributed on New Year's Day 1998 to nine participating practices. To measure the effect of one chapter in the formulary, we will compare PACT data level-3 for the first quartet of 1996 with the same quarter in 1997. The example data (Table 1) refers to one of the nine practice's prescribing of drugs in chapter thirteen of the BNF, the dermatology section. The control data is obtained by subtracting the nine practices from the amalgamated data for the whole county. The units are: items prescribed, cost in £, and the prescribing list sizes in prescribing units as specified in the PACT level-1 data.

1. Influence on volume

List size factor

\[ \text{lsf}_s = \frac{\text{ls}_s(98)}{\text{ls}_s(97)} = \frac{5047}{4929} = 1.024 \]

Demand factor

\[ \text{df}_c = \frac{[i_s(98) / \text{ls}_o(98)]}{[i_s(97) / \text{ls}_o(97)]} \]
\[ = \frac{[77372/642632]}{[76350/638720]} = 1.007 \]

Expected volume of prescribing in 1998

\[ \text{expected } i_s(98) = i_s(97) \cdot \text{lsf}_s \cdot \text{df}_c \]
\[ = 602 \cdot 1.023 \cdot 1.007 = 620 \]

Actual number of items prescribed in 1998

\[ \text{actual } i_s(98) = 572 \]

Intervention caused a change in volume of prescribing of:

\[ 572 - 620 = -48 \]  
(The negative value means volume decreased)

Appendix D. Measuring changes in primary care prescribing
Significance

To find out if the subject practices changed significantly, calculate the change for each of the nine practices. The data for the other eight practices are not included in the above example but give the mean of the differences between actual and expect prescribing volumes as +24.4 items, with a standard deviation of 82.7. For a sample size of 9, the 95% confidence interval is 24.4 +/- 68. This includes zero (no difference between actual and expected) and is not significant. Matched-paired t-test gives t=0.89, well below significance level.

2. Influence on the choice of drug.

Proportion of items prescribed by the subject practice in 1998 which were in the formulary

\[ p_{in}(98) = \frac{265}{572} = 0.463 \]

Demand factor for drugs in the formulary

\[ df_{in} = \frac{[i_{in}(98)/ls(98)]}{[i_{in}(97)/ls(97)]} \]
\[ = \frac{[35442/642632]}{[34295/638720]} = 1.027 \]

Similarly, demand factor for drugs outside the formulary

\[ df_{out} = \frac{[i_{out}(98)/ls(98)]}{[i_{out}(97)/ls(97)]} \]
\[ = \frac{[41930/642632]}{[42055/638720]} = 0.991 \]

Expected number of items prescribed by the subject practice in 1998 which would be in the formulary

\[ expected\ i_{in}(98) = i_{in}(97) \cdot ls_{in} \cdot df_{in} \]
\[ = 246 \cdot 1.024 \cdot 1.027 = 259 \]
Similarly, for drugs outside the formulary:

\[
\text{expected } i_{\text{out}}(98) = i_{\text{out}}(97) \times \text{lsf} \times \text{df}_{\text{out}}_c \\
= 356 \times 1.024 \times 0.991 = 361
\]

**Expected proportion of items prescribed by the subject practice in 1998 in the formulary**

\[
\text{expected } p_{\text{in}}(98) = \frac{259}{259 + 361} = 0.418
\]

Intervention caused a swing towards the use of drugs in the formulary of:

\[
0.463 - 0.418 = 0.045
\]

In other words, a 4.5% swing. Significance for the sample of subject practices can be determined in the same way as in section 1. Calculating the above for each of the nine practices gives a mean swing of 3.1% with a standard deviation of 4.2%. The 95% confidence interval would be 3.1% +/- 3.4%. This just includes the zero, so on the confidence interval one could not claim significance at the 5% level. The power of the statistical test can be improved by pairing each practice's actual and expected proportions. A matched-pair t-test gives \( t = 2.21 \), which reaches 5% significance for a one-tailed test. The one-tail is appropriate for testing the hypothesis that the intervention *increased* the prescribing of formulary drugs. It is unlikely that developing a formulary would decrease the use of the drugs selected for inclusion by the participating practices, so the hypothesis that the intervention *changed* the prescribing choices, which would require a two-tailed test, is less appropriate.
3. Influence on cost.

**Expected cost of items prescribed by the subject practice in 1998 which were in the formulary**

\[
\text{expected } c_{\text{in}}(98) = \frac{[\text{expected } i_{\text{in}}(98) \cdot c_{\text{in}}(98)]}{i_{\text{in}}(98)} = \frac{[259 \cdot 1054]}{265} = \€1030
\]

Similarly, expected costs for drugs outside the formulary:

\[
\text{expected } c_{\text{out}}(98) = \frac{[\text{expected } i_{\text{out}}(98) \cdot c_{\text{out}}(98)]}{i_{\text{out}}(98)} = \frac{[361 \cdot 2999]}{307} = \€3527
\]

**Expected total cost for all items in 1998**

\[
\text{expected } c(98) = \text{expected } c_{\text{in}}(98) + \text{expected } c_{\text{out}}(98) = 1030 + 3527 = \€4557
\]

This can be compared with the actual cost of items prescribed

\[
\€4053 - \€4557 = -\€504
\]

*The negative value means costs were reduced by the intervention*

Remember this represents the saving by one practice, for items in one chapter of the BNF over one quarter year. The overall effect on cost can be found by totalling the change in cost for each of the nine subject practices.
Table 1. Example data. Prescribing of dermatology items by one practice and a large control group 1997 - 1998.

<table>
<thead>
<tr>
<th></th>
<th>Subject practice</th>
<th>Control</th>
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<tbody>
<tr>
<td>Prescribing list size</td>
<td>4929</td>
<td>5047</td>
</tr>
<tr>
<td>Items prescribed</td>
<td>602</td>
<td>572</td>
</tr>
<tr>
<td>..of which in formulary</td>
<td>246</td>
<td>265</td>
</tr>
<tr>
<td>Cost of items</td>
<td>4439</td>
<td>4053</td>
</tr>
<tr>
<td>..of which in formulary</td>
<td>1016</td>
<td>1054</td>
</tr>
</tbody>
</table>
Appendix E  Sharing resources to create a district drug formulary: a countywide controlled trial

This is a reprint of a paper published in the British Journal of General Practice in 1996 as a report on the evaluation of the formulary in South Bedfordshire.
PARTS EXCLUDED UNDER INSTRUCTION FROM THE UNIVERSITY
Appendix F  Comparison of North and South Formularies
## Primary Care Drug Formulary
### Comparison of North and South Bedfordsire

### North

#### Group 1 Gastro-intestinal

1.1 Magnesium Trisilicate  
   Gaviscon and **Infant Gaviscon Infacol**

1.2 Mebeverine  
   Dicyclomine

1.3 Cimetidine  
   Nizatidine  
   **Lansoprazole**

1.4 Loperamide

1.5 **Sulphasalazine**  
   **Mesalazine**

1.6 Fybogel  
   **Regulan**  
   Bisacodyl  
   **Co-danthrusate Glycerol**  
   Senna  
   **Manevac**  
   Lactulose  
   **Micolette**

1.7 Anusol and **Anusol HC Betnovate**  
   Xyloproct

### South

- Magnesium Trisilicate  
  Gaviscon

- Mebeverine  
  Dicyclomine

- Cimetidine  
  Nizatidine  
  **Ranitidine**

- Loperamide  
  **Codeine Phosphate**

- Fybogel  
  Bisacodyl

- Senna  
  **Lactulose**

- Anusol  
  Xyloproct

### Group 2 Cardiovascular

2.1 Digoxin

2.2 Bendrofluazide  
   Frusemide  
   **Bumetanide**  
   Amiloride  
   Coamilofruse

2.4 Propanolol  
   Atenolol  
   **Tenoret 50**
### Primary Care Drug Formulary
#### Comparison of North and South Bedfordsire

<table>
<thead>
<tr>
<th>North</th>
<th>South</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.5</strong> <strong>Doxazosin</strong></td>
<td></td>
</tr>
<tr>
<td>Enalapril</td>
<td></td>
</tr>
<tr>
<td>Lisinopril</td>
<td></td>
</tr>
<tr>
<td><strong>2.6</strong> Glyceryl trinitrate</td>
<td></td>
</tr>
<tr>
<td>Isosorbide MN</td>
<td></td>
</tr>
<tr>
<td>Amlodipine</td>
<td></td>
</tr>
<tr>
<td>Diltiazem</td>
<td></td>
</tr>
<tr>
<td>Nifedipine</td>
<td></td>
</tr>
<tr>
<td>Adalat LA</td>
<td></td>
</tr>
<tr>
<td><strong>2.8</strong> Warfarin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2.11</strong> Tranexamic Acid</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2.12</strong> <strong>Bezafibrate</strong></td>
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</tr>
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<td>Simvastatin</td>
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</tr>
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</table>

#### Group 3 Respiratory

<table>
<thead>
<tr>
<th>North</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>3.1</strong> Salbutamol</td>
<td></td>
</tr>
<tr>
<td>including <strong>Ventolin Easi-Breathe</strong></td>
<td></td>
</tr>
<tr>
<td>Diskhaler</td>
<td></td>
</tr>
<tr>
<td>Volumatic</td>
<td></td>
</tr>
<tr>
<td>Terbutaline</td>
<td></td>
</tr>
<tr>
<td>Nebuhaler</td>
<td></td>
</tr>
<tr>
<td><strong>Salmeterol</strong></td>
<td></td>
</tr>
<tr>
<td>Ipratropium Bromide</td>
<td></td>
</tr>
<tr>
<td><strong>Slo-phyllin</strong></td>
<td></td>
</tr>
<tr>
<td>Peak Flow Meter</td>
<td></td>
</tr>
<tr>
<td><strong>3.2</strong> Beclomethasone</td>
<td></td>
</tr>
<tr>
<td>including <strong>Beclazone</strong></td>
<td></td>
</tr>
<tr>
<td>Budesonide</td>
<td></td>
</tr>
<tr>
<td>(6.4) Prednisolone</td>
<td></td>
</tr>
<tr>
<td><strong>3.3</strong> Sodium Cromoglycate</td>
<td></td>
</tr>
<tr>
<td>Spinhaler</td>
<td></td>
</tr>
<tr>
<td><strong>Insufflator</strong></td>
<td></td>
</tr>
<tr>
<td><strong>3.4</strong> Sodium Cromoglycate</td>
<td></td>
</tr>
<tr>
<td>Spinhaler</td>
<td></td>
</tr>
<tr>
<td><strong>Insufflator</strong></td>
<td></td>
</tr>
<tr>
<td><strong>South</strong></td>
<td></td>
</tr>
<tr>
<td>Lisinopril</td>
<td></td>
</tr>
<tr>
<td>Glyceryl trinitrate</td>
<td></td>
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<tr>
<td>Isosorbide MN</td>
<td></td>
</tr>
<tr>
<td>Amlodipine</td>
<td></td>
</tr>
<tr>
<td>Diltiazem</td>
<td></td>
</tr>
<tr>
<td>Nifedipine</td>
<td></td>
</tr>
<tr>
<td>Adalat LA and <strong>Adalat Retard</strong></td>
<td></td>
</tr>
<tr>
<td>Warfarin</td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td></td>
</tr>
<tr>
<td>Tranexamic Acid</td>
<td></td>
</tr>
<tr>
<td><strong>Bezalip-mono</strong></td>
<td></td>
</tr>
<tr>
<td>Simvastatin</td>
<td></td>
</tr>
</tbody>
</table>

| **3.5** Salbutamol                          |                                                         |
| including **Ventolin Easi-Breathe**         |                                                         |
| Diskhaler                                   |                                                         |
| Volumatic                                   |                                                         |
| Terbutaline                                 |                                                         |
| Nebuhaler                                   |                                                         |
| **Salmeterol**                              |                                                         |
| Ipratropium Bromide                        |                                                         |
| **Slo-phyllin**                             |                                                         |
| Peak Flow Meter                             |                                                         |
| **3.6** Beclomethasone                      |                                                         |
| including **Beclazone**                     |                                                         |
| Budesonide                                  |                                                         |
| (6.4) Prednisolone                          |                                                         |
| **3.7** Sodium Cromoglycate                 |                                                         |
| Spinhaler                                   |                                                         |
| **Insufflator**                             |                                                         |
|  **South**                                  |                                                         |
| Lisinopril                                  |                                                         |
| Glyceryl trinitrate                         |                                                         |
| Isosorbide MN                               |                                                         |
| Amlodipine                                  |                                                         |
| Diltiazem                                   |                                                         |
| Nifedipine                                  |                                                         |
| Adalat LA and **Adalat Retard**             |                                                         |
| Warfarin                                    |                                                         |
| Aspirin                                     |                                                         |
| Tranexamic Acid                             |                                                         |
| **Bezalip-mono**                            |                                                         |
| Simvastatin                                 |                                                         |

| **3.8** Salbutamol                          |                                                         |
| including **Ventolin Easi-Breathe**         |                                                         |
| Diskhaler                                   |                                                         |
| Volumatic                                   |                                                         |
| Terbutaline                                 |                                                         |
| Nebuhaler                                   |                                                         |
| **Salmeterol**                              |                                                         |
| Ipratropium Bromide                        |                                                         |
| **Slo-phyllin**                             |                                                         |
| Peak Flow Meter                             |                                                         |
| **3.9** Beclomethasone                      |                                                         |
| including **Beclazone**                     |                                                         |
| Budesonide                                  |                                                         |
| (6.4) Prednisolone                          |                                                         |
| **3.10** Sodium Cromoglycate                |                                                         |
| Spinhaler                                   |                                                         |
| **Insufflator**                             |                                                         |
|  **South**                                  |                                                         |
| Lisinopril                                  |                                                         |
| Glyceryl trinitrate                         |                                                         |
| Isosorbide MN                               |                                                         |
| Amlodipine                                  |                                                         |
| Diltiazem                                   |                                                         |
| Nifedipine                                  |                                                         |
| Adalat LA and **Adalat Retard**             |                                                         |
| Warfarin                                    |                                                         |
| Aspirin                                     |                                                         |
| Tranexamic Acid                             |                                                         |
| **Bezalip-mono**                            |                                                         |
| Simvastatin                                 |                                                         |

| **3.11** Salbutamol                         |                                                         |
| including **Ventolin Easi-Breathe**         |                                                         |
| Diskhaler                                   |                                                         |
| Volumatic                                   |                                                         |
| Terbutaline                                 |                                                         |
| Nebuhaler                                   |                                                         |
| **Salmeterol**                              |                                                         |
| Ipratropium Bromide                        |                                                         |
| **Slo-phyllin**                             |                                                         |
| Peak Flow Meter                             |                                                         |
| **3.12** Beclomethasone                     |                                                         |
| including **Beclazone**                     |                                                         |
| Budesonide                                  |                                                         |
| (6.4) Prednisolone                          |                                                         |
| **3.13** Sodium Cromoglycate                |                                                         |
| Spinhaler                                   |                                                         |
| **Insufflator**                             |                                                         |

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Primary Care Drug Formulary
Comparison of North and South Bedfordsire

North

3.4 Terfenadine
   Loratidine
   Cetirizine
   Brompheniramine
   Chlorpheniramine

3.6 Oxygen

3.8 Menthol & Eucalyptus

3.9 Simple Linctus
   Pholcodine

Group 4 Nervous

4.1 Temazepam
   Zopiclone
   Diazepam

4.2 Chlorpromazine
   Thioridazine
   Sulpiride
   Lithium

4.3 Amitriptyline
   Dothiepin
   Lofepramine
   Fluoxetine
   Citalopram
   Sertraline

4.6 Metoclopramide
   Prochlorperazine
   including Buccastem
   Domperidone
   Cinnarizine

4.7 Aspirin
   Paracetamol
   Co-codamol 8/500
   Co-proxamol
   Co-dydramol
   Codeine
   Dihydrocodeine

South

Terfenadine
   Loratidine

Chlorpheniramine

Simple linctus
   Pseudoephedrine

Temazepam
   Diazepam

Haloperidol
   Thioridazine

Amitriptyline
   Dothiepin
   Lofepramine
   Clomipramine
   Fluoxetine

Flupenthixol

Metoclopramide
   Prochlorperazine

Domperidone
   Betahistine

Aspirin
   Paracetamol
   Co-codamol 8/500 & 30/500
   Co-proxamol
   Co-dydramol
   Diodyramol
   Dihydrocodeine

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### Primary Care Drug Formulary

**Comparison of North and South Bedfordshire**

<table>
<thead>
<tr>
<th>North</th>
<th>South</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4.7 cont.</strong>&lt;br&gt;Morphine&lt;br&gt;Pizotifen</td>
<td><strong>Diamorphine</strong>&lt;br&gt;Morphine&lt;br&gt;Pizotifen&lt;br&gt;&lt;b&gt;Paramax**&lt;br&gt;<strong>Paramax</strong></td>
</tr>
<tr>
<td><strong>4.8 Carbamazepine</strong>&lt;br&gt;Sodium valproate&lt;br&gt;&lt;b&gt;Phenytoin**&lt;br&gt;<strong>Phenytoin</strong></td>
<td><strong>Tegretol</strong>&lt;br&gt;Sodium Valproate</td>
</tr>
<tr>
<td><strong>4.9 Co-beneldopa</strong>&lt;br&gt;&lt;b&gt;Co-careldopa**&lt;br&gt;<strong>Co-careldopa</strong>&lt;br&gt;Procyclidine</td>
<td><strong>Madopar</strong>&lt;br&gt;Procyclidine</td>
</tr>
<tr>
<td><strong>4.10 Methadone</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Group 5 Infection

<table>
<thead>
<tr>
<th>North</th>
<th>South</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.1</strong>&lt;br&gt;Phenoxympethylpenicillin&lt;br&gt;Flucloxacin&lt;br&gt;Amoxycillin&lt;br&gt;Co-amoxiclav&lt;br&gt;Cephalexin&lt;br&gt;Oxytetracycline&lt;br&gt;Doxycycline&lt;br&gt;M&lt;sup&gt;inocycline&lt;/sup&gt;&lt;br&gt;Erythromycin&lt;br&gt;Clarithromycin&lt;br&gt;Trimethoprim&lt;br&gt;Metronidazole&lt;br&gt;Nitrofurantoin &lt;i&gt;plain &amp; MR&lt;/i&gt;</td>
<td>Phenoxympethylpenicillin&lt;br&gt;Flucloxacin&lt;br&gt;Amoxycillin&lt;br&gt;&lt;b&gt;Co-fluampicil**&lt;br&gt;<strong>Co-fluampicil</strong>&lt;br&gt;Co-amoxiclav&lt;br&gt;Cephalexin&lt;br&gt;Oxytetracycline&lt;br&gt;Doxycycline&lt;br&gt;Erythromycin&lt;br&gt;Clarithromycin&lt;br&gt;Trimethoprim&lt;br&gt;Metronidazole&lt;br&gt;Nitrofurantoin &lt;i&gt;MR&lt;/i&gt;&lt;br&gt;&lt;b&gt;Ciprofloxacin**&lt;br&gt;<strong>Ciprofloxacin</strong></td>
</tr>
<tr>
<td><strong>5.2</strong>&lt;br&gt;Nystatin&lt;br&gt;&lt;b&gt;Terbinafine**&lt;br&gt;<strong>Terbinafine</strong>&lt;br&gt;Fluconazole</td>
<td>Nystatin&lt;br&gt;&lt;b&gt;Miconazole**&lt;br&gt;<strong>Miconazole</strong>&lt;br&gt;Fluconazole&lt;br&gt;&lt;b&gt;Valaciclovir**&lt;br&gt;<strong>Valaciclovir</strong></td>
</tr>
<tr>
<td><strong>5.3</strong>&lt;br&gt;&lt;b&gt;Aciclovir**&lt;br&gt;<strong>Aciclovir</strong></td>
<td></td>
</tr>
<tr>
<td><strong>5.5</strong>&lt;br&gt;Mebendazole&lt;br&gt;&lt;b&gt;Piperazine**&lt;br&gt;<strong>Piperazine</strong></td>
<td>Mebendazole</td>
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## Primary Care Drug Formulary
### Comparison of North and South Bedfordshire

#### Group 6 Endocrine

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<td>Kliofem</td>
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#### Group 7 Obstetrics, Gynaecology and Urinary

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<td>11.8 Hyromellose</td>
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### Group 12 Ear, Nose & Oropharynx

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### Group 13 Skin

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### North

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<td>Daktacort</td>
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<td><strong>Canesten HC</strong></td>
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<tr>
<td></td>
<td>Betamethasone scalp appl</td>
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| 13.5 | Alphosyl | Alphosyl HC |
|      |         | Dithranol   |
|      |         | Calcipriol  |

| 13.6 | Panoxyl | **Quinoderm** |
|      |         | **Benzamycin** |

| 13.7 | Salicylic Acid Colloidion | **Salactac** |

| 13.9 | Capasal | Polytar Liquid |
|      |         | **Nizoral** |

| 13.10 | Fusidic Acid | **Clotrimazole** |
|        |             | Miconazole     |
|        |             | **Terbinafine** |
|        | Aciclovir   | **Benzyl benzoate** |
|        | Malathion   | **Carbaryl**   |
|        | Permethrin  | **Magnesium Sulphate paste** |

| 13.11 | Normasol | **Steripod** |

### South

<table>
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<table>
<thead>
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<td>Daktacort</td>
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| Betamethasone scalp appl |

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### Group 15 Anaesthesia

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Appendix G  Sample data tables
### Appendix G.
Number of items prescribed in the first quarter of each year.
<table>
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Appendix G.
Number of formulary items prescribed in the first quarter of each year.
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Appendix G.
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Appendix G.

Prescribing cost of formulary drugs for the first quarter of each year.

Appendix H Acknowledgements

Supervisors: Professor Andrew Haines and Dr Paramjit Gill
University of London

Statement about conjoint working

Collaboration was an integral part of this research. This is how the work was divided.

Ian Hill-Smith (GP)
Wrote the thesis and supporting papers published so far
Chaired all meetings
Wrote the paper and electronic text versions of all formularies
Analysed the prescribing data
Raised funds and employed or commissioned support via his practice
Disseminated information on results in the form of feedback on prescribing

Lorraine Dakin (Nurse Researcher), Helen Macdonald (Nurse Researcher), and Hazel Reeve (Secretary)
Co-ordinated the process by which items were proposed or excluded from the formularies
Organised meetings
Liased with the Prescription Pricing Authority
Transferred prescribing data from paper to electronic format
Proof read the formularies
Distributed the formularies
Encouraged community nurses to participate

Stephen Jackson (Professor of Gerontology)
Advised on clinical pharmacology at the meetings
Gave helpful suggestions about analysis and methods of feedback on prescribing

Janet Clarbour (Formulary Pharmacist)
Researched the vast majority of the proposals raised by the GPs and nurses
Presented the evidence at the meetings
Proof read and commented on the formularies

100 General Practitioners and 50 Community Nurses in Bedfordshire
Co-operated to create the formularies
Gave access to their prescribing data

Gina Johnson (GP), Lindsay Reyner (GP) and other GP and Nurse members of the South Bedfordshire Practitioners' Group
Proof read and commented on various documents
Contributed to the discussions in the creation of the formularies
Supported the infrastructure via the practitioners' group Culyer fund

Mary Faiers (Consultant Microbiologist) and Lorraine Fitch (Consultant Microbiologist)
Advised at the meetings on prescribing for infectious diseases
Provided local sensitivity data
Proof read and commented on the infection sections of the formularies

Sam Rowlands (GP advisor on contraception to Royal College of Obstetricians and Gynaecologists)
Advised at the meetings on contraception

Veronica Easterbrook (Nurse Advisor) and Claire Bevan (Nurse Advisor)
Advised at the meetings on wound care prescribing

Jacqueline Hill-Smith (Writer)
Proof read and added valuable comments on the thesis and other documents

Smaller contributions were made by other pharmacists: Claire Jones, Dawn Hurrel, Jacqueline Clayton, Masuma Damani, and Karen Homan. Peter Parry-Okeden (GP) and T Hayward converted the formularies into WAX and HTML electronic formats. Peter Clappison (National Pharmaceutical Advisor) initially provided prescribing data for the whole county and gave general support.
Review References

1. Anderson JF, McEwan KL, Hrudey WP.
   Title: Effectiveness of notification and group education in modifying prescribing of regulated analgesics.
   Sample: 54 GPs prescribing high levels of regulated analgesics
   Duration: 13 months
   Outcome: 33% reduction in analgesic prescribing following 1-day group education, 25% following written notification.
   Score: S2 U1 R1 B2 O2 D1 Total=9

2. Angunawela IL, Diwan VK, Tomson G.
   Title: Experimental evaluation of the effects of drug information on antibiotic prescribing: a study in outpatient care in an area of Sri Lanka.
   Sample: 45 doctors 15 institutions
   Duration: 1 year
   Outcome: Group seminars and newsletters showed no effect on antibiotic prescribing.
   Score: S2 U2 R2 B2 O2 D1 Total=11

3. Avery AJ, Walker B, Heron T, Teasdale SJ.
   Title: Do prescribing formularies help GPs prescribe from a narrower range of drugs? A controlled trial of the introduction of prescribing formularies for NSAIDs.
   Sample: 10 practices, NSAID formulary.
   Duration: 1 year
   Outcome: Shift to using drugs in the formulary.
   Score: S2 U2 R0 B2 O2 D1 Total=9
4. Avorn J, Soumerai SB.
Title: Improving drug-therapy decisions through educational outreach. A randomized controlled trial of academically based "detailing".
Sample: 435 doctors
Duration: 9 months
Outcome: Pharmacist visit influenced prescribing.
Score: S2 U2 R2 B2 O2 D1 Total=11

5. Beardon PHG, Brown SV, Mowat DAE, Grant JA, McDevitt DG.
Title: Introducing a drug formulary to general practice - effects on practice prescribing costs.
Notes: The subject GPs had higher costs than the control before the trial.
Sample: 3 GP practice formulary, rest of Scotland as control
Duration: 2.5 years
Outcome: 10% reduction in cost.
Score: S1 U1 R0 B2 O2 D2 Total=8

Title: Impact of a drug-use review program intervention on prescribing after publication of a randomized clinical trial [see comments].
Notes: Cardiac failure treatment.
Sample: 288 doctors
Duration: Under 1 year
Outcome: No change following unsolicited letter and questionnaire.
Score: S2 U1 R2 B2 O2 D0 Total=9

Title: Improving the quality of antibiotic prescription patterns in general practice. The role of educational intervention.
Sample: 182 GPs in Victoria
Duration: Under 1 year
Outcome: Pharmacist visit changed antibiotic prescribing.
Score: S2 U2 R2 B2 O2 D0 Total=10
   Title: Impact of a drug bulletin on the knowledge, perception of drug utility, and prescribing behavior of physicians.
   Ref: DICP 1990; 24(1): 87-93.
   Sample: 186 doctors
   Duration: 6 months
   Outcome: Information bulletin affected stated prescribing for renal colic but not irritable bowel syndrome.
   Score: S2 U2 R2 B2 O2 D0 Total=10

   Title: Effects of "group detailing" on the prescribing of lipid-lowering drugs: a randomized controlled trial in Swedish primary care.
   Sample: 134 health centres
   Duration: Under 1 year
   Outcome: Academic group detailing by pharmacists changed prescribing.
   Score: S2 U2 R2 B2 O2 D0 Total=10

10. Donald JB.
    Title: Prescribing costs when computers are used to issue all prescriptions.
    Notes: Personalised formulary on computer.
    Sample: 1 doctor compared with partners and national data
    Duration: 9 years
    Outcome: 21.5% reduction in cost.
    Score: S0 U1 R0 B2 O2 D2 Total=7

11. Dowell JS, Snadden D, Dunbar JA.
    Title: Changing to generic formulary: how one fundholding practice reduced prescribing costs.
    Sample: 1 practice
    Duration: 1 year
    Outcome: 24% reduction in costs.
    Score: S0 U2 R0 B0 O2 D1 Total=5

Title: Drug prescription attitudes and behaviour of general practitioners. Effects of a problem-oriented educational programme.


Sample: Swedish region

Duration: 10 years

Outcome: Small group education influenced prescribing.

Score: S2 U2 R0 B2 O2 D2 Total=10


Title: Randomised controlled trial of educational package on management of menorrhagia in primary care: The Anglia menorrhagia education study.


Sample: 100 practices in E Anglia

Duration: 6 months

Outcome: Increased use of tranexamic acid for menorrhagia.

Score: S2 U2 R2 B2 O2 D0 Total=10

14. Field J.

Title: How do doctors and patients react to the introduction of a practice formulary?


Notes: The practice that changed was the one that devised the formulary. Association between changing drug and patient discontent.

Sample: 1 subject practice, 3 control practices

Duration: 3 years

Outcome: 72% to 81% increase in formulary drugs.

Score: S0 U2 R0 B1 O2 D2 Total=7
15. Font M, Madridejos R, Catalan A, Jimenez J, Argimon JM, Huguet M.
Title: [Improving drug prescription in primary care: a controlled and randomized study of an educational method]. [Spanish].
Ref: Medicina Clinica 1991;96(6):201-205.
Sample: 244 doctors
Duration: Under 1 year
Outcome: Personalized feedback to high prescribers effective in reducing volume of prescribing.
Score: S2 U2 R2 B2 O2 D0 Total=10

Title: Sleeping with the enemy? A randomized controlled trial of a collaborative health authority/industry intervention to influence prescribing practice.
Sample: 1 Health Authority
Duration: Under 1 year
Outcome: No change resulting from HA/industry representative partnership arranged visits.
Score: S2 U2 R2 B2 O2 D0 Total=10

17. Friis H, Bro F, Mabeck CE, Vejlsgaard R.
Title: An information campaign--an important measure in controlling the use of antibiotics.
Sample: 602 GPs
Duration: 3 separate weeks 1979 - 1987
Outcome: Information campaign reduced antibiotic prescribing and costs.
Score: S2 U2 R0 B2 O2 D2 Total=10
18. Grant GB, Gregory DA, van Zwanenberg TD.
Title: Development of a limited formulary for general practice.
Notes: This is a classic paper on formularies for primary care. All the introduction is salient. Method included a control group of GPs (10 GPs in 8 practices). Formulary classified according to clinical indications. Arbitrary 90% formulary compliance aim. Draft 1 contained 137 drugs, 22 (16%) proprietary.
Sample: Subjects: 25 GPs from 19 practices. Controls 10 GPs from 8 practices.
Duration: 2 x 2 week periods, 1 month apart
Outcome: Formulary influenced choice of drug.
Score: S2 U2 R0 B2 O2 D0 Total=8

19. Green PE.
Title: The general practice formulary: its role in rational therapeutics.
Sample: 5 principals + their trainees
Duration: 2+ years
Outcome: Shift in choice of drugs in formulary.
Score: S2 U1 R0 B0 O2 D2 Total=7

Title: Changing physician prescribing patterns: evaluation of an educational strategy for acute diarrhea in Mexico City.
Notes: Aim to shift prescribing to oral rehydration and away from antibiotics.
Sample: 69 doctors in 2 clinics
Duration: 18 months
Outcome: Sustained change from education and peer review.
Score: S2 U1 R0 B2 O2 D1 Total=8
21. Hadiyono JE, Suryawati S, Danu SS, Sunartono, Santoso B.
Title: Interactional group discussion: results of a controlled trial using a
behavioral intervention to reduce the use of injections in public health facilities.
Sample: 24 public health centres
Duration: Under 1 year
Outcome: Decrease in injection use after discussion group.
Score: S2 U2 R2 B2 D0 Total=10

Title: A randomized, controlled trial of a clinical pharmacist intervention to
improve inappropriate prescribing in elderly outpatients with polypharmacy.
Sample: Doctors of 208 patients, 1 clinic
Duration: 1 year
Outcome: Pharmacist intervention reduced inappropriate prescribing.
Score: S0 U2 R0 B0 D1 Total=5

Title: Prescribing: the power to set limits.
Notes: Review of existing prescribing, taking into account opinions of
practitioners rather than any evidence.
Sample: 1 practice
Duration: 1.5 years
Outcome: GPs willing to change their prescribing.
Score: S0 U2 R0 B0 D1 Total=3
24. Harris CM, Fry J, Jarman B, Woodman E.
Title: Prescribing - a case for prolonged treatment.
Notes: Effect of change in prescribing resulting from detailed feedback every 6 months for a period of 2 years, with discussions, had disappeared at a follow-up study 2 years later.
Sample: 59 principals 2 FPC areas
Duration: 4 years
Outcome: Loss of initial effect.
Score: S2 U2 R2 B2 O2 D2 Total=12

Title: Do drug costs affect physicians' prescription decisions?
Sample: 60 community doctors
Duration: 2 months
Outcome: Knowledge of drug costs influences prescribing by community hospital doctors.
Score: S2 U1 R0 B2 O2 D0 Total=7

26. Hartlaub PP, Barrett PH, Marine WM, Murphy JR.
Title: Evaluation of an intervention to change benzodiazepine-prescribing behavior in a prepaid group practice setting.
Sample: 91 doctors
Duration: 1 year
Outcome: No influence of a variety of methods when applied to a pre-paid group practice.
Score: S2 U2 R2 B2 O2 D1 Total=11
27. Hill-Smith I.
Title: Sharing resources to create a district drug formulary: a countywide controlled trial.
Sample: 50 GPs in 11 practices
Duration: 4 years
Outcome: 1996 Report on the evaluation of this formulary, which influenced drug choice and costs.
Score: S2 U2 R0 B2 O2 D2 Total=10

28. Hux JE, Melady MP, DeBoer D.
Title: Confidential prescriber feedback and education to improve antibiotic use in primary care: A controlled trial.
Sample: 251 GPs in Ontario
Duration: 6 months
Outcome: Mailed educational bulletins and prescribing feedback contained costs and influenced choice of antibiotic.
Score: S2 U1 R2 B2 O2 D0 Total=9

Title: The effects of continuing medical education on family doctor performance in office practice: a randomized control study.
Ref: *Medical Education* 1988;22(2):139-145.
Sample: 31 doctors in 25 practices
Duration: 1 year
Outcome: Changes in treatment of CVS disease and cancer.
Score: S2 U2 R2 B2 O1 D1 Total=10
Title: Cost savings using a stepped-care prescribing protocol for nonsteroidal anti-inflammatory drugs.
Sample: 203 clinicians, 2 military medical centres and 2 affiliated primary care clinics.
Duration: 21 months
Outcome: Try cheaper NSAID first protocol at study site reduced use of more expensive NSAIDs and costs.
Score: S2 U1 R0 B2 O2 D1 Total=8

31. Laxdal OE, Jennett PA, Wilson TW, Salisbury GM.
Title: Improving physician performance by continuing medical education.
Ref: Canadian Medical Association Journal 1978; 118(9): 1051-1058.
Sample: 32 doctors, 5 hospitals
Duration: 3 years
Outcome: Problem-based program on therapeutics changed prescribing.
Score: S2 U2 R0 B2 O2 D2 Total=10

Title: Influences of educational interventions and adverse news about calcium-channel blockers on first-line prescribing of antihypertensive drugs to elderly people in British Columbia [see comments].
Notes: 98423738
Sample: 4403 doctors in British Columbia
Duration: 2 years
Outcome: Gradual reduction in use of Calcium channel blockers as first antihypertensive agent.
Score: S2 U2 R0 B0 O2 D1 Total=7
33. Manning PR, Lee PV, Clintworth WA, et al.
Title: Changing prescribing practices through individual continuing education.
Sample: 94 doctors
Duration: Under 1 year
Outcome: Individualized teaching in response to critical events changed prescribing.
Score: S2 U1 R2 B2 O2 D0 Total=9

34. May FW, Rowett DS, Gilbert AL, McNeece JL, Hurley E.
Title: Outcomes of an educational-outreach service for community medical practitioners: non-steroidal anti-inflammatory drugs [see comments].
Sample: 210 community doctors in Adelaide
Duration: 11 years
Outcome: 28% reduction in use of NSAID and 70% reduction in admissions for GI disorders.
Score: S2 U2 R0 B2 O2 D2 Total=10

35. Molstad S, Hovelius B.
Title: Reduction in antibiotic usage following an educational programme.
Sample: 1 health centre
Duration: 1 year
Outcome: Reduction in use of broad spectrum antibiotics.
Score: S0 U2 R0 B0 O2 D0 Total=4

Title: Antibiotics prescription in primary care: a 5-year follow-up of an educational programme.
Sample: 1 Health Centre
Duration: 5 years
Outcome: Sustained reduction in antibiotics for colds.
Score: S0 U2 R0 B2 O2 D2 Total=8
37. Morton IN.
Title: The introduction of a practice formulary in a military general practice.
Ref: J R Army Medical Corps 1990; 136: 156-158.
Notes: Practice formulary based on existing pattern of prescribing.
Sample: 1 practice
Duration: 15 months + 1 trial month
Score: S0 U2 R0 B0 O0 D1 Total=3

Title: Introduction and audit of a general practice antibiotic formulary.
Notes: Antibiotic formulary based on a survey of existing prescribing.
Sample: 9 GP practice
Duration: 1 year
Outcome: 25% reduction in cost.
Score: S2 U1 R0 B0 O2 D1 Total=6

Title: Randomised controlled trial of effect of feedback on general practitioners' prescribing in Australia.
Sample: 2440 non-urban GPs
Duration: 2 years
Outcome: No effect.
Score: S2 U1 R2 B2 O2 D1 Total=10

Title: Improving the use of aspirin in myocardial infarction: A district strategy.
Sample: South Tyneside
Duration: 1 year
Outcome: Increase in use of prophylactic aspirin following publicity campaign.
Score: S0 U2 R0 B0 O2 D1 Total=5
Title: Improving physician prescribing patterns to treat rhinopharyngitis.
Intervention strategies in two health systems of Mexico.
Sample: 18 practices
Duration: 18 months
Outcome: Changed prescribing from workshops and peer review.
Score: S2 U2 R1 B2 O2 D1 Total=10

42. Peterson GM, Sugden JE.
Title: Educational program to improve the dosage prescribing of allopurinol.
Notes: Visiting pharmacist.
Sample: GPs in S Tasmania
Duration: Under 1 year
Outcome: Academic detailing produced change.
Score: S2 U2 R0 B0 O2 D1 Total=7

43. Ray WA, Blazer DG, Schaffner W, Federspiel CF, Fink R.
Title: Reducing long-term diazepam prescribing in office practice. A controlled trial of educational visits.
Ref: JAMA 1986;256(18):2536-2539.
Sample: American state
Duration: 1 year
Outcome: 18% reduction in benzodiazepine use.
Score: S2 U1 R0 B2 O2 D1 Total=8

44. Reeve JF, Peterson GM, Rumble RH, Jaffrey R.
Title: Programme to improve the use of drugs in older people and involve general practitioners in community education.
Sample: 16 GPs
Duration: Within 1 year
Outcome: Reduced polypharmacy and indicator medications.
Score: S2 U1 R0 B0 O1 D0 Total=4
45. Roberts SJ, Bateman DN, Smith JM.
Title: Prescribing behaviour in general practice: the impact of promoting therapeutically equivalent cheaper medicines.
Sample: 1 UK Region
Outcome: Shift to generics.
Score: S2 U2 R0 B0 O2 D1 Total=7

46. Rutz W, von KL, Walinder J, Wistedt B.
Title: Effect of an educational program for general practitioners on Gotland on the pattern of prescription of psychotropic drugs.
Sample: GPs in Gotland
Outcome: Improve prescribing for mental illness.
Score: S2 U2 R0 B2 O2 D2 Total=10

47. Santoso B.
Title: Small group intervention vs formal seminar for improving appropriate drug use.
Notes: Controlled study, drugs for acute diarrhoea.
Sample: 6 districts of Indonesia
Outcome: Formal seminar > face-to-face > control in achieving change.
Score: S2 U2 R2 B2 O2 D1 Total=11

48. Schaffner W, Ray WA, Federspiel CF, Miller WO.
Title: Improving antibiotic prescribing in office practice. A controlled trial of three educational methods.
Sample: 1 American state
Outcome: 54% reduction in use of certain antibiotics.
Score: S2 U1 R0 B2 O2 D1 Total=8
49. Schectman JM, Kanwal NK, Schroth WS, Elinsky EG.
Title: The effect of an education and feedback intervention on group-model and network-model health maintenance organization physician prescribing behavior.
Ref: Medical Care 1995;33(2):139-144.
Sample: 63 doctors
Duration: 1 year
Outcome: Simple passive educational intervention changed HMO physician prescribing, but not networked physicians.
Score: S2 U2 R2 B2 O2 D1 Total=11

Title: Changing prescribing behaviour: Early low dose aspirin in suspected acute myocardial infarction.
Sample: 96 GPs
Duration: 22 months
Outcome: Increase in use of aspirin in suspected MI, especially doctors aged under 40.
Score: S2 U1 R0 B0 O1 D1 Total=5

51. Smith DH, Christensen DB, Stergachis A, Holmes G.
Title: A randomized controlled trial of a drug use review intervention for sedative hypnotic medications.
Ref: Medical Care 1998;36(7):1013-1021.
Sample: 189 patients receiving hypnotics and their prescribing doctors
Duration: Single event
Outcome: Reduction in use of hypnotics following mailed guidelines, prescribing and patient profiles.
Score: S2 U1 R2 B2 O2 D0 Total=9
52. Soumerai SB, Avorn J.
   Title: Predictors of physician prescribing change in an educational experiment to improve medication use.
   Ref: Medical Care 1987;25(3):210-221.
   Sample: 435 doctors
   Duration: 18 months
   Outcome: Face-to-face education effective for wide variety of doctors.
   Score: S2 U2 R2 B2 O2 D1 Total=11

   Title: Influencing prescribing for urinary tract infection and asthma in primary care in Sweden: A randomized controlled trial of an interactive educational intervention.
   Sample: 204 GPs in 36 groups
   Duration: 1 year
   Outcome: 18% increase in first line antibiotics for UTI. Asthma section both groups changed.
   Score: S2 U2 R2 B2 O2 D1 Total=11

54. Steele MA, Bess DT, Franse VL, Graber SE.
   Title: Cost effectiveness of two interventions for reducing outpatient prescribing costs.
   Sample: 31 doctors
   Duration: 10 months
   Outcome: Visits by pharmacist cost-effective method of reducing prescribing costs.
   Score: S2 U1 R2 B2 O2 D0 Total=9
55. Stewart D, Milne K, Krska J, Downie G.
Title: Adherence to the Grampian joint drug formulary in general practice.
Ref: Journal of Clinical Pharmacy & Therapeutics 1996;21(2):79-82.
Notes: 84% of the drugs taken by patients on admission to hospital were in the formulary
Sample: 449 drugs
Duration: Admission date only
Outcome: Whether drug in formulary or not.
Score: S2 U0 R0 B0 O2 D0 Total=4

56. Strikwerda P, Bootsma-de LA, Berghuis F, Meyboom-de JB.
Title: [Drug therapy in a nursing home; favorable effect of feedback by the pharmacist on family physician's prescribing behavior]. [Dutch].
Sample: 43 GPs
Duration: Under 1 year
Outcome: Pharmacist's feedback changed prescribing.
Score: S2 U1 R2 B2 O2 D0 Total=9

57. Tomson Y, Hasselstrom J, Tomson G, Aberg H.
Title: Asthma education for Swedish primary care physicians--a study on the effects of "academic detailing" on practice and patient knowledge.
Sample: 63 GPs in 30 health centres
Duration: Under 1 year
Outcome: No change in beta-adrenoceptor agonist to corticosteroid inhaler ratio after visit by clinical pharmacologist and pharmacist.
Score: S2 U2 R1 B2 O2 D0 Total=9
58. van Zwanenberg TD, Grant GB, Gregory DA.
Title: Can rational prescribing be assessed?
Notes: Discussions about rational prescribing lead to similar changes as involvement in creating a formulary.
Sample: 12 GPs (+ 9 who did not complete project)
Duration: 6 months
Outcome: Shift towards generic, essential drugs.
Score: S2 U1 R0 B0 O2 D0 Total=5

Title: Evaluation of computer support for prescribing (CAPSULE) using simulated cases.
Sample: 42 GPs
Duration: Single event intervention and evaluation
Outcome: 15% improvement in cost-effective prescribing.
Score: S2 U1 R1 B2 O2 D0 Total=8

60. Zwar N, Wolk J, Gordon J, Sanson-Fisher R, Kehoe L.
Title: Influencing antibiotic prescribing in general practice: A trial of prescriber feedback and management guidelines.
Sample: 157 GP registrars in New S Wales
Duration: 18 months
Outcome: Antibiotic use for URTI reduced by guidelines and feedback.
Score: S2 U1 R2 B2 O2 D1 Total=10
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5. Sowerby Centre for Health Informatics at Newcastle. PRODIGY R1 News. 2-1-2000. (GENERIC)
   Ref Type: Computer Program


Ref Type: Generic

Ref Type: Generic


Ref Type: Bill/Resolution


33. Tonks A. GPs prescribing is irrational, say Audit Commission. *BMJ* 1994; 308: 675


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Ref Type: Electronic Citation


109. Formulary: Blackburn with Darwen PCG. 2000. (GENERIC) Ref Type: Internet Communication

110. Formulary: Central Southampton PCG. 2000. (GENERIC) Ref Type: Internet Communication

111. Formulary: South Manchester PCG. 2000. (GENERIC) Ref Type: Internet Communication

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123. Maxwell M, Howie JG, Pryde CJ. A comparison of three methods of setting prescribing budgets, using data derived from defined


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