Nuffield Trust Series No. 4

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A comparative US-UK study of guidelines

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THE Nuffield Trust

FOR RESEARCH AND POLICY STUDIES IN HEALTH SERVICES

Published by
The Nuffield Trust
59 New Cavendish Street
London W1M 7RD

ISBN 1 902089 12 X

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FOREWORD

The General Medical Council in their publication *Maintaining Good Medical Practice*[1] state that the public has a right to expect considerate and competent attention from doctors and that doctors have a duty to maintain a good standard of professional work. To maintain quality the GMC expects clinical teams normally to use recommended clinical guidelines. This Nuffield Trust publication provides a comparative Anglo/American study of the guidelines movement.

Even during the short history of the guidelines movement there has been a shift of emphasis from professional consensus to scientific rigour. There is an unresolved conflict between seeing guidelines as tools of professional self-assessment and viewing them as instruments for controlling the way in which individual clinicians practise and use resources - between education and enforcement. Equally there is a blurring and shift of boundaries between public and professional policies and finally there is continuing debate about what should count as compelling evidence, a controversy which goes to the heart of the wider debate about the construction of medical knowledge and practice and about the relationship between practice and costs.

John Wyn Owen CB
Secretary
Nuffield Trust

1. Maintaining Good General Practice. General Medical Council. London: July 1998

INTRODUCTION

Across countries there has been increasing recognition, over the past decade or so, that the medical profession is not only responsible for many of the problems facing health care delivery systems but also holds the key to solving them. It is clinical decisions which drive the use of resources. It is clinical decisions which determine how expensive new technologies are used. But variations in the way in which individual doctors practise remains the norm. Increasingly, therefore, the challenge to public policy has become how best to devise organisational structures and tools designed to promote change in medical practice: to devise incentives and sanctions that will persuade doctors to use resources more efficiently and effectively. If only "best practice" could be universalised - always assuming that we can define what it is - many of the difficulties that now afflict health care systems everywhere would disappear. If only medical decisions were based on scientific evidence - always assuming that the evidence speaks with a clear voice - wasteful expenditure could be eliminated and resources concentrated on where they do most good. The expectations invested in this vision may be over-optimistic but it has nevertheless strongly influenced both public policies and professional attitudes.

This paper reports on a comparative Anglo-American study of one aspect of this new direction in health policy: the guidelines movement. For all the differences in the health care systems of the two countries, there has been an explosion in the number of guidelines produced in both over the past decade or so. In this, the United States has been very much in the lead, although Britain is now catching up. Examining their experience therefore provides an opportunity to explore both common issues - the generic problems of guideline production and implementation, as it were - and the

effect of variations in the organisational and financial structure of health care.

Although this study was conceived long before the publication of the Labour Government's 1997 plans for the NHS,[1] the White Paper has given new salience to guidelines. The proposed new National Institute of Clinical Excellence will be responsible for producing and disseminating guidelines, while a Commission for Health Improvement will monitor the quality of clinical services. The White Paper has also underlined the significance of American experience. Primary Care Groups will, in effect, be managed care organisations, with capped budgets. They will have a collective responsibility for controlling the expenditure - the prescribing and referral patterns - of all the general practitioners belonging to them. The use of guidelines by managed care organisations in the US to influence medical practice, on which the American chapter concentrates, has therefore particular relevance.

One common theme to emerge from both sides of the Atlantic is the centrality of the medical profession in the development of guidelines. Guidelines produced by the medical profession have by far the most persuasive power. Government agencies may promote and fund the production of guidelines, as they do in both countries. But if guidelines are seen as tools of management - primarily as a device for containing costs rather than promoting quality - they will be resented and rejected. The professional imprimatur is therefore essential for successful implementation. So, too, is the authority of science: if guidelines are to carry conviction, they have to be based on solid evidence (although there may be debate as to what counts as "good" evidence: in the US there appears to be less emphasis than in the UK on RCTs as the "gold standard").

There are also common problems. In both countries there has been a confusing proliferation of guidelines, with many variations on the same theme. There seems to be a case for birth-control. Economy in the way guidelines are presented is essential, too, given that doctors are over-loaded with information. In both countries, there is uncertainty about the extent to which guidelines should take cost-effectiveness, as distinct from clinical effectiveness, into account.

The difference of tone between the British chapter (which tends to scepticism about the likely impact of guidelines) and the American chapter (which tends to optimism) reflects, however, a difference of experience in one important respect. The American evidence appears to justify faith in the ability of guidelines to influence medical practice, whereas the very sparse British evidence on this point justifies little more than agnosticism. In short, the United States appears to have been - so far - more successful in using guidelines as a tool of change and bringing outliers into line with mainstream practice.

The difference has nothing to do with the way in which guidelines are produced or designed in the two countries: this is very similar, all the more so since the American model has been very influential in shaping developments in Britain. The crucial factor appears to be that managed health care organisations in the US not only have a direct interest in implementing guideline recommendations (for reputational as well as financial reasons) but also have developed the tools needed to get compliance and operate in an environment where doctors have an incentive to conform. Moreover, the US is a more disclosure orientated society where comparative information about health care systems is generally more available, both within the profession and to the public, than in the UK.

In future, PCGs in Britain will also have an interest in ensuring the implementation of guidelines. The American experience points to some of the tools that will be needed and some of the methods that can be used. The first requisite is an information system that allows the practices of individual doctors to be monitored against guideline recommendations. The second is a readiness to use comparative information to secure compliance. Thus the American managed care organisations most successful in implementing guideline recommendations give practice profile data to each doctor. If all else fails, some of them are even prepared to make this information public. Indeed they see patients as allies in the endeavour to make guideline recommendations stick.

However, in pursuing implementation strategies, PCGs will be at a disadvantage compared to their American counterparts in one crucial respect. American managed care organisations operate in an environment where there is a surplus of physicians. They can therefore recruit selectively, picking those doctors most likely to be sympathetic to the guideline culture, with the sanction of jettisoning persistent non-conformists always looming in the background even if rarely invoked. This option will not be available to PCGs although, to an extent, it is available to provider trusts when it comes to recruiting new consultants.

Our study therefore ends with what appears to be a paradox. This is that the highly diffuse, market-based system of the United States provides - whatever its other weaknesses - more levers than the centrally directed NHS for influencing medical practice. In the case of Britain, the hurdles that have to be jumped are more in evidence: in particular, the lack of incentives and sanctions for getting compliance. In the US, the weakness of central direction does not

prevent - indeed seems to promote - implementation. In the UK, there is an inverse relationship between the nominal power of the centre and its ability to wield it. Government is inhibited by the risk of antagonising the medical profession by peering into the secret garden of clinical autonomy.

1. Secretary of State for Health. The new NHS: Modern-Dependable. London: HMSO 1997 Cm 3807

CHAPTER ONE
THE UK EXPERIENCE: CONTROL OVER, OR BY, THE MEDICAL PROFESSION?

1. Background

The 1990s have been marked by the rise, across health care systems, of enthusiasm for evidence-based medicine. Embraced by Governments, supported by public funds, the evidence-based crusade (no less a word will do) has launched new journals, international conferences, research centres and academic careers. It is a remarkable and puzzling phenomenon. It is remarkable because of the speed with which it has taken off and as an example of the rapid diffusion of ideas across frontiers. It is puzzling because of the timing. Why has this new "discipline" - as it has been called[1] - been born at this particular point in time? Intellectually, the roots of evidence-based medicine can be traced back to mid-19th.century Paris and beyond. Technologically, there has been no major break-through: although some new tools, like meta-analysis, have been developed, the foundations of evidence-based medicine rest on long-established research and statistical techniques. It is therefore difficult to explain as an autonomous, spontaneous development within the scientific community, the result of a sudden, mass conversion to new ideas and ways of working. Nor would this account for the readiness of governments to fund the new discipline. If an explanation is to be found, it is therefore more likely to lie in the economic and political environment in which health care systems operate and the consequent, complex pressures on governments and the medical profession.

This chapter explores the development in the United Kingdom of the guidelines movement, one of the close relations of evidence-based medicine, from this wider perspective. Our theme is that the explosion of guidelines, in the 1990s, like the rise of evidence-based medicine, reflects a wider shift in public policy. Three phases in the evolution of policy over the decades can usefully be distinguished.[2] In the 1970s Governments everywhere tended to be preoccupied

with macro-systems strategies for controlling total costs. In the 1980s, they turned to tinkering with the structure of health care systems in order to strengthen micro-management and introduce incentives for greater efficiency. In the 1990s they increasingly sought to influence medical practice more directly, both by changing the context within which doctors work and by invoking science in the service of policy. Given that inexplicable and wide variations in medical interventions appeared to be the norm, given also that much of medicine appeared to be based on tradition rather than demonstrable effectiveness, then it was tempting to equate evidence with economy. However, one more step required to be taken. Evidence had to be translated into practice: enter guidelines, among other tools designed to persuade doctors to change their ways.

One tempting, but as we shall see misleading because over-simple, way of telling the story of the guidelines movement is to present it as an attempt by those managing health care systems to seize on and exploit what started as a professional initiative in order to limit the autonomy of the profession. The hope in doing so, to continue with this line of argument, was that the seemingly inexorable rise in costs could be stemmed by squeezing out ineffective interventions and bringing practice outliers into line. The proliferation of guidelines, drawing on a new "discipline" that harnesses the skills of epidemiologists, statisticians and economists to challenge the hegemony of the traditional clinical crafts in defining good practice, could from this perspective be seen as yet further evidence of the decline of medical dominance.[1] In practice, however, the story turns out to be much more complex than that simple plot-line would suggest. Indeed it invites a radically different interpretation. This is that the medical profession has demonstrated its continued dominance by maintaining control over the

production and implementation of guidelines: that while the autonomy of individual clinicians may be diminishing, the collective autonomy of the medical profession as a whole remains virtually undented. From this alternative perspective, the guidelines movement can be seen as a successful strategy by the medical profession which, in its own self-interest, has sought to control the outliers within its own ranks in order to fend off managerial pressure.

In what follows, we explore the UK evidence bearing on these two alternative interpretations. The guidelines movement, like evidence-based medicine itself, may be an international phenomenon. But the way in which guidelines are used depends, as noted in the introduction, on the structure and culture of the health care systems in individual countries. Even within the UK, as we shall see in section 6, Scotland differs from England and Wales. And even though health care systems may not be transferable, there are opportunities for cross-national learning from the techniques and tools employed in different systems to implement guidelines.

2. A word and its history

Guidelines are not a new phenomenon. At one London Teaching Hospital the first edition of its "Guidelines for the Management of Common Medical Emergencies" was produced as long ago as 1979.[4] Similarly, many other hospitals developed their own "Black Books" or "Grey Books". These were designed to help staff in decisions about the treatment of patients and to reassure consultants that, even in their absence, junior doctors would do what they would have done if they were present. In other words, national and local attempts to codify "good practice" long pre-date the rise of the guideline movement; traditionally, too, text-books have performed

this function. Even now, despite attempts to develop a more rigorous vocabulary and to stipulate more precise meanings, there is still much verbal confusion about the precise boundary between guidelines, protocols, clinical algorithms and other statements of good practice. The most frequently quoted definition of guidelines - that they are "systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances"[5] - is perhaps popular precisely because of its bland, inclusive scope: as a tool for discriminating, it is remarkably elastic.

However if guidelines are not a new phenomenon, the guidelines movement is: that is, the public commitment, alike by Government and the profession, to the notion that good practice can be defined in documents that carry both legitimacy and authority - a commitment that found expression in a snowball of both activity and funding. Legitimacy derives from the fact that guidelines are the product of the medical profession and carry its imprimatur: they represent a professional consensus about good practice. Authority derives from the fact that guidelines are based on systematic evidence: they are therefore seen to speak with the voice of science. In all this, there are ambiguities and tensions. First, even during the short history of the guidelines movement, there has been a shift of emphasis from legitimacy to authority: from professional consensus to scientific rigour. Second, there is an unresolved conflict between seeing guidelines as tools of professional self-improvement and viewing them as instruments for controlling the way in which individual clinicians practise and use resources: between education and enforcement. Third, and following on from the last point, there is a blurred and shifting boundary between public and professional policies: the role of

central government continues to evolve. Fourth, there is continuing debate about what should count as compelling evidence, a controversy which goes to the heart of a wider debate about the construction of medical knowledge and practice,[6] and about the relationship between good practice and costs.

In what follows, this paper explores these four, inter-laced themes. Before doing so, the contention that there has been an explosion of activity in guideline production - that the 1990s are different from preceding decades - requires justification. No central index or repository of guidelines exists for the present, let alone the past: interesting evidence, in itself, about the anarchic development of the movement. There is general agreement that the number of guidelines produced in the UK - nationally and locally - has proliferated and continues to do so. They are certainly counted in hundreds though perhaps not yet in the thousands as in the United States. Anecdotal evidence is confirmed by Table 1. This shows the number of references containing the word "guidelines" generated by a Medline search in each of the 16 years after 1980, for both the UK and the United States. The figures confirm the position of the US as the pioneer of the guidelines movement[7]: the Agency for Health Care Policy and Research, charged at one time with developing guidelines, was set up in the late 1980s. But the UK followed the same upward trajectory, albeit some years behind. Following a slow upward drift in the 1980s, the number of references to UK guidelines quadrupled between 1990 and 1996. So the quantitative evidence supports the view - based on the evolution of both public and professional policies and activities - that there is a real phenomenon to be studied on both sides of the Atlantic.

Year	References on the UK	References on the US
1980	11	103
1981	10	94
1982	12	82
1983	21	98
1984	19	118
1985	21	145
1986	20	154
1987	23	171
1988	21	172
1989	40	232
1990	63	394
1991	73	453
1992	88	587
1993	127	635
1994	154	730
1995	180	850
1996	252	903

3. Launching the movement

The national guideline movement in England was initially the product of a series of unco-ordinated initiatives by the Royal Colleges, representing the various medical specialties; the story of Scotland is rather different, as noted above, and is told separately in section 6 below. No precise date can be attached to the take-off point, when a trickle turned into an avalanche, although most of the participants interviewed agree that it came sometime in the early 1990s. The Royal College of General Practitioners started to publish a series of guidelines for good practice in 1986. The Royal College of Physicians started to be active in producing guidelines from 1990 onward; the Royal College of Surgeons followed a couple of years later; the Royal College of Psychiatrists' Clinical Practice Guidelines Programme was only set up in 1995.[8] Some of the differences in activity reflect terminological confusion: what some Colleges called guidelines, others described as standards. Other differences reflected the internal dynamics of the Colleges and, in particular, the presence or absence of a group of enthusiasts for the guidelines cause.

One common element in the initial wave of activity was the link between interest in medical audit and clinical guidelines. Interest in medical audit, seen as a process of professional self-improvement through self-examination, had been growing through the 1980s; most Royal Colleges made the existence of some form of audit a condition for the training of junior staff and set up audit units to encourage the process. In addition, guideline production offered sub-specialists an opportunity to improve their own standing by staking a claim to the management of particular conditions. Audit was, however, given new salience, by the reforms of the National Health Service announced in 1989.[9] These, in effect, institutionalised medical audit, setting up the expectation that every doctor would

routinely take part in reviewing practice. Subsequently the Government elaborated its proposals for medical audit[10] and provided generous funding for its development.

Audit, however, presumed the existence of some standards of good practice against which performance could be assessed. Guidelines were therefore increasingly seen as one (though only one) instrument for providing such criteria: for codifying the professional consensus of the individual specialties. If the professional bodies did not produce such guidelines, moreover, there was always the danger that others would. The Government's proposals were emphatic that audit must be medically led but accountable to management; indeed they even suggested that management should be able to commission independent audits. In the outcome, the profession appears to have succeeded in controlling the audit process and management has played a very recessive role[11]: a point to which we return in section 5. However, the spectre of possible managerial interference in clinical matters had been raised. The production of guidelines can thus also be seen as part of a pre-emptive strategy by the medical profession, designed to maintain its control over the way in which good performance is defined. For guidelines, to anticipate a theme to be developed further in subsequent sections, are a double-edged weapon. On the one hand, they allow (in theory at least) managers to question what doctors do and even to set the parameters of their performance: so, for example, the Joint Consultants' Committee was initially hostile to guidelines, which were seen as a restriction on clinical freedom. On the other hand, they give doctors leverage for extracting resources: if performance falls short of expectations, it may be because the configuration of services or the level of staffing and support are not adequate in terms of the profession's own definition of good practice.

This, it has to be stressed, is a highly speculative interpretation. The pre-emptive strategy was certainly neither a conscious nor an explicit one, and those interviewed rejected the notion that they were pursuing it: some saw guidelines simply as a natural development from the production of text books. In any case, one of the characteristics of the guidelines movement - certainly in its first phase up to the early 1990s - was its sheer heterogeneity, in terms both of motives and methodology. Consider, for example, the activities of the Royal College of Radiologists, whose interest in guideline production began in the 1970s.[13] This led in the late 1980s to the publication of its "Guidelines for Doctors"[12] among other guidelines. The aim of these was not to set standards for radiologists but to change the way in which other doctors used radiology departments. A large scale study had demonstrated eight-fold variations in referral rates for in-patients and 13-fold variations in referrals for out-patients. In turn, as the radiologists saw it, this suggested that there was scope for reducing the pressure on their departments by eliminating unnecessary expenditure and avoiding the exposure of patients to redundant examinations.

The Royal College of Radiology's guidelines were somewhat unusual in that they were the product of a long-term strategy and a large scale study. Generally, though, the process of producing guidelines, in the first phase of the movement, was rather more haphazard and anarchic. The case of the Royal College of Physicians, itself the umbrella organisation for 20-odd specialist societies, illustrates the point. The RCP's highly regarded audit unit produced a proliferation of guidelines. However, the choice of topic was largely a response to initiatives by the component specialist societies and to the enthusiasm of individual specialists: the College, as such, had little control. And the methods for producing them tended to be eclectic.

The usual model was to call a meeting of the leading clinicians in the relevant field - "the good old boys" approach, as one of those interviewed put it - and rely on them to review the relevant evidence. No experts on methodology, statistics or epidemiology were involved. Following a one day meeting, draft guidelines were then circulated for comment. Once approved, the guidelines were left to find their own way in the world: there was no set policy for their diffusion, let alone for monitoring how they were used in audit or whether they changed clinical practice. The parsimony of the process reflected, in turn, the lack of funds for anything more ambitious.

To a large extent, this remains the model today. However, in the course of the 1990s, the clinically led model of guidelines production was increasingly challenged by the evidence-based model: a trajectory following , and influenced by, the pattern of development in the United States.[14] The emphasis switched from professional consensus to systematic evidence: from legitimacy derived from professional endorsement to authority derived from science. A growing literature began to devote itself to the methodology of guideline production, stressing the crucial importance of systematically scanning and organising the evidence.[15] Using the criteria developed by the Institute of Medicine in the US to assess the desirable attributes of guidelines, many existing ones were found wanting. As one study pointed out "many guidelines are of poor quality, having been produced by expert groups through informal ad hoc methodologies. Guidelines developed through this approach are more likely to suffer from biases and to recommend ineffective or dangerous practice than their more rigorously developed counterparts".[16]

The rise of the ideology of evidence-based medicine deserved a study in its own right. But in the UK the beginnings of its ascendancy can be dated, with some confidence, to the launch of a new NHS research and development strategy in 1991. Introducing this, the Chief Scientist, Michael Peckham (subsequently Sir) stressed the centrality of "evaluative clinical science". The need for evaluation, he argued "applies to many currently used methods of diagnosis and treatment. Every clinician knows that there is indefensible diversity in the use of diagnostic methods and therapies and that there is unacceptable variation in the quality of treatment delivered by different clinical treatment".[17] From this flowed an emphasis on generating more evidence - preferably in the form of randomised control trials (RCTs) - and harnessing the skills of epidemiology, health service research and health economics. Such a strategy, Peckham argued, represented "the only way of resisting the sometimes unreasonable and often unproven resource-consuming demands of lay, professional, and industrial pressure groups".

The production of guidelines did not feature, as such, in the new NHS R &. D strategy. However, they clearly had a potentially important role to play in the evidence-based medicine project as a transmission-belt between science and practice. If evidence-based medicine was to deliver the promised benefits - if , as some hoped, it could transmute scarcity into plenty by eliminating ineffective practices and the consequent waste of resources - then means had to be found of persuading clinicians to adopt the new faith. Guidelines seemed to be one instrument for so doing. It would therefore seem reasonable to assume that the Department of Health would promote them with the same enthusiasm with which it embraced evidence-based medicine: that it would take the lead in shaping the guideline movement. But, as the next section shows, in

the event the Department played a somewhat tentative and reactive role: laissez-faire rather than strong direction characterised its policy stance.

4. The role of the centre

Somewhat surprisingly, given the explosion of activity from the turn of the decade onward, the Department of Health - acting through the NHS Executive - did not publish its first authoritative policy statement on guidelines until 1996.[18] This long time lag does not appear to have stemmed from a lack of interest in the Department - it funded some guideline development long before 1996 - but from a realisation, prompted by reactions to the first initiatives taken, that it was entering a potential minefield. In particular, the reaction to the publication of a 1993 circular," addressed to purchasing authorities, provided a warning of likely explosions. The circular drew the attention of purchasers to guidelines as part of its strategy for promoting clinical effectiveness; in addition some were specifically commended. This was interpreted, and resented, by the medical profession as the first step towards incorporating guidelines in service contracts: i.e. using guidelines to control clinical activities. Those involved in the Department deny that this was the intention, although the evidence on this point is mixed. However, the reaction of the medical profession may explain some of the subsequent caution; the Department was anxious to avoid offending the delicate sensibilities of the profession, following the blood-letting that accompanied the introduction of the 1991 reforms.[20] Additionally, there was a growing realisation within the Department that the assumption that guidelines, or effectiveness evidence in general, could be translated into purchasing requirements was naively over-optimistic: the contracting process was simply not sophisticated enough.[21]

Thereafter, the Department was careful to say nothing which might imply that guidelines could be used by managers to monitor - let alone control - the patterns of work of clinicians. It saw its task as being primarily to encourage the profession itself to produce better quality guidelines. In 1993 the NHS Management Executive organised a national workshop on critically appraising guidelines. Subsequently, guidelines were subject to an independent appraisal before receiving official endorsement by the Clinical Outcomes Group, a committee chaired by the Department's Chief Medical Officer with members drawn from professional bodies, purchaser and provider management, researchers and patient groups. Indeed the main problem, from the perspective of the Department, was to find guidelines of a sufficiently high quality to endorse. Further, the Department was reluctant to endorse guidelines which appeared to be staking a claim for extra resources by stipulating staffing levels or service configurations,- defining standards that involved resources took the shape of "guidance" to purchasers from the NHS Executive - for example, on the organisation of cancer services[22] - as distinct from professionally produced guidelines. Individual guideline projects were funded on an ad hoc basis, although the Department did not have an identifiable budget for this purpose.

The work on guidelines has, however, to be set in the wider context of the Department's continuing commitment to promoting evidence-based medicine.[23] It funded a number of centres, such as the Cochrane Collaboration and the NHS Centre for Reviews. It sponsored a variety of publications, such as *Effective Health Care* bulletin which reviews and synthesises the available evidence on particular topics. It supported a unit for developing the methodology for appraising guidelines. It continued to encourage clinical audit, although the relationship between audit and guidelines remained

somewhat fuzzy: a point explored further below. But, partly because of tensions between different sections of the Department, guideline development appeared to be on the margins of official interest; similarly, there was a lack of co-ordination within the Department, with different sections sponsoring the production of overlapping guidelines.[24]

The 1996 document was carefully drafted in order to avoid offending the susceptibilities of the medical profession. Its starting point was that "The development, publication and maintenance of guidelines remains the responsibility of the appropriate professional body, be it medical, nursing dental or other". Further, in a section devoted to examining the legal situation, it stressed that:

> "Even when endorsed by the relevant professional bodies or commended by the NHS Executive, guidelines can still only assist the practitioner; they cannot be used to mandate, authorise or outlaw treatment options. Regardless of the strength of the evidence, it will remain the responsibility of the practising clinicians to interpret their application taking account of local circumstances and the needs and wishes of individual patients. It would be wholly inappropriate for clinical guidelines to be used as a means of coercion of the individual clinician, by managers or senior professionals".

Variations on this theme run through the document. But it stopped short of giving total licence to clinicians to ignore guidelines. If guidelines have established universal support and endorsement, it pointed out, "clinicians will need to have good justification for deviation". Further, in discussing the dissemination and

implementation of guidelines, the policy statement stressed the importance of monitoring their impact, nationally and locally, whether through audit or in other ways: "the impact of guidelines will be assessed by monitoring quantitative changes in patterns of activity and partly by considering qualitative changes in clinical experience". A certain ambiguity therefore remains. Guidelines are expected to influence clinical practice as part of the wider programme of work to "promote clinical effectiveness". But they are not in any sense mandatory. The ambiguity underlines a central dilemma faced by policy makers in the guidelines project. If they were not to antagonise the medical profession, it was essential that they should be presented and seen as an exercise in persuasion appealing to the medical profession's own sense of practising its craft according to the best available evidence. This, however, left open questions about what should count as the best available evidence and what was to be done if persuasion failed to change practice.

The 1996 document side-stepped the question of what, if anything, should be done if persuasion failed. But it did address the question of what should count as the best available evidence. Guidelines could be submitted for commendation by the Clinical Outcomes Group(COG), on behalf of the NHS Executive, only if they had the endorsement of the relevant professional body. This ensured their legitimacy. But their authority would depend on the quality of the evidence. A classification system for evidence was introduced: ranging from A for RCTs to C for "expert opinion" based evidence, through B for "robust experimental or observational studies". Only recommendations based on RCTs should be considered for use in contract specifications (an echo of the 1993 circular which, this time round, did not cause any perturbations - partly, perhaps, because by this time it had become clear that guidelines were not

being incorporated into contracts]. There was much emphasis, too, on systematic critical reviews of the literature as the basis for guidelines development and the need to link any recommendations made to the evidence. All guidelines, further, would be subject to independent appraisal before being considered by the COG for approval. Finally, the document set out the criteria which would be used by the NHS Executive when considering funding guidelines development. These included areas where there is wide variation in clinical practice, where the services involved are resource intensive or where there is excessive morbidity, disability or mortality. A list of 60 possible topics was prepared.

The 1996 statement of policy marks a significant step towards a more pro-active, systematic approach to the development of guidelines by the centre. It, however, left unresolved - or delicately skated over - a number of issues. One such has already been noted: the ambiguity about the balance between persuasion and enforcement, between the role of the centre in commending certain guidelines and that of providers and purchasers at the periphery in implementing them. The ambiguity was well captured in the conciliatory tone of a circular drawing the attention of purchasers and providers to four guidelines - on angina, asthma, radiology and low back pain - commended by the NHS Executive: "Clinical guidelines are not disseminated by the NHS Executive as instructions to patients, clinicians or managers. This letter brings them to your attention so that you might consider supporting their use by clinicians".[25] There were others issues, too. Emphasising methodological rigour in the production of guidelines was all very well, but ignored the fact that there was by no means universal agreement about what should count as good evidence, who should interpret it and how or the way it should be used to influence

clinical practice: a point further explored in Section 7. Moreover, the document appeared to be speaking with two voices about an issue central to the medical profession's concerns: the suspicion that guidelines were a covert instrument for controlling costs. On the one hand, it pronounced "Clinical guidelines are produced for one reason, and one reason only: to improve the quality of care". On the other hand, it stressed that "guidelines should make clear both the costs and benefits of implementation": that they should promote "cost-effective practices". We examine these issues in the sections that follow.

5. Implementing guidelines

While the 1996 document stressed the importance of monitoring the impact of guidelines on clinical practice, no attempt to do so systematically has followed: one of the weak areas of the new strategy.[26] Given that there is no register of national guidelines, let alone of the proliferating local guidelines, there is not even a base line for anything like a comprehensive review. What follows, therefore, is a mosaic of the available, rather fragmentary evidence, supplemented by interviews with both purchasers and providers. The evidence from the latter is not, however, based on a representative sample and is therefore used illustratively only. The result can thus only be an impressionistic picture. In particular, we do not know whether the avalanche of guidelines produced since the turn of the decade has succeeded in reducing variations in medical practice across the country: one of the major concerns of public policy in supporting the movement.

There is indeed evidence that guidelines can change medical practice.[27,28] However, when it comes to determining the specific characteristics of guidelines that determine whether or not they do

influence practice, there is some disagreement in interpreting the evidence. Specifically, there is disagreement about how important "local ownership" is: i.e. whether the fact of guidelines are locally produced and agreed, reflecting the concerns of the clinicians engaged in developing them, is crucial. Nor is it clear that the quality of the guidelines themselves, and the methodological rigour with which they have been developed, is the decisive factor. As one review[29] concluded: "there appears to be a conundrum, that national guidelines are likely to be valid but not used, local guidelines are likely to be used but may not be valid"

However, knowledge about the local development and use of guidelines is fragmentary. Only one conclusion can be drawn with any confidence. This is that guidelines are rarely used in the contracting process. There was consensus among the purchasers interviewed that contracts are too crude an instrument for trying to influence clinical practice. Contracts, it was generally agreed, are about activity and finance. They are not effective instruments for trying to change clinical practice. Accordingly, purchasers have tended to engage directly with clinicians in order to devise local guidelines which may or may not draw on national ones. So, for example, Oxford Health Authority produced a series of guidelines on the evidence-based management of common cardiac conditions, generated by a series of working groups of hospital clinicians and general practitioners.[30] Similarly, the Birmingham Health Authorities produced guidelines for acute myocardial infarction "prepared by a cross-sectional group" drawn from a variety of specialties and providers.[31] Coventry and Newcastle are among the many other purchasers engaged in involving local clinicians in the development of guidelines.

The local process of generating guidelines thus mirrors the national picture. It is essentially an exercise in persuasion, designed to harness the enthusiasm and co-operation of clinicians. Further, while a sense of local ownership may be a necessary condition for the incorporation of guidelines into local practice - although even that, as we have seen, is a contested view - it is certainly not a sufficient one. Once again, we are back to the question of to what extent guidelines are used and change clinical practice. And, once again, the evidence needed to answer it is lacking. The routine statistics collected in the NHS - in contrast to the US - rarely, if ever, allow purchasers or providers to assess whether practice has changed: whether, for example, the use of aspirins and beta blockers in the management of acute myocardial infarction has increased as a result of introducing guidelines (leaving aside the wider issue of whether it is guidelines, rather than the professional literature, which have produced the desired change).

There is one mechanism which, in theory at least, could be used to monitor the implementation of guidelines locally. This is clinical audit. As already noted, interest in audit was one of the factors that initially sparked off interest in guidelines. These, it was argued, were needed to provide the benchmarks against which to assess performance. Subsequently, audit was institutionalised in the wake of the 1991 reforms, with central government investing more than £200 million in its development. In theory, audit provides the means for assessing the impact of guidelines: that is, in reviewing practice, audit committees could examine the extent to which the recommendations of guidelines (e.g. the use of aspirin and beta blockers) had been implemented over time. However, there is no evidence that it has been used to do so. The reason is that clinical audit remains very much a medical domain: an extension of

traditional peer review.[32] Participation by individual clinicians is voluntary. Although audit programmes are now funded by purchasers, and have to be approved by them, they do not appear to feed into the management process. They tend to reflect the interests of clinicians rather than representing an attempt to review practice systematically. The annual audit reports that result tend to be rather elliptical in style, largely impenetrable to lay audiences: which is no doubt why they seem to be rarely used by purchaser or trust boards. More generally still, it has been argued that "audit has failed to win the hearts and minds of the medical profession".[33]

Guidelines do feed into the audit process. A survey carried out by the National Audit Office in 1993-94 in three NHS regions,[34] showed that 6,983 clinical audit projects had been undertaken. In just over a quarter of them - 1,682 - guidelines had either been used or developed. But this study is silent on the crucial question of whether the use of guidelines had resulted in any change of practice: indeed given that change resulted from only a third of all the audits carried out, guidelines can have had only a minor influence on service delivery. Given that at present there is no machinery for collating and comparing the results of local audits, although there is a national centre for diffusing information about audit methodologies and activities, it seems unlikely that a more precise picture will emerge. For the time being, the only conclusion that can be drawn is that audit has still to fulfil its potential as a mechanism for monitoring the compliance of clinicians with guidelines, let alone prodding them into conformity with them..

There is one other source of information about the implementation of guidelines. This is the Clinical Standards Advisory Group (CSAG), explicitly given a monitoring role in the Department of Health's

1996 policy statement . The CSAG was set up under the legislation introducing the 1991 NHS reforms as an independent source of expert advice to Health Ministers. And in its 1996 study of elective surgery,[35] it addressed the question of how guidelines were being used. The result of its survey of surgeons suggested that while guidelines made them examine their own practices more critically, they did not necessarily lead them to follow their recommendations. More clinicians, it further concluded, were aware of guidelines than using them. However, the study only examined the process of guideline use. It did not address the question of impact: the extent to which guidelines changed practice. So once again one is left with the paradox that the Department of Health's strategy for promoting evidence based evidence through guidelines is based on more faith than evidence about their use, let alone their impact on clinical practice or their cost-effectiveness.

For a leap of faith is involved in making the transition from evidence that guidelines *can* be effective in specific *local* circumstances to moving policy forward on the assumption that they *will* be effective as a *national* strategy. Of course, there are instances of the successful use of guidelines: for example, the Central Middlesex Hospital[36] has used locally developed protocols - drawing on but not inspired by national guidelines - to implement agreed care plans for 85% of elective cases and 35% of emergency cases. Compliance is monitored through the audit system. In the case of myocardial infarcts, the audit of patients going through the cardiac department - using case notes - showed an increase in the use of beta blockers and aspirins from 64% to 96%. Inspired by American experience, this system seems to have been the product of a combination of economic pressure and dedicated local champions. But all that can safely be concluded from examples such

as these is that there are no structural impediments, anchored in the nature of the NHS, that preclude the implementation of guidelines: a point further explored in the next section which deals with the Scottish experience.

6. The Scottish model

Working within the same structure as the NHS in England, albeit endowed with more resources, policy makers in Scotland followed a rather different path of guideline development. First, the centre took the initiative earlier. In the late 1980s a visit to Scandinavia by a senior official of the Scottish Home and Health Department convinced him that protocols were useful tools for changing clinical practice - a reminder that the United States has no monopoly of influence. Subsequently, in 1991, a Working Group was set up under the auspices of the Department's Clinical Resources and Audit Group (CRAG). Its report, published in 1993,[37] provided professional endorsement for the "the systematic development of appropriate national guidelines and local protocols to help clinicians in their practice". Second, having succeeded in engineering a professional consensus, Scotland adopted a more directive and systematic approach to the development and implementation of guidelines. The Scottish InterCollegiate Guidelines Network (SIGN) was set up[38] to co-ordinate work on the development of guidelines.

The policy of SIGN is to promote national guidelines which can then be translated into local protocols. Proposals for developing guidelines have to be submitted to, and approved by, SIGN as a condition to getting access to the £500,000 a year budget set aside for this purpose. There is a form for applicants to fill in and a standardised methodology: as in England, there is much stress on a

systematic review of the evidence, although not the same emphasis on giving primacy to RCTs. There is guidance about the desired composition of the groups developing guidelines: these should be multi-disciplinary with representation from all the key disciplines. There is also a flow-chart which shows the requisite stages of the process of guideline development, including peer review and consultation with interested parties. The process of consultation includes purchasers; the usual pattern is to hold a meeting where the differences between the clinician and purchaser perspectives can be thrashed out. Much emphasis is put on dissemination. Some 10,000 copies of each of the 16 guidelines produced by SIGN up to mid-1997 were sent out to general practitioners, consultants and registrars, with a four page "easy use" summary. CRAG also allocated funds to Health Boards to facilitate the development of the local protocols through which national guidelines will be implemented.

As in England, audit offers the mechanism for monitoring whether guidelines are changing clinical practice. But, as in England, the existing information system does not generate the requisite data. The guidelines therefore usually specify the outcome indicators and the minimum data sets that must be put together for the purposes of audit. Further, the officials of the Scottish Home and Health Department regularly inquire about the use of guidelines in their annual review of audit when meeting the Chief Executives of Trusts. However, the systematic monitoring of guideline implementation remains an aspiration rather than an achievement. Evidence about whether guidelines are used, whether they are changing clinical practice or whether they are reducing variations is sparse ; even when practice has changed - for example, all vascular surgery is now carried out by specialist surgeons - it is difficult to

know whether the change can be attributed to guidelines. And although the 1993 report of the Working Group on guidelines raised the question of what sanctions and incentives could be used to promote the use of guidelines, it has not been answered. "Stroking rather than pushing" is the dominant philosophy. Nor is there any evidence that guidelines are much used in purchasing; essentially they remain part of the medical domain.

The Scottish model reflects some distinctive Scottish circumstances. If the structure of the NHS in Scotland is the same as in England, the culture is not. The Scottish medical profession is homogeneous - most doctors are home produced - and linked in a series of tight networks. In a relatively small country, it is easy to bring together the various interests: so, for example, the issue of how to control the use of interferon-beta was dealt with not by devising guidelines but by calling all the neurologists in Scotland together to agree on a policy. It was therefore much easier to build on the prevailing enthusiasm for producing guidelines - and to harness the rivalry between competing teaching hospitals in Glasgow and Edinburgh - in order to bring about the kind of disciplined and directive development that SIGN has promoted.

This said, Scotland shares some key characteristics with England. First, guidelines development, although encouraged by CRAG, is seen as being very much a matter for the professions. SIGN was set up not by the Scottish Home and Health Department (although this certainly played a prompting role) but by the Conference of Royal Colleges and their Faculties in Scotland. Second, guidelines are seen as "only one instrument in a chamber orchestra" in a wider exercise in persuasion designed to change medical culture and practice. Finally, in Scotland as in England, guideline development

raises the same generic conceptual and practical problems: the subject of the next section.

7. Problems and tensions

The high hopes, professional enthusiasm and pubhc money invested in the guideline movement - as in its first cousin, the evidence-based medicine movement - rest on an assumption that has come to look increasingly fragile. This is, that if only the evidence encapsulated in guidelines - given legitimacy by a professional consensus and authority by appropriate methodological rigour - can be translated into clinical practice, the result will be to iron out existing, seemingly inexplicable variations in practice, improve the quality of care, eliminate ineffective interventions and perhaps even lead to a reduction in costs. However, the very process of engaging in the production of guidelines has also helped to give a sharper focus to the limits, as well as the potentials, of the whole enterprise. It has raised questions about the scope for using them as instruments of change, about the availability and interpretation of evidence, about how it should be translated into guidelines and about their relevance to day-to-day clinical practice and to the purchasing of health care.

One limitation of guidelines - as Hopkins has pointed out in a critique[3,] which is all the more authoritative in that it conies from one of the pioneers of the movement - is that the scope for producing and applying them is restricted by the sheer messiness and complexity of much of medicine. Most guidelines, Hopkins argues, are written for patients with specific disorders where there is a clear clinical diagnosis. In practice many patients - particularly the elderly, who account for such a large proportion of admissions - may suffer from a variety of medical and social problems. Further, clinical guidelines - because they are largely concerned with the

technical aspects of care - are not suitable for the management of patients with chronic conditions where there is no technical relief and where the role of the doctor is largely to provide support, reassurance and explanation. In the case of many chronic disabling conditions - perhaps the main challenge to Western health care systems[40] - technical interventions may do little to affect outcomes. But the whole point of guidelines is that they are intended to identify interventions that actually improve outcomes: that they should be translating evidence about effectiveness into advice to clinicians. If outcomes cannot be used as the benchmark of effectiveness - if the ability of patients to cope with their disabilities depends as much on individual and social factors as on medical intervention - then, clearly, the scope for developing evidence-based clinical guidelines is limited as a result (although there may still be scope for producing guidelines about how best to organise the delivery of support, reassurance and explanation).

Even leaving aside the case of patients with chronic conditions, there are problems about using outcomes as the benchmark of effectiveness. As McKee and Clarke[41] have put it: "outcomes can be expressed prospectively only as probabilities applying to populations. Consequently, studies cannot predict with certainty the outcome for an individual". Further, the valuation put on specific outcomes may differ as between patients, as may their willingness to accept risk or to live with pain or disability. In other words, the definition of an "effective" intervention may often be contingent on the specific circumstances of a doctor-patient encounter. Attempts to incorporate guidelines into purchasing agreements therefore risk imposing "a spurious rationality on a sometimes inherently irrational process" given the inherent uncertainty of medicine.

Guidelines are, of course, an attempt to reduce uncertainty by bringing together and synthesising the available evidence: a function which, it can be argued, is all the more important given that the ability of doctors to process information is being outstripped by the mushrooming volume and complexity of the data that is being produced.[42] From this perspective, they can be seen as a useful tool for professionals seeking to improve their own practice, rather than as an instrument for purchasers seeking to control practice. However, even with this caveat, there remains the problem of what should count as good evidence. Here the trend has been, as already noted, to emphasise evidence generated by research rather than evidence based on professional experience: to invoke scientific authority rather than professional legitimacy.

But scientific authority does not always speak with a clear, unambiguous voice. Even RCTs, the presumed "gold standard" of evidence-based medicine, do not provide an infallible or universal basis for preparing guidelines. As Sir Douglas Black has argued/[3] "there remain issues of clinical importance whose complexity makes them, for the present, 'insoluble' by the RCT route, and whose solution must await further resolution by conventional clinical or pathological analysis". For example, RCTs may be inappropriate for surgical interventions where new operations emerge stepwise as modifications of established procedures.[44] Evidence therefore has to be interpreted in the process of drafting guidelines. And interpretations, like the quality, quantity and relevance to clinical practice of the available evidence, vary. So, for example, a comparison of the guidelines produced in Britain, the United States, Canada and New Zealand - drawing on the same body of evidence, including RCTs - showed significant variations in their recommendations for the assessment of patients for the

control of hypertension.[45,46] The publication in 1997 of guidelines for the use of statins, endorsed by the NHS Executive, provoked six pages of letters to the British Medical Journal challenging the recommendations,[47] many of them criticising the assumptions made about cost-effectiveness (thus raising the wider issue of whether cost-effectiveness should be one of the criteria used in guidelines, a point further elaborated below).

If evidence has to be interpreted, if research findings have to be extrapolated to day to day clinical practice, then the question of who does the interpretation and extrapolation becomes crucial. Not surprisingly, there is the evidence that the composition and dynamics of the groups producing guidelines influences their output. The balance of disciplines may affect the recommendations made.[48] For example, an American study found that physicians and surgeons differed about the appropriate indications for abdominal aortic aneurism surgery.[49] These differences, the authors of this study noted, "may result from a natural tendency to recommend and promote one's occupation": a reminder that guidelines are - among their other functions - a form of occupational imperialism by individual specialties staking a claim to particular areas of practice. Nor can such specialty competition necessarily be resolved by an appeal to evidence: in this particular case, it was "impossible to determine with scientific confidence which source of appropriateness assessment is more valid". Hence the general stress on the need for multi-disciplinary guideline development,[50] and a wide representation of interests, on the assumption presumably that the biases will cancel themselves out. But the social and psychological dynamics of multidisciplinary groups create, in turn, their own problems.[51] One study of multi-disciplinary guideline development, for instance, found that "the

relative input of the different professions reflects professional hierarchies".[52] If the evidence is not clear-cut, or if its relevance to day to day clinical practice is in question, status and personality may be decisive. For all the emphasis on rigorous methodology and systematic reviews, deciding what should count as good evidence, and weighing up different sources of evidence, is a social process: guidelines do not spring from the head of Zeus but are the product of negotiation (a conclusion which would seem merely platitudinous to the sociologists of science).

But if guidelines are sensitive to the composition of the groups producing them, and the different perspectives that may be brought to formulation of recommendations, then clearly the question of who should be represented on them becomes central. It is now accepted that general practitioners and nurses, as well as hospital specialists, should be included as a matter of routine. Increasingly, too, patients are now represented. But the rhetoric of patient representation is difficult to translate into practice: the articulate and confident lay person - able to challenge the professionals - will, by definition, almost certainly be unrepresentative of patients in general. If a patient perspective is to be incorporated into guidelines, then it may be necessary to carry out elaborate consultative exercises." However, given that the valuation of outcomes and risks varies not only between patients and professionals but also within the patient population, then the search for a "representative" view may in any case be illusory: the weighing of benefits and risks is perhaps something left to the encounter between individual patients and clinicians.

Similarly, there is the question of whether working groups should include an economist. This touches on a larger issue, going to the

heart of the debate about the guideline movement is meant to achieve. There is no dispute that guidelines are designed to promote effective care; that is their whole raison d'etre. But are they also meant to promote cost-effective care? How is a balance to be struck as between the benefits that individual patients may derive from a specific intervention and optimising the use of resources for the population as a whole? If it is the latter, then clearly economic analysis should be an integral part of the process of guideline production. But, in practice, economic analysis rarely features in guidelines and, as we have seen, the Department of Health's 1996 policy statement speaks with two voices on this point (although guidelines commended by the Department are first screened by its own economists). More generally, there is ambiguity about how far guideline recommendations should take resource considerations into account. Are guidelines seeking to develop ideal standards of clinical practice? Or are they aiming to achieve optimal performance within the constraints of available resources, in the words of the 1993 report of the Scottish Working Party?

If only implicitly, most guidelines appear to settle for the best that can be done within the limits of existing resources. But it is important to recognise that this will not necessarily be the case: guidelines can also be used to stake a claim to extra resources. From the perspective of cost-containment, guidelines are a double edged weapon. On the one hand, they may eliminate waste: in those (rare) cases where the evidence demonstrates incontrovertibly and unambiguously that a given intervention does not benefit patients or those (more frequent) cases where the evidence suggests that a given intervention should be used more selectively. On the other hand, they may generate extra demands by promoting services that are currently under-utilised.

7. Conclusions

The 1997 White Paper,[54] setting out the Labour Government's plans for the NHS, announced the setting up of a new National Institute for Clinical Excellence. The role of this new Institute is to be "to give a strong lead on clinical and cost-effectiveness, drawing up new guidelines and ensuring that they reach all parts of the health service". Much will depend on the specific remit, and budget, given to the Institute; even more will depend on how the various competing interests in guideline production - the clinical professions, the new discipline of evidence based medicine and economists - are represented in its governance. Similarly, it is not apparent what the balance will be between clinical and cost effectiveness. But it is clear that the more pro-active stance of the Department of the Health and the NHS Executive - already apparent in the 1996 policy statement - will be further strengthened. England is now travelling along the same road as Scotland.

There is, clearly, much scope for the new Institute to rationalise the production of guidelines. The proliferation of guidelines, national and local, has meant that there is a confusing babble of sometimes contradictory advice and there is a strong case for central co-ordination.[55 56] Beyond that, the evidence reviewed in this paper suggests we should not invest too much hope in this new initiative. In summing up this evidence, we return to the four themes enunciated in Section 1. First, our review suggests that legitimacy remains as important as authority, despite the increasing emphasis on the latter. Professional endorsement remains critical for the acceptance of guidelines in clinical practice and, to the extent that evidence based medicine overtly challenges the profession, may be difficult to obtain. Second, and reinforcing this point, if the model of guideline implementation were to move from persuasion to

enforcement, if guidelines were overtly used by managers to try to control practice, professional resistance could be expected. Third, central government lacks a system of incentives and sanctions for promoting the use of guidelines; similarly, it is not clear that the new Primary Care Groups will have either the technical capacity or the collective will to monitor - far less to insist on the implementation of - guideline recommendations. Fourth, evidence is always likely to be too partial and ambiguous to cover the whole range of clinical activity and will in any case be interpreted differently by the various actors in the health care arena, all bringing different perspectives to bear: the search for certainty, the assumption that more research will provide the answers, may well end in disillusion as it becomes apparent that this enterprise represents an attempt to attain a moving and ultimately elusive target.[575]

In the absence of further Government initiatives to introduce a system of sanctions and incentives, which might well risk a major confrontation, it therefore seems likely that guidelines will continue to be produced and controlled by the medical profession rather than becoming an instrument for controlling clinical practice. This said, clinical guidelines - seen as instruments of persuasion and education rather than control - may indeed play a significant role in gradually changing practice: all the more so, if the audit were used to monitor systematically the way in which guidelines are applied in practice. They will reinforce existing peer pressure on doctors whose practices are conspicuously out of line. Similarly, they offer a way of giving patients access to information about what is considered best practice, so changing the balance of power in the process of negotiating treatment. Like evidence-based medicine, from which it draws so much of its inspiration, the

guideline movement offers the promise of incremental change over time: not driving towards uniformity, an undesirable as well as impracticable goal, but gradually narrowing the range of acceptable variations in practice.

References

1. David Sackett, William M.C.Rosenberg, J.A.Muir Gray, R. Brian Haynes and W.Scott Richardson. Evidence based medicine: what it is and what it isn't. British Medical Journal Vol.312 13 January. 1996, 71-72
2. Chris Ham. Lessons and conclusions Chapter 7 in Ham ed. Health Care Reform: learning from International Experience. Buckingham: Open University Press 1997, 119-140
3. Frederic W.Hafferty and John B.Mckinlay eds. The Changing Medical Profession Oxford: Oxford University Press 1993
4. J.Collier, Ina Ismail and P.Littlejohns. Distribution and Perceived Value of Treatment Guidelines in a London Teaching Hospital District: the impact of promotion. Proceedings of the Royal College of Physicians of Edinburgh Vol.25 1995 118-120
5. M.J.Field and K.N.Lohr (eds) Clinical Practice Guidelines: directions for a New Program. Committee to Advise the Public Health Service on Clinical Practice Guidelines, Institute of Medicine Washington, D.C.: National Academy Press
6. Sandra J.Tanenbaum. Knowing and Acting in Medical Practice: The Epistemological Politics of Outcomes Research. Journal of Health Politics, Policy and Law Vol.19 No.l Spring 1994 27-44
7. Andrew Farmer. Medical practice guidelines: lessons from the United States. British Medical Journal Vol.307 31 July 1993 313-317
8. Audit Activities of the Medical and Non-Medical Royal Colleges and Professional Societies in the UK, 1996, London:CASPE 1997
9. Secretaries of State for Health, Wales, Northern Ireland and Scotland Working for Patients. London: HMSO Command 555 1989
10. Working for Patients: Working Paper 6 Medical Audit London: HMSO 1989
11. Christopher J.Pollitt. Audit and accountability: the missing dimension? Journal of the Royal Society of Medicine Vol,86 April 1993 209-211
12. The Royal College of Radiologists Multicentre Guideline Study: Implications for Clinical Practice. Editorial Clinical Radiology Vol.45 1992 365-368.
13. The Royal College of Radiologists. Making the best use of a Department of Clinical Radiology: Guidelines for Doctors. Third Edition. London: Royal College of Radiologists 1995

14. Steven H.Woolf. Practice Guidelines, a New Reality in Medicine: 11. Methods of Developing Guidelines. Archives of Internal Medicine Vol.152 May 1992 946-952
15. Jeremy Grimshaw and Ian Russell. Achieving health gain through clinical guidelines: 1.Developing scientifically valid guidelines. Quality in Health Care Vol.2 1993 243-248
16. Francoise Cluzeau, Peter Littlejohns, Jeremy Grimshaw and Anthony Hopkins. Appraising clinical guidelines and the development of criteria - a pilot study. Journal of Interprofessional Care Vol.9 No.3 1995 227-235
17. Michael Peckham. Research and development for the National Health Service. The Lancet Vol.338 August 10 1991 367-371.
18. NHS Executive Clinical Guidelines. London: Department of Health 1996
19. NHS Management Executive Improving Clinical Effectiveness El(93)115 21 December 1993 Leeds: NHS Management Executive
20. Patricia Day and Rudolf Klein. Constitutional and Distributional Conflict in British Medical Politics: the case of general practice, 1911-1991. Political Studies Vol.XL 1992 462-478
21. Anthony Hopkins and Juliet Solomon. Are Clinical Guidelines Any Use In The Process Of Contracting For Health Care? London: Royal College of Physicians Mimeo.
22. NHS Executive. Guidance for Purchasers: Improving Outcomes in Breast Cancer. London:Department of Health 1996.
23. NHS Executive. Promoting Clinical Effectiveness: A framework for action in and through the NHS London:Department of Health 1996
24. Anthony Hopkins. Some reservations about clinical guidelines. Archives of Disease in Childhood Vol.72 1995 70-75
25. Graham Winyard, Medical Director, NHS Executive. Letter to Chief Executives and Directors of Public Health: Clinical Guidelines Leeds:NHS Executive 30 September 1996
26. Elizabeth West and John Newton. Clinical guidelines: An ambitious national strategy. British Medical Journal Vol.315 9 August 1997 p.324
27. Effective Health Care No.8 Implementing Clinical Practice Guidelines: can guidelines be used to improve clinical practice? Leeds: University of Leeds 1994
28. J.M.Grimshaw and I.T.Russell. Achieving health gain through clinical guidelines: Ensuring that guidelines change medical practice. Quality in Health Care Vol.3 1993 45-52
29. Debra Humphris and Peter Littlejohns. The development of multiprofessional audit and clinical guidelines: their contribution to quality assurance and effectiveness in the NHS. Journal of Interprofessional Care Vo.9 No.3 1995 207-225
30. Oxfordshire Common Cardiac Conditions Group Evidence Based Management of Common Cardiac Conditions 1-111 Oxford: Oxfordshire Health 1995

31. Dr.Bernard Crump Birmingham's Clinical Guidelines for Acute Myocardial infarction Birmingham: South Birmingham Health Authority 1995

32. A.Miles, P.Bentley, A.Polychronis, N.Price and J.Grey. Clinical audit in the National Health Service: fact or fiction? Journal of Evaluation in Clinical Practice Vol.2 No. 1 February 1996 29-35

33. Anthony Hopkins. Clinical audit: time for a reappraisal? Journal of the Royal College of Physicians of London Vol.30 No.5 September/October 1996 415-425

34. Comptroller and Audit General. Clinical Audit in England. London:HMSO 1995 HC27

35. Clinical Standards Advisory Group. District Elective Surgery. LondomHMSO 1996

36. Graham Morgan and Amanda Layton: Clear winners. Health Service Journal 30 May 1996 p.27

37. D.Maclean (chairman) Clinical Guidelines: Report of a Working Group set up by the Clinical Resource and Audit Group. Edinburgh: The Scottish Office 1993

38. J.C.Petrie, J.M.Grimshaw and Adam Bryson. The Scottish Intercollegiate Guidelines Network Initiative: Getting validates guidelines into local practice. Health Bulletin Vol.53 No.6 November 1995 345-347

39. Anthony Hopkins. Some reservations about clinical guidelines. Archives of Disease in Childhood Vol.72 1995 70-75

40. Daniel M. Fox. Power and Illness. Berkeley: University of California Press 1993

41. Martin McKee and Aileen Clarke. Guidelines, enthusiasms, uncertainty, and the limits to purchasing. British Medical Journal Vol.310 14 January 1995 101-104

42. R.L.Logan and P.J.Scott. Uncertainty in clinical practice: implications for quality and costs of health care. The Lancet Vol.347 2 March 1996 595-598

43. Sir Douglas Black. The limitations of evidence. Journal of the Royal College of Physicians of London Vo.32 Nol. January/February 1998 23-26

44. Bryan Jennett. High Technology Medicine 2nd.edition. Oxford: Oxford University Press 1986

45. Rodney T.Jackson and David L.Sackett. Guidelines for managing raised blood pressure: evidence based or evidence burdened? British Medical Journal Vol.313 13 July 1997 64-65

46. T.P.Fahey and T.J.Peters. What constitutes controlled hypertension? Patient based comparison of hypertension guidelines. British Medical Journal Vol.313 13 July 1997 93-96

47. Letters: use of statins. British Medical Journal Vol.313 13 December 1997 1615-1620

48. Jeremy Grimshaw and Ian Russell. Achieving health gain through clinical guidelines: 1. Developing scientifically valid guidelines op. cit.

49. Jeph Herrin, Jeff A.Etchason, James P.Kahan, Robert H.Brook and David J.Ballard. Effect of panel composition on physician ratings of appropriateness of abdominal

aortic aneurysm surgery. Health Policy Vol.42 No.1 1997 67-81

50. Jeremy Grimshaw, Martin Eccles and Ian Russell. Developing clinically valid practice guidelines. Journal of Evaluation in Clinical Practice Vol.1 No.I September 1995 37-48

51. Jeremy Grimshaw, Claudia Pagliari and Martin Eccles. Clinical Guidelines: Scientific Derivation and Clinical Validity. Aberdeen: Health Services Research Unit Mimeo. 1997

52. Christine Bond and Jeremy Grimshaw. Multi-disciplinary Guideline Development: A case study from community pharmacy. Health Bulletin Vol.53 No.l January 1995

53. Jonathan Lomas. Making clinical policy explicit. International Journal of Technology Assessment in Health Care Vol.9 No.l 1993 11-25

54. Secretary of State for Health. The New NHS. London:HMSO 1997 Cm 3807

55. Francoise Cluzeau, Peter Littlejohns, Jeremy Grimshaw and Gene Feder. National survey of UK clinical guidelines for the management of coronary heart disease, lung and breast cancer, asthma and depression. Journal of Clinical Effectiveness Vol.2 No.4 December 1997 120-123

56. Richard Thomson, Helen McElroy, and Mark Sudlow. Guidelines on anticoagulant treatment in atrial fibrillation in Great Britain: variation in content and implications for treatment. British Medial Journal Vol.316 14 February 1998 509-513

57. Rudolf Klein. The NHS and the new scientism: solution or delusion? QJ Medicine Vol.89 1996 85-87

58. David J.Hunter. Effective practice. Journal of Evaluation in Clinical Practice Vol.1 No.2 1995 131-134

CHAPTER TWO
MANAGED CARE ORGANISATIONS: THE KEY TO GUIDELINE IMPLEMENTATION?

1. Origin & Development of the U.S. Guidelines Movement

As in the U.K., the U.S. specialist societies generally took the lead in formulating consensus and evidence-based practice guidelines decades ago.[1,2,3] The federal government augmented their efforts with a massive formal guideline-developing effort in the late 1980s through the newly-created Agency for Health Care Policy and Research (AHCPR). AHCPR assembled prestigious (and well-staffed) panels of the relevant stakeholders to conduct comprehensive, in-depth reviews of the scientific literature on medical conditions affecting large segments of the US population.[2,3] Significantly, the agency down-played any cost-containment rationale for formulating guidelines. It concentrated on developing guides for treating patients presenting with defined medical conditions, based on the best available scientific evidence about what "works" in health care. AHCPR hammered out evidence-based guidelines on which the panel participants could come to agreement.

These federally-sponsored guidelines covered such common and perennially troublesome conditions as low back pain, urinary incontinence and benign prostatic hyperplasia. In addition, they dealt with relatively mundane patient care problems such as bed sores and pain relief. All told, 19 guidelines were issued under the aegis of AHCPR before the agency abruptly shifted its mission, from producing to serving as a support centre for guideline production by outside professional groups and other reputable entities. Complex political factors dictated this governmental retreat from a leadership role in formulating guidelines, but the most aggressive opposition apparently stemmed from alternative medicine rather than from the medical profession itself. Chiropractic medicine took intense exception to the AHCPR guideline on low back pain which advised "watchful waiting" rather than active intervention, and successfully

applied political pressure on Congress to shift the Agency's focus away from guideline production.

The government still nonetheless indirectly influences guideline development and implementation. Although AHCPR no longer initiates guideline formulation, it funds twelve centres aimed at grounding medicine (including developing guidelines) in solid science and population-based analyses. Since government now pays for 47% of US health care - a fact not always understood by the US public, let alone the British - its potential influence with respect to guideline development and implementation is substantial, particularly in regard to their use in the federally-financed Medicare and Medicaid programmes.[4]

2. Background

Twelve managed care organisations (MCOs), two medical specialty networks, two government agencies, a prestigious health policy think-tank, and seven management consulting and other groups involved with guideline development, implementation and use were interviewed for this study. (See listing of entities interviewed at the end of this report.) The MCOs varied widely in size, geographical location and organisational structure, while the other entities differed significantly in focus and clientele. All, however, were deeply involved in the guidelines implementation effort, and all contributed valuable pieces to this report. Generally speaking, geography mattered; the west coast, with the most tightly-organised plan structures, had made the greatest progress implementing guidelines, while New York had made the least. In fact, New York was described by the Medical Director of Empire Blue Cross & Blue Shield as "the last managed care hold-out," but exactly why has been difficult to pin down. This report focuses on MCOs, for they

have nonetheless had the greatest impact on moving guidelines into mainstream U.S. medical practice.

In a sense, the current U.S. guidelines story begins where the British one leaves off. Few U.S. doctors - at least among the younger ones - now publicly question the basic concept of clinical guidelines. The pioneering work of Dr. David Wennberg, Dr. David Eddy and others beginning 20 years ago persuasively demonstrated wide variations in physician practice styles that could not be explained on scientific or demographic grounds, or on the basis of patient idiosyncracy.[5,6,7] Those researchers demonstrated that many doctors' practice styles reflect more what they were taught, as modified by their experience, than what clinical studies may have established as the most effective treatment.

The U.S. medical profession has had little choice but to accept the basic premise that individual doctors do not always necessarily "know best" how to practise medicine. Although practice guidelines (which guide a physician what to do with a patient presenting with a given clinical picture, rather than how to do it) may still be anathema to some of them, doctors can no longer disparage the core rationale now that advances in technology have made medical practice so sophisticated, complex, and expensive. According to an Institute of Medicine Practice Guidelines Committee, formal recognition of the practice guidelines movement "can be seen as part of a significant cultural shift . . . away from unexamined reliance on professional judgement toward more structured support and accountability for such judgement".[3]

Very occasionally a guideline achieves iconic status to become recognised as a gold standard of medical practice, as was the case in

1986 when the Harvard teaching hospitals first published their standards for administering anaesthesia in the Journal of the American Medical Association.[8] The scientific evidence supporting their recommendations was so overwhelming and compelling that within two years the Harvard anaesthesia guidelines were being followed in virtually every operating room in the US. Moreover, adherence was not merely voluntary,- hospitals compelled anaesthesiologists to observe them as essential for good patient care, motivated in part by fears of malpractice liability. Hospitals were prepared to impose the ultimate sanction - dismissal - against anaesthesiologists who failed to follow them.

This is an unusual case, however, because the guideline involved an institutionally-based procedure where serious patient-safety issues were at stake, and the potential costs of medical misadventure were so high. Moreover, the evidence about what would significantly improve patient care was crystal clear, the solution was relatively simple, hospitals had strong incentives to enforce the guideline, compliance monitoring was easy, and the publicity surrounding the problem and its solution was so pervasive. Few guidelines have the benefit all of those factors to spur effective implementation.

3. Guidelines Information in the US

The American Medical Association compiles an annual listing of recognised practice guidelines, and the 1997 edition listed about 2200.[9] Quite obviously there are guidelines, and then there are guidelines. Many of those the AMA lists overlap and are redundant, and some - those issued by the specialist societies, the Agency for Health Care Policy and Research or prestigious think-tanks like the Rand Corporation, for example - carry far more weight and prestige

than others. The AMA makes no attempt to evaluate or distinguish among them, however. Commercial information entities like the publisher Faulkner &. Gray in its 1998 Medical Outcomes and Guidelines Sourcebook do a somewhat better evaluative and organisational job in guiding the uninitiated among available guideline offerings,[10] but no single source yet appears to have sorted all the wheat from the chaff in thoroughly reliable fashion. Certain guidelines applicable to conditions widely observed in primary care patient populations, such as those dealing with diabetes, asthma and hypertension, have nonetheless achieved widespread endorsement and acceptance by MCOs and their contracting physicians. All twelve of the MCOs interviewed for this study indicated that they utilised guidelines for these conditions derived from those formulated by the relevant specialist societies or AHCPR, but only after tailoring them for local use. Most plans enlist the aid of a small and highly-specialised cadre of management consultants to aid them in this endeavour. These consultants have developed sophisticated software packages that target guideline problems and propose solutions quite effectively.

The Department of Health and Human Services has recently announced a massive effort to make all existing and reputable guidelines available to practitioners - and the public at large - through the internet at its AHCPR web site. This constantly-updated Guideline Clearinghouse will also "compare and contrast the recommendations of guidelines on similar topics, with summaries covering the major areas of agreement and disagreement," in an effort to facilitate their intelligent use. Thus any interested entity - or person - in the world (including the U.K.) should soon have an easily-accessible and comprehensive source of information about all of the practice guidelines considered

currently relevant to medical practice. What use will be made of this resource is quite another matter. Whatever comparative guideline information may appear can only begin to scratch the surface, and will be no substitute for informed evaluation of the appropriateness for using a particular guideline in specific circumstances. One thing is clear, however; it will no longer pass the straight-face test in the U.S. for anyone to claim ignorance of the existence of guidelines relevant to a particular practice area, or to plead inability to find them. The information will be easily and instantly available to anyone determined to look for it. Managed care organisations have already exhibited that determination.

4. Guideline Implementation

Market forces, in conjunction with managed care, have been far and away the most influential factors in the actual take-up of guidelines in the U.S.[11] Managed care insurers competing for health insurance contracts from employer/purchasers (who underwrite most private health insurance in the U.S. as an employee benefit) have been far more ruthless in implementing guidelines than government ever would have dared to be. As U.S. health costs have escalated, these employer-payors have increasingly demanded evidence of value for the substantial sums of money they expend to subsidise employee health care. This has pressured MCOs to demonstrate in objective fashion that they deliver good-quality medicine at a reasonable price.[12] Practice guidelines, provider profiles, outcome studies, and other data-based sources of information are tailor-made for this task.[13]

The government is, as in the U.K., reluctant to incur the wrath of the medical profession by appearing to be dictating clinical practice, but has more recently begun to examine the efficacy of using these measures in its role as purchaser as well. It has announced that

henceforth all Medicare contractors must supply it with HEDIS information (see page 54) about, inter alia, guidelines, designed to provide it with objective data about quality of care the plan delivers. Although other entities, such as hospitals, have adopted - and in cases like that of the Harvard anaesthesia standards, sternly enforced - guidelines, this report focuses on MCOs because they have had the greatest overall influence on guideline implementation.

Fierce competition among health care providers for MCO contracts, fuelled by the U.S's excess supply of doctors and hospitals, has given MCOs the bargaining power to require providers to cooperate with data-based measures designed to promote better practice. This is the reality in which U.S. doctors are now being trained, and younger doctors accept these intrusions on their clinical autonomy - and generally the need for them - as a matter of course. They may not greet them with unbridled enthusiasm, but they understand the value of mechanisms designed to promote more effective (and cost-effective) patient care.

Some of their senior colleagues, trained in mid-century's golden age of medicine when physician prestige and autonomy were at their highest, and medical science was finally starting to yield broad promise for cures, may still resist them. The more discerning among this group nonetheless recognise the value of a more objective and scientific approach to medicine, implemented in close concert with the undisputed art of medical practice.[14] When physicians take the time to examine the scientific support for a guideline, they usually find that, in the words of a Group Health Co-operative of Puget Sound clinical director, "A good guideline sells itself."

5. Guidelines Use by Managed Care Organisations

A. MCO Incentives to Implement Guidelines

The stimulus for guideline implementation in the US has come from the private sector, primarily at the instigation of MCOs competing for contracts to offer health insurance to employees.[1213] Regardless of what one thinks of the (un?(suitability of competition for structuring a health sector, market forces do theoretically promote efficiency, in medicine as well as anywhere else. An efficient MCO manager will seek to provide medical services at an optimum mix of quality and price. Side-stepping the question of what we really mean when speaking of health care quality, practice guidelines do offer a theoretically valuable tool for ensuring that patient/subscribers receive useful medical services. No MCO willingly chooses to spend money on useless care, and presumably health insurers have strong incentives to provide subscribers with care of reasonable quality so they will neither develop preventable expensive illnesses nor defect to rival plans. The recurrent MCO rhetoric emphasising the way guidelines promote good patient care provides an excellent example of enlightened profit-maximisation.

Market incentives thus promote the use of guidelines to channel physician practice into more effective patterns, and to show purchasers that MCOs are spending money on care likely to benefit patients. The National Commission on Quality Assurance, which accredits MCOs on a voluntary basis and is relied on by many employers when selecting employee plans, furnishes a more subtle incentive for guideline implementation. It collects information on plan use of guidelines - and more recently on the efficacy of certain medical interventions - as part of its Health Employer Data Information Set (HEDIS), which is widely used by employer/

purchasers (and others) in evaluating health plans. As noted previously, the federal government has also recently announced that it will require all MCOs with which it contracts to furnish HEDIS data on a annual basis. Thus far only a small percentage of Medicare beneficiaries (around 12%) is enrolled in managed care, but that number is expected to increase dramatically around the year 2010 as post-war baby boomers age, and the number of U.S. senior citizens increases substantially.

This study found that virtually all U.S. MCOs have now formally adopted clinical practice guidelines to assist their providers in delivering care. We emphasise that for purposes of this study, the term practice guidelines refers to those written principles, algorithms, charts, etc. which guide a doctor in deciding what to do in order to treat patient ailments most effectively, often in a cost-effective manner. The term does not encompass more administrative measures which are not focused primarily on patient care (but which sometimes also adopt guideline terminology), such as length-of-stay guidelines. The American Association of Health Plans, the trade association for managed care plans, confirms that "all" U.S. health plans have now implemented at least "some" practice guidelines. The twelve MCOs and two provider networks interviewed for this study had adopted an average of twenty to thirty guidelines each, while Kaiser Permanente of Southern California (the most advanced of all the plans interviewed in many ways) had implemented an astonishing eighty-four.

B. Implementation Effectiveness

The plans interviewed mentioned that guideline format should always be tailored to accomplish the task at hand, rather than shoe-horned into a standardised format for the sake of consistency.

Although according to Harvard/Pilgrim Health Plan and others, clinicians seem to relate best to simple guidelines in the form of bullet points, some clinical problems, such as cancer diagnoses, do not lend themselves to that form. The National Comprehensive Cancer Network guidelines, for example, generally take the shape of algorithms, because so many intervening factors can change the course of cancer therapy. Other guidelines, such as many of those used by United Health Care, are presented in chart form to give a broader range of information. The most professional guidelines direct the user to further information on the subject, state the clinical studies on which they were based, and identify specific individuals within the plan who were involved in its adoption and can be contacted with questions, or provided with new information. This reinforces the notion of guideline use as an open, accessible, ongoing educational process.

How well - or even whether - MCOs have implemented these guidelines is quite another matter, depending on a variety of factors. Primary among those factors is the organisational structure of the MCO. Broadly speaking, the more tightly-organised the MCO, the more assertive and effective its implementation policy is likely to be. No surprise there, for opportunities for persuading physicians to change practice - and sanctioning the non-compliant - are obviously greater in closely-knit organisations. Moreover, the more tightly-organised the MCO is, the greater the likelihood that it will have integrated computer services, which greatly facilitate both implementing guidelines and collecting data to monitor their use and effectiveness. As the Medical Director of Empire Blue Cross and Blue Shield, which is experiencing problems in getting its widely-scattered New York physicians belatedly used to managed care, let alone to implementing guidelines, put it, "We don't have a

magic bullet yet, but we do have a magic direction,- the computerised patient record is the answer".

C. Types of Guidelines Implemented and Implementation Strategies

This study found that all MCOs had implemented the same core of primary care guidelines, dealing with commonly-seen patient conditions such as asthma, diabetes, chronic headache, low-back pain and hypertension. The plans all emphasised the dual advantage of such guidelines; not only do they promote practices resulting in better patient health, they save the plan money. If the primary care physician manages these common problems well on an out-patient basis, they rarely culminate in expensive hospital admissions. There was remarkably little variation in the substance of these primary care guidelines among plans, because all of them were derived from guidelines promulgated by the specialty societies and other authoritative sources like AHCPR. Very few of the plans were willing to expend the time and the resources on formulating their own guidelines from scratch, although all of the MCOs said that they "tweaked" the specialty society guidelines to fit their own purposes. Generally the plans constituted physician groups from among their own clinician leaders to simplify guidelines for use by the plan's participating doctors, who inevitably had differing interests and abilities. These groups also customised the guideline in question to local resources and conditions. The MCOs all considered this important to create local physician "ownership" of the measure, because committee members could then be more effective champions of its utilisation.

Respected local clinician champions were considered critical to the success of any guideline's implementation, because clinicians were

the most effective change agents not only in drawing rank-and-file physicians' attention to its value, but in effectively encouraging them to change practice in line with the guideline. All plans commented on the difficulties of getting physicians to change habitual patterns of practice - "like kicking a ten-ton marshmallow" is the way one plan administrator put it. The MCOs said that one-on-one contact is by far the most effective way to get doctors to focus on problem areas. One-on-one contact is clearly not feasible on a wide-scale basis in large, loosely-integrated plans, but one respected "champion" could nonetheless motivate groups of up to ten doctors fairly well to adopt a guideline, according to Harvard/Pilgrim Health Plan. Beyond that, the returns were not worth the effort of trying to convene the group. All plans agreed that a guideline simply sent out on paper was likely to end up in the doctor's wastebasket. Something else was always required to accomplish change, on which more later.

Most significantly, all of the plans interviewed insisted that guidelines were intended to be flexible tools for improving patient care, and that no guideline worth its salt would be presented as the right - or only - way to proceed for all patients. "A good guideline will always leave the clinician wiggle room to accommodate the idiosyncratic patient" was the way one medical director expressed it. "A guideline is just a guide, not a rule," said another. Whether plans actually believe this notion, or just consider it necessary hype to de-fuse physician resistance to the guidelines concept - or to snow interviewers - a fairly thorough examination of scores of plan guidelines reveals the general validity of the statement. They usually do give clinicians leave to vary their practices, but often require them to justify the variation. That in itself, however, constitutes a disincentive to deviate.

A notable exception to the general rule of plans piggy-backing on specialty society guidelines was presented by Kaiser Permanente of Southern California. With more than a million subscribers, primarily salaried physicians, and fourteen plan-owned hospital facilities, Kaiser has had both the resources and the incentive to do innovative work in guideline formulation. Moreover, with its tightly-knit organisational structure and highly-computerised facilities it is in an excellent position to implement guidelines. At the time of my interview in June of 1997 Dr. David Wennberg, the internationally-known physician-Ph.D. who pioneered work on practice variations, was spending one week per month on the plan's administrative premises helping to devise guidelines applicable to technological procedures such as bone-density scans.

Kaiser has implemented by far the largest number of guidelines of any plan studied here - eighty-four of them as of 1997 - and they cover not only primary care, but certain specialty procedures as well.[15] At the time of the 1997 interview Kaiser of Southern California was in the midst of merging with its Northern California counterpart, which has a more independent and fragmented physician culture. Moreover, both entities were affiliating with Group Health Co-operative of Puget Sound to form an extremely large managed care network stretching the length of the Pacific Coast. Whether this new entity will absorb the pace-setting Kaiser S. C. guidelines ethic is an interesting question, worthy of further research on its own.

Kaiser of Southern California has for six years frankly promoted at least one guideline (that for contrast media used in radiographic studies) as a cost containment measure.[15] This is a highly unusual move for a plan to make, because MCOs are all wary of public-relations backlashes when plans appear to be "saving (making?)

money at the expense of patient health". Although 5% of all Kaiser patients will have a serious negative reaction to the cheaper high-ionic contrast medium, they can be effectively identified in advance and given the more expensive non-ionic medium. Even if screening fails to detect someone who is susceptible ahead of time, the contrast agent is always administered by a Kaiser technician, the reaction will manifest itself instantly, and the technicians are trained to administer drugs which reverse the negative effects immediately. According to Kaiser, its subscribers generally approve in principle of cost-containment to keep premiums in check. When they are presented with the facts supporting implementation of the contrast medium guideline very few of them insist on the higher-cost agent. Kaiser reportedly saved $12 million on radiographic studies in the first five years after it implemented the guideline.

The key to the Kaiser strategy lies in educating both physicians and patients to the value of the guideline, in terms of patient safety as well as cost-effectiveness. In fact, all the plans interviewed said that the key to all implementation success was an emphasis on presenting guidelines to physicians in an educational rather than an adversarial manner. They believed the co-operative educational approach defused traditional physician hostility to "cookbook medicine," and achieved far better compliance than would have been the case had guidelines been imposed by the plan along with threats of sanctioning for non-compliance.

To return to the subject of effective strategies for implementing guidelines, Kaiser's contrast media guideline demonstrates the approach most likely to lead to successful implementation: the guideline is embedded in the computerised process of patient care. When a Kaiser physician orders radiographic studies, the computer

immediately asks a series of questions which should identify those patients susceptible to reactions. The lower-cost medium will be selected by the computer unless the physician overrides the default selection by signifying that the patient is in a high-risk category for reacting, or the patient - who has been informed via a cascading computerised consent form of the risks and benefits of the two options - elects the more expensive medium. It takes a highly sophisticated and integrated information system to imbed a guideline in the process of care like this, but it certainly can be accomplished effectively for procedure-based therapies.

Another highly-successful implementation technique involves feeding back to physicians their own performance profiles in following guidelines, in a format which permits comparison with the aggregate of all other physicians in the plan. "Doctors hate being outliers," according to the President of Health Care Microsystems, Inc., a management consulting firm which markets software that identifies outliers quickly. When physicians see that their own practice deviates significantly from that of their peers, usually little more need be said to accomplish modifications. Professional pride, perhaps leavened with a touch of anxiety about the potential consequences of failure to modify, does it. Some plans say - or insinuate - that if modifications are not forthcoming, profiles may be publicised within the plan identifying all physicians for their peers to see who the outliers are. As a final resort, plans can always make provider profiles publicly available, and reportedly some plans provide subscribers with comparative profiles as a matter of routine full-disclosure policy.

If merely furnishing comparative practice information does not effectuate desired changes where problems are observed, a visit to

the outlier from a "friendly senior clinician" in the plan usually does the trick. Another effective strategy is to make those senior clinicians responsible for the performance of the physicians below them in the plan organisational hierarchy. Comparative profiling is a powerful motivator at the supervisory level as well. All of this assumes, however, that the scientific underpinnings for the guideline at issue are strong and unassailable. All plans averred that if they could not persuade clinicians of the scientific justifications for a guideline, "forget about it". They all recognise that plan physicians are capable of completely boycotting any guideline they do not consider authoritative, and none was anxious to court the public relations disaster which would ensue if they tried to force a scientifically unsupportable guideline down their participating physicians' throats. Guideline legitimacy was thus a critically important factor in implementation.

Remarkably few plans said they used financial incentives (either positive or negative) to achieve guideline compliance - apart from the indirect financial incentives that inhere in capitation, and the partial financial withholds some plans retain if their physicians over-utilise in light of projected actuarial need. The few MCOs that did employ direct financial incentives used them primarily to reward those physicians achieving screening targets. Only one plan, again Kaiser Permanente of Southern California, admitted "very rarely" directly penalising physicians financially for poor performance.

In line with the educational rather than the punitive approach to implementing guidelines, no plans admitted that they "de-selected" physicians merely for failing to follow guidelines. However, several plans, most notably United Health Care, said they take great care in

selecting their participating providers in the first place, and all plans have access to resources like the Health Care Financing Administration's MEDQUAL data base to help them identify in advance those doctors most likely to be practising cost-effective care. In the current U.S. environment of significant physician surplus, this fact alone could account for a great deal of U.S. doctors' relative willingness to follow practice guidelines "advocated" by MCOs. Effective implementation strategy was not the only reason for MCO reluctance to de-select doctors who fail to adhere to guidelines once they become participating physicians, however. MCOs admitted they couldn't take the media "hit" if a doctor whose participation had effectively been terminated thereafter went to the media and defended his practices on the ground that he was "just trying to give his patients a 'higher quality of care than the plan allowed'". The MCOs said it would be too hard for them to get the true quality issue before the public in such a case. All plans said, however, that they would not hesitate to get rid of a physician who put patient care in jeopardy. "That one's easy; like motherhood and apple pie," according to Kaiser.

D. Monitoring Guideline Implementation

Apart from profiling physician practices, several other techniques were used by most plans to monitor physician adherence to guidelines. Tufts Affiliated Health Plan, for example, required its providers to dummy-bill each patient encounter electronically even though they were paid on a capitated rate. In this way, the plan had an ongoing picture of physician "inputs" to patient care that mirrored the picture traditionally generated by fee-for-service medicine. Tufts and many other plans also employed a software program keyed to a series of "sentinel events," such as hospitalisation of diabetics or asthmatics, that alerted them to

avoidable practice problems. Frequency of office visits, frequency of specialist as well as hospital referrals, patient laboratory results, and patient pharmacy use were other markers widely utilised to inform plans of the efficacy of patient care, and therefore indirectly to illuminate physician compliance with guidelines.

6. Conclusion

Although practice guideline implementation is still in its relative infancy in the US, it is well under way. Professional resistance to the general concept is no longer automatic, and is observed less and less because blanket opposition to guidelines is considered increasingly unsupportable in medical environments of any sophistication. The more tightly organised MCOs, particularly those on the west coast, have led the way in devising effective implementation techniques, and today's competitive MCO environment ensures that what has been seen there to achieve good quality, cost-effective, care will be tried elsewhere. Guideline implementation has already been dramatically successful in cutting down on, if not eliminating, a great deal of outlier physician behaviour. As U.S. health care becomes more and more highly computerised, this trend can only increase. Thus this relatively optimistic report about the state of guideline implementation is influenced by the reasonably foreseeable long-range outlook. Increasingly computerised patient records will make the collection of detailed medical input and output data a routine matter, and ideally this will provide continuing feedback for improving guidelines - and therefore medical practice - on a long-term and continuing basis.

Major Findings:

- "All" US managed care organisations report having "formally instituted at least some practice guidelines"
    - All 12 MCOs interviewed had implemented guidelines for common primary care conditions
    - Few plans report implementing specialist guidelines

- All MCOs piggyback on guidelines produced by specialist societies or other prestigious bodies rather than creating their own
    - But all MCOs customise guidelines for their own plan use
    - Most plans use specialised management consultants for implementation

- Implementation success guidelines correlates with plan organisational structure
    - Guideline format varies according to complexity of medical condition addressed; "each guideline is unique"

- Guideline implementation strategies vary
    - All plans say key = unassailable scientific back-up for guideline
    - All plans say they focus on "educating" doctors to adopt more effective practices rather than on sanctioning non-compliance per se
    - All plans say data feedback essential to effective implementation
    - Comparative provider profiling effectively generates better practice
    - Positive financial incentives sparingly used; direct financial penalties for non-compliance rarely found

- Guideline compliance monitoring techniques
  - Provider profiles
  - Lab values
  - Frequency of specialist referrals
  - Frequency of office/hospital visits
  - Pharmacy use
  - All MCOs present guidelines as "guides, not rules"
  - MCOs consider guidelines & outcomes complementary data-based tools for improving medical practice; "neither is of much use without the other"
  - Implementation rhetoric focused on giving patients good quality care, but according to insiders, "the bottom line is still the bottom line"

Entities Interviewed:

Managed Care Organisations

- Harvard/Pilgrim Healthcare (MA]
- Tufts Affiliated Health Plans (MA)
- Blue Cross & Blue Shield of MA (MA]
- United Healthcare (MN)
- United Healthcare (FL)
- Salicknet (FL)
- Kaiser-Permanente of Southern California (CA)
- Kaiser Mid-Atlantic (MD)
- Avanti Healthcare (NYLCare - NY)
- HIP (NY)
- Empire Blue Cross & Blue Shield (NY)
- Group Health Co-operative of Puget Sound (WA)

Provider Networks

- Institute for Clinical Systems Integration (ICSI) (MN)
- National Comprehensive Cancer Network (NCCN)

Management Consultants

- HPR, Inc. (MA)
- Health Care Microsystems, Inc. (MA)
- InterQual (MA)
- Milliman & Robertson (MN)

Other Private Not-for-Profit Entities

- American Association of Health Plans (DC)
- Institute of Medicine (DC)
- Massachusetts Health Data Consortium (MA)
- Tufts (AHCPR-funded) Centre for Evidence-Based Medicine (MA);

Government Agencies

- Agency for Health Care Policy &. Research (DC)
- General Accounting Office (DC)

SELECTED REFERENCES

1. Lewin & Erickson. Leadership in the development of practice guidelines: the role of the Federal Government and others: 1998 (revised 1989]
2. Marilyn J Field & Kathleen Lohr (eds). Guidelines for clinical practice: from development to use: 1992
3. Marilyn J Field & Kathleen Lohr (eds]. Clinical practice guidelines: directions for a new program. Institute of medicine: 1990
4. Office of Technology Assesment, U.S. Congress, OTA-H-608. Indentifying health technologies that work: searching for evidence: 1994
5. John E Wennberg. Dealing with medical practice variations: a proposal for action. Health Affairs 6: summer 1984
6. David M Eddy. Clinical decision making: from theory to practice. 263 JAMA 287, 441, 877, 1265: 1990

7. David M Eddy. Variations in physician practice: the role of uncertainty. Health Affairs 74: Fall 1984
8. John H Eichorn et al. Standards for patient monitoring during anaesthesia at Harvard Medical School. 256 J. Am. Med. Ass'n 1017: 1986
9. Margaret C Toepp et al (eds). Directory of clinical practice guidelines: titles, sources and updates. Am. Med. Ass'n: 1997
10. Faulker &. Gray. 1988 Medical outcomes & guidelines sourcebook.
11. General Accounting Office. Report on practice guidelines implentation: 1996
12. Arnold J Rosoff. Role of clinical practice guidelines in health care reform. 5 Health Matrix 369: 1995
13. Maxwell J Mehlman. Assuring the quality of medical care: the impact of outcome measurement and practice standards. 18 Law, Med &. Health Care 368: 1990
14. Jonathan Lomas et al. Do practice guidelines guide practice? 321 New. Eng. J. Med. 1306: 1989
15. Clinical practice guidlelines (3rd ed). Kasier Permanente of Southern California: 1997