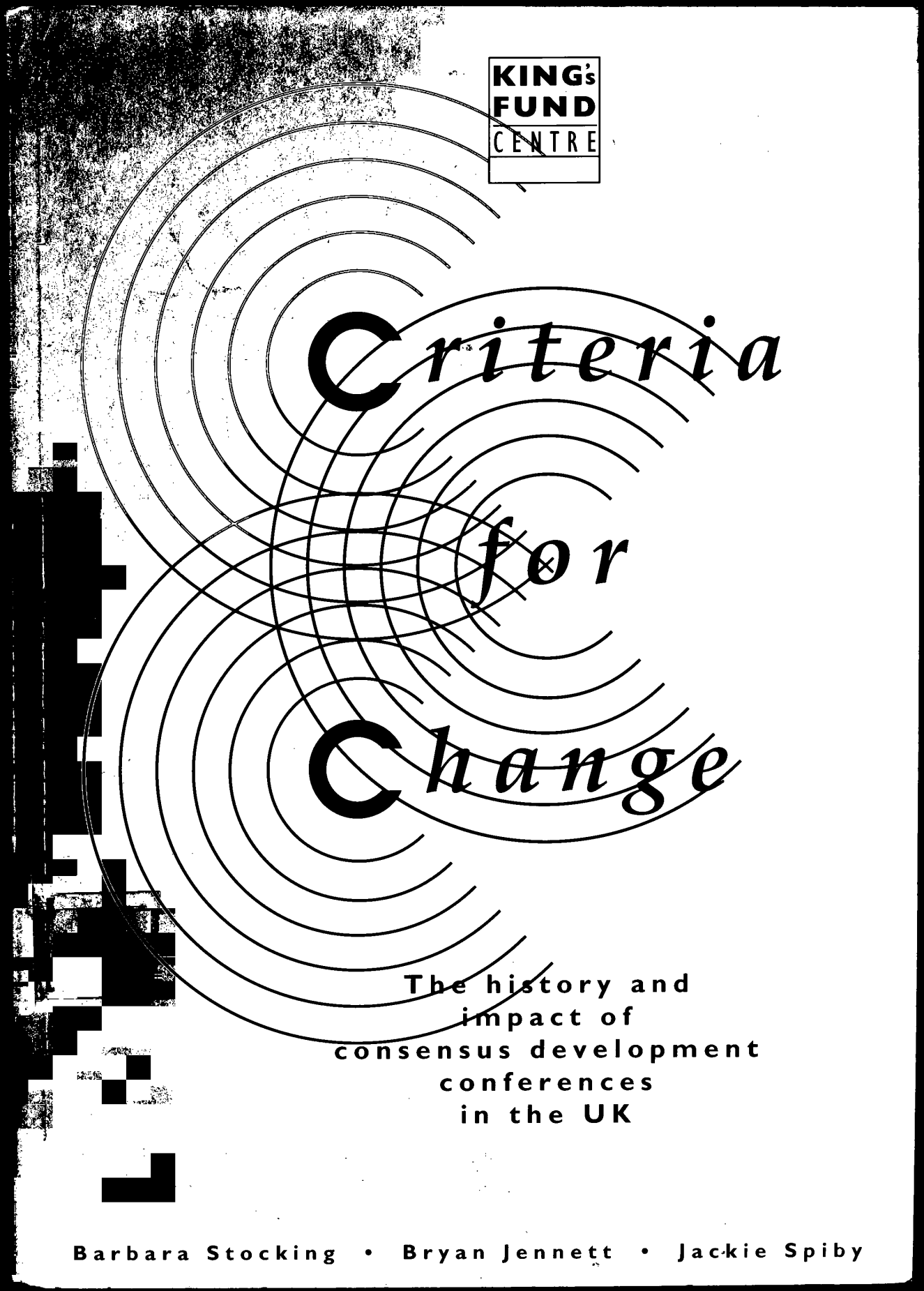
KING's
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Criteria for Change

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Consensus Steering Committee

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The King's Fund Centre is a health services development agency which promotes improvements in health and social care. We do this by working with people in health services. We encourage people to try out new ideas, provide financial or practical support to new developments, and enable experiences to be shared through workshops, conferences and publications. Our aim is to ensure that good developments in health and social care are widely taken up.

The King's Fund Centre
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Foreword

The story of the King's Fund consensus conferences, which this book tells, is an intriguing one. Initially developed in the United States, these conferences are a way of ventilating an important controversy in medicine, at a stage when enough evidence is available to reach at least an interim conclusion, with a view to influencing the development of clinical policy and practice. Outside the United States of America, we in the King's Fund were among the first in this field. Our aim was experimental: to test the value of this method as a means of shaping the national use of medical technology.

There have proved to be some excellent features in the approach. The experts have been willing to apply themselves to present the issues clearly, and the panels and audiences have worked equally hard to absorb complex evidence. For myself, I have felt privileged to listen and have never learned so much so quickly about the fields of medicine under scrutiny. While it is virtually impossible to prove their precise impact, they have clearly had some influence, especially, for example, on the treatment of breast cancer, and the discriminating use of cardiac surgery.

Two features of the King's Fund approach have been unusual, and both have been successful. One was to hold the meetings in public, with a substantial lay element in the audience and a non-specialist majority on the panel. The second was to include ethical and economic considerations about the priority (relative to other therapies) of the technology under discussion. I well remember the amazement and indignation with which the economic concept of QUALYs (quality adjusted life years) was first greeted at one of these conferences. Arguably, that type of challenge to medical thinking will prove to be one of the most enduring legacies of the series so far.

Why, therefore, are we suspending the initiative at this stage? The most obvious reason is financial. It has cost about £40,000 a year to run the programme, or £20,000 per conference, since very substantial staff work is required before and after each one. The King's Fund would be willing to contribute, but not to bear the whole cost. But more important than the fact that there are many other financial calls on the Fund, it has seemed to us a necessary test that some other organisation (such as the Department of Health, the NHS Management Executive, or the MRC) should show tangible support, if the initiative were to continue for the long term. To date, they have not been inclined to do so. I consider this a pity, although I am far from claiming that we have yet 'got it right' in all particulars.

For example, substantially more follow-up would be well justified by the need to diffuse the findings, assess their impact on practice and determine when to revise them. This might be achieved better by other approaches and I sometimes wonder whether we should actually be aiming for a consensus statement, as opposed to an analysis of the evidence and the opposing arguments, to be followed at some later date by an authoritative statement of national policy for the time being – which would by definition have to come from an official source. I hope this book will help to stimulate discussion of these issues.

While I am sure that we are right to suspend the initiative at this stage, I shall be surprised and disappointed if it is not resumed. There is such an obvious need constantly to review our use of medical technologies and practices, and a forum of this kind seems a useful component of any national process for this purpose. Perhaps we were just a little too early. It is not, I believe, a coincidence that so many countries have now taken up the method, just when we are setting it on one side. Nor is it simply a craze that will go out of fashion. It may be superseded by some better mechanism, but the need for something like it is too important and too enduring to ignore for long.

Robert Maxwell
Chief Executive, King's Fund

Acknowledgements
The greatest thanks for making the consensus development conferences successful must go to the conference panels who devoted so much time and effort to the process, and to the presenters who were prepared to have their knowledge and opinions subjected to such scrutiny. Thanks are also due to the Consensus Conference Steering Group for guiding the programme through this contentious territory. Allyson Pollock, Bobbie Jacobson and Chris Ham were each responsible for the success of an individual conference. Nichola Nightingale and Pat Tawn carried a huge organisational burden. Finally, Peter Woodford has ensured that this book is readable.

David Costain
King's Fund Centre

Introduction

Consensus conferences are one response to increasing concern in Western societies about some aspects of technological developments in medicine. The 1970s saw exponential growth in the number of intensive care units, in the use of renal dialysis, aggressive chemotherapy for cancer, coronary bypass grafting, renal transplantation and, at the end of the decade, of heart and liver transplantation. Equipment for CT scanning in the mid-1970s, followed shortly thereafter by magnetic resonance imaging, revolutionised the diagnosis of many conditions as radically as had the discovery of X-rays at the end of the last century, and there was great eagerness on the part of the medical profession to acquire these expensive devices. The developments were taken up more rapidly in the USA where by 1980 there were ten times as many ICU beds, and six times as many CT scanners and bypass operations per head of population than in the UK. Concern about the explosive growth of technology was therefore felt earliest and most keenly in the USA. In this book we trace the antecedents of the US consensus conference programme which began in 1977, and the subsequent events in the UK that led the King's Fund to set up its programme in 1984.

The increasing use of technologies in clinical medicine has attracted considerable criticism from within and beyond the health care professions. In the mid-1970s concern in the USA focused on the inappropriate use of life-saving and life-sustaining technologies in intensive care units. Attempts to ensure that patients could refuse unwanted treatment and avoid becoming prisoners of technology when hopelessly ill, included do-not-resuscitate orders, living wills and natural death acts, which began to appear in 1976. In the debate about the social repercussions of the widespread application of some technologies, bioethicists charged doctors with sometimes doing more harm than good, and with failing to respect the autonomy of their patients. One result was emphasis on informed consent, which required doctors to explain more to patients about the implications of proposed interventions and to ascertain their wishes.

At the same time the costs of medical technologies were posing a problem for providers. Rationing of health care is not new, but its inevitability became evident as costly equipment and facilities multiplied. Various regulatory mechanisms were imposed to constrain the spread of technologies that involved expensive capital investment. Meanwhile economists urged doctors to consider the cost-benefit and cost-effectiveness of alternative interventions. This required them to consider wider aspects of outcome than immediate mortality or the duration of survival, and to assess the quality of life as well as medical outcome. It soon became obvious that there was a serious knowledge gap about the efficacy and effectiveness of many interventions, and in 1975 the Congressional Office of Technology Assessment (OTA) began its health programme. This implied that policy decisions about the introduction into practice of new medical approaches should not be left to the professionals alone.

Reviewing the National Institutes of Health (NIH) in 1976, the US President's Biomedical Research Panel concluded that the NIH had a role in validating medical innovations, and Dr Donald Fredrickson (Director of the NIH) accepted some responsibility for evaluating existing and new technologies that had resulted from basic and biomedical research, the funding of which had hitherto been the main role of the NIH. His office published a paper 'The Responsibilities of the NIH at the Health Research/Health Care Interface' in 1977. The Consensus Development Program began that year under the aegis of the NIH, within which the Office of Medical Applications of Research (OMAR) was established to coordinate the programme. Its aim was limited to assessing the scientific evidence for the appropriate use of various technologies.

However, the next year the National Center for Technology Assessment was set up, with the wider task of considering the economic, social and ethical aspects of various technologies. Both programmes accepted the need for discussion in a wider context than with the technological experts themselves, according to a recent review.[1] There were only three or four doctors on the 18-person Advisory Council, and the American Medical Association claimed that it interfered with the practice of medicine. The Health Industry Manufacturers Association was equally unhappy, maintaining that the centre stifled innovation and restricted trade. Congress was lobbied and the centre was closed after only three years.

In the UK also the early 1970s saw concern about the over-use of technologies that prolonged dying rather than saving lives of quality. Consultative documents from the Health Departments on priorities in 1976 recommended shifting some resources from acute hospital specialties to primary care, geriatrics, psychiatry and preventive medicine. An open letter[2] to the Royal Commission on the NHS suggested that rather than simply limiting acute technological medicine, its efficacy and cost-effectiveness should be evaluated more critically. That same year McKeown's Rock Carling Lecture[3] castigated technological medicine for often failing to prolong life for long

enough, or to improve its quality sufficiently, to justify its cost. As a public health doctor he maintained that the reduction in mortality over recent years had mostly resulted from improvements in nutrition and the control of infectious diseases. This provoked protest on both sides of the Atlantic, with public health and primary care doctors among those defending the contribution of acute medical care.

As in the USA, the development of CT scanning did much to provoke debate about the factors that determine the acquisition and distribution of expensive new technologies. By 1973 the DHSS had agreed to fund a head scanner for each regional neurosurgical centre, without waiting for formal evaluation, because the reports from the centre using the prototype were so encouraging. However, acquisition was very slow and there were soon very many more CT machines in the US. The whole body scanner was twice as expensive and by no means so obviously more effective than alternative investigations. Health Authorities decided to delay provision of these machines through normal fiscal allocations until evaluation data were available, but before long several machines had been bought with alternative funds. A study concluded[4] that Britain had no satisfactory system for the evaluation of major new technologies on a broad enough basis to be of value to policy makers.

In 1980 Ian Kennedy's BBC Reith Lectures, *The Unmasking of Medicine*, accused doctors of pursuing their own interests more than those of their patients, whom they failed to keep adequately informed to allow them to participate in decisions. In some respects he was echoing the 'informed consent' movement in the US and his message was particularly directed at technologically oriented specialties. His combative style provoked a strenuous defence from many thoughtful doctors, who felt that he was attacking aspects of practice that were already rapidly changing. This debate therefore maintained the momentum of questioning and challenging hospital doctors about their activities from a societal viewpoint.

In 1982 a report on *Expensive Medical Techniques* from a working party of the Council of Science and Technology[5] listed many abandoned, dubious and over-used technologies. It analysed reasons for the failure to evaluate new technologies adequately, particularly their societal or economic impact, and for the reluctance to recognise the limited value of some established techniques. Among these reasons were the weakness of central advice in the NHS and the strength of vested interests in medicine and industry; also the influence of the media, which often over-sold new technologies and failed to emphasise the need for critical assessment. It recommended that funds for evaluation be made available from outside the NHS, and that this process should include expertise beyond the specialists involved in a particular technology, as well as other interested parties (consumers, policy makers, economists). Many of these suggestions were similar to those associated with the technology assessment and the consensus programmes in the USA, although no reference was made to these. The *British Medical Journal (BMJ)* gave this report a cool reception perhaps because of the somewhat adversarial and negative tone of the report vis-a-vis clinicians (there was no practising acute hospital doctor on the working party). *The Lancet* welcomed the report and commented that the NHS had no rational basis for decision making about technologies, while doctors' narrow outcome criteria for the success of their interventions tended to pay inadequate attention to quality of life.

In 1983 Bryan Jennett attended the NIH Consensus Conference on Intensive Care Medicine in Washington as a speaker and he discussed the organisational methods with the staff of OMAR – where doctors from government departments in Sweden and Holland were making similar enquiries. Impressed by the programme and the conference, he discussed the possibility of such a programme in the UK with the Chief Medical Officer of the DHSS and the Secretary of the MRC, but neither was encouraging. The Presidents of the Royal Colleges of Surgeons of England and of Physicians of London expressed interest in being associated with such an initiative, but were not prepared to be prime movers or financial contributors. After Robert Maxwell was approached separately by both Barbara Stocking and Bryan Jennett the King's Fund agreed to fund and organise a pilot conference, and this took place in November 1984. It was on coronary artery bypass grafting. In June 1984 Stocking and Jennett published a brief note[6] on consensus conferences in the *BMJ*, and the same month Jennett's Rock Carling Lecture/Monograph[7] on *High Technology Medicine* referred at length to the NIH consensus conferences. Both this and the planned London conference were noted in an editorial[8] in the *BMJ* in August 1984.

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2 The UK Experience

WHAT IS A CONSENSUS DEVELOPMENT CONFERENCE (CDC)?

A consensus conference takes a specific diagnostic or therapeutic medical procedure or condition and assesses the evidence in order to produce a statement summarising the current state of knowledge about best practice. The statement should be based on evidence and not opinion. The consensus development conference combines elements from three models:

- **the judicial process**, where evidence is heard by knowledgeable but impartial judges or juries of peers;
- **the scientific meeting**, where experts discuss their work with peers in a collegial manner;
- **the town meeting**, where a forum is provided for all interested persons to express their views.

The basic principles of a CDC are as follows:

- **Independent panel.** An independent, broadly based panel, whose task is to prepare the consensus statement, is assembled for each CDC in order to give balanced and objective attention to the topic.
- **Meetings**. A public session for the presentation of all data, commentary, and discussion from which the consensus statement is prepared.
- **Previously posed questions**. The principal job of the panel is to develop responses to four or five specific questions which serve to determine the scope and direction of the conference. These questions are developed in advance, widely circulated, and known to all participants at the conference.
- **The consensus statement.** The draft statement is prepared by the panel in private and presented at a plenary session. Following public discussion any amendments deemed appropriate by the panel are made immediately. The statement thus agreed stands as a record of the conference.
- **Dissemination of the consensus statement**. Wide dissemination of the consensus statement through the medical and general media is sought in an effort to achieve maximum impact on health care practice.

THE ACTORS IN THE PROCESS

There are five main groups in the CDC process:

- **The planning committee** formulates the programme, questions and chooses the panel and speakers;
- **The speakers** are chosen for their expertise in the field under discussion. They are asked to provide an overview of the evidence available or present the evidence for a particular point of view, usually in relation to one or more of the questions before the panel;
- **The panel** is charged with the task of assessing the evidence put to them and producing the consensus statement;
- **The audience** is multidisciplinary and includes members of the public. The conferences are public events open to anyone to participate;
- **The chair** has the difficult task of chairing both the public sessions and the panel in their task of producing a statement in a limited time.

Figure 2.1 *Outline timetable of UK CDC*

Day 0	Pre-conference dinner and briefing for panel
Day 1 *(am & pm)*	Public conference: speakers present their case to the panel, and audience asks questions or responds
(evening)	Panel starts drafting consensus statement
Day 2 *(am)*	Public conference continues
(pm)	Panel drafts
Day 3 *(am)*	Statement finalised
(pm)	Statement presented to audience, comments are received and panel makes revisions if required
(late pm)	Press conference

WHY WERE CONSENSUS CONFERENCES STARTED IN THE UK?

As discussed in Chapter 1, the primary reason for starting the UK CDCs was to provide a forum for medical technology assessment, which seemed at that time to be neglected in the UK. (*Technology assessment* is defined as assessing the full range of impacts of a technology. In health care this includes the technical and clinical evaluation of a technology, as well as its economic, social and ethical consequences whether intended or unintended. *Medical technology* refers to techniques, drugs, equipment, and procedures used by healthcare professionals in delivering medical care to individuals, and the systems within which such care is delivered.) There was also an implicit desire, which became more explicit as the conferences developed, to ensure that the results of the assessments were implemented.

After the first experimental conference, the King's Fund Management Committee agreed to support a further three conferences, which would explore the place of the CDC in the UK context, and experiment with NIH method as a form of technology assessment. In the end the King's Fund supported all eight in the series (see Table 2.1), as although funding was sought from other sources for the later conferences it was not obtained.

A key feature of the UK CDCs was that they considered all relevant issues: economic, legal, organisational, sociological, and ethical, not only efficacy and safety as do the American NIH CDCs.

Table 2.1 *The King's Fund series of consensus development conferences (CDCs)*

Year	Subject	Comment*	Reference
1984	Coronary artery bypass grafting	First UK conference	BMJ 1984; 289: 1527-9.
1986	Treatment of breast cancer	Lay chairperson	BMJ 1986; 293: 946-7.
1987	The role of asylum	CDC approach used for matter of public policy	King's Fund, April 1987.
1987	Genetic screening	Major ethical issues First screening issue tackled	THS 1987; 4; 12: 6-80.
1988	Treatment of stroke	Return to traditional approach	King's Fund, June 1988.
1989	Intensive care	Change in format: panel experts met over nine months	Anaesthesia 1989; 44: 428-31.
1989	Cholesterol screening	Major public health issue	King's Fund, June 1989.
1990	Colorectal cancer	Recent controlled trial reported	BJS 1990; 77: 1063-5.

* as discussed later

THE ROLE OF THE KING'S FUND

The sole sponsorship by the King's Fund of the conferences was logistically a definite advantage in ensuring that they were not dominated by any one group of professionals. In accord with the overall philosophy of the King's Fund all relevant aspects were addressed, including the consumer viewpoint. Several of the conferences brought together on an equal footing groups who would not normally attend a public conference together, let alone debate as equals. The net result was that the non-medical points of view were taken seriously. For each conference links were made with the relevant national organisations and lobby groups for help in planning the conference and identifying speakers.

'This whole initiative was taken by a private body with, at best, lukewarm support from the official and professional bodies who should have been throwing their considerable resources behind it. There are of course great advantages from having controversial matters handled by bodies with no axe to grind, and had the King's Fund been put in charge of the process deliberately by these other bodies because of its special capabilities in that respect, great credit would have been due all round. But that wasn't the case.'

Alan Williams (Steering Group Member)
Professor of Economics, University of York

THE STEERING GROUP

After the success of the first CDC and the agreement to fund further conferences a Steering Group was established (Figure 2.2) to oversee the programme, and a part-time public health physician was appointed to plan and implement the future programme.

The Steering Group reflected the multidisciplinary emphasis of the programme. One of the first decisions it made was to change the name of the conference programme to the King's Fund Fora, the intention being to make it clear that the panel's role was not necessarily to reach agreement but to clarify the reasons for any disagreements that might persist. However, the name has reverted to 'CDCs' since that title has been accepted internationally, although the reason for the change is still valid. The Steering Group members attended the conferences and were able to guide the programme, especially the choice of topic and changes in format.

'I was always conscious of the narrow range of choice that seemed available to us when all the various considerations were brought to bear on the selection of topics, and, once a short list of candidates had been arrived at, the breadth of knowledge required to identify dependable, well-informed, articulate, respected people who would not only perform their assigned individual roles effectively, but also collectively be seen as a "balanced" cast. The other problem that continually exercised me as a Steering Group Member was trying to see the whole series as an entity, and thus seeking to ensure that we tackled a wide variety of topics so as to test out the resilience of the format. My desire to widen the scope of the mechanism and to keep on innovating must have made the organiser's job a lot more difficult, because it limited the extent to which it was possible to carry forward the lessons learned from earlier meetings to help in the organisation, except on a purely logistical level.'

Alan Williams
Professor of Economics, University of York

Figure 2.2 *Membership of the CDC Steering Group*

Professor Bryan Jennett (Chair), Department of Neurosurgery, Glasgow

Dr N P Halliday, Senior Principal Medical Officer, Department of Health

Sir Raymond Hoffenburg, President, Wolfson College, Oxford

Dr M J Prophet, Senior Medical Officer, Department of Health

Dr R P H Thompson, Consultant Physician, St Thomas' Hospital

Dr Geoff Watts, Presenter of Science Programmes, BBC Radio

Professor Alan Williams, Centre for Health Economics, University of York

Attended by the following members of King's Fund staff (at various times between 1984-90):

Dr David Costain, Director, Acute Services Programme, King's Fund Centre

Dr Bobbie Jacobson, now Director of Public Health, City and Hackney Health Authority

Mr Robert Maxwell, Chief Executive, King Edward's Hospital Fund for London

Dr Allyson Pollock, now Consultant in Public Health Medicine, Newham Health Authority

Dr Jackie Spiby, Director, King's Fund Consensus Programme, now Director of Public Health, Bromley District Health Authority and Medical Director, Bromley Family Health Services Authority

Ms Barbara Stocking, Director, King's Fund Centre

THE PLANNING PROCESS

A planning team was assembled to advise the King's Fund on the questions to be posed and the content of the programme. It often initiated a list of potential presenters. This group of about eight people included key medical and lay experts to reflect the various aspects to be considered. Usually the group would meet only once or twice but they would be asked to comment on the programme as it developed. Expert members of the planning group were excluded from being members of the CDC panel but not from presenting. In fact once on board they were usually only too keen to participate. The planning group also provided the organisers with softer data on political sensitivities and the capacity of various individuals to fulfil certain tasks, especially potential speakers who were expected to present scientific data intelligibly to the lay audience. Any one conference took 12–15 months to organise.

Much of the credibility of the conferences depended on the ability of the planning process to remain unbiased. Thus the whole topic had to be researched thoroughly, and repeated consultation with a wide range of people and organisations was necessary. To take one example, the funding of coronary artery bypass grafting came unintentionally to be an issue of that conference, and those who were not cardiologists or cardiac surgeons suspected that the conference had been set up to show that increased funding of a relatively new and expensive technique was required. In fact the subject had been selected because the results of a large, well-conducted trial had just become available and no other studies would yield results for a number of years. As a result of this later CDCs carefully avoided topics where resources were a central issue; the conferences were aimed at clarifying evidence only and decisions on priorities for funding have to be taken elsewhere.

THE CHOICE OF TOPIC

The choice of topic is a key decision in determining the success of a CDC conference. Figure 2.2 shows the criteria used. Too wide a focus tends to produce a vague statement that is hard to translate into practical recommendations for change (for example, the CDC on genetic screening). Too narrow a focus results in a limited statement which has little relevance to anyone other than the experts. Without data the conference becomes a series of subjective views, which was the reason the panel considering intensive care eventually decided not to hold a public event.

In the planning stage, defining the topic also proved to be a crucial feature. The most difficult topic to define was 'The need for asylum in Society' where the title and especially the word *asylum* caused major problems which were probably not resolvable but certainly led to difficulties in staging the conference.

> *'The definition of asylum developed for use at the conference was:*
>
> > *a safe place of refuge or shelter providing protection and support, which may or may not involve total or partial withdrawal or removal from the rest of society. It may or may not involve treatment.*
>
> *The conference's working definition of asylum was never wholly accepted by the whole range of speakers or participants in the audience.... Essentially, the problem was that while the conference's working definition of asylum attempted to fudge the differences between the main schools of thought in an effort to create neutral ground for debate, the format of the programme inadvertently accentuated existing divisions.'*
>
> **Assessors' report, King's Fund Institute**

This conference was itself an experiment, as in funding the CDCs the King's Fund Committee had asked whether the process could be used for public policy as well as scientific issues. The conclusion was that CDCs were not a good tool, because the panel members have little evidence on which to base their judgement. Public policy issues are likely to involve strong value judgements. Since the panel is not representative but 'independent' then the statement can only be based on their values as individuals. In the scientifically based conferences to which the King's Fund then reverted, an independent non-representative panel can reach conclusions because they have to be based on the evidence.

Perhaps the two most successful conferences were on the treatment of breast cancer and of stroke: the topics were easily definable, there was wide interest, including from consumers, and there was sufficient evidence with which to debate some real controversies. However, as in all the conferences, the areas not directly related to clinical medicine were less well researched and data more sparse.

Initially the Steering Group members were presented with a series of possibilities from which they identified a short list using the criteria set out in Figure 2.3. Further work was done on the remaining topics, usually to establish whether there was adequate evidence available and whether the timing was appropriate. Many topics were judged unsuitable because there was insufficient scientific evidence, or because a vital controlled trial or Government working party was due to report. However in the case of the conference on cholesterol measurement the topic was chosen partly because a working party of the Department of Health's Standing Medical Advisory Committee (SMAC) was considering the issue at that time, and it was felt that this working party was overly biased by its composition in favour of screening. The exact timing of the CDC was precarious as it was uncertain when the SMAC working party would report. In the event, the latter did not publish until after the CDC, and although there is no evidence for this, the report's moderate tone may have been a consequence of the CDC statement, which urged caution in the development of population screening.

Figure 2.3 *Criteria for choosing a CDC topic*

- Importance as a public health topic (this could include a disorder which affects many people, or an expensive procedure with major economic importance)
- Multidisciplinary aspects and interest
- Real controversy over scientific aspects
- Adequate research data of acceptable quality for presentation and discussion

The sequence of conferences was developed to investigate the CDC process. The first two could be said to have been on conventional topics. CABG was an expensive, new medical technology effective in specific circumstances, which was generating long waiting lists as the demand exceeded the supply. Actually the public health physicians in the audience were disappointed by the narrowness of the conference and felt that a key opportunity had been missed to consider the balance between primary and secondary treatment.

> *'The CABG conference was called in order to decide how much CABG should be done. From the outset the chairman accepted, without challenge, speeches that stated that the current level was too low. The focus of the meeting thus shifted subtly on to how much more should be done rather than how much should be done. This change in emphasis was almost entirely created by the way that the meeting was handled by the chairman. Later, a number of speakers from the floor endeavoured to suggest that equal consideration ought to be given to other ways of dealing with ischaemic heart disease such as various methods of prevention. These were ruled out*

of order on the grounds that the meeting was about CABG alone. Several speakers suggested that prevention was important because it might reduce the need for CABG. The chairman insisted that this was outside the scope of the conference. When the conclusions of the conference were broadcast there was no attempt to explain this context and it was put across that the only solution to dealing with ischaemic heart disease was to do more CABG.'

Rod Griffiths (Professor of Public Health Medicine, University of Birmingham) (CABG audience)

The third conference, 'asylum' (as discussed above) provided a key part of the examination of the CDC process. Because of the lack of evidence the speakers found it particularly difficult to refrain from presenting their views rather than the evidence. However, this conference proved to be one of the most successful in bringing together as equals groups who rarely met, and for many helped define some of the issues.

The next conference, on genetic screening, was chosen because it addressed major ethical issues, concerned a new technique (or rather, a series of them), was timely, interested a variety of professionals and consumers and was a screening procedure which had not been previously tackled. In the event it was too broadly focused and lacked controversy except in the area of abortion, the one area the planning committee had made a firm decision not to concentrate on for fear that the conference would turn into a debate on this issue alone. Without controversy the conference lacked spirit, although late on the second night one member of the panel prevented the panel from working for several hours by asking why the fundamental issue of abortion was not being addressed.

Having learned considerably from the experiences of the first four conferences, the steering committee decided to return to a relatively straightforward topic, the treatment of stroke. This topic proved to fit much more comfortably into the CDC format with an easily definable remit, concise questions to be asked and sufficient data, which all generated a good conference and statement.

For the sixth conference high technology was again chosen. The format was also changed, and this will be described later. The final two conferences were about major public health issues: cholesterol measurement and colorectal cancer. As pointed out earlier, timing was crucial with the cholesterol conference. Colorectal cancer, like stroke, is a substantial public health issue but not particularly attractive for the media. Of major relevance to the choice was the fact that a controlled trial had recently been reported and the results needed a wider audience.

THE QUESTIONS

Any vagueness in the choice of topic quickly becomes reflected in the questions, and makes it difficult for the panel to produce a precise statement with achievable recommendations. The questions need to be carefully constructed so that there is no ambiguity and that they clearly identify the major controversial issues. Usually the questions need redrafting frequently over the 2–3 months that they are developed, with a variety of people as well as the planning team looking at them. It was later found prudent to let the panel review the questions to ensure that members understood them and had a consistent interpretation of them. This also ensures that panel members are fully conversant with the questions before they start drafting the consensus statement and do not spend precious time 'tinkering' with them or questioning their validity. Inevitably, because of the problems discussed above with defining the topic, the most difficult and tortuous questions to develop were those for the asylum conference.

The questions set for the UK CDCs also reflected the multidisciplinary basis of the UK conferences. The lack of data for some non-clinical areas made it difficult to structure relevant questions in order to facilitate a useful outcome. For example, 'What social and ethical issues arise?', a question set the genetic screening conference, is too vague, and can only result in a general response with no firm recommendations; whereas 'How should services for treating breast cancer be organised to maximise benefits and minimise disadvantages?' demands a firm outline for service providers to follow.

THE CHAIR AND PANEL MEMBERS

The 12 persons on the panel led by the conference Chair wrote the final product of the conference, the consensus statement. Despite requests and constant temptation the King's Fund staff did not participate in the writing of the statement, except to advise on style and clarity and when an issue had not been fully addressed. The composition of the panel was unique to the UK, in that the members were mostly not knowledgeable in the topic area but chosen for their proven expertise in other areas. The composition of the panel depended on the conference topic and questions, see for example, Figure 2.4 for the breast cancer panel. To ensure that the statement was

Figure 2.4 *Range of professionals on the CDC panel on breast cancer treatment*

Surgeon	Epidemiologist (screening expert)	Nurse/manager
Oncologist	Statistician (trial expert)	Sociologist
Radiologist	Economist	Representative of health media
General practitioner	Ethicist	Lay person

credible scientifically, several panels did include a specialist in the topic area. The panel was also selected to ensure a fair gender and geographical balance. The actual identity of the final membership emerged after a period of research and discussion with a wide range of people.

The choice of Chair was again critical: he/she had to chair not only public meetings but also the intensive statement-writing sessions. The mixture of tasks was approached differently by each Chair, some concentrating their energies on the public conference and allowing a strong member of the panel to lead the writing session, others dominating the panel to the point that initially contentious issues were suppressed, though never for long. The UK also pioneered the use of a non-medically qualified Chair, a feature that the USA has still not tried. The conclusion is that a non-medical Chair can be successful but it does need to be someone who is skilled in assessing scientific evidence, can grasp when the evidence does not withstand scrutiny or when the panel has not tackled the question in full or taken into account all the evidence.

'Arriving at a consensus relating to a controversial subject and involving up to a dozen individuals representing different special interests and then defending it before an audience composed of another hundred committed individuals, each with a very particular approach to the topic, is of necessity an unpromising task. The surprise is that it bears fruit at all. The chairman's major task is not merely to ensure that viewpoints are heard and discussed but that in addition none is neglected nor overwhelmed by loudness of voice or persistence of argument. The chair has to remember to draw in participants who do not press their case with vigour but who sit quietly and patiently, often reluctant to engage in an intellectual brawl. The tendency for people to try to dominate consensus conferences is well known. Less well recognised is the tendency, particularly amongst academics, to opt out of debate and instead to wield an impact through silence through that helpless air of resignation that powerfully suggests that the barbarians are in control and all that is left to men of integrity is silence!

There are particular difficulties with the notion of consensus. It is not that areas of agreement do not emerge. They do, and do so quickly. The problem is when a majority of the participants agree on a position which the one member of the panel best equipped to make a judgement opposes. How does one know whether the minority position is a sound or an idiosyncratic one? It is here that the background literature, if appropriate, can be of considerable assistance. It can help those less knowledgeable at least to ask the relevant questions of those better qualified to answer them. The chairman's role is important here too for he/she can help ensure that participants less familiar with technical or other aspects of the issue can be encouraged to admit their difficulty and have the relevant issue explained and discussed.'

Anthony Clare
(Chair of the CDC on treatment of stroke),
Medical Director, Psychiatric Unit,
St Patrick's Hospital, Dublin

By concentrating the whole process into three days the panels went through a very concentrated experience. The intensity produced a greater sense of involvement and commitment than is usually achieved within a committee that meets for a few hours every so often and then communicates by post.

The main criticism of the panel made by conference audiences was that they consisted of the 'usual' people who represented the 'ivory towers' of academia rather than working practitioners. The panellists chosen were also criticised for being too 'middle of the road' and thus too willing to achieve a consensus view. The organisers had to take into consideration the need for panel members who could work as a team, and very occasionally, one or two potential panellists were ruled out because they were considered too maverick, but in practice this certainly did not lead to an acquiescent panel. In fact, several panels continued to work well into the morning of the third day simply because an easy resolution of differences was not forthcoming.

Concern was also expressed that 'the person on the street' was not included. Previous experience in the USA has shown that having one patient as the lay representative did not work. Lay people can be valid members of the panel but they must have some experience in dealing with scientific material and medical issues in order to be able to hold their own with the rest of the panel. Medical journalists, lawyers, civil servants and consumer group representatives were generally used. A researcher who considered the lay input to the proceedings reported:

'The closed session is the crucial time for the lay members of the panel. How well can and do the lay members of the panel represent the public at large, and what weight do the views of the lay panellists carry, as opposed to those of the medical members?... Interestingly, almost all non-medical panellists to date have had an academic, scientific or nursing background. While this does not preclude panellists from holding entirely different perspectives from health to the 'scientific' medical model, the setting is not one in which radical views are likely to gain much ground. The agenda of the event has been too closely prescribed in advance within the medical model to allow for radical departures at the time of statement formulation.

One panellist who was questioned about the role stressed that it was essential that the lay panellists were fully equipped to operate in a difficult intellectual and micro-political environment; lay members are disadvantaged enough by not being able to draw on medical knowledge, without being oppressed by rarefied debate. Another panellist felt that it could be difficult for someone who was not well to participate fully, especially given the late night working, thus limiting the possibility for including 'patients'. Some panellists, however, have been known to suffer from conditions which may have given them considerable insight into the views and preferences of other sufferers.

The enduring problem of how to involve the less advantaged groups in determining the shape of health care is perhaps no more successfully addressed by this means than by any other, whether it is intended to do so or not... In this process the interests of the laity are granted some legitimacy for the duration of the event at least, which provides a valuable potential for them to influence proceedings and so participate in health policy-making, even if there are certain constraints upon this.'

Margaret MacArthur Contracts Development Manager, Planning Dept., SW Surrey Health Authority

THE SPEAKERS PRESENTING THE EVIDENCE

The speakers supply the expert evidence to the panel during the public conference. Usually they were asked to provide an overview of all the evidence on a particular aspect of the topic. Occasionally, when there was an area of controversy, two speakers were asked to present evidence for the opposing arguments. The speakers had to be provided with a clear remit to ensure that all the relevant issues were covered. Speakers also had to ensure that their presentation could be understood by non-experts. This proved easier for some experts than others and several commented on the challenge it represented. To enable the panel to examine the speakers' evidence all speakers were asked to submit the text of their paper, including any original data, in advance.

The panel received evidence from three sources:

- prior reading of material selected by the CDC staff and planning committee, following a computerised literature search and consultation with experts, consisting of the major original papers, published overviews, and occasionally books – especially lay publications for the non-medical members;
- the speakers' written and oral presentations and subsequent questioning;
- audience comments and questioning.

The panel was asked to base its final statement on the published evidence received, the expert submissions and audience comment. It was asked to consider the validity of the data according to the quality of the research from which it had been derived. At an international conference on CDCs in 1989 it was recommended[9] that 'prior to a CDC, the organisers should provide an ordered and categorized compilation or synthesis of research reports and related evidence concerning the technological aspects at issue.... When resources and time permit, a meta-analysis of applicable data should be provided.'

The UK organisers have not had the resources to go quite this far, although clearly this would be a desirable goal.

One major concern to the organisers was the inclusion of the consumer view. It was felt that to have individuals speaking from their experiences was not appropriate because they can give only a subjective view, probably related to a single event. Therefore wherever possible a sociologist or writer who had collective data was used.

The audience

Between 200 and 300 people attended the public part of each conference. A considerable amount of time was made available for the audience to ask questions of the speakers, develop discussion points and put forward their own points of view to the panel. The audience was also at liberty to submit written points to the panel, and during the later conferences an open session was included in the programme. This allowed for ten concurrent three-minute submissions from members of the audience and proved very successful, with a wide range of issues being covered. Two particularly stood out: one at the genetic screening conference, when a participant in the open session identified himself as a parent of handicapped children – see below. During the three minutes he was able to make the conference face the true complexities of such situations and identify with the personal traumas families suffer.

'Our attendance at the King's Fund Forum on screening for fetal and genetic abnormality was under the weight of three hats. The professional hat carries some knowledge, with our backgrounds as a nurse and public health doctor. We know of increasing scientific and technological achievements and the stated advantages of a screening procedure including its cost benefits. The second hat is as parents of twin boys (now aged 10 years) who are both severely mentally handicapped from an as yet undescribed genetic condition. The emotional and practical burden has frequently been almost intolerable. Yet through it all we have become more aware of our own limitations and have added a previously unknown dimension to our lives without which we would have been the poorer. The other hat is as Christians who believe that God cares for all creation, especially those who for whatever reason are themselves unable to defend their rights. The decisions of individuals determine the nature of our society's conscience. Yet some sort of framework in which individuals' decisions can be taken is necessary. It is our view that within its terms of reference the consensus conference did this very well. However the total social, moral and emotional costs cannot be quantified in any cost-benefit analysis and perhaps unfortunately the arguments defy consensus.'

Gwen and Barry Evans
(audience members)

An open session speaker at the Stroke Conference had suffered a stroke and told the conference of some of his problems, one in particular being how, unable to communicate verbally with the ambulance men who came to take him to hospital, he used his personal computer. Inevitably these sessions were anecdotal and

subjective, in contrast to the highly objective formal presentations but they did serve to remind the panel and audience of some of the real problems faced by the general public and helped to ensure that the panel took consumer issues seriously when producing their statement.

To reduce the barrier of the registration fee to consumers it was usually waived for voluntary organisations and genuine members of the public. Even so it still proved difficult to get to the general public, perhaps because the organisers were not well equipped to target them, and personal contact was usually the most effective method. The conference most successful in involving consumers was the one on breast cancer treatment when a national newspaper ran a feature on it. In general the media proved more interested in the outcome of the conferences than in making them known in advance. It also appeared that the women who attended the breast cancer treatment conference were more willing to put forward their views, or just more used to doing so, and in contrast to the other conferences the consumers sat at the front of the conference hall alongside the doctors and researchers. Of course it is unlikely that many people would want to spend three days at a conference on a particular subject without having a reason for doing so – perhaps as a patient themselves or caring for someone with the condition.

'At the breast cancer conference information was put forward to the panel suggesting that there is no evidence that mastectomy is necessarily more conducive to long-term survival than breast conservation in the treatment of primary breast cancer. Yet the chances of receiving either type of treatment may depend on random variables such as where you live, or which doctor you are referred to, rather than the disease type presenting. The medical profession may understandably feel uncomfortable that the public should hear of its shortcomings. On the other hand, given that the event is open to the public anyway, one could ask whether it really matters if there are more or less of them.

Margaret MacArthur,
Contracts Development Manager, Planning Department, SW Surrey Health Authority

THE CONSENSUS STATEMENT

The consensus statement is the end-product of the conference. It was disseminated to the wider audience of health professionals and general public. On the model of the American format the statement was usually written as answers to the previously posed questions. Following early negotiations with the *British Medical Journal (BMJ)*, panels in the UK were told they had a maximum of 3000 words in which to write the statement. The organisers felt that the statement would get the widest audience if published in the *BMJ* rather than a specialist journal and were therefore willing to accept a word limit. Initially all the panellists complained about this limit but most agreed on reflection that it was a useful discipline and enabled them to produce a more readable and well-edited statement.

As stated earlier the statement is a product of the whole panel, therefore the King's Fund resisted ideas of using a professional writer or some form of staff secretariat. Although this made the panel's task harder it did ensure their continued commitment and involvement to the very last words. Inevitably some members found the task of writing easier than others but interestingly, where the panel included a journalist or well-known writer such as Anthony Clare, these did not by choice or default become the scribes.

The statement needed to be easy to read and contain recommendations that were implementable. The topic and working of the questions were vital in enabling the panel to do this, but it can also be seen that as the series progressed the King's Fund staff also became more skilled at steering the panel towards making firm recommendations.

It was hoped that the statement would be of use to members of the public. The most successful in this was that on breast cancer treatment, which got considerable coverage from the women's press and resulted in several thousands of women writing and asking for a copy. A subsequent survey showed that they were 30 – 60 years of age, a quarter with a family history of breast cancer or with the disease themselves. Most wanted the statement for information but a few had used it to discuss the disease with friends or their GP – the most public being a woman journalist who wrote to the *BMJ* of her experience in trying to discuss the statement's recommendations with her surgeon when she was diagnosed as having a malignant tumour.[10]

'The next morning the radiotherapist returned to warn me that the surgeon would be coming back to try to persuade me to have the operation. Thus forewarned, I waved a copy of the King's Fund Forum consensus statement at the surgeon and made my case. "There is no evidence that mastectomy or more extensive surgery, as opposed to local removal of the tumour, leads to longer survival."

(The surgeon was unmoved, she asked for a second opinion and opted for lumpectomy with radiotherapy.)

'... I learnt a lot from my experience and try to let as many women as possible know about it. I hope that in future all women will be given the opportunity to choose the most appropriate form of treatment on the basis of clearly presented information. Until there is a clear consensus that one form of treatment is better than all others in terms of survival the patient must be able to participate in any decision about what is to be done with her body. Every effort should be made to help her to do this.'

Angela Prior
(*Br Med J* 1989; 295: 920)

TRYING A DIFFERENT MODEL

As part of the experimentation with the CDC process and to take account of the critics who suggested that the panel were unable to get to grips with the issues in three days it was decided to ask an expert panel to prepare the consensus statement prior to the public meeting, in the course of three- or four- day panel meetings over a period of nine months. The plan was that the statement, on the usefulness of intensive care, would then be discussed at a public meeting with interested parties, when the panel would be called on to defend their statement. Panel members were expected to prepare the statement by reviewing the literature and considering further information provided by other experts. As before, the questions set addressed all relevant issues and the panel was multidisciplinary.

As the time for the public conference came nearer it became apparent that panel members were not confident that enough data existed for them to produce a statement. It was therefore decided not to hold the conference but to publish the statement as a report. Whether there really were insufficient data remains open to question.

The format tended to increase the differences between the medical experts and the non-medical members, who inevitably were not so intimately involved with providing intensive care services. The extended timescale also meant that some members, though informed of the dates well in advance, were unable to attend every meeting and became less committed to the final product. Interestingly this report provoked considerable interest from the media and now nearly two years later, it is clear that those working in intensive care units have responded to the challenge of the report.

DISSEMINATION

Two main strategies for dissemination were used: direct mailing to relevant individuals and groups, and publication in the medical and popular press. Surveys showed that inclusion in the *BMJ* or *Health Service Journal* was of key importance for dissemination. The most media interest was created by the breast cancer and CABG conferences and the intensive care report, the latter mainly because the media picked up on the suggestion that there was no evidence for the value of intensive care units and were able to make a story out of it. The breast cancer conference and cholesterol conference became part of television programmes, and the asylum conference was made the sole topic of a 'Medicine Now' BBC radio programme. The main deficiencies in the dissemination were the impossibility of reaching enough practising clinicians and the public.

Margaret MacArthur studied coverage of the breast cancer statement by the media. Of the 103 specific issues or recommendations identified in the consensus statement the medical journals and the *Health Service Journal* included the largest number while the women's journals used the least. The type of items most frequently used by the lay press were points which a potential patient rather than a manager or clinician might wish to know. By assessing the readership of the journals involved MacArthur estimated that over 2.8 million circulating copies could be expected to contain something about the conference. Readers were predominantly social class I–II.

Publication of the statements is crucial but at times proved difficult, as editors have different priorities from CDC organisers.

'The CABG statement was published within a few days in the BMJ, together with a brief editorial comment. Eight letters commenting on the conference and the statement appeared in later issues and three of the participants published accounts of their experiences.

In many ways the rapid, wide dissemination of the statement by publication in a weekly medical journal might seem ideal both for the organisers and for the likely audience. So are there any problems? Unfortunately the answer is Yes. Firstly, the publication in the journal of correspondence critical of the statement must tend to diminish it and take something away from its authority.

The second problem with the publication of CDC statements in a journal is that the editor is virtually certain to lay down conditions. He will want the exclusive right to publish the full text, and that may well lead to other journals and papers giving the statement less attention than they might have done. Furthermore he is likely to insist that he must be free to choose which statements he is prepared to accept. Some may be too specialist or the panel may be thought to lack authority. Occasionally the content may be too similar to that of a previous statement.

Underlying these refusals by journals to publish more than a selection of the consensus statements offered to them is their very variable content and quality. The range of topics considered has extended and pressure groups have recognised that there is no copyright in the title "consensus conference" and that anyone can set up such a meeting. Some so-called consensus conferences have been thinly disguised promotions for a particular line of treatment.

What, then, is there in it for an independent organisation that plans to arrange a series of consensus meetings and wants the widest possible dissemination? The best answer may be a series of monographs – ideally, available free of charge. A second possibility is to invite the specialist press to the final session, ensuring plenty of publicity, but few journals or newspapers will be prepared to publish more than extracts from the statement. If an agreement is made with one journal that it will publish the full text of the statements this will need careful negotiation. For example, publication of a programme of conferences over, say, two years might be agreed, with both sides then free to reconsider. Agreement on a bigger series is unlikely, for editors have the journalistic belief that concepts quickly become stale and they dislike committing their journals to long-term plans.'

Tony Smith (Associate Editor, *BMJ*)

3 Impact in the UK

One of the main reasons for initiating the CDC series in the UK was to promote change in health care policy or practice by identifying good practice from the body of scientific evidence. Where that change was directed depended on the conference topic and the way the panel interpreted the questions. Thus the conference on stroke primarily related to clinical practice in hospitals and community services, while that on asylum focused mainly on policy makers.

The first stage in ensuring the continued success of the conferences themselves was to review the details of each one. After each conference a questionnaire was sent to all the panellists, speakers and audience members asking them about the various aspects of the conference from their perspective. This repeated feedback was used to improve the conferences–for example, the open session developed out of comments made by audience members, as did the appreciation of just how confusing the asylum conference had been for the audience because of the difficulties in defining asylum. Following wide dissemination of the statement further work was then undertaken, which will be discussed below, to evaluate the actual impact of the conference and statement. Because of the limited resources available, and the vast range of areas that might have been evaluated this work had to be done piecemeal and consisted of snapshots of each point in time.

FROM A WRITTEN STATEMENT TO ACTUAL CHANGE

The organisers realised that to produce a good statement was only the first part of the process of change. Work at the Rand Corporation[1], looking at what constituted a statement conducive to change, analysed the content of the statements of 24 American consensus statements published between 1979 and 1983. They described three different styles of statement: discursive, didactic and scholarly. According to communication theory these stylistic variations should make a difference, with a didactic style tending to produce the most change. Very little work has been done, however, on the effects of such message characteristics on degree of acceptance by doctors. As might be expected, the work raised the question, 'What could be done to improve the style of the statement to ensure it has maximum impact?' The conclusion was that more didactic statements arise when the state of the scientific knowledge is least adequate, so that a major factor controlling the impact of a statement lies in the choice of topic.

Work on promoting change tells us that even with a 'good' written statement that is carefully targeted to the desired audience, many forces from a wide range of sources influence the final outcome. This is confirmed by the work undertaken in the late 1980s by Lomas[2] who produced a very didactic consensus statement after a Canadian CDC on the value of repeat Caesarean sections, and then instituted a concentrated implementation programme.

Nationally he achieved considerable coverage in the medical and popular press. This was followed by a mass mailing of the statement to all relevant individuals in the medical world. More locally he established a controlled trial with three arms. One consisted of a regular review of the clinical data with written feedback to the obstetricians, the second was an intensive educational programme led by a local opinion leader who had been identified as such by his/her peers, and finally the control locality. After the project had been in progress for two years Lomas concluded that 'guidelines for practice may predispose physicians to consider changing their behaviour, but unless there are other incentives or the removal of disincentives, guidelines may be unlikely to effect rapid change in actual practice. We believe that incentives should operate at the local level, although they may include system-wide changes.'

Although most clinicians reported knowledge of these guidelines only one-third admitted having changed their practice because of them. In fact, most of the doctors knew little of the details of the statement and there was little evidence of change in clinical practice. The main constraints were: perceived threats of malpractice litigation from potentially dissatisfied patients, inadequate skills, economic and socioeconomic incentives to perform elective Caesarean section, and pressure from women who wished to avoid vaginal delivery. Lomas concluded that the practices of clinicians are influenced by many things besides research evidence, even when such evidence is packaged in a set of clear and concrete recommendations.

The international community of CDC organisers recognised the problems of moving from a creditable and well-disseminated statement to actually making anything happen, and at an international meeting in 1989 two

recommendations aimed at increasing the impact of CDCs were agreed:[3]

- CDC programmes should be sponsored by organisations that have the ability to implement or effectively disseminate consensus findings; and
- Programmes should adopt the goal of bringing about changes in health and medical practice and the related policies of national health authorities, industry, payers, academic institutions, and other agents. Sponsors and panellists should be cognisant of the intended audience for the consensus findings and the intended means for disseminating the findings. The consensus programme should identify the ways in which the programme in general, and each conference in particular, are intended to effect change.

THE CABG STATEMENT: OPINIONS OF GENERAL MANAGERS

One year after the conference on coronary artery bypass grafting (CABG) in 1984, a questionnaire was sent to all district and regional general managers in Great Britain, asking whether they were and had been aware of the conference and its conclusions; if policy concerning CABG had changed; if the CDC statement had influenced these changes; and if the statement had been useful in any other way.

Of those contacted, 80 per cent responded, although two-thirds of the managers had passed on the questionnaire to a public health physician or clinician. Of the respondents 80 per cent had seen or heard of the statement even though CABG is performed in only a tiny minority of hospitals. Most knew about the statement via a journal (it was published in full in the *BMJ* and discussed in the *Health Service Journal*). Fewer recollected seeing the King's Fund publication that had been mailed directly to every district and regional general manager and medical officer. The main use to which the statement had been put was to initiate or influence existing discussions on policy, especially those relating to resources, and to help in discussions with Community Health Councils or patient groups. Nobody in this survey suggested that it had been used by management to define the appropriateness of the use of CABG. This was not surprising, for in 1987 few managers questioned clinical practice.

THE CABG STATEMENT: CLINICIANS

In an attempt to discern whether the consensus statement had any impact among clinicians a third of the members of the British Cardiac Association were asked if they were aware of the statement, if they had read it and if it had made them change their clinical practice. Most had heard of the conference and the majority had read the statement in the medical press. Few admitted to changing their practice, the majority saying that they already adhered to the recommendations. Again, however, they reported its use in discussions with other clinicians and managers, particularly when reviewing resources.

The CABG conference, as discussed earlier, had two main emphases: the appropriateness of CABG for individual patients and the national availability of the procedure. The statement appears to have had little effect on clinical practice, despite Hutchison and Millar-Craig's showing[4] that the management plan in the statement is clinically useful. But it does seem to have had an effect on the accepted national norm for coronary bypass operations. The panel recommended a rate of 300 operations per million population and over the next few years this figure became adopted by the Department of Health. This was a major achievement in 1987, but worrying in 1991, when without another CDC on the topic and no other national review of the area, the figure 300 seems to have been fossilised despite rapidly changing medical technology in cardiothoracic medicine, with new procedures and therapies regularly emerging.

THE STATEMENT ON BREAST CANCER TREATMENT: USE BY THE PUBLIC

The breast cancer treatment conference (1986) was particularly exciting in that at least a third of the audience suffered from the disease, albeit many of them were also health professionals. The media were also particularly interested in this conference, and good coverage was given in the women's press and on BBC radio's *Woman's Hour*. The King's Fund had several thousand requests for the statement from members of the public, who were later sent a questionnaire asking why the statement had been requested and to what use it had been put.

Most were women, aged between 30 and 60 years, and a quarter had a family history of breast cancer or had the disease themselves. They had requested the statement because they wanted information. A few had used it to discuss the disease with friends or their GP; the most public one was a woman journalist discussed in Chapter 2. The response of these women indicates that a CDC statement can be a powerful tool in patients' hands, but it is clear that the medical profession also need to be educated in how to share clinical decision making with their patients.

Readability of the breast cancer treatment statement

In an assessment of the potential of the consensus statement as a means of communication to the general public a pilot survey of 22 women was carried out. Aged between 18 and 70, from various educational backgrounds (approximately a third were professional, the remainder secretarial or not working), none had any specialist nursing or medical experience or been treated for breast cancer. Each participant was given a short set of instructions, a copy of the statement and a short questionnaire. Each was asked to mark those items in the statement which she found 'particularly interesting or informative and easy to understand', and those which she felt were 'particularly confusing, irrelevant to you or too medical'. Their opinions were also sought on readability, on the interest value of the material, and on the benefits they thought they had gained from reading it.

All but four women felt they had benefited from reading the statement. The main reason given was that they felt it gave them a better knowledge of the facts. There were negative comments on some of the technical parts of the statement, for example the sentence: 'Gross involvement of the axilla is normally treated by surgical axillary clearance, and radiotherapy is reserved for recurrence' was marked as being too medical by all the women. Pharmaceutical terminology was also singled out as too medical, making the text for some of the women too technical and complicated. However, two-thirds rated the statement as very easy to read or easy to read.

All the CDC panels were asked to write the statement in language that 'a community medicine specialist or *Observer* reader' would be able to understand, rather than the highly technical language of the clinician practising in that particular specialty. The statement on breast cancer seems (according to this small survey, and other comments) to have achieved that aim. The conflicts between writing a generally informative statement and one that meets the requirements of the medical profession are obvious. A solution might have been to include specialist terminology in the main statement, but to produce a summary for public consumption that retained the vital content but avoided specialist terminology. This might also ensure that the full range of aspects would be covered, whereas the popular press tended to concentrate on one aspect, and often included details from several other sources.

THE BREAST CANCER STATEMENT: USE BY NON-MEDICAL HEALTH PROFESSIONALS

A substantial group at the conference were nurses, either working as breast counsellors or on surgical wards where breast cancer patients were admitted. The statement endorsed the role of the nurse counsellor and nurses as core members of the breast team. To investigate the role of nurses in using the statement all the members (about 250) of the Royal College of Nursing Breast Cancer Forum were sent a copy of the statement and a questionnaire asking if they knew about the statement and if they had used it; if not, how did they think it could be of use now that they had a copy. The majority felt that it was useful for patient, nurse and general staff education. Some commented on potential use as a support document for resource bids.

PRACTICAL PROBLEMS IN IMPLEMENTING A STATEMENT

One of the problems of implementing a statement produced nationally is that local circumstances may be such that change is inappropriate or impractical, as discovered by two public health physicians.

> *'... When the results of the King's Fund consensus conference on breast cancer appeared in 1986 I was employed as a registrar in public health in an area board in Northern Ireland. Fired with enthusiasm for extending the role of community medicine into improving clinical practice, the guidelines stimulated me to look at the services that we were providing for women with breast cancer.*
>
> *The area is predominantly rural, with several market towns, each of which has a hospital, and has a resident population of almost 400,000 among whom there were approximately 60 deaths each year due to breast cancer. As a consequence of the road networks and the geography of the area a substantial proportion of the population receives hospital treatment in Belfast. Mastectomies were being undertaken in five different hospitals, some of which were performing only about five operations each year, with no mechanism for coordination. This was clearly at variance with the statement guidelines that a single surgeon should run the service and that there should be a single breast clinic.*
>
> *Bringing about change is always difficult but there were a number of particular problems involved in this case. In 1986 the role of community medicine in areas of clinical policy was rarely considered. More importantly, the Area Board had been trying to rationalise hospital services for many years. Any attempt to centralise services was rejected by the supporters of the individual hospitals, who were principally concerned about local employment. Also a loose coalition of Board members (who saw themselves as representing their local hospital rather than the interests of the board as a whole) would block the move. The work of the community*

medicine department was already dominated by the general issue of rationalising services onto two sites. To tackle a further contentious issue was simply not worth while.

Clearly the new role of areas as purchasers changes the situation entirely. There is now a clear case for using CDC statements as the basis for contracts.'

Dr Martin McKee
(Senior Lecturer, London School of Hygiene and Tropical Medicine)

'... I have been having thoughts about implementation since the conference. These are hard times in which to develop anything, especially if there is expense involved. However, experience in a different field has shown that where there is a group of credible and able people willing to act as a reviewing panel and sufficiently good evidence, the topic can be brought to the top of the agenda.

The question is how to get breast cancer onto the agenda. Lobbying the DHSS and regions is essential and within the powers of the King's Fund. I shouldn't think that articles in the journals are particularly useful, for the committed already know the news. As to districts, it is very much up to folks like me to work with interested clinicians to probe and encourage. We are doing that in various ways here, we have just got a pilot mammography scheme off the ground and this has already thrown up an interested surgeon. Mind you, any move like setting up a day surgery or getting a nurse counsellor that requires resources is going to take a long time. However, perhaps we have moved from the acorn to the seedling stage?'

Dr Mike Vaile
District Medical Officer, Maidstone Health Authority, (written in 1986)

IMPLEMENTING A STATEMENT ON A SOCIAL POLICY ISSUE: 'ASYLUM' (1989)

As already discussed, this conference was experimental, aiming to look at how useful the format of a CDC could be when a social policy issue is considered.

Its immediate impact was limited and it received little media exposure (not unusual when dealing with the so-called 'Cinderella services'). However, *Medicine Now* (BBC Radio 4) devoted a whole programme to the conference.

Did the conference produce any long-term changes? On its own, probably not, partly because of the inherent deficiencies of the conference and partly because it was ahead of its time. But it may have acted as a stimulus to motivate thought about the issue. Three and a half years later, asylum is on the agenda and talked about, whereas in 1987 that was not so.

INFLUENCING POLICY: 'GENETIC SCREENING' CONFERENCE (1989)

Because genetic screening was a newly emerging preventive medical technology with major ethical issues, the main aim of the conference was to influence policy. A survey set out to review whether the statement had influenced the policy of regional health authorities (the level of the NHS where genetic screening policy might be expected to be developed). Ten of the fourteen RHAs replied. Five said that the statement had been useful in formulating regional policy, three that it had influenced a change in policy and four that it had informed policy discussions with clinicians. Two authorities reported that no use had been made of it, although one said that all the recommendations were already implemented. Only one region reported that they had a service possessing the components of a good service as identified in the statement, interestingly not the one who claimed that all the components of the statement had already been implemented.

INFLUENCING POLICY AND PRACTICE AT A LOCAL LEVEL: 'THE TREATMENT OF STROKE' (1988)

After the experimentation with policy issues and broad-ranging topics, this conference returned to considering a service that is delivered in all districts.

In an attempt to identify if there was potential for change, all district health authorities in the UK were contacted to ascertain how closely their services mirrored the recommendations of the statement. A questionnaire was also sent, two months after the conference, to all district physiotherapists (or equivalent) working in units providing services for stroke patients. Where there were several relevant hospitals the respondent was asked to fill in one questionnaire for each hospital, and asked to reply on behalf of the stroke team as a whole.

Of the 68 per cent of districts that responded, only 11 per cent had a district stroke policy, and only 1 per cent were able to identify a named person responsible in the district for stroke services. Of the 282 individual hospitals reported on, only 4 per cent had a stroke policy and 8 per cent a named person responsible for managing stroke services.

The statement recommended the establishment of a 'core stroke team'. Few hospitals (26 per cent) had such a team and of these, just over a third worked only in the

Figure 3.1 *Major problems in the provision for stroke patients*

- Misunderstandings and rivalries between professionals, patients and their carers.
- Breakdown of communication between professionals, patients and their carers.
- Insufficient appreciation of the impact of stroke on the patient's family.
- Ill-prepared and sometimes unplanned discharge home.
- Serious shortage of therapy.
- Failure to recognise and respond to mood disturbances.
- Delegation of care to inadequately trained medical staff.
- Confusion caused by too many people being involved.

community. Another recommendation on the organisation of services was the adoption of a 'key worker' for each stroke patient to coordinate rehabilitation. Again few hospitals (6 per cent) were using this model for allocating responsibility.

One of the most contentious parts of the statement was the recommendation that hospitals should designate a specific location for stroke patients. In the survey, 76 per cent of the hospitals did not have such an area and most of those that did provided only very specialist therapy. The statement also identified a series of key problems in stroke rehabilitation in hospitals (Figure 3.1).

Of these the lack of therapists, patient inactivity, and the lack of residential places and community services were seen by the respondents as major problems.

What actually seemed to happen was that the statement was used as a catalyst to stimulate interest in stroke services and debate about change. Quite often it was used to empower paramedics and managers to challenge the status quo and identify gross shortages of resources. However, as in the case of the breast cancer statement there was little evidence of change in clinical practice.

One important result of the conference was a funding initiative by the Chest, Heart and Stroke Association – the major charity for stroke patients. It allocated funding for four consultant posts to specialise in the care of stroke patients. These posts are now established in Lothian, Leeds East, Canterbury and Bristol.

'As a result of the consensus statement being sent to Unit General Managers, Brighton's Specialist in Community Medicine convened a working party consisting of a variety of different disciplines of health workers and managers. As the only person who had attended the Forum I was invited. We have met three times, and will meet once more. The changes we hope to make are:

- *have all stroke patients on one hospital site instead of five;*
- *have a standard set of investigations to be done on all stroke patients, whether admitted to hospital or staying at home;*
- *improve communication and liaison with care workers.*

Personally I have:

- *reorganised our team of four to keep the key worker with each patient the same, with me (as team leader) involved with all patients;*
- *tackled liaison visits with more confidence and knowledge;*
- *become aware of the need for improved communication in our team;*
- *realised that our working party is still overly medical biased;*
- *developed a quality circle and put an increased emphasis on meeting and working with other therapists.*

For me the Forum has opened many doors. Brighton's management is taking an interest in change and has identified the need for change.'

Jan Nowak
(Stroke Rehabilitation Sister, Brighton HA), 1989

'I have drawn extensively on the consensus statement in both a circular to all the consultant staff in this hospital suggesting changes in the way we manage patients with stroke. Also, like many others, it has formed the basis of our application to the Chest, Heart and Stroke Association for a Senior Lecturer in Medicine. I myself found the conference useful and will be working to implement many of its recommendations.'

Dr G S Venables
(Consultant Neurologist, Sheffield HA), 1988

'Following the publication and distribution of the consensus statement the physiotherapists in the Health Authority are anxious to take up the challenge of initiating the development of a District Stroke Policy. We plan initially to invite representatives of all agencies involved in the management of stroke patients to a seminar, out of which we hope a working party will emerge to start developing a policy.'

Ms Penny Roberts
(Research Physiotherapist, Chesterfield and North Derbyshire Royal Hospital), 1988

'I found certain elements of the statement and of the philosophy behind it useful when considering strategies for services both for the elderly and for the physically disabled. I feel that some of the more detailed requests for services, particularly of a diagnostic nature, were not adequately backed up by the evidence, and perhaps more detailed work would be needed before this could happen.'

Dr Georgina Unsworth
(Specialist in Community Medicine, South Western Regional Health Authority), 1988

INFLUENCING RESEARCH PRIORITIES: THE 'INTENSIVE THERAPY UNIT' REPORT

This conference was approached in a different way, with an expert panel and a statement prepared in advance. Although there was no public conference, and a press release rather than a press conference, the media dedicated more space to this report than to several of the other conferences. They were able to make a 'story' out of the panel's conclusions that although 'ICUs provide facilities which have resulted in major improvements in the chance of survival in some conditions which were previously considered life threatening ... evidence is less clear-cut on the benefits and costs of treatment for the complex illnesses which now afflict the bulk of patients admitted to intensive care units. Furthermore, there is concern about the ill effects which may arise.'

'Intensive Care "Wasted" on Likely Fatalities'
Patients brought into hospital with such severe injuries or illness that they are likely to die should not be given expensive treatment in intensive care units, a group of leading doctors says in a report today.'

Daily Telegraph

The response from the ITU community has also been considerable, and it is clear that the recommendations of the report are now being considered by more than one body.

CONCLUSIONS

It is clear that it is important that a CDC statement is seen to be produced by a creditable process, written in clear, concise and didactic language, and disseminated both in the medical press and directly to all the relevant people including doctors, non-medical health professionals, managers and the public. However, that is not enough. The reading of guidelines alone, even if they are accepted and totally agreed with, will not make people change their practice. The processes of making change are complex and require further consideration and research, and resources are also required to provide the necessary incentives to change.

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4 Consensus Conferences in Other Countries

The NIH programme had already held 31 conferences over a period of five years (1977-81) before Europe began to follow. In 1982 the Netherlands and Sweden each held a conference, with Denmark, the UK and Finland joining at yearly intervals thereafter. By early 1991 there had been 84 NIH conferences, 31 in The Netherlands and at least 41 spread over seven other European countries. The meetings and journal of the International Society for Technology Assessment in Health Care have formed the main focus for exchange of views between those involved in consensus conferences. An international workshop was held in association with the Society's annual meeting in London in June 1989. This was organised by the Council of Health Care Technology of the Institute of Medicine in Washington , and a workshop under the same aegis later that year reviewed the NIH programme. The reports of these meetings[1,2] provide the most extensive source of data about consensus conferences in North America and Europe up to 1989, and a summary[3] was also published. We have attempted to discover progress since then.

MECHANISMS OF ORGANISATION

There appear to be more similarities than differences in the programmes in different countries. Most countries regard health professionals as their main target but several also specify health planners or policy makers. Most are concerned to address issues of effectiveness and appropriateness, under various labels; some explicitly consider economic or ethical aspects, and the NIH is now broadening its terms of reference. The estimated cost per conference (US$50,000–60,000) is similar in most countries, but twice this at the NIH.

The panel

In choosing members for panels, some have attempted to achieve a balance between people who have opposing views. Finding that such panels are liable to become deadlocked, most organisers now opt for a so-called neutral panel. This is true also for the NIH in their more recent conferences. This means excluding as panel members people whose opinions or stance are known to be towards one extreme or another on controversial issues. In Norway, Sweden and the UK only half the panel members are medical, but most of the others are in related fields such as biological science, nursing, health economics, statistics or medical sociology. In some places efforts are made to ensure that most medical panel members are experts in fields other than that under discussion. Most places have one or two public figures with no declared interest or expertise, such as a journalist, church minister or politician.

Organisers normally select the Chair, but the panel may select its own; Sweden shares out the leadership among the panel, with no Chair. Only the UK seems to have consistently opted for a Chair who was not expert in the subject and who for two conferences was non-medical.

Use of evidence

There are variations in the detail and formality of the reviews of published evidence and of current practice that are prepared for the panel. In few countries does the final consensus statement refer explicitly to the evidence on which it is based. Some places have preliminary meetings of the panel, which may produce a draft consensus statement that will become the focus of the public meeting.

CONSENSUS STATEMENTS

All countries have sessions before a public audience, who are encouraged to participate in discussion. However, all make clear that the statement comes from the panel, albeit taking account of audience reaction. It is unclear how disagreements within the panel are handled in different countries, but most statements refer to important aspects of the topic about which a consensus could not be reached. Most places produce a statement by the end of the meeting, although few now believe that an overnight writing session is sensible. Some review their statement after a month, and do not publish it until after reflection.

In the Netherlands five of the original consensus statements were revised some years later, because of new evidence or changing attitudes. In only one case, however, was a second conference held on the same topic before an amended or updated statement was issued, perhaps because the Dutch panels are more like expert groups. Revision is important in The Netherlands (CBO) programme as the statements are used to devise guidelines which form part of the quality assurance programmes in hospitals. The titles of the 84 topics of the NIH programme indicate that at least six have been repeats or had a substantial degree of overlap; three of these topics have each been the focus of three conferences over the years.

CONFERENCE TOPICS

Most countries claim to choose topics that are controversial, sufficiently well established (or at least far enough developed) for there to be adequate data for discussion. Most topics relate to technologies of sufficient scale that their importance is obvious, usually because of ethical or economic aspects of their use. However, the size of the NIH and CBO programmes has allowed them to deal with some topics which are of more limited interest and significance, at least when seen from an international perspective. There are various ways to classify the topics, some of which qualify for inclusion under more than one heading (Table 4.1).

Table 4.1 *Consensus conference topics (chronological by country)*

USA

1977	Breast cancer screening
1978	Educational needs of physicians and public regarding asbestos exposure
	Dental implants: benefit and risk
	Mass screening for colorectal cancer
	Treatable brain disease in the elderly
	Indications for tonsillectomy and adenoidectomy
	Availability of insect sting kits to non-physicians
	Mass screening for lung cancer
	Supportive therapy in burn care
	Surgical treatment of morbid obesity
1979	Pain, discomfort and humanitarian care
	Antenatal diagnosis
	Transfusion therapy in pregnant sickle-cell disease patients
	Improving clinical and consumer use of blood pressure measuring devices
	Treatment of primary breast cancer: management of local disease
	Steroid receptors in breast cancer
	Intraocular lens implantation
	Oestrogen use and post-menopausal women
	Amantadine: does it have a role in the prevention and treatment of influenza
	Use of microprocessor based intelligent machines in patient care
	Removal of third molars
1980	Thrombolytic therapy in thrombosis
	Febrile seizures
	Adjuvant chemotherapy of breast cancer
	Cervical cancer screening: the pap smear
	Endoscopy in upper GI bleeding
	Caesarian childbirth
	CEA as a cancer marker
	Coronary artery bypass surgery: scientific and clinical aspects
1981	Diagnosis and treatment of Reye's syndrome
	Computer tomographic scanning of the brain
1982	Define diets and childhood hyperactivity
	Total hip joint replacement
	Clinical application biomaterials
1983	Critical care medicine
	Liver transplantation
	Treatment of hypertriglyceridaemia
	Precursors to malignant melanoma
	Drugs and insomnia – the use of medications to promote sleep
	Dental sealants in the prevention of tooth decay
1984	Diagnostic ultrasound imaging in pregnancy
	Analgesic associated kidney disease
	Osteoporosis
	Mood disorders: pharmacological prevention of recurrences
	Fresh frozen plasma: indications and risks
	Limb sparing treatment of adult soft tissue and osteosarcomas
	Lowering blood cholesterol to prevent heart disease
1985	Travellers' diarrhoea
	Health implications of obesity
	Anaesthesia and sedation in the dental office
	Electroconvulsive therapy
	Adjuvant therapy for breast cancer

Table 4.1 *Consensus conference topics (continued)*

1986	Health implications of smokeless tobacco use
	Prevention of venous thrombosis and pulmonary embolism
	Integrated approach to the management of pain
	Utility of therapeutic plasmaphoresis for neurological disorders
	Impact of routine HTLV-III
	Antibody testing of blood and plasma donors on the health of the public
	Infantile apnoea and home monitoring
	Platelet transfusion therapy
	Diet and exercise in non-insulin dependent diabetes mellitus
1987	Newborn screening for sickle-cell disease and other haemoglobinopathies
	Management of clinically localised prostate cancer
	Differential diagnosis of dementing diseases
	Neurofibromatosis
	Geriatric assessment methods for clinical decision making
	Magnetic resonance imaging
1988	Prevention and treatment of kidney stones
	Cochlear implants
	Dental implants
	Perioperative red cell transfusion
	Urinary incontinence
1989	Therapeutic endoscopy and bleeding ulcers
	Oral complications of cancer therapies: diagnosis, prevention and treatment
	Sunlight, ultraviolet radiation and the skin
	Treatment of destructive behaviours in persons with developmental disabilities
1990	Noise and hearing loss
	Surgery for epilepsy
	Treatment of sleep disorders in older patients
	Adjuvant therapy for colorectal cancer
	Therapeutic uses of gammaglobulin
	Treatment of early stage breast cancer
	Therapeutic uses of botulinum toxin
	Hyperparathyroidism
	Melanoma
	Treatment of morbid obesity
1991	Treatment of panic disorder
	Acoustic neuroma
	Impotence
	Diagnosis and treatment of depression in late life

The Netherlands

1982	Blood transfusion therapy
1983	Traumatic lesions of the back
	Mammography policy
1984	Severe traumatic brain damage
	Melanoma of the skin
	Thrombocyte transfusion policy
1985	Solitary thyroid nodules
	Prevention of bedsores
	Osteoporosis
	Foot problems of diabetic patients
1986	Diagnosis of deep venous thrombosis
	Non-scrotal testis
	Treatment of bedsores
	Drug addicts in prison
1987	Prevention of herpes neonatorum
	Haemophilia
	Follow-up of colon polyps
	Cholesterol
	Suspect lymph nodes in the neck
	Diagnosis of atopic syndrome
	Total hip joint replacement
	Follow-up of colorectal cancer
1988	Diagnosis of dementia
	Sports and cardiac pathologies
1989	Prevention of deep venous thrombosis
	Prevention of hospital infections

Table 4.1 *Consensus conference topics (continued)*

1990	Diagnostics for lung cancer
	Hypertension
	Melanoma
	Acute otitis media
	Nutrition and allergy
1991	Cerebrovascular accident
	Diabetic retinopathy
	Diagnosis of pulmonary embolism

Sweden

1982	Total hip joint replacement
1983	Treatment of myocardial infarction
1984	Treatment of depressive disorders
	Sight improving surgery
1985	Diagnostic imaging for liver tumours
	Cerebral haemorrhage and stroke – diagnosis and treatment
1986	Urinary incontinence in adults – diagnosis and treatment
1987	None
1988	Chronic leg ulcers – diagnosis and treatment
	Post-operative wound infection – hygienic routines in hospital
1989	Pre-operative routines
	Venous thrombosis – diagnosis, prevention, treatment indications
1990	In vitro fertilisation
	Chemotherapy treatment for cancer
1991	Otitis media
	Eye complications in diabetes
1992	Asthma/allergy (Nordic conference)

Norway

1986	Ultrasound in pregnancy
1989	Mammography screening
	Reducing cholesterol in the population
1990	Oestrogen and the menopause
1991	Unknown
1992	Asthma/allergy (Nordic conference)

Finland

1985	Acute otitis media
1987	Treatment of schizophrenia
1989	Cholesterol and coronary heart disease

Denmark

1983	Early detection of breast cancer
1985	Prevention and treatment of dental caries
1986	Cholesterol and ischaemic heart disease
1987	Secretory otitis media (glue ear)
1988	Physical training and health
1989	Senile dementia
	Avoidable deaths from cancer
1990	Extremely premature babies
1992	A Nordic Consensus Conference in Stockholm will deal with diagnosis of allergic disorders – organised by NOS-M (collaborating MRCs in Nordic countries)

UK

1984	Coronary artery bypass grafting
1986	Breast cancer treatment
1987	Role of asylum in society
	Prenatal screening
1988	Treatment of stroke
1989	Intensive care
	Cholesterol measurements in prevention of coronary heart disease
1990	Colorectal cancer

There has naturally been considerable overlap between the topics in different countries (Table 4.2).

Table 4.2: *Consensus Topics (main subject groups)*

Surgery

USA only

Lens implantation
Cochlear implants
Surgery for epilepsy
Burns – supportive therapy
Biomaterials, clinical applications
Liver transplant
Limb sparing treatment of osteosarcomas
Acoustic neuroma
Therapeutic endoscopy and bleeding ulcers
Tonsillectomy and adenoidectomy
Surgical treatment of obesity
Health implications of obesity
Treatment of morbid obesity

USA and Europe

CABG – scientific and clinical aspects: UK, Canada
Hip joint replacement: Netherlands, Sweden
Otitis media: Finland, Denmark, Netherlands and Sweden

Europe only

Traumatic lesions of back: Netherlands
Treatment of bedsores: Netherlands
Suspect lymph nodes (neck): Netherlands
Non-scrotal testis: Netherlands
Solitary thyroid nodules: Netherlands
Post-operative infection: Sweden, Netherlands
Pre-operative routines: Sweden
Leg ulcers: Sweden
Sight improving surgery: Sweden

Cancer

USA only

Breast cancer screening
Adjuvant chemotherapy for breast cancer x 2
Steroid receptors in breast cancer
Treatment of early stage breast cancer
CEA as a cancer marker
Cervical cancer screening – pap smear
Precursors to malignant melanoma
Sunlight UVR and the skin
Management of clinically localised prostate cancer
Mass screening for lung cancer
Oral complications of cancer therapies: diagnosis, prevention and treatment
Limb sparing treatment of osteosarcoma
Liver tumours – imaging

USA and Europe

Mass screening for colorectal cancer: UK
Adjuvant therapy for colorectal cancer: UK
Treatment of primary breast cancer – management of local disease: UK
Melanoma: Netherlands x 2

Europe only

Diagnosis of breast cancer: Denmark
Mammography: Norway
Mammography policy: Netherlands
Follow-up of colon polyps: Netherlands
Follow-up of colorectal cancer: Netherlands
Avoidable deaths from cancer: Denmark
Diagnostics for lung carcinoma: Netherlands
Chemotherapy for cancer: Sweden

Drugs

USA only

Drugs and insomnia
Treatment of sleep disorders in older persons
Analgesic associated kidney disease
Mood disorders: pharmacological prevention of occurrences
Oral complications of cancer therapies

USA and Europe

Oestrogen use in menopausal women: Norway

Europe only

Drug addicts in prison: Netherlands

Dental

USA only

Implants (benefits and risks)
Removal of third molars
Sealants in prevention of tooth decay
Anaesthesia and sedation in the dental office
Dental implants

USA and Europe

Dental caries: Denmark

Table 4.2 *Consensus topics (continued)*

Diagnostic technologies

USA only

Diagnostic CT scanning of the brain

MRI imaging

Endoscopy for GI bleeding

(also screening for colorectal, breast, lung, cervical cancer: imaging for liver tumours: antenatal screening)

Mental disease

USA only

Mood disorders; drugs prevention of recurrences

ECT

Differential diagnosis of dementing diseases

Destructive behaviour in persons with developmental disabilities

Treatment of panic disorder

Diagnosis and treatment of depression in later life

Europe only

Dementia and the elderly: Denmark, Netherlands and UK

Depressive disorders: Sweden

The place of asylum in society: UK

Schizophrenia: Finland

Neurological

USA only

Febrile seizures

Acoustic neuroma

Neurofibromatosis

Utility of plasmaphoresis for neurological disorders

Surgery for epilepsy

Treatable brain disease in the elderly

Diagnostic CT scanning of the brain

USA and Europe

Cerebrovascular accidents/stroke: UK, Netherlands, Sweden

Paediatrics

USA only

Diagnosis and treatment of Reye's syndrome

Apnoea and home monitoring

Defined diets and childhood hyperactivity

Newborn screening for sickle-cell disease and other haemoglobinopathies

Europe only

Treatment of the atopic syndrome: Netherlands

Extremely premature babies: Denmark

Prevention of herpes neonatorum: Netherlands

Non-scrotal testis: Netherlands

Obstetrics/Gynaecology

USA only

Caesarian childbirth

Transfusion therapy in pregnant sickle-cell disease

USA and Europe

Ultrasound imaging in pregnancy: Norway

Antenatal diagnosis: UK

Europe only

Extremely premature babies: Denmark

Public Health/Prevention

USA only

Travellers' diarrhoea

Asbestos (educating physicians/public)

Amantadine: does it have a role in the prevention and treatment of influenza

Improving clinical and consumer use of blood pressure measuring devices

Availability of insect sting kits for non-physicians

Use of microprocessor based intelligent machines in patient care

Health implications of smokeless tobacco use

Noise and hearing loss

Treatment of hypertriglyceridaemia

Impact of routine HTLV-III antibody testing of blood donors on health of public

USA and Europe

Lowering blood cholesterol to prevent heart disease: Netherlands, Denmark, UK, Norway, Finland

Blood products and diseases

USA only

Thrombolytic therapy in thrombosis

Therapeutic uses of botulinum toxin

Impact of routine HTLV – testing of donors

Transfusion therapy in pregnant sickle-cell disease

Perioperative red cell transfusion

Therapeutic uses of gammaglobulin

Table 4.2 *Consensus topics (continued)*

USA and Europe

Fresh frozen plasma: indications and risks: Netherlands

Prevention of venous thrombosis and pulmonary embolism: Netherlands, Sweden

Europe only

Platelet transfusion therapy: Netherlands

Blood transfusion therapy: Netherlands

Thrombocyte transfusion policy: Netherlands

Diagnosis of deep venous thrombosis: Netherlands

Haemophilia: Netherlands

Prevention of deep venous thrombosis: Netherlands

Venous thrombosis: Sweden

Others

USA only

Treatment of MI

Pain, discomfort and humanitarian care

Diet and exercise in non-insulin dependent diabetes

Geriatric assessment methods for clinical decision making

Integrated approach to management of pain – 1986

Prevention and treatment of kidney stones

Impotence

Hyperparathyroidism

USA and Europe

Critical care medicine: UK

Europe only

Severe brain damage (head injury): Netherlands

Physical training and health: Denmark

Urinary incontinence: Sweden

Treatment of bedsores: Netherlands

Osteoporosis: Netherlands

Nutrition and allergy: Netherlands

Diabetic retinopathy: Netherlands

Foot problems of diabetic patients: Netherlands

Of the 78 different topics in the NIH programme 11 have also appeared in European programmes – seven of them in the Netherlands. Cholesterol screening or reduction has featured in five countries as well as twice in NIH, and stroke and otitis media in three countries each as well as at NIH. Breast cancer was the topic of five NIH conferences and of one each in the UK and Norway; colorectal cancer appeared twice in NIH and in the Netherlands and the UK. The Swedish and NIH conferences on hip joint surgery resulted in very similar consensus statements on this topic.[4]

DISSEMINATION OF CONSENSUS STATEMENT

Most publish the consensus statements first in medical journals which have wide distribution, but secondary publication in full or in summary is common. Statements are usually also mailed to people and organisations expected to be interested, including the audience who attended the conference.

Most organisers also make statements available to the media, often at a press conference. The amount of media or public interest varies with the topic. Some NIH statements that had commercial implications for the drug or equipment industries have attracted comment in the *Wall Street Journal* and the like.

IMPACT

Some countries have attempted to evaluate the impact of their conferences. Only a few are claimed as having definitely caused an immediate change of policy or practice. If a conference has been well timed it may rather serve to confirm or accelerate the adoption of changes already imminent. In any event there are so many influences on medical practice that it is always difficult to determine the relative importance of each in any given case. Studies in the USA have been the most extensive; almost all of them focused on the proportion of various target groups who were aware of the existence and/or content of statements. In Nordic countries the agencies concerned with delivering health are closely concerned with consensus conferences and there is a high degree of awareness among professionals, policy makers and politicians. Certainly the statement on hip joint surgery resulted in reallocating surgical resources in Sweden to increase access to this surgical procedure. Similar awareness and responsiveness probably applies also in the Netherlands, where the consensus programme is part of an established quality assurance programme for hospitals.

SPONSORING OR HOSTING ORGANISATIONS

A marked difference between the UK and other places that has not been emphasised in these international comparisons is the nature of the sponsorship (Table 4.3).

The Medical Research Councils are involved in all four Scandinavian countries together with national hospital organisations, institutes of public health or health departments; in Sweden the co-sponsors are the regional (county) councils which determine local funding of health care. The Netherlands conferences depend on the national organisation for quality assurance in hospitals (CBO), which produces guidelines for medical specialists. It includes representatives from all 34 scientific medical associations, and the consensus programme is therefore largely in the hands of the medical profession. In the USA the NIH (with many of the functions of research councils in Europe) has ownership of the programme, albeit through OMAR which keeps it at one remove. Without specific input from providers or planners there is therefore less concern in the US programme with issues of access to and economics of the medical developments under scrutiny.

In Britain neither the MRC nor the Department of Health has offered any sponsorship, nor did the medical associations in the form of the Royal Colleges, which represent the major medical specialties. Although each of these official bodies showed interest in specific conferences, the organisation and funding of the programme as a whole and of each conference was borne by the King's Fund – an independent charity with interests in the management and development of health services. It seems likely that consensus statements will have more impact on provision and practice where those responsible for providing services and setting standards are themselves involved in the organisation of conferences. There is some evidence of this in the Nordic countries and the Netherlands.

Table 4.3 *Sponsors of consensus conferences in Europe*

Country	Sponsor(s)	
The Netherlands	Scientific Council of CBO, which represents all 34 scientific and medical associations CBO was set up by the Dutch Specialist Association and the Association of Medical Directors as the National Organisation for Quality Assurance in hospitals	
Sweden	Medical Research Council Planning and Rationalisation Institute for Health and Social Services (SPRI) (The Federation of County Councils and the Society of Medicine each suggest topics)	
Denmark	Medical Research Council	National Hospital Institute
Norway	Medical Research Council Department for Health and Social Affairs Committee for Medical Technology Assessment Institute for Hospital Research	
Finland	Medical Research Council	League of Hospitals Institute of Public Health
Switzerland	Public Health Institute	Federal Office of Social Insurance
UK	King Edward's Hospital Fund for London	

OTHER RELATED DEVELOPMENTS

A number of other countries appear to be taking an interest in the consensus process. From the published reports and informal information it is, however, not always clear how closely the NIH model is being followed.

France

Attempts by INSERM to launch a consensus programme in 1987 failed to win support from either the social security system or the physicians' organisations. Several individual institutions have, however, held one-off consensus conferences (Table 4.4). The report[5] of last year's conference on pulmonary embolus listed an organising committee, panel and experts. The National Agency for the Development of Medical Evaluation (ANDEM) recently published guidelines[6] for standardising the methodology on the NIH model. It is, however, unclear whether this agency will organise future conferences and coordinate the programme.

Table 4.4 Retrospective list of consensus conferences in France by organising body (Data from ANDEM 7)

	College of Obstetricians and Gynaecologists
1987	Applications of ultrasound in obstetrics
	Society for Breast Disease
1987	Adjuvant therapy for breast cancer
	Society for Intensive Care (in French language)
1987	Treatment of acute chloroquine poisoning
1988	Prevention of gastric haemorrhage from stress
1988	Management of severe asthmatic crisis in adults
1989	Choice of blood expanders for hypovolaemia in adults
1989	Diagnosis of nosocomial lung infections in intensive care
1990	Emergency X-rays of chest and skull
1990	Management of raised intracranial pressure in intensive care
	ARCOL
1988	Cholesterol
	APNET
1988	Rational choice and strategy for menopause
1989	Limits of HTA
	Osteoporosis Research Group (GRIO)
1988	Osteoporosis
	Futures Foundation
1989	Blood cholesterol, diet and coronary risk
1990	Treatment of nasopharyngitis from 6 months to 6 years
	Association for Continuing Education in Infectious Diseases
1989	Treatment of urinary infection in young urban adults
1989	Acute otitis media under the age of 7
1990	Paludrin prophylaxis in travellers
1991	Treatment of acute sore throat and prevention of complications
	Assistance Publique (Hopitaux de Paris)
1990	Diagnosis of pulmonary embolism
1990	Imaging for sciatica (with Radiological Society)
1991	Prophylaxis of deep venous thrombosis and post-operative pulmonary embolus
	Association of Urology
1989	Detection of localised cancer of prostate
	Federation of Obstetrics and Gynaecology
1990	Detection of cervical cancer
	SNIP
1990	Evaluation of hypnotics and tranquillisers
	Society for Infectious Diseases
1990	HIV pneumocystus
1990	Antibiotics for urinary infection
	Society of Oncology and Radiotherapy
1990	What target volumes in conservative treatment of breast cancer?

Israel

When WHO was asked for advice about scanning by positron emission tomography (PET) the result was an NIH/WHO consensus conference. Its conclusion that PET was primarily a research tool probably accounted for the cancellation of a conference on PET planned for by NIH in Washington.

Switzerland

A conference on NIH lines on magnetic resonance imaging was held in 1989, and another on lasers in medicine is planned for 1991. A review article[7] in 1989, entitled 'Expert Committees and their Intellectual Abridgements' appears to be a critique of consensus conferences. As an example it refers to the recommendations of a Working Group of the Swiss Cardiological Foundation in 1989 on cholesterol. Various means of collective decision making are planned, including classical consensus conferences.

New Zealand

An MRC conference on Hospital Day Surgery in 1989[8] appears to have used the NIH model.

Germany

Three conferences have been organised by Departments of Theoretical Surgery in the Universities of Cologne and Marburg using most of the mechanisms of the NIH model. The topics were histamine analysis,[9] pain after surgery and trauma,[10] and quality of life assessment in surgery.[11]

Spain

An editorial 'Consensus Conferences – a form of rationalising medical interventions' referred[12] to a conference on the control of cholesterolaemia promoted by the Society of Cardiology and the Ministry of Health and Consumers.

OTHER CONSENSUS STATEMENTS

The term 'consensus' has been adopted by a number of organisations as a label for statements produced by means other than the NIH model or its European variations. Most of these appear to come from expert groups of physicians.

The WHO consensus statement on anticholinergics in patients on neuroleptic treatment was only 500 words long,[13] but was accompanied in the British Journal of Psychiatry by a longer comment[14] by a British psychiatrist. The authors were the WHO heads of centres collaborating in studies on biological aspects of mental illness – three each from Japan, Switzerland and Italy, two each from the USA and Federal Germany and one each from 15 other countries.

The Rand/UCLA model[15] attempts to rank the appropriateness of various interventions by a series of secret ballots among a group of experts – who may first have met to define the questions. The Canadian consensus system promoted by McMaster University (described in ref 1) is a variant of this, in which the iterative process between experts can last one to two years; there is no public component.

Specialist medical organisations in Britain have produced guidelines for practice that could be regarded as representing expressions of professional consensus.[16,17,18] Such guidelines or protocols are widely used in Scandinavian hospitals, and the output of the CBO consensus conferences in the Netherlands is a practice guideline for use in hospitals.

Some pharmaceutical companies may sponsor meetings which result in statements that claim to represent consensus. These again reflect the views of an expert group, but the selection of participants and of the data presented may not have been without bias. It is therefore important to consider carefully the methodology that has been employed in producing what claims to be a consensus view. In practice all consensus statements come from a limited group of people, and represent only their consensus, not the consensus among a much wider constituency. There are, however, occasional statements that carry the imprimatur of major institutions, the best example in Britain being the criteria for brain death agreed by the Conference of Medical Royal Colleges in 1976.[19]

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5 Conclusions about Consensus Conferences in the UK

When the UK consensus development conference programme began in 1984 there was limited interest in the assessment of health technologies, general management was about to be introduced into the National Health Service, and no separation of 'purchasers' and 'providers' was in sight. The intention in introducing CDCs was to experiment with this method as one approach to technology assessment. Although the UK already had a long tradition of clinical trials, and had developed strength in health economics, there had by 1984 been little attempt to synthesise information about the effectiveness and use of 'technologies' or to make these data readily available to clinicians, decision makers and consumers. The attraction of experimenting with CDCs was that they dealt with assessment of technologies in a multidisciplinary way and emphasised public participation.

In reviewing the impact of the individual consensus statements (Chapter 2), we concluded that there were some examples of local changes in policy and practice, and some evidence of the general raising of awareness of controversies. While some consensus conferences had apparently contributed at least to changes in attitude, there was little to suggest that any one statement had immediately been accepted by all relevant parties, or had led to a strategy for implementation on a wide scale. Accepting that impact has been limited to specific examples, we consider below the broad philosophies that underlie consensus conferences and whether those held in the UK have influenced events. We look for reasons why the CDC programme has not been more widely supported in this country, and suggest that this approach might become more relevant in the new health care agendas of the 1990s.

ACHIEVEMENTS

The CDC programme appears to have contributed to three areas of understanding and activity. These are: public understanding and involvement in medical issues; more critical evaluation of medical technologies by professionals; and the use of consensus methods to resolve controversies about medical care.

Public involvement

Few doctors have to explain the issues and uncertainties about a medical technology to lay people, outside the individual doctor or patient conversation and the occasional media discussion. At a consensus conference they were instructed to present their evidence to an intelligent lay audience, as well as to a wider professional group than they were used to. Many commented that they found it a salutary and rewarding experience to have to explain the complexities in lay language. Some acknowledged surprise at how well lay people on the panel and in the audience appeared to grasp the issues.

In the early days there were concerns that exposing the uncertainties of medical practice might undermine confidence in their doctors, but that comment is now heard less often. To claim that there is a change in the public's understanding of the 'art of medicine' might be stretching a point, but there is no doubt that the frequency of medical documentaries and dramas on TV have made it clear to the public that doctors often differ about what is best.

The exposure of medical issues in a public forum, both at the conference itself and in the media reporting of it, is only one aspect of public involvement. Considerable effort was made to ensure that patients and their representative organisations were included as presenters and in the audience, and that the panel members included key people from outside the health care field. Attempts were made to bring together and coordinate whatever evidence was available on what patients had experienced concerning a technology, and to ensure that what the panel heard was not limited to or dominated by the perspective of individual patients heard at the conference. Accumulated and well-researched evidence of consumer views is, however, scarce – but these conferences have shown that patients' views can be not only important but useful. Indeed the assumptions of professionals about what patients want or have experienced are often mistaken.

On the issue of public understanding and involvement in policy and personal decisions about health care, we believe that consensus conferences can make a significant, even a unique, contribution. Although listening to the users of services is becoming more commonly accepted in the NHS, this has hitherto focused mostly on concerns about the environment in which health care is delivered, or about access to facilities and communication between staff and patients and their families or friends. There is little systematic work on patients' perceptions of medical care itself, in particular of whether it appeared to have been appropriately chosen – as distinct from being competently and kindly carried out. That patients, individually and collectively, have much to contribute, has

been clearly demonstrated by CDCs, which provide one mechanism for patients' views to be heard.

Critical evaluation of medical technology

Despite its research traditions the UK has shown less interest in the more comprehensive assessment of medical technologies than several other European countries which have followed the US lead (see Chapter 4). The tight budgetary constraints in the NHS, together with the cautious and sometimes sceptical attitudes of many British doctors towards new technologies, have limited their spread and have also constrained the use of established procedures. This may be why there has not been as much concern with this issue in the UK as in some other countries. Limited financial allocation is, however, a blunt instrument for controlling the scale of use of medical technologies, and it is apt to limit activities which are beneficial as well as those which are less so.[1] We believe that the UK needs a much more coordinated approach to technology assessment in order to provide better information on which to base decisions.[2,3] Decision makers range from health service policy makers and managers controlling resources at national, regional and local levels, to individual clinicians and their patients who wish to form judgements about what is appropriate. Consensus conferences as a form of technology assessment have kept this issue alive over the past few years, while the new purchaser/provider contractual relationships may create a new demand for technology assessment.

However, not everyone accepts that CDCs are a good way of reviewing scientific evidence in order to assess the effectiveness and indications for using technologies. Some advocates of randomised controlled trials (RCT) have argued that these conferences are not sufficiently rigorous in reviewing evidence, and are therefore a poor relation to the 'gold standard' of the RCT. This is to misunderstand the objectives of a consensus conference, which are wider than those of an RCT. While an RCT is primarily concerned with establishing efficacy in limited circumstances, a consensus conference deals with the total range of effectiveness, appropriate indications, ethical and economic considerations. Another misconception is that the members of the panel are under pressure to reach a consensus. In fact we have (as organisers) always encouraged panels to ensure that they base their arguments on evidence rather than on opinions, and to state where they cannot reach a consensus – and whether this is due to lack of data or to conflicting evidence. This in itself may act as a stimulus to further research.

Consensus methods

A full-scale three-day public conference is only one way that data can be analysed and synthesised. Some issues do not warrant this degree of public exposure and investment, while others are unsuitable for this approach. It is encouraging that different groups in Britain are now experimenting with alternative methods. For example, the Royal College of Physicians, groups of cancer specialists, academic departments and others are developing clinical standards, guidelines and protocols. There has also been some experimentation in the UK with the approach of the Rand Corporation in the USA, in which a small group of experts develop appropriate indications for a procedure by an iterative formal process.[4] One motivation for the increasing interest in consensus approaches is a growing realisation that there is marked variability in clinical practice in a particular field,[5] with some variations clearly conflicting with what is aknowledged as good practice.

The word consensus is now used for a range of statements resulting from a variety of different mechanisms. While the UK conferences have emphasised a multidisciplinary and public approach, in other places it is pure expert groups who develop guidelines for practice (e.g. the CBO conferences in the Netherlands, see Chapter 4). The King's Fund CDCs are known to have provided a stimulus to some of these other activities, which we warmly welcome. However, we do believe that there is a special need for public consensus conferences with lay involvement. At the same time it is important to identify the issues which primarily require doctors and scientists themselves to reach conclusions about good technical practice, or to conclude that the evidence indicates that variation in practice is in fact acceptable. The development by health authorities of medical audit and of risk management schemes is likely to encourage doctors to address the issue of guidelines or standards for clinical practice in this way or others.

The processes involved in consensus development conferences should not be underestimated. The King's Fund programme had panels that included only one or two experts in the technology under discussion, although several others were expert in other areas of health care. Panels that include more experts in the field are likely to contain powerful professionals, who may have a stake in the outcome and some of whom may already have adopted positions on the issue under discussion. Group dynamics are fascinating to watch in panels – for example, how medical members of the panel are influenced by economic or sociological arguments. We suspect that in expert groups many members remain oblivious to the importance of group dynamics, although strongly feeling their effects.

DISAPPOINTMENTS

We believe that the CDC programme has made a significant contribution in a number of areas. However, we are disappointed that it has not been more widely accepted and supported. During our discussions with individuals and organisations about the benefits and limitations of these conferences we have learnt much about how they are perceived.

An important issue concerns the role of the sponsoring organisation, the King's Fund. It has the advantage of not belonging to any one interest group, but the disadvantage of being outside the health care system. Its independence makes it an appropriate body to bring together various professional disciplines and lay people, as a consensus conference requires. We did our best to resist particular

biases but were still accused in the early days of giving too much space or emphasis to the experts who presented evidence.

It is, however, difficult to see who else could present technical evidence. We went to some length to choose people known to take a broad view, and to include experts with different biases. Furthermore we actively counselled experts to give a balanced view, and not simply to repeat their latest paper from a medical or scientific conference.

There was perhaps some concern that the King's Fund should be entering the area of clinical practice and policy. However, we firmly believe in the need to have health care issues discussed in a broader forum than the standard conference of experts. A more significant problem is that the Fund has no direct way of implementing the results of consensus conferences. In countries where the organisations sponsoring consensus conferences are themselves key policy bodies, implementation has been easier, particularly in Scandinavia and the Netherlands (see Chapter 4).

The UK national bodies whose sister organisations in other countries have been involved in consensus conferences include the Medical Research Council, the Department of Health and the Royal Colleges. The Medical Research Council in the UK has argued that consensus conferences are not research and are therefore not part of its remit. This is in complete contrast to other countries in Europe and the NIH. Nevertheless, this view fits with the very limited role that the MRC in the UK has played both in health service research and in the dissemination of research findings.

The Department of Health might have been expected to welcome these conferences, but their reluctance to become involved may have reflected concern about the potential of a CDC to make policy in an area where no clear policy was wanted or felt necessary; perhaps also that CDCs might produce recommendations which did not conform to current government positions, or which committed resources to a particular activity.

The Royal Colleges and the medical profession as a whole are more complex. Undoubtedly there has been concern that a body outside medicine should be investigating clinical issues, and perhaps also concern about professionals publicly confronting their mutual differences as well as the paucity of scientific evidence for their practice.

However, after a certain amount of controversy at the start of the programme there seems to have been little opposition from the profession, and only one invited expert refused on principle to take part. Critics in the UK and in the US have pointed out that no new data are generated by consensus conferences, and that research might be stifled because of a false sense of consensus. Some within the medical profession have been highly supportive of the conferences, particularly after taking part in one. Experts have valued the experience of setting out their evidence to a broader audience than usual, and panel members have been surprised at the degree of analysis involved and the intensity of work needed to produce a statement. By its nature a programme of conferences moves from one topic to another and from one group of specialists to another. This widely changing constituency may have militated against the building up of momentum in the programme as a whole. However, similar diversity of topics in other countries has not led to programmes being abandoned.

There has been little criticism of individual consensus statements from the specialties concerned. This may be because most confirmed the synthesis that specialty leaders had already accepted, and it was acknowledged that the statements summarised best practice. However, such practice was not necessarily yet common practice, nor was there usually any published synthesis based on scientific evidence to support such practice. We reject the criticism that consensus conferences represent a bland lowest common denominator. Indeed, most have given clear conclusions and called for some action. Most criticism appears to have come from those who have not attended a conference, or those who have not read the statements in detail. These critics may not realise the amount of evidence presented or the rigour of the discussion before a statement is agreed. We believe that the statements have added authority because they come from a broadly based panel, rather than from a narrow professional group with vested interests.

FUTURE ROLE

It might be expected that the nationalised health system in the UK, as compared with the pluralistic provisions in other countries, would have produced a greater demand for activities such as consensus conferences, and a greater willingness to implement agreed recommendations. Neither such demand nor willingness has been obvious. Indeed Britain seems to be the only country to have embarked on a consensus programme and then abandoned it (even if, perhaps, only temporarily). As observers of the NHS are aware, that organisation is characterised by great diversity in practice together with a frustrating record of 're-inventing the wheel' from place to place and time to time. The changes in the service in the 1990s may, however, lead to a greater acceptance of, even a demand for, technology assessment. Consensus development conferences might therefore come to be welcomed.

The last six years have seen more integration of doctors and their technical activities into a more managed system. General management and the resource management initiative have focused on the need for agreement about the work to be done, and about the resources required and available to do it. The split between purchasers and providers is a fundamental change, and in time purchasers will have to be well informed about the services and technological procedures that they are prepared to buy, and they may even specify indications for the use of some procedures. Ultimately they may be able to specify desired outcomes and targets rather than the detailed indications.

However purchasing develops, purchasers will need

much more information than has hitherto been available about effectiveness, cost and patient preferences. Consensus conferences could never be the only source of such information, but they could make an important contribution. To meet purchasers' needs the degree of detail provided in consensus statements would, however, need to be expanded .

As well as purchasers, clinicians are another target group for statements. Clinicians are becoming more accepting of the development of standards and protocols, but there is little evidence yet for wide usage of these in the UK. Medical audit activity is likely to encourage such development, but consensus statements do not usually go into the level of detail found in clinical standards and protocols, nor are they written in algorithms or in the form of guidelines. Such detail may best be left to expert groups, once some of the key decision points have been clarified.

The evidence (Chapter 3) suggests that the information in consensus statements can be useful for patients, although it is not always written in language that is readily understood by non-experts; journalists can have a key role in popularising the information. There is every indication that patients, their families and friends and carers will increasingly demand the kind of information that is provided by consensus statements. We therefore conclude that consensus statements, or similar types of information, will be increasingly required and valued in the newly structured NHS. UK consensus conferences have the unique strength of lay input and public exposition.

If multidisciplinary consensus conferences are to have a place in the future, they will need to have certain features.

- It does not make sense for the King's Fund to go it alone. The King's Fund's independence may make it a good place to manage the conferences, but if the recommendations are to affect policy and practice there has to be more sponsorship from those involved in providing (or purchasing) services. The challenge is to do this in a way that minimises bias in the statement and recommendations.
- One-off consensus conferences, where the conference and statement are seen as ends in themselves, are not enough. It would be more effective if statements were to be re-written in several formats to meet the needs of different target audiences. Some topics may be covered by the questions set for a panel, but others would need further development.
- There is also much work to be done on strategies for implementing key recommendations. Changing clinical policy and practice is known to be difficult, and information by itself is seldom enough to effect this. The strength of the consensus conferences is that they target a range of groups, and it is therefore more likely that change will come about if each of these groups is involved. Implementing consensus recommendations will never be easy, and it will require significant funding in addition to that needed to organise a conference.
- If consensus conferences do not continue, the UK will have lost an important, perhaps unique, means of exploring medical issues beyond the forum provided by the immediate specialties concerned, and involving a wider group of interested disciplines and lay people. It would be ironic if this occurred at a time when consensus conferences are becoming established in more European countries, and when the NIH programme has been extended for a further period.

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CORONARY ARTERY BYPASS SURGERY

The First UK Consensus Development Conference: Consensus Statement

Coronary artery disease is one of the major health problems in the western world today. Coronary artery bypass surgery (CABG) is a technique in which a blocked or narrowed section of a coronary artery is bypassed using part of a vein or artery from elsewhere in the patient's body. The treatment has two separate objectives: the relief of angina and the prolongation of life. There are, however, alternative methods of treatment for coronary artery disease and there are a variety of views about which patients stand to benefit from CABG, especially in comparison with these alternatives.

Britain shares with Sweden, France and Germany a rate of bypass operations per million population that is about one sixth of that in the United States, a quarter of that in Australia and a third of that in Holland. Within the UK the rates over the five year period (1977-82) varied ten-fold between regions. These variations reflect differences in the availability of facilities for investigation and surgery and probably also the differing views of doctors and patients about the indications for the procedure. A major question is whether there should be any change in the number of CABG operations over the next few years, taking into account other demands on health care resources. CABG is only one aspect, albeit important, of the whole massive problem of coronary artery disease.

The King's Fund in association with the Royal College of Physicians and Royal College of Surgeons of England sponsored this first consensus development conference on the subject of coronary artery bypass surgery in an effort to resolve some of the questions about this procedure. For one and a half days a 12 member panel listened to evidence from experts and from the participants at the open conference. The panel then prepared answers to four questions which had been set in advance.

Question I: What are the pros and cons of CABG (compared with alternatives) for various types of patient (including age and sex), in terms of survival and quality of life?

It is possible to list advantages and disadvantages of medical and surgical treatment which apply to some extent to all patients with coronary artery disease.

- For the relief of angina, surgery is effective in most cases where medical treatment including drug therapy and modification of lifestyle is ineffective or unacceptable.
- Beta-blocking drugs in particular, even when relieving angina, are liable to produce various side-effects and a general lowering of vitality. Surgery on the other hand is often followed by an improvement in well-being.
- Medical treatment can be implemented immediately following diagnosis. Surgery under present conditions is liable to involve considerable delay which will add to the patient's anxiety.
- Surgery must be preceded by costly and arduous investigations. These can be avoided with medical treatment, but at the price of the detailed pathology remaining unidentified.
- The immediate financial costs of surgery are considerably higher than those of drug therapy. In the medium to long term, the balance of cost is less certain; medical cases require closer medical supervision in hospital and in the community. Either treatment may become ineffective so that further treatment (possibly surgical) may have to be undertaken. The full benefits of surgery require counselling and rehabilitation measures, and these are not always provided.
- Surgical cases are subject to a small operative mortality (1 per cent is being achieved in some centres; the UK average in 1982 was 3.2 per cent). There is post-operative pain and discomfort and also a liability to complications. All open heart surgery may be followed by adverse psychological effects and temporary neurological changes have been reported.

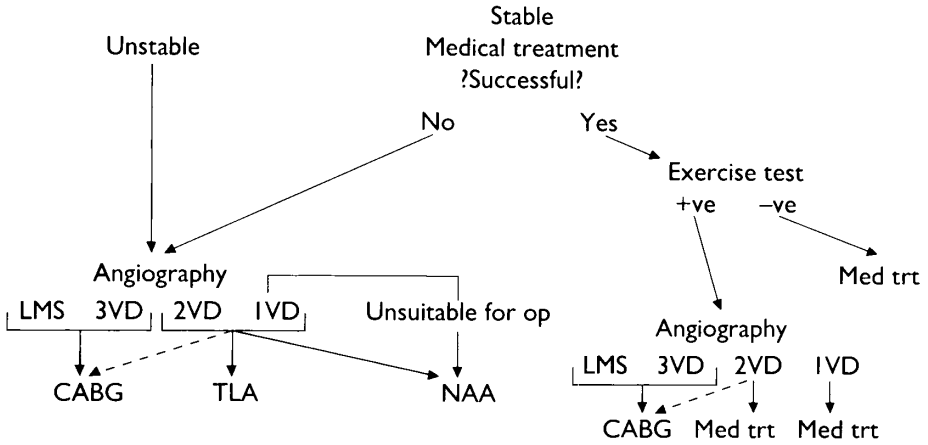
As far as specific groups are concerned, women, who form around 10 per cent of all cases, have a higher operative mortality than men. Older patients in general have a higher operative mortality and morbidity, and are more likely to be able and willing to alleviate symptoms by reducing activity, though increasing numbers of older patients are receiving surgery with beneficial effect. On the other hand, complete symptom relief may be more important to younger men and women with work and family responsibilities.

It is important to re-emphasise that treatment has two separate objectives - relief of angina and prolongation of life. For relief of angina, surgery succeeds in many cases where drugs fail, and avoids their side-effects.

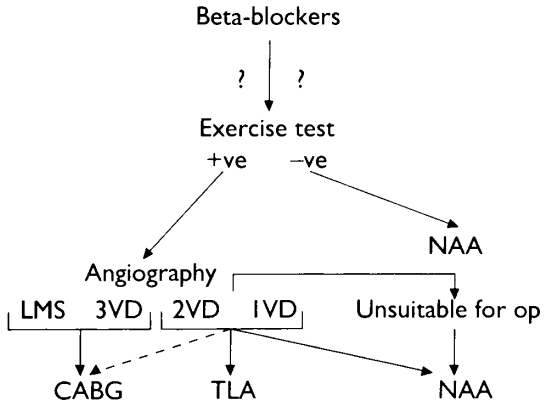
For survival the situation is more complex. In anatomically severe (main stem) disease, it is widely agreed that surgery prolongs life. With less severe forms, the evidence mainly comes from the European Coronary Surgery Study and Coronary Artery Surgery Study trials. These are not in full agreement, but are consistent with a somewhat better five-year survival with surgical rather than medical treatment in patients with three vessel disease. Less severe cases (one vessel disease) have a good prognosis without surgery. It must be remembered that both trials excluded as not randomisable, cases with severe angina and used the medical and surgical methods of the last decade. More refined classification now possible can lead to better decisions about treatment.

For the quantitative discussions below, it is necessary

1. Angina



2. Post-MI, Asymptomatic



TLA: Trans-luminal angioplasty
NAA: No additional action
LMS: Left main stem
3VD: 3 vessel disease
2VD: 2 vessel disease
1VD: 1 vessel disease

1. Patients with stable angina are given immediate medical treatment. If this is effective, there is a case for further investigation by exercise (stress) testing (and echocardiography where available). If these tests are judged positive at a low work-load angiography follows. 'Severe' cases (left main stem [LMS] and triple vessel [3V] disease) receive CABG; 'mild' cases (two vessel [2V] and single vessel [1V] disease) receive either CABG or angioplasty. Patients whose medical treatment is unsuccessful require angiography without preliminary exercise testing, as do those whose angina is unstable.

2. Asymptomatic patients who survive a myocardial infarct (myocardial infarction) may receive beta-blocking drugs and may require exercise tests. Those with positive tests require angiography and surgery as above.

to have an explicit pattern of investigation and treatment. In the light of what we have heard, we make the suggestions on page 37 for good clinical practice (irrespective of resources).

Question 2: What are the indications for various investigations for coronary artery disease?

Investigations should usually be limited to implementing the management pattern suggested above. The first and most crucial 'investigation' is thorough clinical assessment based on a good medical history and examination. Angina which is controlled medically should be investigated with chest X-ray, resting ECG, and exercise (stress) ECG under cardiological supervision based on an accepted protocol. Echocardiography may be helpful. Significant and relevant cardiac abnormalities should be followed up with cardiac angiography (with or without supplementary radionuclide investigation) with a view to determining suitability for operation.

Another category of patients who may need investigation in this way, because a proportion of them may be suitable candidates for CABG, comprises patients who have had myocardial infarction but who do not have angina. Angina which is not controlled medically should be investigated by cardiac angiography. Again, additional radionuclide investigations may be helpful in elucidating remaining uncertainties.

Coronary artery angiography in a regional centre is generally considered to be the definitive investigation for accurate diagnosis of coronary artery pathology and estimation of left ventricular function and is necessary in all cases being considered for CABG. However, it is expensive and carries a small risk of mortality and morbidity. For these reasons and the convenience of patients we recommend a preliminary assessment in the district general hospital using non-invasive exercise ECG testing. This technique when carried out according to an acceptable protocol will identify most patients who might benefit from CABG. Echocardiography is recommended both for its assistance in determining left ventricular function and to elucidate other cardiac, notably valvular, pathology.

Question 3: What are the size of potential pools of patients for investigations and for CABG, taking account of alternative therapies? Are these estimates likely to change substantially in the next 5-10 years?

The panel has considered numerous estimates of the potential CABG workload, based on international activity levels and limited UK data on the incidence and prevalence of angina and myocardial infarction. There are three types of patients.

1 New angina patients with an annual incidence of between 110-140/million crude population with characteristics making them suitable for surgery.

2 A sizeable backlog of patients with 'chronic' angina which will undoubtedly vary because of the gross geographical differences in the level of service provision.

3 Patients who have survived recent myocardial infarction. Of these about a third develop angina which is in addition to the estimate of new angina patients. Those without angina may have patterns of vessel occlusion that make them at high risk of recurrence of myocardial infarction. The exact number of these cases is uncertain but applying American workload figures to the sparse UK data gives an annual range of between 200-550 CABG cases/million population.

However, there appears to be no information nationally available about the distribution of these three types of cases in the current CABG throughput in the UK, nor is there data on the seventy categories of these patients. Nevertheless, the above categories produce an annual range of between 300-700/million. Any additional CABGs performed will obviously add to the burden on the investigative services.

Increased use of angioplasty will create greater demands on the cardiac laboratories. The impact on the demand for surgery is not clear. Of much more concern, because of the service implications, is the introduction of thrombolytic drugs for the treatment of acute myocardial infarction. These drugs given immediately after infarction may prevent death or limit damage to the myocardium, but such use may increase survival rates and therefore may add to the pool of patients who will require CABG. Many of these patients will require early operation. The effectiveness of thrombolytic therapy must be assessed; meanwhile it should only be available in centres undertaking this research.

We considered that the UK Cardiac Surgical Register is an excellent professional initiative and a most useful source of data. However, from what has been said earlier a great deal more detail is required; for example, analysis of types of cases operated on for coronary artery disease with mortality and morbidity rates. We were surprised at the paucity of good data about investigative activity and medically treated cases. A patient register is essential in order to plan services and to monitor performance in an area of activity that commands such substantial resources and where techniques and results are changing.

Question 4: What would be the cost and implications for service organisation of increased provisions for investigations and therapy?

In 1982 the number of CABG operations performed in Britain, per million population, were Scotland – 165; metropolitan regions – 169; rest of the United Kingdom – 47. The lowest estimate we have accepted of current need is nearly twice the highest and six or seven times the lowest of these figures. To attempt to cost all possible clinical need seemed to us a fruitless exercise. A strong case has been made for CABG as the most effective treatment in cases of intractable angina. Therefore, in our view, a clear lead needs to be given nationally

about the future direction and rate of expansion of cardiac services, so that priority needs are met and the grossly unequal distribution of service across the country is corrected. The achievement of these two goals should be closely monitored. Until the gaps in the data required for future planning are filled, we would endorse the suggested rate of 300 CABG operations per million, as a realistic short-term target, if this represents provision only for high benefit patients.

Taking a notional figure of £3,580 per operation this would require an additional £35 million per annum, although some progress towards this figure will have been made by the NHS since 1982. To arrive at a true assessment of extra cost will require a region by region review to establish:

- what level of service is currently available and what capacity there is to absorb an expanded workload;
- what additional facilities are required by way of theatres, laboratories, and beds (recognising that to introduce additional cardiac surgical work may disturb the balance of services within a DGH and may overload other support services including general intensive care facilities);
- what additional staff will be required. We have been told that no more than 12 additional cardiologists is very much greater if each DGH is to have at least one physician with a special interest in cardiology, and each main centre up to six. The precise number is difficult to estimate as some appointments will be achieved through changes in workload in related specialties, but a considerable number of nurses may be required for theatres, wards and intensive care.
- a separate assessment of the need for investigative facilities at DGH level, and of increased facilities for angiography in the regional centres will need to be made.

Providing regional policy is clear and specific targets are set we would hope that maximum autonomy and delegated financial responsibility would be given to those with clinical responsibility in the major centres and their associated DGHs to develop a service appropriate to local needs. Only in this way can any real incentive be given to good practice and efficient performance.

We consider that angioplasty should be fully evaluated in those centres where it is already being developed before it is generally introduced. Also new therapies such as thrombolysis should be introduced only in a limited number of centres, until they have been fully evaluated. The proposed national register, which should be centrally funded, should be given priority over any future service development beyond the immediate phase. Attention should also be given to preventive programmes and their evaluation.

These developments require considerable funds. Whether these are found from reallocation of NHS funds or from additional money the problem of assessment of priorities remains. This in turn should take account of estimations of the relative cost-effectiveness of other procedures competing for resources. We were impressed by one method of measurement combining quality and duration of life. Further development of this approach is recommended so that it can be of help not only in comparison between CABG and other priorities but also between the various subgroups of patients whom it is proposed should be treated by CABG. Such techniques would also help to identify health service activities which are being continued despite low benefit.

Panel members:

Professor Bryan Jennett (Chair), Dean, Faculty of Medicine, University of Glasgow; Mr John Dark, Cardiothoracic Surgeon, Wythenshawe Hospital; Professor Gerald Dworkin, Department of Law, University of Southampton; Dr Malcolm Forsythe, Regional Medical Officer, South East Thames Regional Health Authority; Dr Ranaan Gillon, General Practitioner and Director, Imperial College Health Service; Ms Oriole Goldsmith, District Administrator, Coventry Health Authority; Professor Michael Healey, Department of Medical Statistics, London School of Hygiene and Tropical Medicine; Ms Angela Heslop, Clinical Tutor, Bloomsbury Health Authority; Professor Desmond Julian, Professor of Cardiology, University of Newcastle upon Thames; Ms Anne Ludbrook, Deputy Director, Health Economics Research, University of Aberdeen; Dr Geoff Watts, presenter of medical television programmes; Dr Antony Wing, Consultant General Physician, St Thomas's Hospital, London

Speakers:

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TREATMENT OF PRIMARY BREAST CANCER

The Second King's Fund Forum: Consensus Statement

One in 12 women in the United Kingdom will develop breast cancer in their lifetime and 25,000 will do so every year. It is the commonest cancer in women, accounting for one in five of female cancer deaths, and is the leading cause of death in women aged 35 to 54. The clinical course of breast cancer is variable. Some cancers disseminate early, but others may recur only many years later, or not at all.

In the past the main treatment for breast cancer was radical mastectomy. This led frequently to side-effects such as arm swelling and limitation of arm movement. Although in recent years there has been a trend towards less radical surgery (used alone or in conjunction with radiotherapy or systemic drug therapy), there is no consensus about optimum treatments.

Question 1: When a woman is first suspected of having breast cancer, what information is required by the doctor and the patient in order to plan management?

Suspected breast cancer can cause alarm and despondency for the woman and her family. Nine out of ten breast lumps turn out to be benign and it is important that women know this.

If clinical examination suggests that cancer is possible, the general practitioner needs to be sensitive to the woman's fears and expectations, and to the extent to which she wishes to be involved in decisions about her care. Some patients want to consider all the options, while others do not. She should be referred promptly for diagnosis. The general practitioner has a responsibility to outline what the patient should expect when she reaches hospital, and explore with her how she will share her concern with those close to her.

At the hospital all new patients should be seen and examined by the consultant at their first visit. All staff should be aware of the anxiety woman face and should arrange that waiting times are minimal and conditions are comfortable. Mammography may give additional information and define abnormalities in either breast. If either clinical examination or mammography reinforces the suspicion of cancer a sample from the breast must be obtained for microscopic examination.

This may be done using fine needle aspiration cytology or Trucut needle biopsy under local anaesthesia. In a minority of women these investigations will not yield adequate samples, and open surgical biopsy may be required. This should be a separate diagnostic procedure so that there is an opportunity for the woman to know the results and to discuss and decide treatment options with the surgeon. Frozen section biopsy followed immediately by mastectomy is rarely justified.

Once breast cancer is confirmed, factors which may influence the choice of treatment include the patient's age, menopausal state, tumour size and local extension, spread to the regional lymph nodes and presence of distant metastases. Spread to the nodes cannot be determined accurately by clinical examination, and axillary nodes should be sampled at the time of breast surgery. Involvement of these nodes by cancer usually indicates systemic disease. X-ray of the chest and sometimes of the lumbar spine and pelvis will be undertaken, but isotope scanning is not usually necessary.

Prognostic indices which bring together consideration of tumour size, histological grade, oestrogen receptor state and more extensive node sampling, discriminate more accurately between good and poor prognosis patients. The value of this approach in deciding treatment remains unclear.

The woman must be offered every opportunity of full discussion of the implications of these results. Involvement of a female counsellor may help the woman to understand and adjust to her diagnosis and treatment options.

Question 2a: For various subgroups of patients what are the best forms of initial local treatment (surgery, radiotherapy) in terms of local recurrence, distant spread, long-term survival and quality of life, and how do these influence the need for other therapy?

The effects of all procedures on survival and recurrence rates, and on the quality of life of the woman, require careful evaluation. Such evaluation should use a wide range of quality of life measures.

There is no evidence that mastectomy or more extensive surgery, as opposed to local removal of the tumour, leads to longer survival. The risk of local recurrence is greater with breast conservation. However, this risk can be reduced substantially by radiotherapy although there is no evidence that radiotherapy prolongs life. The treatment takes several weeks and has limited term side effects both locally and on the patient as a whole. Travelling distance will also be an important factor for some patients. The long term effects of radiotherapy still require careful study.

The possibility of reconstructive surgery should be discussed with all women in whom a significant loss of breast tissue will be necessary. Reconstruction may take place at the time of the original operation, in a unit with requisite skills, or may take place later. All patients undergoing mastectomy without reconstruction should be given advice about prosthesis by the surgeon and a female member of staff experienced in the selection and fitting of breast prostheses.

For tumours which are multifocal or involve a large portion of the breast mastectomy will often be the best surgical treatment. Mastectomy may also be preferred by some women with small tumours to reduce the risks of local recurrence and the need for adjuvant radiotherapy. Gross involvement of the axilla is normally treated by

surgical axillary clearance, and radiotherapy is reserved for recurrence. However, these patients will usually have large primary tumours, so that modified radical mastectomy (without radiotherapy) may be preferable. Women with locally advanced cancer involving skin or underlying muscle, and those found to have metastatic disease, will generally benefit from radiotherapy, endocrine therapy and/or chemotherapy. This complicated issue is not considered here.

Question 2b: For various subgroups of patients what are the best forms of systemic treatment (chemotherapy, endocrine therapy) in terms of local recurrence, distant spread, long-term survival and quality of life?

An overview of all randomised trials shows that relapse can be reduced in women under 50 with cytotoxic drugs immediately after initial surgical treatment. Single agents have not been shown to reduce mortality rates at five years. Use of a combination of agents (cyclophosphamide, methotrexate and 5-fluorouracil – CMF) in women with mode involvement reduces their risk of death over the subsequent five years from 36 per cent to 27 per cent compared with similar women who had either single agent or no chemotherapy. Any benefits are substantially less in women over 50. Furthermore, these drugs may have unpleasant side effects, so their costs and benefits must be carefully assessed. There is no evidence that courses of treatment lasting more than six months enhance this effect. Indeed a study with a 20-year follow up shows a reduced mortality rate after a six-day course of cyclophosphamide.

Data from all randomised trials assessing the effects of destroying ovarian function (by surgical removal or irradiation) show reductions in mortality in women under 50 comparable to those achieved with CMF.

The beneficial effect of CMF in women under 50 may be partly due to its effect on ovarian function. Destroying ovarian function results in menopausal symptoms and an increased incidence of cardiovascular disease.

Endocrine therapy with tamoxifen given for two years after initial treatment in patients over 50 results in both reduced relapse rate and a reduction in risk of death from 30 per cent to 24 per cent over five years. In patients under 50 there is so far no convincing evidence of a reduction in mortality following tamoxifen therapy, although there is some evidence of a reduced relapse rate. Tamoxifen has minimal side effects compared with CMF but its long term effects are unknown.

Question 3: What are the pros and cons of different degrees of involvement of women in deciding about their own treatment?

Although some women do not wish to be involved in decisions about treatment, others feel excluded and resentful if they are not fully informed and consulted. In general, doctors underestimate the amount of information patients want.

While some women may feel threatened by being given unsolicited information, and their confidence in treatment may be undermined if the doctor seems uncertain, there are strong arguments in favour of women's involvement in treatment decisions. These are that: if the woman is fully involved in decisions about her own care without feeling patronised she is more likely to feel positive about the treatment she elects, however distasteful it may be; if she is free to refuse treatment, frank discussion of her reasons for refusal will minimise resentment on either side and a relationship of trust will be established, making it easier for both parties should problems occur. Openness also makes it easier for the woman to understand the need for a randomized trial of alternative treatments, and why she is being asked to participate.

The woman needs time to take in the news that she has breast cancer. Because immediate treatment is not essential woman can be safely offered an interval before treatment decisions are made. She should be told that she is welcome to bring a family member or friend with her at the next consultation. Again it is essential that counselling should be available, supplemented by a booklet or tape-recording which may be taken home.

Question 4: How should services for treating breast cancer be organised to maximise benefits and minimise disadvantages?

As yet there is no evidence that the outcome of treatment in terms of survival or recurrence is any better in specialist units than general hospitals. Nonetheless, a strong case can be made for grouping together the services for women with breast cancer. Surgeons with no special interest in breast cancer are less likely to be aware of trial results and other advances. They may also be less skilled in appreciating the woman's need for information and psychological and practical support.

In each health district one surgeon should be encouraged to take primary responsibility for running and auditing a service for women with breast cancer. This will involve the establishment of an outpatient breast clinic incorporating the services of a trained nurse counsellor. The clinic needs to be backed up by mammography using dedicated equipment and staffed by an experienced radiographer and radiologist. A histopathologist with experience of breast cytology is also required.

The team of surgeon, radiologist, pathologist and nurse will also need to consult closely with a radiotherapist and/or oncologist, preferably in a joint clinic. These links should help to minimise travel to radiotherapy centres.

After treatment has been started the breast team, together with the general practitioner, needs to be aware of the likelihood of practical problems, as well as depression or anxiety, which can be successfully treated. In each district there should be a psychiatrist attached to the breast team. Good communication between the general practitioner and the breast team will ensure that both parties are aware of the services provided both in hospital and in the

community, and of the woman's adjustment to knowledge of her disease and its treatment. Self help support groups in the community are useful in assisting with both practical problems and psychological support, provided there is appropriate training.

These services do require some additional resources as well as reorganisation, together with training of certain categories of staff. The present state of knowledge of both the costs of care and its outcome in terms of quality adjusted life years does not permit any assessment of the value of different patterns of care, nor of how they compare with the value of other health procedures.

These remarks apply to existing services. If a screening programme were to be introduced the resources for diagnostic services would mean an enormous expansion. The breast clinics suggested would be a useful starting point from which to develop a screening programme.

Much of the evidence on which the panel's recommendations are based comes from randomised trials in which women with breast cancer have participated when the best treatment has been unknown. Advances in knowledge are likely to continue to come from properly controlled trials of different treatments. Women should not be entered into trials without the opportunity to give their informed consent. In such trials information should be collected not only on survival and recurrence but on quality of life, on costs both to the health service and the woman, and on women's satisfaction with their care.

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Speakers

Professor M Baum, Professor of Surgery, Rayne Institute, King's College School of Medicine and Dentistry; Professor R Blamey, Professor of Surgery, Nottingham; Dr D Brinkley, Consultant Radiologist, King's College Hospital, London; Mr M Buxton, Senior Research Fellow in Health Economics and Director of Health Economics Research Group, Brunel University; Ms S Denton, Nurse Counsellor, King's College Hospital, London; Ms C Faulder, Journalist and Broadcaster; Professor Sir Patrick Forrest, Regius Professor of Clinical Surgery, University of Edinburgh; Dr S Gore, Statistician, Cambridge; Mr J Hayward, Director, Breast Unit, and Consultant Surgeon, Guy's Hospital; Professor L Hughes, Professor of Surgery, University of Wales College of Medicine; Dr G P MacGuire, Consultant Psychiatrist, Withington Hospital, Manchester; Dr R Peto, Head of Cancer Studies Group, Radcliffe Infirmary, Oxford; Dr M Pike, Epidemiologist, New Zealand, (late Oxford); Professor R Sellwood, Professor of Surgery, Manchester; Dr I Smith, Consultant Medical Oncologist, Royal Marsden Hospital; Dr D Wild, Director of Professional Services, South West Thames Regional Health Authority

THE NEED FOR ASYLUM IN SOCIETY FOR THE MENTALLY ILL OR INFIRM

The Third King's Fund Forum: Consensus Statement

The third King's Fund Forum was held in London from 8 to 10 April 1987. A panel of 12 from a range of backgrounds listened to evidence from experts in public sessions attended by 200 people, including representatives from many consumer and voluntary organisations as well as health care and social service professionals. After closed sessions the panel discussed its report with the audience; the agreed consensus statement was then presented at a press conference.

The conference was asked to confine its attention to three groups of people who might need asylum:

1 adults with persistent major mental illness including the mental illnesses of old age and dementias;

2 the mentally impaired with behavioural problems;

3 people who are aggressive or have seriously irresponsible behaviour.

The definition of 'asylum' given to the conference was: 'A safe place of refuge or shelter, providing protection and support which may or may not involve total or partial withdrawal or removal from the rest of society. It may or may not involve treatment'.

The conference has been concerned with 'asylum', a word which evokes a cluster of images. Some are positive ('shelter', 'retreat', 'sanctuary') others are darker, resonating in the public consciousness with the madhouse of the Victorian era. We have used the conference definition to seek a modern interpretation of the function of 'asylum' in this first, positive sense.

The evidence of history indicates the existence of an enduring body of disordered people with a need for care who have proved resistant to treatments of the day and are not tolerated in their society. Those offered 'asylum' have been chronically mentally ill, elderly and mentally handicapped people, who were homeless and friendless and who could not be contained within their families. Relief was given to families by removing the responsibility for caring when family tolerance was declining.

Various social changes, the advent of pharmacological treatment and social security benefits, have reduced the necessity for 'in-relief'. This has decreased the numbers in large long-stay hospitals. Critics have justifiably challenged the status of the large mental hospitals which contribute to the disability of patients. Despite reforms, those mental hospitals have become symbols of the outdated. Present concern with 'asylum', as an alternative to abandonment, does mean acceptance of the essential chronicity and intractability of many psychiatric disorders.

We are conscious that the winding down or closure of the large mental hospitals is proceeding at differing paces in different localities. Where this may lead to a loss of 'asylum' and its consequences (misplacement or homelessness) either through lack of appropriate planning or failure of proper investment in community services, we believe this is wrong. The development of replacement local services concurrently with hospital closures is critical in maintaining the confidence of recipients, carers and professionals in the new local service, and as a guarantee against loss of service during the transition.

The panel addressed together two of the questions asked (Questions 1 and 3).

Question 1: Who might need some sort of 'asylum', for what reasons and for how long?

Question 3: What alternative types and levels of 'asylum' should be provided for those needing it, having regard to acceptability and benefit and to feasibility in terms of organisation and cost?

The British model of care is strongly rooted in the concept of providing services to meet the needs of a geographically defined population. Existing data do not provide a sound basis for drawing conclusions about the frequency and nature of psychiatric disorders, and this is a fundamental barrier to diagnosing the community's needs.

We believe that the psychiatric case-register concept and population based surveys of the prevalence of dementia, which were described to us, provide examples of the kinds of epidemiological data which are close to what is required. Greater account should also be taken of socio-demographic differences between populations when planning services.

We accept, too, the importance of broadening the basis of the definition of need in individual patient groups to provide a common currency for the multiple agencies involved in providing care; to place a greater emphasis on functional capacity; and to ensure that the user perspective is fully incorporated.

In addressing ourselves to Question 1 we have related it to the three main groups of adults identified in our remit. We have used medical diagnoses as categories, but clearly behaviour and personal need, not diagnosis, are paramount.

1a) People with functional psychoses and some severely neurotic persons

Schizophrenia. There is a need for people with schizophrenia and their families to feel that the sufferer is able to have acceptable accommodation and support. This relieves tensions in the family, and gives respite to them as well as the sufferer. Individuals unable to look after themselves adequately in relation, for example, to diet, clothing, heating and to avoid recurrent infringements of the law (usually obscenity, and petty crimes) will need help. Other dangers include serious crime and the infliction of self injury. It is important not to exaggerate these in a way which too readily limits the individual's freedom. 'Asy-

lum' should be offered on an informal basis whenever possible. The views of the patient (or any advocate) and the family, if they are the carers, should be diligently sought and carefully considered.

Affective psychoses. Some numbers of persons with affective psychoses (primary disorders of mood) require, usually on an episodic basis, 'asylum'. Self harm when depressed, as well as sexual, financial and other indiscretions whilst manic, are the main problems. However in manic states, rejection by the family is quite frequent.

Neurotic illnesses. Severe neurotic illnesses, rarely but occasionally produce such obsessional, hysterical and anxious states that asylum is required. Such people require some on-going support to improve their ability to cope, despite their difficulties. Ideally a persistent and forceful therapeutic attempt to improve their predicament more fundamentally is needed.

1b) Demented people (and others with clearly organic brain disorders)

We have separated this group from 1a) because there is no real scope for pharmacological treatment of the illness per se, and no discussion about the role of interpersonal relations in the aetiology. Still it is important to encourage imaginative and humane approaches to the management of their conditions, and certainly to offer support to the family. This is a large and increasing group.

The families of demented people should not be left overwhelmed. They need to be reassured about risks that must be taken, if freedom is not to be too severely restricted (for example, getting lost in the street, leaving the gas on). With reassurance and respite, the need for 'asylum' can be delayed, carefully planned and if possible introduced gradually. In the end, it is frequently necessary either because there are no relatives or they are too old, or because of the complete incapacity of the old persons to live normally. Old people like this can be exploited; they can sometimes be aggressive; men can present sexual behaviour with which it is difficult to cope. The commonly concurrent physical illnesses of old age also lead to need for supervision.

2) Mentally impaired people

A small number of mentally handicapped people require 'asylum' for their intellectual impairment itself; however, mental handicap can be associated with behaviour disorders. The latter involve stealing and aggressive, destructive, and self-mutilating behaviour and which can lead to their rejection. Technically this category does not include autistic adults, but they may have similar needs for 'asylum'. It is for those whose behaviour disorder had not responded to treatment, and particularly when the carers are aging, that some form of 'asylum' is indicated.

3) People who are persistently aggressive and who have other irresponsible behaviour (in a mental health context).

We include here substance abusers, because they are involved recurrently in illegal behaviour, and might be said to display personality disorders. They often need rehabilitation hostels offering, for example, therapeutic community regimes for periods of up to a year.

Persistently psychopathic people present one of the most difficult groups for whom to provide, as there is no agreement about who should be responsible. They recurrently appear as psychiatric outpatients, as well as in court. The need for 'asylum' for this group is primarily because of their difficulties in taking responsibility for their actions; this is possibly best provided in therapeutic communities or hostels.

For all these people, however, it is not easy to use the word 'asylum' to produce answers. The concept involved is a range of opportunities for safekeeping.

It is certainly possible to provide 'asylum' as defined. However it is considered that the concept is likely always to involve 'treatment' or care, but only if that is taken to include nursing, habilitation and rehabilitation in the widest definition.

In an even broader sense, some form of refuge may be wanted by people outside these categories. What matters is to start with the people, see what they need and then design facilities to meet their needs. As the needs will be diverse, so should the facilities. Quality will be assessed by relevance to each of those needs.

In the past the tendency was to provide the buildings and then try to fit the recipients of care and their needs into them. This should not happen, especially as needs can change more quickly than buildings can be put up.

The range of needs will vary from meeting a short crisis to long-term residence. The latter can be the more difficult. The cause may be senile dementia, which will not improve; it may be behaviour which is just not acceptable to society, and in some cases this can be improved. There are illnesses which mean a long stay in a suitable caring institution. For those people, the place where they are will be their home for a long time. Large wards in large institutions cannot and should not be regarded as 'home' for anyone.

A number of other important facilities are also required. The needs they met are, for example, those of people who are making their way back from severe mental disorder into some sort of independence. There are also fluctuating illnesses which need treatment in different environments at different times.

Whilst we received no detailed evidence, we recognised the importance of planning for the needs of at least two other groups. First, the predicted increase in numbers of people with the acquired immune deficiency syndrome (AIDS) and the advent of new generations of drugs to prolong survival, will mean a sharp increase in numbers of people in this category with mental disorder. Second, it is important to resolve the more long-standing problem of devising an appropriate model of care for younger people with severe long-term effects of brain damage.

There is the difficulty of care being provided by a variety of agencies. Examples are: inappropriate placement of people in different types of care; apparent duplication of provision to some recipients; the existence of others, in need, who are not satisfactorily helped. At worst, services could be described as 'fragmented', at best as a 'spectrum' of provision. However they are far from

being a continuum operating as an integrated whole, matching help to need in an appropriate way. Any use of private services by the statutory agencies must be specifically planned as part of a local network of services and properly regulated.

This has so far not been resolved by joint planning between health, social services and other authorities. Services must be able to provide individual care plans for each person, together with the possibility of moving between different kinds of care, and also moving out altogether. The minimum aims must be to reduce behavioural disturbance and to improve each person's ability to cope, or at least retain such competence as exists; and that is crucial for long-stay patients as well.

Versatility will lead to greater response to innovative ideas; authorities and staff should look out for these, and see if they are suitable for implementation. Such practices, however, need much greater flexibility in funding, as between health (regions and districts) and social service authorities. Evidence suggesting a new statutory agency is not supported but an overhaul of current arrangements would often lead to a better use of scarce resources. Consideration should be given to one of the agencies taking prime responsibility for running the services. Better financial incentives are needed to improve joint planning leading to more coherent services. Another way to improve planning is to involve the local community and, if possible, users.

There are examples of good practice in hospital and community provision in various parts of the country which work well in their local setting. The charismatic leadership which has led to some of the successes may not be easy to reproduce, but more should be done to publicise good practice. The system outlined above will not appear everywhere overnight. This transition must acknowledge the fact that, for example, a large number of dementia patients are still in traditional psychiatric hospitals.

The DHSS's stated policy is to provide a comprehensive mental health service on a local basis. So expressed we would agree. As the range of services increases and improves, the number of hospital beds will be reduced; although there will remain an irreducible minimum. That presents a challenge alike to authorities and agencies in the health district and to their staffs. For the authorities (and central government) it may involve a reversal of priorities. Patients in the groups defined above should not be at the tail of the queue for care. Their needs should be at the top. The greater their dependency, the greater the case for positive discrimination. The public will have to be educated in this change. A commitment to a first class mental health service should be judged as urgent as, for example, a first class service for rapid hip surgery. Improvement of the image of mental health care may be hard work, but it must be done.

That should bring a double benefit. The whole range of staff, too, the most valuable resource of all, should be able to enjoy a greatly increased status and esteem. It does not follow that, in future, qualified nursing staff will be required to fill all the roles. To complement their contribution, thought should be given to training people with other skills to participate in the new and more versatile system.

Such a service is much more likely to be attractive to the recipients of care and their families and these recipients would be more likely to stay in their own homes. There would be scope for choice, or even negotiation. The services should be accessible over 24 hours, seven days a week. The community would come to appreciate that, for every mentally disordered person's needs, a suitable facility exists; that should reduce apprehensions. Sometimes, a person will still have to be detained by compulsion but the development of a range of facilities will provide a greater opportunity to choose the least restrictive alternative. When detention is necessary it should be subject, as now, to statutory supervision.

Question 2: What happens if there is insufficient provision of appropriate 'asylum' for people considered to need it?

This situation inevitably leads to social breakdown, increasing disability and, probably, isolation. It may result in the criminalisation of certain aspects of disturbed behaviour, leading to imprisonment. The evidence is that mentally disordered people are in prison who should not be there.

Abnormal behaviour may also lead to a loss of accommodation, and if permanent homelessness is the consequence then the person may be left vulnerable to abuse and even danger to both themselves and to others. There are also misplaced referrals and inappropriate admissions. The end result may be totally unsatisfactory. Therefore the provision of an appropriate form of 'asylum' will be cost-effective, and may also prevent deterioration of the individual and the family, and the misuse of other expensive facilities.

We are fully committed to the policy of care in the community. There is, however, clear evidence that a product of the change is often a quite unreasonable burden being placed upon carers. This burden can lead to great distress and even emotional breakdown. In the planning of resource allocation, the interests of the carers have not been taken properly into account.

Evidence before the conference suggested that some mentally disordered people, and/or their families, battle on without any form of assistance. There are at least three possible reasons for this: a perception that the institutional care is not acceptable; negative attitudes on the part of the referring professional; and the inability, or unwillingness, of the services to cope with the problem. Carers may not be the first to ask for help; yet it is not automatic for the community mental health services to keep track and look out for signs of crisis. These services should discuss with the carers plans for the patient. This is not just a matter of what the patient might choose, but of what is also necessary to meet the needs of carers.

There was also evidence of the importance of funding a range of facilities able to respond to a variety of special needs encompassing age, physical and psychiatric conditions. These should provide both short and long-term

care, and control and treatment based upon an assessment of each individual; but where appropriate this must be in the context of the family as a whole. This is elaborated on under the earlier questions.

Question 4: How should the quality of 'asylum' and the adequacy of provision be monitored and regulated?

The modern concept of 'asylum' programmes, whether in a hospital or anywhere else, should demonstrate characteristics which attach explicit social value to the recipients of care and the staff providing it. This implies recipient rather than staff orientated regimes of care which emphasise choice and autonomy characterised by:

- no regimented care or treatments;
- personal space and privacy (own room, own possessions);
- participation and relationships with non-disabled people;
- minimum restriction on movement;
- facilities which minimise segregation but which recognise the individual needs of staff and recipients for privacy;
- an attractive small scale physical environment (which would be regarded as generally appealing):
- individuality in dress and appearance;
- taking responsibility for everyday tasks (washing, cooking, laundry);
- help in achieving greater competence, if possible to obtain work or occupation;
- respect for recipients by others;
- proper receipt of financial benefits.

While a variety of mechanisms already exist to monitor the quality of services for mentally ill people, the concept of evaluation should be broadened and extended. This includes both external monitoring and internal regulation, achieved by high levels of staff training and sensitivity to individual needs of recipients.

Individual needs and the development of remedial programmes will be a matter for determination and review through regular discussion with recipients, their families and other staff. We consider that advocacy schemes, including self-advocacy, may be a way to ensure that the voice of the recipient is heard and acted upon.

Finally, the scope of the conference was deliberately limited and did not deal with primary care, children, disturbed adolescents and political 'asylum'. However we believe that six issues are of such importance that investigation and further research into them should be urgently reviewed. They are:

- ways of preventing mental disorder;
- assessment of the real needs of mentally disordered people, including local or regional variations – such assessment is vital for proper planning;
- cost-effectiveness and cost-benefit of different forms of care – such information would greatly assist allocation of funds;
- staffing and training implications of running a new style mental health service;
- the possible role of ethical committees;
- ways of providing a safety net for those who nobody will accept.

Panel members:

Lord Colville (Chair), Chairman of the Mental Health Commission; Mr Paul Beard, Priority Services Unit General Manager, Islington Health Authority; Dr Douglas Bennett, Consultant Psychiatrist; Ms Tessa Blackstone, Master Elect Birbeck College, University of London; Mr David Bowden, District General Manager, Brighton Health Authority; Mr Kenneth Boyd, Scottish Director, Institute of Medical Ethics; Dr Liam Donaldson, Regional Medical Officer/Head of Clinical Policy, Northern Regional Health Authority; Professor Alec Jenner, Professor of Psychiatry, University of Sheffield; Ms Tessa Jowell, Deputy Director of MIND; Ms Joy Kinsley, Governor, Brixton Prison; Mr Herbert Laming, Director of Social Services, Hertfordshire County Council; Ms Usha Prasher, Director, National Council for Voluntary Organisations

Speakers

Professor T Arie, Department of Health Care of the Elderly, University of Nottingham; Dr D Cunningham, Head of Community Medicine, Paddington and North Kensington Health Authority; Dr D Dick, Consultant Psychiatrist, Herrison Hospital, Dorchester; Mr S Etherington, Director, Good Practices in Mental Health; Professor D Goldberg, Professor of Psychiatry, University of Manchester; Professor J Gunn, Professor of Forensic Psychiatry, Institute of Psychiatry, London; Mr C Heginbotham, National Director, MIND; Dr E Johnstone, Consultant Psychiatrist, Northwick Park Hospital; Dr Parry Jones, Consultant Psychiatrist, Warnford Hospital, Oxford; Dr M Knapp, Deputy, Director, Personal Social Services Research Unit, University of Kent; Ms S McKechnie, Director, Shelter; Ms A Norman, Deputy Director, Centre for Policy on Aging; Dr J Reed, Senior Principal Medical Officer, Department of Health; Dr F Seymour, Director of Clinical and Scientific Services, North West Thames Regional Health Authority; Dr G Shepard, Psychologist, Fulbourne Hospital, Cambridge; Dr David Towell, Fellow, King Edward's Hospital Fund for London; Mrs S Turner, Barrister at Law; Ms M Wallace, Writer

SCREENING FOR FETAL AND GENETIC ABNORMALITY

The Fourth King's Fund Forum: Consensus Statement

Three factors have contributed to a growth in interest in the management of genetic and congenital impairments. First, the continued decline in mortality and morbidity due to other causes has increased the proportion due to genetic and congenital abnormality and led to demand for improved management of these conditions. Second, the rapid advances in molecular biology provide radically new means for identifying the carriers of deleterious genes. Third, the Health for All initiative by the World Health Organisation has included a focus on disabled people.

A number of concerns have been expressed about the development of screening programmes and particularly those in which termination of pregnancy is an option. There is fear that a *de facto* programme of crude eugenics might be introduced. The claims of the fetus and the principle of the sanctity of life have been urged as constraints on the mother's freedom of choice. There are concerns that the diversion of resources to screening may impair other services, including those for disabled people; that screening of high risk ethnic subgroups may foster racist attitudes; and that screening may lead to over-medicalisation of the process of child-bearing. There has also been fear that there might be increased stigmatisation of disabled people and their families particularly those who opted out of a screening programme.

A goal of our society is to promote the autonomy of its citizens and health services should contribute towards this goal. Although economic considerations are proper determinants of choice between different ways of attaining a goal, economic arguments should not in themselves determine what goals are to be sought.

Screening is only one possible approach to reducing disability. The primary prevention of environmentally determined congenital impairments, and improvement of the facilities and attitudes of society to physically or mentally impaired people, must be components of a comprehensive approach.

Screening should be seen as a means of acquiring information that increases the scope for choice by participants. While selective termination of pregnancy is one option to which this may lead, the success of a screening programme should not be judged only by its effect on the prevalence at birth of impairments, but by its total effect on the wellbeing of women and their families.

The purposes of screening for genetic and congenital disorders are:

a) to assist in informed decision-making before pregnancy. Accurate information on possible risks may allow some couples to avoid high-risk pregnancies, while other couples may elect to embark upon pregnancies that they would, without this knowledge, have avoided.

b) to provide the option of not continuing with an abnormal pregnancy or to enable the mother and her family to prepare for the care of a disabled child;

c) where fetal abnormality has been identified, to allow optimal management of delivery and postnatal treatment.

Question 1: What kind of screening and diagnostic tests are possible for genetic and congenital disorders?

The disorders with which we are concerned include:

a) the 'single-gene' disorders, eg. haemophilia, muscular dystrophy and thalassaemia

b) the chromosome disorders, eg. Down's syndrome

c) congenital malformations eg. neural tube defects (NTD)

There are two broad overlapping categories of procedures:

1) those which are cheap and safe, and therefore suitable for screening total populations

2) those which are expensive and/or invasive, suitable only for groups already known to be at high risk.

Multi-stage screening to define a high-risk population may begin simply by ascertaining age, family history and ethnic origin – eg. cystic fibrosis is common in Caucasian populations, sickle-cell disease in those of Afro-Caribbean ancestry and Tay-Sachs disease in Ashkenazi Jews. Tests for carrier status of inherited disorders, such as the haemoglobinopathies and mucopolysaccharide disorders, can identify couples at high risk of having affected children. The techniques of the 'new genetics' will soon include detection of the cystic fibrosis gene carried by about 5 per cent of the UK population.

The level of risk at which a diagnostic test should be offered will depend on the natural history and severity of the condition screened for and the test's validity, safety, acceptability, availability and cost. Gene markers for many of the common disorders, including haemophilia, sickle-cell disease, muscular dystrophy, cystic fibrosis, and Huntington's chorea, are already available, and have reduced the numbers of unaffected male fetuses being aborted in the sex linked disorders.

Current techniques based largely on gene tracking require a prior detailed family study. More specific mutation site assays will circumvent this for many disorders, but not necessarily those caused by a variety of mutations eg. Duchenne muscular dystrophy.

Testing for fetal chromosome abnormalities is commonly undertaken at relatively advanced maternal ages, since the birth prevalence of Down's syndrome is strongly age dependent. Recent evidence shows that low maternal serum level of alpha fetoprotein (AFP) at 16 to 20 weeks of pregnancy is an important independent predictor of

Down's syndrome, which may increase the efficiency of detection of this disorder.

Fetal material for laboratory analysis may be obtained by chorion villus sampling (CVS), by amniocentesis or by sampling fetal blood or other tissues in the second trimester. Only CVS is useful much before the 16th week of gestation, but it is not applicable to the detection of NTD. Neither the risks of CVS nor the error rates in subsequent chromosome analysis have yet been fully evaluated, but the procedure is thought to cause more miscarriages than amniocentesis.

Screening for NTDs is widely practised by maternal serum AFP measurement at 16-20 weeks gestation as estimated by ultrasonic scan. The diagnostic procedure may be an amniocentesis to obtain fluid for measurement of AFP and acetyl-cholinesterase, with extremely high accuracy rates (but with a small additional risk of miscarriage) or ultrasonic scanning, which is not invasive, but seems to have higher false negative and false positive rates. The widespread replacement of AFP screening by ultrasound scanning would be premature until better data are available.

Routine ultrasound scanning performed at early gestation for confirmation of gestational age and presence of a heart beat, will sometimes incidentally detect fetal malformations. In contrast, detailed anomaly scanning at 18-20 weeks is, in experienced hands, highly effective in the detection of many malformations.

Identification by ultrasound in late pregnancy of conditions such as diaphragmatic hernia or exomphalos allows delivery at an appropriate time in a hospital with immediately available paediatric surgery.

Neonatal screening to detect treatable conditions (PKU, sickle-cell disease, hypothyroidism) is widely practised, whereas screening for cystic fibrosis and muscular dystrophies has not come into common use.

Question 2: What are the benefits and costs of these tests?

There is evidence that some programmes pay for themselves from the resources saved by having fewer disabled people. If the condition is relatively common and causes serious disability, these savings can be substantial. Even if this were not so, such programmes might be justifiable by their social and clinical outcomes. At least 6,000 (one in every hundred) babies born alive each year in the UK are seriously impaired in spite of nearly 2,000 planned terminations for fetal and genetic abnormalities.

In the past new procedures have not been subjected to scrutiny of cost and benefit. But evaluation research of this type is necessary, given competing claims on resources. A characteristic of such research is that costs in the sense of value of resources used are generally presented as quantitative and monetary. The outcomes, whether positive or negative, are descriptive and qualitative, and are often taken as no more than points for consideration. The principal justification for providing screening programmes lies in such currently unquantified effects. Examples of benefits are: the provision of authoritative information, relief from uncertainty, support during a period of crisis and the expansion of an individual's scope for exercising choice. Examples of potential harms are: the introduction of worrying delays while confirmatory tests are conducted, the distress that may result from false positives and the illusory reassurance given by false negatives. Another set of considerations concerns long-term social effects such as changes in the status and integration of disabled people.

If only monetary information is considered there is a danger that the quantified may drive out the important in a kind of Gresham's Law of screening.

This is a particular danger when the quantified costs of a service exceed the subsequent financial savings. A further difficulty occurs when the costs of the tests are borne by one sector of the community and the savings are found in another. This may happen when a preventive programme funded by the NHS reduces costs later for a family or a social services department (eg. screening for Down's syndrome).

The only secure way to avoid biased appraisals is to attempt to account comprehensively and imaginatively for all possible costs and benefits. The weights attached to the components may differ according to the level at which a decision is being made. Those used in determining a budget for a population would not necessarily correspond to those used in a clinical encounter.

Question 3: What social and ethical issues arise?

The development and improvement of screening services should not be seen as an alternative to improving services for people who have impairments. A woman's informed and considered decision not to participate in a screening programme should be respected and appropriate care and support offered to her, her baby and her family. Decisions require the free and informed participation of the woman: where there is a conflict of interest between parents it must be the woman who ultimately decides. She should however be entitled to involve her partner as much as she wishes, in particular to support her during the course of a termination. If it is desirable to include relatives and partners in screening, this must also be based upon informed consent.

A woman's access to a screening or diagnostic test should be independent of any decision she may make about the continuation of the pregnancy.

Genetic tests bring particular problems of confidentiality. Providers must take adequate steps to safeguard the interest of the screened individual. The woman should have access to information about herself and the pregnancy. Some parents prefer not to be told the sex of the fetus, and this wish should be respected. Where the sex is revealed, that fact alone should not be a reason for termination.

The early stages of pregnancy are not the best time to inform and educate people about the types, extent and purposes of screening. Education should start in schools; health, including basic genetics, should be in the core curriculum.

Government and health authorities have an ethical responsibility to ensure that screening services are provided

equitably. The quality of, and access to these services, should meet the reasonable expectations of an informed public. Doctors and other professionals have a duty to provide services that are both technically competent and sensitive to the personal dilemmas that screening involves.

There is no consensus about the meaningfulness or extent of any 'rights' of the early fetus. Some people have deeply held views against abortion, but while such a personal view should be respected people should be allowed to follow their own conscience in this matter. There is evidence that a conscientious objection to abortion on the grounds of fetal abnormality is the view only of a minority in our society.

The rapid pace of technical advance will open the prospect of prenatal testing for anomalies of a wide range of severity. Society may justifiably place limits on the types of conditions for which to provide testing.

Questions 4 and 5: The criteria for provision of screening programmes; their organisation and monitoring

Screening for fetal and genetic disorders can be carried out on the fetus, on the newborn, or potential parents. A programme of screening should ensure that each screening test is offered at the optimal time.

While there should be a nationally agreed policy for the provision of screening programmes the pattern of screening required dictates a need for facilities to be organised at supraregional, regional and district levels depending on disease prevalence and the complexity of the investigational procedures.

A single person should have overall managerial responsibility for the entire process, from public information and primary ascertainment to post-delivery care and support. This person would be responsible for quality assurance, and for co-ordinating the relevant professionals, and fostering support networks with self-help groups within the community. Such people should be identified at regional and district level. There is disturbing evidence of current inadequacy in communication among professionals and between them and the users of the services.

Once decisions have been made about what screening procedures are to be offered it will be possible to decide on which aspects of the screening programme require to be associated with a specialised clinical genetics service and which can satisfactorily be carried out by hospital and community obstetric services. Basic pregnancy screening is best carried out as part of normal antenatal care.

The confirmation of dates and the screening procedures should be carried out as early in pregnancy as is possible, and delay will affect outcome.

The next stage of the screening programme involves the further investigation of those found positive to the screening tests. Further investigation may require referral to more specialised services. In a significant proportion of cases the necessary investigations will not be completed by the middle of the second trimester. Current proposals to remove the availability of abortion above 18 weeks would severely restrict the potential benefit of screening programmes and are opposed by the panel. Any reduction in the availability of abortion couched in terms of weeks and not in terms of viability will not deal adequately with this issue.

At present, the pregnancy screening techniques with general application are largely limited to those concerned with neural tube defects and Down's syndrome and to the haemoglobinopathies. In the future, screening for heterozygotes, for the haemoglobinopathies, and possibly for common recessively determined disorders such as cystic fibrosis, will seek to identify carriers during their pre-pregnancy period and this will require a different pattern of organisation.

Carrier testing for heterozygote status for those genes for which particular ethnic groups are at high risk must be sensitively performed to avoid any suggestion of racism, and must involve the full support and understanding of the individuals and community concerned. A regional genetic service will require an effective database including some form of genetic register and a DNA bank.

Another essential requirement of a genetic and screening service is the provision of counselling. Experienced specialist counsellors should form part of a genetics service but training in counselling will also need to be more widely provided for health professionals in obstetric and community services. There should be specialised genetic counselling available to mothers at every stage of the screening programme. If a termination of pregnancy ensues, the mother should have access to a bereavement counselling service which should be available in every district to those who have undergone termination of pregnancy for whatever reason. An introduction to the appropriate support groups may be very helpful for mothers with affected fetuses whether terminated or not.

At a national level there will be a need to promote genetic services and initiatives from Royal Colleges on postgraduate training for this specialty are to be commended. There is evidence that basic education in modern genetics is deficient in the curriculum of medical students and other health professionals, and this should be remedied in basic and post basic training.

The Health Education Authority should initiate a specific programme to raise general public understanding of advances in genetics and of the developing services associated with them.

Monitoring and evaluation of screening services needs to be organised both in relation to process and to outcome. Definition of target groups makes it possible to assess the extent to which members of some groups have been offered screening, have taken it up, have been found to be positive and have taken up intervention options. Whenever possible confirmation of abnormality in terminated pregnancies should be sought. Simple systematic statistical monitoring along these lines is a logical extension of suitably devised recording procedures. Because of cross boundary flows for the services, district-based records systems are inadequate.

Outcome monitoring is essential despite the undoubted difficulties posed by the breadth of the objectives screening. Monitoring of changes in birth prevalence of

the disorders for which screening is carried out provides an assessment of only one legitimate objective. Facilitating access and choice in matters of reproduction are much more difficult to monitor and this may require specific research.

Research and development is required, not only for the technical advances of more effective screening but also for the identification and assessment of service innovation – especially in respect of the nature and adequacy of counselling services.

The complexity of these issues suggests a need for planning and co-ordination at national level with a remit to see that the good quality services at present deployed in some regions should be available throughout the country. Services should be able to respond appropriately to the opportunities to be expected from the new genetic technologies. These developments seem inevitably to require new monies not provided from within the National Health Service.

Panel members:

Professor Grimley Evans (Chair), Professor of Geriatric Medicine, University of Oxford; Professor Eva Alberman, Clinical Epidemiologist, The London Hospital; Ms Ruth Ashton, General Secretary, The Royal College of Midwives; Professor Martin Bobrow, Professor of Paediatric Research and Director, South East Thames Regional Genetics Centre, Guys Hospital; Professor Anthony Culyer, Professor of Economics, University of York; Dr Marian Hall, Consultant Obstetrician and Gynaecologist, Aberdeen Maternity Hospital; Dr Roger Higgs, General Practitioner, Camberwell, London; Mr David Kenny, Regional General Manager, North West Thames Regional Health Authority; Dr Marianne Rigge, Director, College of Health; Professor Hilary Rose, Professor of Applied Social Sciences, University of Bradford; Professor Alwyn Smith, Professor of Epidemiology and Social Oncology, University of Manchester; Professor Albert Weale, Professor of Politics, University of East Anglia.

Speakers:

Ms E Anionwu, Head of Brent Sickle Cell and Haemoglobinopathy Centre, London; Professor D Brock, Professor of Human Genetics, University of Edinburgh; Dr H Cuckle, CRC Senior Lecturer, Department of Environmental and Preventive Medicine, St Bartholomew's Hospital; Professor G Dunstan, Hon Research Fellow, University of Exeter; Professor M Ferguson-Smith, Professor of Pathology, University of Cambridge; Dr A Harding, Senior Lecturer in Neurology, The National Hospitals for Nervous Diseases; Professor R Harris, Professor of Medical Genetics, University of Manchester; Mr J Henderson, Associate Research Fellow, Health Economics Research Unit, University of Aberdeen; Professor B Hibbard, Professor of Obstetrics and Gynaecology, University Hospital of Wales; Mrs C Lavery, Honorary Secretary, The Society for Mucopolysaccharide Diseases; Dr S Macintyre, Director, MRC Medical Sociology Unit, University of Glasgow; Ms M McTair, Director, National Sickle Cell Programme; Dr B Modell, Consultant in Perinatal Medicine, University College Hospital; Dr M Pembury, Professor of Paediatric Genetics, Institute of Child Health; Dr M Richards, Lecturer in Social Psychology, University of Cambridge; Professor C Rodeck, Professor Obstetrics and Gynaecology, Queen Charlotte's Maternity Hospital; Mr S Thomas, Medical Writer, London; Professor N Wald, Head of Department of Environmental and Preventive Medicine, St Bartholomew's Hospital; Professor Sir David Weatherall, Nuffield Professor of Clinical Medicine, University of Oxford

THE TREATMENT OF STROKE

The Fifth King's Fund Forum: Consensus Statement

Every five minutes someone in the United Kingdom has a stroke. It is the cause of one in eight deaths and constitutes a formidable burden of disability and misery for patients, their carers and the wider community. Half of all first strokes occur in individuals aged 75 and over and, given the continued rise in the number of very elderly people in the population, stroke can be expected to remain a significant source of suffering for the foreseeable future. Despite these facts and their financial implications – the average health district in England and Wales spends at least £3 million on stroke services each year – policy makers, professionals and educators do not regard it as a high priority. There is no clear policy at district, regional or national level regarding the appropriate planning, organisation, implementation and evaluation of services for stroke patients and their carers. Such services as are provided in hospital, primary care and the community appear haphazard, fragmented and poorly tailored to patient needs and there is a striking lack of convincing data on the effectiveness of widely used medical, psychological and specific rehabilitative treatments. In the light of these deficiencies, this consensus conference was set up to establish the appropriate responses to stroke in the acute phase and up to six months after the event. Some of our recommendations will continue to be relevant at later stages.

Question 1: What are the responsibilities of service providers for patients and their carers?

The chief service providers for stroke patients are health and local authorities, family practitioners and voluntary organisations. A typical health district can expect to be providing care for about 1500 stroke survivors at any one time. It is essential that service providers ensure that these people and their families receive integrated and individualised care.

Each health authority should have a district stroke policy, laying down standards, identifying services and allocating resources. A named individual should be made accountable for its implementation and monitoring and for coordination with local and other authorities.

A stroke service should aim to achieve an accurate initial diagnosis, rapid identification of those needing specific treatment, skilled and knowledgeable nursing care, an early assessment of the patient's disabilities and implementation of a multi-professional care plan.

While there is no one model of good practice, it is recommended that *an integrated stroke service* should be developed. Such a service would develop a core team of nurses, therapists, social workers and doctors with expertise in meeting the needs of stroke patients and their carers. It would also provide a necessary focus for the education of doctors, nurses, and other professionals and could be a resource for information.

Inpatients frequently suffer from being scattered throughout the hospital. In future they should be managed in one specific location. This approach would have the advantage of drawing together patients requiring similar treatment and rehabilitation and would facilitate the development of a mobile stroke team which could span hospital and community. It could also provide day and respite care. Different models along these lines should be established, properly resourced and evaluated.

However, a high proportion of stroke patients are never admitted to hospital while many who are admitted go in for social reasons. The district stroke policy should take into account the needs of those not admitted, together with their carers, many of whom are elderly themselves. It should also embrace patients in private and voluntary establishments.

There must be continuity of care between the hospital and community. This requires good liaison between health and local authorities at all levels. Patients should not be discharged until adequate preparation has been made for both the patient and carer. There should be realistic assessment of the carers' ability to look after the stroke patient before discharge is attempted. The carer should be given a genuine choice about arrangements. The patients and carers should be kept fully involved at all times. Some patients are currently spending longer periods in hospital than their clinical state warrants due to a shortage of appropriate facilities in the community. This is unacceptable.

Little information is given to patients and carers. All patients are entitled to a clear account of the nature and causes of their stroke, an honest discussion of the risks of recurrence, the speed and nature of recovery and possible complications and clear advice about the resumption of physical, social and sexual activity. This should be assisted but not replaced by a clear fact sheet about stroke in general and other written material. Such material should be available in more than one language, and possibly in audio-visual form. More information rather than less should be given, care should be taken not to hold back information unnecessarily and the importance of listening to patients and carers is emphasised. Doctors can be overprotective towards patients, leading to resentment and complaints of unnecessary secrecy.

Stroke patients should also be put in touch with voluntary organisations, such as stroke groups and the Chest, Heart and Stroke Association, and carers with the Carers' National Association.

Where patients are not admitted to hospital, the GP has a key role in caring for the patients and in arranging any necessary diagnostic tests. After discharge, the onus is also on the GP to coordinate rehabilitation and continuing care services. If the GP does not undertake this personally, then he or she should nominate a key worker to undertake these responsibilities. The key worker should be easily available to the patient and carers. It is the role of the GP or key worker to fulfil the patient's information needs, as outlined above, although all professionals have a

responsibility to communicate fully at all times.

The GP or key worker should arrange to see and re-assess the patient at regular intervals. At the very least, this will help to overcome the feelings of isolation and abandonment expressed by so many stroke patients and carers. It would also enable the GP to discover any further medical or social problems.

Question 2: For presumed stroke sufferers what has been shown to be of diagnostic value?

An accurate history and a careful examination, are paramount in the diagnosis of stroke. Tests should be directed to specific questions:

1 Has the patient had a stroke?

2 Is the stroke due to an infarct or haemorrhage?

3 Is the stroke a manifestation of an underlying disease which requires treatment in its own right?

4 Are there identifiable factors such as high blood pressure which, if treated, may reduce the chance of recurrence?

A neurological deficit of sudden onset in a patient who on clinical examination has signs compatible with a vascular lesion permits a confident diagnosis of stroke. In some cases, however, there may be an inadequate history (as in a patient who lives alone or who has impairment of consciousness). The differential diagnosis will then include other intracranial pathology and the various causes of coma.

Stroke may be a manifestation of an underlying disorder – common diseases such as diabetes, or rarer conditions such as cranial arteritis or infective endocarditis. The clinical features will direct suspicions but screening tests (see Table 1) should be undertaken routinely in all cases. A chest X-ray may also be required. These tests will also cover identifiable risk factors whose correction may be of benefit in preventing recurrence.

Table 1: Routine Investigations in Stroke Patients

A full blood count (including platelets)

Erythrocyte sedimentation rate

Urea and electrolytes

Glucose

Cholesterol

Syphilis serology

Sickling test (when appropriate)

Urinalysis

Electrocardiograph

The differentiation of haemorrhage from infarct is, under certain circumstances, critical. It is impossible to do this clinically and the best way of determining the type of stroke is a CT scan within two weeks. The indications for CT scanning are in Table 2.

Table 2: Major Indications for CT Scanning

1 Uncertain diagnosis of stroke

2 Current or contemplated anticoagulation/antiplatelet therapy

3 Cerebellar haematoma suspected

4 Possible carotid endarterectomy

5 Suspected subarachnoid haemorrhage

6 Young patient

CT scanning can be undertaken as an outpatient investigation. There is a strong case for scanning the majority of patients who present with a presumptive stroke, excluding those in whom antiplatelet therapy is contra-indicated. The resources required to scan this large group of patients may well be outweighed by a reduction in recurrence of strokes, in myocardial infarcts, and in the associated costs of health care. At present only half of all health districts have a CT scanner. Nonetheless, local access to scanning facilities should be an essential part of a district stroke service.

Lumbar puncture should only be used where meningitis is suspected or where subarachnoid haemorrhage cannot be diagnosed by CT scanning. Isotope brain scanning is appropriate only when subdural haematoma has to be excluded and CT scanning is not available. Magnetic Resonance Imaging is a very sensitive method of imaging the brain, but it has not yet been proved to be of very great practical value in strokes. The use of angiography in an ischaemic stroke is usually linked to the intention to carry out a carotid endarterectomy. But ultrasound scanning as a preliminary screen will reduce this requirement. Echocardiography should be carried out where there is a strong clinical suspicion of cardiac embolic stroke and anticoagulation or other specific treatment is seriously considered.

Question 3a: What treatments have been shown to be effective in the first few days following a stroke?

No treatment has been shown conclusively to be effective in limiting the neuronal damage associated with stroke. Small randomised trials have suggested that some drugs (notably glycerol, naftidrofuryl and nimodipine) may be effective. There is insufficient evidence to justify these drugs outside large randomised trials.

Neurosurgery may be indicated in a few patients – those with a cerebellar haematoma or a haemorrhage due to aneurysm or arteriovenous malformation. A few strokes will be due to an underlying disease which should respond to treatment; for example cranial arteritis, myelomatosis, polycythaemia, thrombocytopenia or infective endocarditis. Care should be taken to avoid early complications of stroke including: chest infections and other causes of hypoxia, venous thromboembolism, urinary infections and incontinence, dehydration, constipation, pressure sores, falls and injuries, painful shoulder and spasticity.

Question 3b: What has been shown to reduce recurrence?

There is strong scientific evidence that antiplatelet therapy for ischaemic strokes reduces recurrence. We recommend low dose aspirin (150-300 mgs daily). In the absence of CT scanning, used to exclude intracerebral haemorrhage, prophylactic aspirin may still carry a favourable benefit-risk ratio but cannot be safely recommended.

There is also evidence that the reduction of high blood pressure and high blood cholesterol levels reduces the risks of subsequent vascular events. Nevertheless, it is important that hypotensive therapy should not be too vigorous or begin too early, because of the risk of reducing the blood flow to the brain.

Anticoagulation is frequently being used in the treatment of ischaemic stroke associated with atrial fibrillation, cardiac valve disease, myocardial infarction with presumed mural thrombus or carotid stenosis. Although this has theoretical appeal, there is little supportive scientific evidence. Similarly, carotid endarterectomy is frequently performed for carotid artery disease, with even less empirical support. Randomised trials addressing some of these issues are currently in progress.

Excessive alcohol consumption should be reduced to facilitate the control of high blood pressure. Patients should be encouraged to stop smoking as this may reduce cerebro-vascular events and will certainly reduce ischaemic cardiac events.

Question 4: What assessment and rehabilitation is appropriate in the first six months for patients and their families or carers?

Multidisciplinary assessment should begin at once and rehabilitation as early as possible. In addition to a precise definition of neurological deficit, assessment should cover motor and sensory function, swallowing, cognitive function and mood, communication skills and performance of activities of daily living. For carer as well as patient assessment should include general health, psychological and social problems, support network, housing, finance, employment and leisure activities.

Assessments according to agreed standards must be done at regular intervals, the exact interval being determined for each individual.

Certain principles should be applied throughout rehabilitation of the stroke patient. These include:

- documenting impairments, disabilities and handicaps and where possible measuring them using simple, valid scales
- maximising independence and minimising learned dependency
- taking account of the whole person and the environment

Participants in the rehabilitation process include nurses, physiotherapists, occupational therapists, speech therapists, dieticians, chiropodists, social workers, psychologists and doctors. They should work as a team. For the team to work effectively, there must be trust and respect for each other's expertise. A key worker should be identified for every patient at every stage to coordinate an individual plan and to provide education and positive support. The professional's role is not only to assess and treat but to provide education and positive support to carers.

Throughout the rehabilitation period, the key worker has a responsibility to keep patients informed of the nature of their problems and carers should be actively involved in the entire process. The prospects for improvement and the goals of therapy must be discussed with patients and, where appropriate, carers.

Major problems in the rehabilitation phase need to be addressed. These include:

- misunderstandings and rivalries between professionals
- breakdown of communication between professionals, patients and their carers
- insufficient appreciation of the impact of stroke on the patient's family
- ill-prepared and sometimes unplanned discharge home
- serious shortage of therapy
- long periods in which patients are unoccupied
- ill-considered admission to hospital
- failure to recognise and respond to mood disturbances
- delegation of care to inadequately trained medical staff
- confusion caused by too many people being involved.

There is no doubt that many consumers derive considerable satisfaction from the general stimulating effect of therapy and the practical benefit of much of the advice given. It is clear that the rehabilitation process can be effective, but there is little evidence of which aspects are beneficial. The personal and professional skills of therapists must not be undervalued. Many therapists are themselves keen to evaluate rigorously their work and to identify those components which are most effective. We support them.

Question 5: Considering the costs and benefits of the components of stroke care, what are the principles of good practice in the provision of services?

Stroke care should be reorganised according to the following:

- Standards must be agreed in collaboration with all the professionals involved, taking account of the views of patients and carers. The service must be strongly led and co-ordinated, be cost-effective and kept under regular review, bearing in mind the large numbers of

different professional groups involved. The service should be planned at district level to include primary and community as well as hospital services. Where there is a joint care planning team this should be one of its prime responsibilities.

- The delivery of care must be monitored to ensure that the agreed standards are being implemented for individual patients. Monitoring should include consumers' views.
- For most stroke patients the stay in hospital is a short prelude to a life-long disability. In considering the balance between hospital and community care it should be remembered that costs and benefits fall not only on the NHS and other agencies but, above all, on patients and their families. An effective community service must take account of this and plan accordingly. Since the needs of individual patients and carers vary there should be flexibility in the provision of community care, both upon the onset of stroke and after hospital discharge. In particular, attention should be paid to integrating hospital and community care at all times.
- New organisational structures and changes in budgetary systems for stroke services may be required to encourage this flexibility. One approach could involve the named individual responsible for implementing and monitoring a district's stroke policy. This person could have budgetary responsibility, and be able to buy individual components of care, including those provided by the voluntary sector.
- There has been little evaluation of the effectiveness and cost of most components of stroke care. This is urgently needed. In evaluating treatments, or even packages of care, the randomised trial is almost always the most effective method provided appropriate outcomes are measured, including patient satisfaction. However, at times other research methods might be more practical and appropriate. Multi-professional approaches to research should also be encouraged. Research should be seen as part of the career development of all professionals and not just hospital doctors. In particular therapists need to develop research skills and this will require access to research funds and, more importantly, training in research methodology. The lack of evaluation can be rectified only by earmarking research funds in proportion to the health care resources devoted to stroke.
- Education and training should be provided for all professionals, carers and patients to increase their knowledge about stroke, improve their skills in dealing with the condition and change attitudes so that the needs of stroke patients are given higher priority and more status. Additional resources must be provided.

It is important to raise the awareness of politicians, public and the media and a programme of education and promotion of what needs to be done should be undertaken.

All the recommendations in this consensus statement could and should be accomplished within the present system of health care in the UK. The quickest and most effective way to implement these recommendations would be the formation of integrated district stroke services to encompass care, education and research at every level both in hospital and in the community. To ensure that such a service can be implemented health authorities must provide sufficient staff and resources.

The cost of better services for stroke patients will increase but this could be considerably offset by concentrating existing resources, avoiding unnecessary investigations and ineffective treatments, and setting and monitoring standards of care.

Panel members:

Anthony Clare (Chair), Medical Director, Psychiatric Unit, St Patrick's Hospital, Dublin; Michael F Drummond, Professor of Health Service Management and Director of the Health Service Management Centre, University of Birmingham; Annabelle Ferriman, Health Correspondent, Observer Newspaper; Bryan Heiser (Lay representative), Project Officer, Consumer Research, Camden Council, London; Nora Lamb, Chief Officer, Eastern Health and Social Services Board, Northern Ireland; Jill Pitkeathley, Director, National Council for Carers and their Elderly Dependants, and Director, Carers National Association; Ian Russell, Director, Health Services Research Unit, University of Aberdeen; Simon Street, GP Trainer and Tutor, Department of Community Medicine and General Practice, Oxford University; Raymond Tallis, Professor of Geriatric Medicine, University of Manchester; John Todd, District Medical Officer, Sheffield Health Authority; Catherine van de Ven, Superintendent Physiotherapist, Roehampton Disablement Services Centre; Charles Warlow, Professor of Medical Neurology, Edinburgh University

Speakers:

Robert Anderson, Research Manager, European Foundation for Improvement of Living and Working Conditions in Dublin; Janet Askham, Assistant Director, Age Concern Institute of Gerontology at King's College London; Dr David Bainton, Department of Epidemiology and Community Medicine, University of Wales College of Medicine; John Bradshaw, Consultant Neuroradiologist, Frenchay Hospital, Bristol; John Brocklehurst CBE, Professor of Geriatric Medicine, University of Manchester; Rory Collins, Medical Co-director, Clinical Trial Service Unit, Oxford University; Christopher Davidson, Consultant Physician, Birch Hill Hospital, Rochdale; Pam Enderby, District Speech Therapist, Frenchay Health Authority; Alan House, Oxfordshire Community Stroke Project; Meryl Hudson, HIV Information Research Nurse, St Mary's Hospital, Paddington; Richard Langton Hewer, Director, Stroke Unit, Frenchay Hospital, Bristol; Nadina Lincoln, Research Co-ordinator, Research Unit, Nottingham General Hospital; Pru Oswin (Lay representative), National Administrator, Chest, Heart and Stroke Association's Volunteer Stroke Scheme; John Pathy, Professor of Geriatric Medicine, University Hospital of Wales; Frank Clifford Rose, Director, Academic Unit of Neuroscience, Charing Cross and Westminster Medical School (University of London); Peter Sandercock, Senior Lecturer and Honorary Consultant in Neurology, University of Edinburgh; Derek Smith, District General Manager, South Bedfordshire Health Authority; Joy Townsend, Health Economist, Medical Research Council; Derick Wade, Consultant Neurologist, Rivermead Rehabilitation Centre, Oxford

INTENSIVE CARE IN THE UNITED KINGDOM

Report from the King's Fund Panel – May 1989

Intensive care units (ICU) provide facilities which have resulted in major improvements in the chances of survival in some conditions which were previously considered life threatening; in these cases the effectiveness of intensive care is not in doubt. Yet evidence is less clear cut on the benefits and costs of treatment for the complex illnesses which now afflict the bulk of patients admitted to intensive care units. Furthermore, there is concern about the ill effects which may arise. These include loss of the patient's dignity, privacy and autonomy, and the perception (however it is founded) that some procedures may produce more harm than benefit. These issues are relevant to all medical practice but they have particular application in the case of intensive care, not least because of the high costs of intensive care provision. At a time when resources for health services are tightly constrained, it is important to ensure that the money available is used effectively and efficiently.

Against this background, the King's Fund convened a multidisciplinary panel (members are listed on page 58) to consider the following questions and to prepare a statement for discussion at a consensus conference:

- Is there scientific evidence that ICUs cause a decrease in mortality and morbidity?
- What criteria should be set for admission and discharge to ICUs?
- Which classes of patients are likely to benefit most from which procedures that are carried out in an ICU?
- For what extra cost is therapeutic benefit gained by using intensive care?
- What scale of provision is needed in the NHS? What are the pros and cons of a large multi-specialty unit or small sub-specialty units?

The panel met on four occasions during 1988. It drew on the experience of its members in addressing the above questions, reviewed the published literature on ICUs, and considered papers prepared by Professor Bryan Jennett, University of Glasgow, Mr Alan Shiell, University of York, Dr Saxon Ridley, Western Infirmary Glasgow, and evidence from two surveys of ICUs prepared by the Association of Anaesthetists and the Medical Architecture Research Unit (MARU) at North London Polytechnic.

It soon became apparent that the lack of data in the United Kingdom (UK) would make it impossible to answer the questions posed. Accordingly, the panel determined not to hold a consensus conference, but instead to produce a report highlighting the absence of evidence, and calling for a substantial programme of research.

Definitions of intensive care

A definition favoured by the panel is:

> *a service for patients with potentially recoverable diseases who can benefit from more detailed observation and treatment than is generally available in the standard wards and departments.*

An ICU is then a place and not a form of treatment. It provides special skills and experience from medical and nursing staff for the care of critically ill patients and particularly those in whom there is expectation of failure of one or more organ systems. It also provides a centre for physiological measurements, nursing procedures and therapeutic manoeuvres which are not practicable in the general wards. Procedures undertaken in an ICU are done there on the assumption, understandable but unproven, that the concentration of special facilities and expertise gives better results and reduces costs.

What intensive care provides varies according to the activities of the relevant hospital and the predominant mix of patients admitted for intensive attention. The outcome of intensive care depends not only on the facilities provided in the unit and the skill and timing with which they are administered, but also on the case mix of problems presented by the surgeons and physicians who make the initial decisions which result in their patients requiring intensive care.

Generalisation about intensive care units may be quite inappropriate unless their heterogeneity is better recognised. Hospitals specialising in a particular condition may regard as routine a procedure considered specialised elsewhere, and so undertake it in a ward or department other than ICU. There are relatively few conditions for which an ICU is essential, and few procedures which can only be done, or done safely, in such a unit.

Much of intensive care involves temporary replacement of the function of one or more organs, for example ventilation for respiratory failure or dialysis for renal failure, and it is in these cases of single organ failure that the best results are achieved. It is also used for monitoring to detect and respond rapidly to serious complications in patients judged to be at risk of becoming critically ill. The bulk of intensive care work in the UK today concerns the management of patients who, after trauma, major surgery or overwhelming illness, suffer from malfunction of several organs. The outcome for such patients is much more unpredictable, depending fundamentally on the severity of the presenting problems.

Criteria for admission to ICU

Primarily intensive care should be given in the expectation of beneficial consequences when such benefits can be achieved at acceptable cost. It should not be provided in situations where possible harm outweighs the remote prospects of benefit. Within a group of patients for whom intensive care is considered, the likely outcome of such care is a major consideration. The panel suggests that a simple scale is used:

- Expected to survive; potentially recoverable (a good chance)
- Prognosis uncertain
- Death probable shortly whatever is done
- Death apparently imminent

In view of public expectations of what medicine can achieve, the panel recommend that in the UK intensive care should be considered for the first two of these categories if the costs are not prohibitive.

It may also be appropriate to admit potential organ donors (that is those patients who fulfil the criteria of brain stem death, or expected to do so) because procedures such as mechanical ventilation are required to keep the organs in good condition. In such cases the recommended policy is to provide optimal care for the dying patient until it is agreed that further therapy is useless, when there is a shift in emphasis from prolongation of life to the maintenance of organ viability.

There is a more difficult problem with those whose prognosis is uncertain because these patients will eventually be reclassifiable into one of the other categories. In the absence of sound data on which to base decisions these patients should also be treated in ICUs. But it is this group for whom there is an urgent need to conduct clinical trials to evaluate the need for intensive care.

Patients whose death is probable shortly whatever is done provide a different dilemma. It is often possible to produce temporary improvement and to allow time for relatives and the medical team to come to terms with the inevitability of death. It is in these cases that the question of benefit to the patient is most difficult to assess and here also that the question of the use of resources which might benefit others instead must be considered.

The panel recommends that each ICU should prepare a set of guidelines setting out criteria for admission to the unit to help doctors and other staff determine priorities for treatment.

The concept of benefit

There is often disagreement about what constitutes benefit. Doctors and others disagree about the probability of the benefit and about degree of benefit that should be regarded as worthwhile. In such cases, benefit should be assessed not only in terms of survival but also in terms of the quality of life.

The concept of benefit has been the subject of numerous interpretations. The panel considered the question of whose judgement of benefit should prevail in doubtful cases? The Hippocratic (also the British and the American Medical Associations') view is that, the physician should benefit the patient according to his/her ability and judgement.

This statement is paternalistic and depends solely on the doctors' subjective judgement. It makes no provision for the autonomy of the patient and as an extreme has even been evoked in defence of bizarre experimental therapy and of enforced feeding and unwanted invasive treatment. The panel prefers the following: The physician should benefit the patient according to the most objective judgements available unless the patient expresses a competent and informed wish for an alternative course.

Our firm support of the right to make an informed decision to forego intensive care or any other therapy should not be construed as an endorsement of euthanasia or assisted suicide, active or passive. Moreover the right to refuse intensive care should be exercised only by an informed person who is evidently rational and competent. In cases in which competence cannot be assessed, decisions must rest with the doctor, but always in the context of close consultation with the family, and a presumption in favour of the preservation of life must predominate. Conversely, there is no moral or legal obligation to provide treatment on request when there would appear to be no possibility of benefit.

An ability to provide a more accurate prognosis than is possible at present would help avoid some of the conflicts which arise. Severity of disease scores such as the Apache II[1] (acute physiology and chronic health evaluation) score have a good deal to recommend them, provided they are not applied rigidly in individual cases. Selection for intensive care should be based on broad concepts of prognosis derived from statistical analysis of comparable cohorts of patients backed up by sound clinical trials. Such data are sadly deficient in the field of intensive care in the UK.

Criteria for discharge from ITU

Four broad situations can be envisaged:

- the patient has recovered and is stable
- the immediate threat has been alleviated but the patient remains at risk unless under close observation
- the immediate threat has been alleviated but the patient is expected to die shortly
- death is agreed to be imminent, even if intensive care is continued.

Patients in the first category should be discharged as soon as possible. Those in the second may be discharged or retained depending on the needs of other patients and the available facilities elsewhere in the hospital.

Patients who are stable but expected to die can be discharged from the ICU but the panel recognised that in some circumstances this may generate a sense of rejection in patients and family at a a time of particular distress. In other situations, the atmosphere of another department may be a better environment in which to come to terms with the patient's position. Competing pressures in ICU or the general ward will inevitably affect this decision.

Withdrawal of support for patients in whom the outcome looks hopeless is always difficult. Often one manifestation of the disease can be alleviated when the

1. The APACHE II system was developed by the ICU Research Centre at the George Washington University Medical Center, USA, to estimate the pretreatment risk of death before treatment in severely ill patients.

underlying illness cannot be reversed. This ability to achieve limited success, and the rapidity with which deterioration and death follows cessation of treatment, make it difficult to withdraw support. The decision is then how best to terminate unsuccessful management.

Sometimes it is necessary to delay implementing decisions to withdraw treatment while relatives assimilate and come to terms with the situation. Part of the cost of intensive care is incurred by responding to these humanitarian requirements as distinct from those relating simply to the patient's prognosis. But again, competing pressures may restrict the ability of an ICU to devote more than a limited resource to caring for the terminally ill, a task which may sometimes be better undertaken elsewhere. At all stages during treatment, relatives should be kept informed of the patient's condition and prognosis, and any information about withdrawing support must always coincide with discussion of what will be done to ensure comfort and dignity.

Criteria for the use of various interventions

The reasons for intervention in intensive care include diagnosis, monitoring and treatment. Invasive interventions give rise to most concern because they can result in unjustified discomfort, harm and unnecessary expense if used routinely rather than when specifically indicated. Careful audit is needed, particularly when procedures initiated for diagnostic purposes are continued as a means of monitoring. This progression is only justified if there is a significant risk of change and earlier or more accurate recognition of it would influence outcome. *The panel recommends that each ICU should prepare a set of written guidelines on the use of various interventions and procedures by which their efficacy may be audited in each case.*

Therapeutic interventions in the ICU are curative, supportive or prophylactic. The support of individual functions is a major part of intensive care, designed to buy time for natural resolution or a response to other often simpler measures. This means that it is difficult to equate the results of specific activities with outcome. Many of the most expensive and time consuming manoeuvres do no more than modulate results which are largely dictated by the nature of the underlying disease.

Cost/benefit relationships

There are no published evaluative studies relating cost to outcome from British ICUs. Those that are available from the USA, Europe and Australia are unlikely to be applicable to the UK because of differences in case mix, quality and availability of support. Standard methods of costing in the NHS do not allow direct calculation of ICU costs. New methods of budgeting and resource management which are envisaged in the plans to develop the NHS may help to overcome this but the information systems which would enable ICU costs to be identified precisely are not yet part of routine health service management.

To assist in our enquiry, the King's Fund and the Centre for Health Economics at York University jointly financed and conducted an exploratory study, in collaboration with three ICUs to attempt to relate, in a systematic way, data on workload, treatment, costs and outcome. The results, though not conclusive statistically, indicate that such investigations are feasible, and potentially rewarding. The panel recommends that priority should be given to extending this and other comparable analyses as a matter of urgency.

Levels of provision

Current Department of Health policy is set out in Building Note 27, originally published in 1970 and revised in 1974. This recommends that the number of beds in an ICU should be some 1 to 2 per cent of total acute beds and that the average DGH should have an ICU with 6 to 8 beds. According to recent surveys conducted by the Association of Anaesthetists and the Medical Architecture Research Unit, most units are smaller than envisaged by the Department of Health but there is considerable variety. Those units providing less than 4 beds and handling fewer than 200 cases per annum may be uneconomic. Such units may be undertaking too little work to provide the highest quality of care as has been suggested by the Association of Anaesthetists. There may be a case for concentrating intensive care provision in a smaller number of units each of which would have a workload large enough to enable it to develop appropriate expertise.

The absence of data on workload, outcome and costs, and the heterogeneity of ICUs, make it evident that any recommendation about future provision must be highly speculative. There would appear to be a need for flexibility and for local rather than national planning. In some situations, the patient will benefit most from specialist care at regional centres so that expensive ICU facilities would not need to be replicated in every DGH.

Recommendations

Having carefully considered the published literature on intensive care and evidence submitted, the panel has reached the view that there is a serious lack of evidence about its costs and benefits. In part, this stems from uncertainty about who is responsible for organising and managing these services, and the consequent failure to collect data about activity and outcomes. Understandably, there has been no clinical trial of intensive care as such a trial would present formidable practical difficulties. The absence of the economic evaluation of intensive care is much less defensible and requires urgent attention. Against this background, the panel recommends:

Responsibility

Each intensive care unit should identify someone to be responsible for:

- ensuring the unit has a clinical policy in the form of written guidelines
- ensuring that the above policies are implemented

- collecting and evaluating data on the clinical outcome and costs, in general and of the care of individual patients
- coordinating the clinical care of individual patients

The person responsible need not necessarily be the same in each case. As conflicts may still arise despite clinical guidelines, an independent mechanism for their resolution should be available.

Research

There is an urgent need for intensivists to agree what data (clinical and economic) should be collected by every ICU to allow proper audit. Especially important is the need for prospective research to evaluate certain specific practices in intensive care. Differences between units and the variability of their practices might be used to evaluate areas of uncertainty and create hypotheses which could be tested if necessary by randomised controlled trials.

Panel members:

Dr John G G Ledingham [Chair], Nuffield Department of Clinical Medicine, John Radcliffe Hospital, Oxford; Dr Pat Ashworth, Department of Nursing and Health Visiting, University of Ulster; Dr Margaret Branthwaite, Consultant Physician, Brompton Hospital; Professor Ronald G Clark, Department of Surgery, University of Sheffield; Mr Chris Ham, Health Analyst, King's Fund Institute; Professor Ian McA Ledingham, Department of Emergency and Critical Care Medicine, United Arab Emirates University; Dr David Lamb, Department of Philosophy, University of Manchester; Mr Alistair Liddell, General Manager, East Anglia Regional Health Authority; Dr Klim McPherson Department of Community Medicine and General Practice, Radcliffe Infirmary, Oxford; Dr Joseph Stoddart, Consultant in Charge ITU, The Royal Victoria Infirmary, Newcastle upon Tyne; Mr Reginal Talbot, Director, Headway, National Health Injuries Association; Professor Alan Williams, Institute of Research in Social Science, University of York

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BLOOD CHOLESTEROL MEASUREMENT IN THE PREVENTION OF CORONARY HEART DISEASE

The Sixth King's Fund Forum: Consensus Statement

The sixth King's Fund Forum was held in London from 26 to 28 June 1989. A panel of 12 listened to evidence from experts in public sessions attended by 200 people including professionals from many fields as well as public and press.

We were asked to address the following questions:

1 What is the relationship between dietary fats, blood cholesterol levels and coronary heart disease?

2 What individual or community-wide dietary or other interventions can reduce blood cholesterol levels and the risk of coronary heart disease safely?

3 How useful is the measurement of blood cholesterol levels in identifying individuals at risk of coronary heart disease and in their subsequent management?

4 Should the measurement of blood cholesterol levels be an integral part of the assessment of individuals at risk of coronary heart disease, and what are the most effective options for organising such services?

5 How will the costs of such services influence the choice of options made?

As a Panel, we took the view that cholesterol testing should be seen in the context of the primary goal of reducing mortality and morbidity from coronary heart disease (CDH). This drove us to the conclusion that cholesterol should not be considered in isolation, but in association with other risk factors for CHD. Thus, we have dealt with the points raised in the questions in a more general context. However, we believe that we have provided answers to the five questions we were set, although not in the form of direct responses.

Some of the debate seemed to rest on insufficient data, not all of which had been validated by research, and much of what we heard was mere assertion. We were particularly struck by the lack of information on costings, and the frailty of the assumptions on which the economic assessments presented to us were based.

Coronary heart disease

Coronary heart disease (CHD) is the most important cause of death in middle aged men in most industrialised countries. It is a major cause of death in women and a significant cause of morbidity in both sexes. The rates for CHD in the United Kingdom are among the highest in the world. CHD accounts for over a third of all deaths in men aged between 40 and 70. In the UK rates have changed comparatively little over the last 20 years, but there has been a marked decline in some other countries, notably the USA. Within the UK, CHD death rates are higher in Scotland and Northern Ireland. There is also a higher risk in the Asian community and in manual socio-economic classes.

Epidemiological evidence shows that the incidence of CHD is largely determined by life-style and environmental factors. In certain parts of the world CHD is comparatively rare. Yet when people from these countries emigrate to areas where CHD is more prevalent, their rates move towards those of the new country.

Among risk factors found to be strongly associated with CHD are high blood cholesterol levels, a family history of the disease, cigarette smoking, high blood pressure, and a lack of exercise.

Blood cholesterol and CHD

In those countries with a high incidence of CHD, average blood cholesterol levels in the population are also high. Correspondingly, average blood cholesterol levels are low in countries where the incidence of CHD is low. Within populations, the higher the blood cholesterol level of an individual the more likely that person is to develop CHD. This relationship is continuous and there is no threshold of risk.

Although those with the highest cholesterol levels are at the highest risk of CHD, most deaths attributed to CHD occur in people with blood cholesterol levels in the moderate range. This is because the majority of the population falls into the 'moderate' category. High cholesterol levels interact with other risk factors synergistically modifying the risk of CHD. The risk attributable to a high blood cholesterol level on its own is not as high as that when it occurs in conjunction with other risk factors.

Expert reports based on international epidemiological evidence, and controlled dietary experiments, show that blood cholesterol levels are influenced by the amount and ratio of polyunsaturated and saturated fat in the diet. We accept the recommendations of other expert reports such as the Government's own COMA Report.[1] On the prevention of heart disease which have the following common features:

- a reduction in total energy derived from dietary fats
- a reduction in the intake of saturated fats, which could be achieved through an increase in the intake of polyunsaturated fats.

The prevention of coronary heart disease

The most promising strategy for reducing CHD is by tackling the three major risk factors: smoking, high blood pressure and high blood cholesterol.

Much of the success in reducing coronary disease so far is likely to have been a result of the reduction in cigarette smoking. The treatment of high blood pressure has reduced death rates from stroke, heart failure, and

1. Committee on medical aspects of diet. Diet and cardiovascular disease. Report on health and social subjects no. 28. London, HMSO,1984.

kidney failure, but appears to have had little effect upon mortality from CHD.

It is probable that a major further impact on CHD mortality will only be achieved through reducing blood cholesterol levels and will depend on a general reduction of blood cholesterol levels in the whole community. This is because virtually the whole of the British population has levels of blood cholesterol which are high by international standards, and is therefore at increased risk. This requires a change in national dietary habits.

If diet fails to reduce high blood cholesterol levels there are several categories of drugs which may do so – especially the recently introduced HMG Co-A reductase agents. These drugs show promise, but have not yet been tested adequately for their long-term adverse effects and efficacy. Previously available drugs have been shown to reduce the incidence of heart attacks, but they have not been shown to lower overall mortality, and may have increased non-cardiac mortality and morbidity.

A national strategy

We believe that any serious attempt to reduce the general blood cholesterol in the entire population requires a national strategy linking food supply with health.

The aim of such a strategy must be to achieve an overall reduction in blood cholesterol levels in the whole population by dietary means. It should be part of a broad health promotion strategy aimed at reducing risk factors for CHD and other diseases. If this were achieved a much smaller proportion of the population would require cholesterol-lowering drug treatment or need treatment for subsequent CHD. The failure to initiate such a preventive programme places an undesirable reliance on medical correction of blood cholesterol levels through medication.

Such a strategy is long term but is long overdue and now urgently required. It requires clear objectives, co-ordination across government departments with concerted action and regular review at national and local levels. Most of all it requires political will.

Existing food policies do not amount to a coherent national strategy to promote health. They often ignore health considerations and may even be inimical to health. It is both desirable and feasible to introduce health objectives into UK national food policy and to incorporate this into all national policies affecting food. The negative aspects of existing policies such as those which subsidise the consumption of saturated fat should be removed.

Such a national policy needs to take account of supports to food producers, production quality, food composition, food prices, food labelling, catering and education. Recent fiscal measures in favour of lead-free petrol and the positive public response to them indicates that price changes can profoundly affect demand. Welfare policies can also influence the nutritional value of the national diet. A national strategy should not be divorced from local health promotion initiatives which need to work through a diversity of agencies. Health authorities or boards have a clear leadership role, particularly in ensuring that relevant services reach those with traditionally poor access.

It is not our remit to define a national policy, but such a policy is a prerequisite for successful health promotion initiatives. The public will then be better able to respond and act upon a consistent message linking food and health in policy, provision and promotion. It is for government to decide how to implement an effective food strategy given the division of responsibility between government departments, other agencies and the European Community.

We recognise that this is a new departure for public policy in the UK, but the increased public demand for healthy food and a growing commercial interest in meeting this demand indicates that the climate is right.

We would emphasise that mass public education campaigns aimed at behavioural change at the individual level cannot be expected to succeed in the absence of the overall national strategy which we advocate. Individually oriented campaigns are known to be least readily accepted by those social groups most at risk. Also, behaviour, especially in the area of food choice, is not always voluntary. National policies are required to remove the barriers to change experienced by the most disadvantaged members of the community.

Risk assessment and health promotion

The second major element of our recommended approach is a strategy to identify men and women at increased risk of CHD and to target interventions at this group. We recommend therefore a concerted approach which would make opportunistic risk assessment and health promotion an important priority in primary care. A high proportion of cases of CHD arise in individuals who have easily identifiable risk factors for the disease, that might be detected either by the individuals themselves or with assistance from a health worker. These include cigarette smoking, a high fat diet, high blood pressure and a family history of CHD under the age of 50 years. We consider it essential that all GPs be encouraged to record such risk factors in their practice records, and that patients be provided with appropriate advice on healthy lifestyles by a member of the primary health care team. This must be reinforced and complemented by the work of the health authorities and their community health services, occupational health services, voluntary bodies and the private sector. The aim of this strategy is to enable people to know their risk status in order to modify their behaviour accordingly.

Measuring blood cholesterol

It is essential that blood cholesterol levels should not be seen in isolation from other risk factors, because the risks associated with raised blood cholesterol are synergistic with other risk factors rather than simply being additive. For this reason we recommend that individuals should be selected for blood cholesterol testing based only on the presence of one or more other major risk factors for CHD (including those with previously identified CHD). Those without such risk factors should not be encouraged to have their blood cholesterol assessed but all individuals should

be encouraged to change their diet in order to lower cholesterol levels. We are unconvinced that offering blood cholesterol testing to all individuals is justified, given that a high proportion of those at increased risk of CHD could be identified through the opportunistic risk factor assessment and selective cholesterol testing strategy outlined above.

Cholesterol measurement is of value in identifying people at high risk who may benefit from special dietary regimes or drug therapy. We therefore recommend cholesterol testing for those with a family history of premature coronary disease, clinical features of hyperlipidaemia, those with manifest coronary disease, those under treatment for diabetes and high blood pressure and those with a long history of heavy smoking. Strict adherence to rigid blood cholesterol threshold levels recommended by several groups is not justified by the evidence.

Blood cholesterol tests should only be carried out where there is access to facilities for obtaining accurate assays of blood cholesterol which are subject to regular and strict quality control. Information and counselling should be available to help interpret the results of tests (including the variations in measurement that may arise due to natural variations in individuals and errors in the testing procedure). Advice and counselling should also be given to people identified as at high risk to help them to take appropriate corrective action. Care should be taken that those tested are not unduly alarmed by the results, so that those with high levels are encouraged to take positive action while avoiding unnecessary anxiety, and that those whose blood cholesterol levels are not regarded as high are not lulled into a false sense of security.

An argument advanced for testing blood cholesterol levels in all individuals is that it may be a potent means by which people can be motivated to follow advice to alter their diet. While theoretically plausible we were presented with no evidence to support this.

One of the most strongly expressed arguments for universal testing is the need to identify individuals with very high levels of blood cholesterol due to a genetic defect (familial hypercholesterolaemia) who are at high risk of early death from CHD and whose cholesterol levels are unresponsive to dietary change. However, this condition affects only a small percentage of the population (about 0.2 per cent). Other approaches might be used to detect many of these individuals through detailed family histories of CHD and establishing registers of such families. In addition, all first degree relatives of any person who develops symptomatic heart disease and who has a high blood cholesterol level should have their cholesterol measured. Case-finding should be led by lipid specialists and cardiologists.

A possible danger associated with widespread testing is that it may distract from, rather than complement, other health improvement strategies, such as the development of population-wide approaches to healthier eating. We also fear that it may create an inappropriate demand for drugs for people whose risk could be lowered by dietary measures.

Costs

The available economic evidence on the cost-effectiveness of alternative strategies for reducing blood cholesterol is unsatisfactory, not least because of the absence of good data on the relative effectiveness of the specific intervention strategies that have been proposed. There is no clear evidence available on morbidity and mortality changes, whether in response to diet modification or to drug intervention strategies.

However, a few general points about cost are fairly clear. While the unit cost of taking and measuring blood cholesterol may be low (an estimate of £2.50 was suggested to us), establishing baseline levels and monitoring change would require a sequence of several tests. The cost of counselling following cholesterol measurement depends critically on who does it. To be effective it cannot be limited to a short, one-off, consultation. Drug therapy costs about £500 a year for each patient, and may have to be provided for the rest of the patient's life. Estimates from a variety of sources suggest that drug therapy is currently an expensive way of generating 'life-years saved' relative to other interventions. But, even if drug treatment becomes more effective any policy that leads to sizable proportions of the population receiving drug treatment will represent a major financial commitment. If we accept, as has been implied by a number of participants, that drug treatment might be appropriate for up to 10 per cent of men aged 40–69, the NHS drug bill in England and Wales would be increased by some £400 million annually, or approximately 20 per cent.

In the absence of firm costings we are not able to express a view on cost in relation to benefits, except that drug based therapy is likely to be considerably more expensive than dietary interventions. We believe, but regrettably are not in a position to be able to prove, that our proposed population strategy is likely to be more cost-effective particularly when account is taken of all the beneficial health effects of dietary modification. But however cost-effective, this strategy will consume resources.

Training and service implications

The strategy we have outlined needs to be supported by an extensive training programme. There will be an increase in demand for training in the primary health care sector in particular, as this is where most of the demand for advice and care will fall.

Although primary health care teams will shoulder the major responsibility and will require additional training in counselling and giving dietary advice, other health professionals, including hospital consultants, should also participate in the education programme. This will require the deployment of more dietitians and health promotion specialists. These additional responsibilities, as well as the possible increase in demand, must be recognised in setting up budgets and allocating resources. Special targeting of resources will be required for deprived areas.

A major initiative such as we propose will not succeed unless there is coordination of the provision of such services at a local level. The general practitioner's records

should be regarded as the focus for all information on CHD. The results of risk assessments and advice given in other settings should be communicated to the general practitioner.

We recommend that the implementation of our proposals for primary care be included in the proposed medical audit system to be developed by family practitioner committees. In addition we recommend that the overall provision of health promotion and risk assessment be an integral part of the public health responsibility of regional and district health authorities.

Research

We have mentioned the lack of information on some topics. We would particularly recommend additional research in the following areas:

- the possible motivational effect of cholesterol measurement in encouraging people to accept and act on dietary and other life-style advice
- the effectiveness of drugs currently in use, or new drugs as they are introduced, with particular reference to costs, safety and possible side effects. This will require large-scale trials
- the cost-effectiveness of the approaches we have recommended and the costs of selective or other screening programmes
- the development of effective alternative strategies to widespread cholesterol measurement to identify people at risk of familial hypercholesterolaemia
- the predictive value of high levels of cholesterol and other risk factors for CHD in pre-menopausal women, members of the Asian community, lower socio-economic groups and elderly people.

Recommendations

1 The most important and effective way to reduce CHD is through a national food and health strategy to reduce the general level of blood cholesterol in the population.

2 Clear and consistent information about risk factors and the means of reducing those which are affected by changes in individual behaviour, especially smoking and diet, should be disseminated.

3 Everyone should be encouraged and advised to make appropriate dietary changes.

4 Mass measurement of cholesterol levels in the population is not justified.

5 CHD risk assessment should be made on the basis of factors other than measured blood cholesterol levels. If one or more major risk factors is present we then recommend cholesterol testing.

6 Cholesterol measurement should never occur without access to advice and counselling services.

7 Only when dietary changes are seen to be ineffective or inappropriate, should drug therapy be considered.

8 The initiation of drug treatment requires specialist medical advice.

9 All lipid lowering drugs should be subject to adequate evaluation and monitoring.

Panel members:

Dr Maurice Hayes (Chair), Ombudsman for Northern Ireland; Mildred Blaxter, Research Fellow, University of East Anglia; Martin John Buxton, Senior Research Fellow in Health Economics and Director of the Health Economics Research Group, Brunel University; Philippa Champion, freelance dietetic consultant in the fields of health and social policy; Professor Desmond Julian, Consultant Medical Director, British Heart Foundation; Shirley Goodwin, Visiting Felow, King's Fund Institute; Professor James McEwen, Professor of Public Health, and Head of Department of Community Medicine, University of Glasgow; Tara Kumar Mukherjee, President, Confederation of Indian Organisations; Professor Peter Smith, Head, Tropical Epidemiology Unit, London School of Hygiene and Tropical Medicine; Dr Lesley Southgate, Senior Lecturer in General Practice and Primary Care, Medical Colleges of St Bartholomew's and the London Hospitals; Jill Stern Chair, Ealing, Hammersmith and Hounslow Family Practitioner Committee; Barbara Young, General Manager, Parkside Health Authority

Speakers:

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CANCER OF THE COLON AND RECTUM

The Seventh King's Fund Forum: Consensus Statement

Last year, 22,000 people died of cancer of the colon and rectum in Britain and of those diagnosed this year less than 30 per cent will survive five years. Cancer of the colon and rectum is the second most frequent cause of cancer death in Britain and the Western World. In the past 20 years, treatment has had little impact on the survival. It is a disease mainly of older people, and the numbers of new cases and deaths will continue to increase with the growing numbers of the elderly. There is little public recognition of the fact that in Britain today there may be over a quarter of a million people living with cancer of the large bowel. This may partly be due to the stigma and embarrassment of bowel cancer. Some patients delay seeking help through fear and ignorance. Others require major emergency surgery for which they are totally unprepared. Knowledge about this cancer has remained rather more in the medical domain than some others such as breast cancer. For this reason it is hoped that our consensus statement will raise public awareness of this common and often devastating disease.

The panel was asked to address the following questions:

1 Would the detection and treatment of polyps reduce the incidence of cancer of the colon and rectum?

2 Are there other preventive measures which will safely reduce the incidence and mortality of cancer of the colon and rectum?

3 How effective are current treatments for cancer of the colon and rectum at improving survival and quality of life?

4 What is the direction for future research?

Throughout the statement specific recommendations have been highlighted in italics.

Question 1: Would the detection and treatment of polyps reduce the incidence of cancer of the colon and rectum?

It is important to define a number of terms before discussing particular questions of prevention and management. Most polyps and all colorectal cancers are neoplasms or new growths. Cancer is diagnosed histologically when the growth invades locally through the inner lining of the bowel. A more precise term for a neoplastic polyp is an adenoma. Three types of adenoma can be defined by the pathologist: tubular, tubulo-villous and villous, of which the latter is thought to have the greatest invasive potential.

Whether or not the detection of polyps would reduce the incidence of cancer of the colon and rectum depends upon the premise that most colorectal cancers develop from adenomatous polyps. There is now a great deal of circumstantial evidence to support this, although alternative mechanisms may account for the carcinomas which arise in patients with longstanding ulcerative colitis and the rare cancers which arise apparently *de novo*.

When the adenoma-carcinoma sequence was first proposed the evidence came from epidemiological and clinical studies alone. For example, in countries with a low prevalence of adenomas the incidence of colorectal carcinoma is also low. Studies of patients with the genetic condition familial adenomatous polyposis (FAP, formerly known as Gardner's syndrome or polyposis coli), where affected individuals have multiple large bowel tubular adenomas and a high risk of colorectal cancer, support this hypothesis. Recent molecular genetic studies have added strong evidence for the concept of the adenoma-carcinoma sequence.

If the great majority of cancers develop within an adenoma, it follows that detection and removal of polyps in asymptomatic individuals should theoretically reduce cancer incidence and mortality. The problem is that autopsy studies have shown adenomas to be far more prevalent than carcinomas (30 per cent compared to 2 per cent). Double contrast barium enema may be used to diagnose polyps but the most reliable diagnostic technique for the detection of adenomas, is colonoscopy. However, it is invasive and there are no good colonoscopic indicators of malignant potential other than size. *There is therefore no case for colonoscopic screening on a population basis.*

Evidence from occult blood screening of asymptomatic populations suggests that it may detect the larger and more friable adenomas with a higher risk of malignant change, but at present no judgement can be made on whether this confers survival benefit. The results of the European randomised controlled trials for screening will consider this question and may provide evidence as to whether the smaller adenoma detected by the screening method presents as a cancer at a later screening round or as an interval cancer (ie presenting between screening rounds).

We recommend that the use of colonoscopy in the asymptomatic individual is justified only in those with a high genetic risk of developing cancer and in the follow-up of some of those patients who have had a symptomatic adenoma previously removed endoscopically.

We recommend that in the symptomatic patient with a polyp the whole of the large bowel is examined and polyps greater than 5mm in diameter removed. The management of polyps less than 5 mm is a problem which will be resolved only by more studies of their natural history.

It is uncertain which patients require follow-up after removal of symptomatic polyps and how often. Development of new (metachronous) adenomas is variable and information regarding this comes mainly from retrospective surgical and only a limited number of prospective endoscopic studies. *Follow-up is not indicated for patients with a single small tubular rectal adenoma and those over the age of 75.*

Those individuals with a large adenoma or any type of multiple adenomas should undergo colonoscopic surveillance at 3-5 yearly intervals. The risks of colonoscopy are small but real and can be minimised by an expert colonoscopist.

We recommend that in order to deal adequately with the existing demands of symptomatic individuals and screening of high risk groups, provision for colonoscopic services including training need to be improved.

Question 2: What preventive measures are there which will safely reduce the incidence and mortality of cancer of the colon and rectum?

Reduction in incidence and mortality may be achieved by reducing exposure to causative factors, eg diet or by detecting the condition at a pre-malignant stage through screening.

Diet

The wide geographical variations in colorectal cancer incidence which exist suggest a strong environmental influence and this is confirmed by studies of migrant groups. Interest in dietary actiology began with the hypothesis that the higher fibre intake of low incidence populations protected them against colorectal cancer. There are great methodological difficulties in studying the association between diet and cancer. Most of the epidemiological evidence is weak, based mainly on correlations at a population level and a small number of adequate case-control studies. It is necessary to be cautious about generalising from animal studies.

A dietary actiology is plausible because diet has been shown to have an important influence on bowel function and metabolism. So far, the main factors linked with increased colorectal cancer have been high intakes of fat and energy and low intakes of fruit and vegetable fibre. Cereal fibre does not appear to provide any protection against colorectal cancer.

Although there is a general view that diet is probably the most important environmental cause of colorectal cancer *the evidence is not strong enough to recommend dietary changes*. However, a reduction in fat and energy intake and an increase in fruit and vegetable fibre would be in line with recommendations for dietary change relating to other diseases.

Screening

It has been suggested that screening may decrease morbidity and mortality of colorectal cancer by the detection of early cancers in high risk groups and the population.

Population screening

Rectal examination, sigmoidoscopy and faecal occult blood (FOB) testing have all been suggested as methods of screening asymptomatic populations. The first two are impracticable as screening tools and would detect only a small proportion of distal cancers. Faecal occult blood testing (eg haemoccult) is non-invasive but has problems of limited specificity and sensitivity and is taken up by around 60 per cent of those offered it.

Because of various biases the efficacy of screening must be evaluated by randomised controlled trials (RCTs) using population mortality and other outcome measures.

Results from RCTs suggest that cancers detected in the screened population are more likely to be at an early stage than cancers presenting in an unscreened population and that a higher proportion can be dealt with endoscopically rather than surgically. However we do not yet know whether screening will significantly improve the duration or quality of life in a population offered screening compared with a population not offered screening. Any decision on a screening programme must take account of all the costs including the foregone benefits of displaced alternative projects. In addition to the effects on NHS and other public sector costs, the costs to patients and their families must be considered including the unnecessary anxiety and the risks of complications of colonoscopy for false positives. In the event that screening is introduced, it will be necessary to ensure that there are additional diagnostic facilities available to meet the demand for additional tests generated by the programme. It will also be important that people offered screening are told about the implications of the different outcomes of the tests. A large study of FOB screening is currently in progress in Nottingham and its results are expected in 1995. *We recommend that no decision on the introduction of FOB population screening is made before 1995.*

Screening of high risk groups

In individuals with a high genetic risk of developing adenomas/carcinomas the balance of benefits of screening in relation to risks and costs is more favourable than for the general population. Response and detection rates are improved and invasive procedures may be justified.

Those at highest genetic risk are the offspring of individuals with FAP and the two hereditary non-polyposis colorectal cancer (HNPCC) syndromes. These conditions are autosomal dominantly inherited and are estimated to account for 0.5-1 per cent and 5-10 per cent of all colorectal cancers respectively. The diagnosis of FAP is straightforward although clinicians should be aware that 30 per cent of people presenting may have no family history. The clinician should be alerted to the possibility of the HNPCC syndromes by the occurrence of colorectal cancer in young people and particularly where the lesion is rightsided. Affected relatives may be identified in the family with either colorectal disease or adenocarcinoma elsewhere (eg, of breast, uterus, ovary).

There is a significant increased frequency of colorectal cancer in first degree relatives of people with colorectal cancer. The empiric risk of developing cancer varies from 1:17 for individuals with one first degree relative affected to 1:6 with two first degree relatives. *We recommend that a comprehensive family history is taken as part of the assessment of all individuals with colorectal cancer.*

Those families in which a significant genetic risk is suspected should be referred for genetic counselling and accurate risk determination. *We recommend that, given the number of people involved and the resource consequences, such screening must be evaluated.*

Recent advances in molecular biology mean that

there is the potential to use linked DNA markers in FAP families to determine genetic risk, thus confining the need for regular colonoscopic surveillance to those family members at high risk. Markers for other dominant syndromes may be available in the near future.

Case finding

This is the identification of affected but asymptomatic individuals by opportunistic screening, eg when a patient presents to the GP with an unrelated condition. In the absence of an adequately evaluated non-invasive screening method, case finding cannot be recommended. However, the taking of a good family history is essential as it may identify a high risk individual who should be referred for further investigation.

Assessment of the symptomatic patient

Patients with colorectal cancers usually present to their general practitioner with non-specific gastrointestinal symptoms. Delay in referral and diagnosis may influence outcome. Abdominal and rectal examinations are essential to determine the urgency of referral. There is evidence that they are not carried out on a large proportion of patients who are subsequently found to have colorectal cancer. FOB testing is of no value in the assessment of the symptomatic patient in general practice because of its low specificity and sensitivity.

Question 3: How effective are current treatments for cancer of the colon and rectum at improving survival and quality of life?

The efficacy of treatment is limited. Survival and quality of life after treatment for colorectal cancer will vary according to the individual patient, the site and stage of the tumour, its presentation, its treatment as an emergency or an elective case, and between hospitals. Increasingly, treatment involves a number of disciplines and a team approach is essential.

Surgery

Most patients referred to hospital will first be seen by a surgeon. There is good evidence that variations in operative mortality, post-operative morbidity, and survival are all surgeon related. The skill and training of the operating surgeon has a crucial effect on outcome. This particularly applies to rectal surgery, in which major procedures carry a significant risk of damage to nerves supplying the bladder and sexual organs. There is no formal organisation for colorectal surgery in the UK, and it is not yet recognised as a separate sub-specialty. The newly formed Association of Colorectal Surgeons of Great Britain and Ireland should assist in this development. *We recommend that each district should have at least one colorectal surgeon or, failing this, colorectal cancer patients should be referred to another hospital which does have a specialist.* Even then local surgeons should be organised so that one can assume responsibility for colorectal cancer. *Proper local referral and treatment protocols should be developed for both elective and emergency colorectal surgery.*

Advanced surgical techniques, encouraged by specialisation, have reduced the need for a permanent colostomy, but despite this increasing trend some patients are treated with a colostomy unnecessarily. Tumours close to the anal canal still have to be treated by excision of the rectum and a colostomy. *Those patients who do require a temporary or permanent colostomy will continue to need the support of specialist stoma nurses.* Adequate resources must be properly provided. Their extended role will include both information on new appliances and techniques, and counselling before and after surgery.

Pathology

The accurate reporting of histopathology on resection and polypectomy specimens is time consuming but essential for the assessment of prognosis and further treatment. Standards of reporting have recently been outlined by the United Kingdom Central Committee for Cancer Research (UKCCCR) and should be adhered to. Adequate support, staff and resources must be provided for this important task.

Radiotherapy

For rectal cancer preoperative radiotherapy reduces the incidence of local recurrence, but some early cancers may be treated unnecessarily.

Similar benefit accrues from radiotherapy given postoperatively which permits the selection of those patients with later stage disease. There is however a greater risk of side effects. Although radiotherapy helps to prevent recurrence there is no evidence that it prolongs survival. Palliative radiotherapy may also have a useful role to play in patients with established disease particularly in the pelvis.

Chemotherapy

Adjuvant chemotherapy (that is, given at the time of surgery) aims to control the metastatic potential of a tumour. Up to 25 per cent of patients with colorectal cancer develop liver metastases. The recently introduced AXIS national trial of adjuvant chemotherapy and radiotherapy is assessing the effect of 5 fluoro-uracil (5FU) infusion into the portal vein. We recommend that surgeons enter suitable patients into the AXIS national trial.

Recent evidence suggests that patients with advanced (Stage C) colon tumours may be improved by adjuvant therapy with 5FU and levamisole, and such patients not entered into trials should be considered for this treatment.

Studies in advanced colorectal cancer treated with 5FU and folinic acid show some value and may be effective as palliation in patients with advanced disease.

Other palliative treatments

Older patients who are frail and might otherwise have a colostomy or major resection with a high mortality can be treated by laser therapy or transanal resection to reduce distressing symptoms. In carefully selected cases, partial liver resections for one or two metastases confined to a single lobe of the liver may prolong survival and offer useful palliation. General palliative care is crucially important as with other cancers.

Follow-up

Arrangements for follow-up in the UK are haphazard and poorly organised. The aims of follow-up are the detection of overlooked synchronous tumours, the detection of recurrent cancer and new tumours at an early stage, patient support, and the audit of results. *Follow-up is expensive and studies of its efficacy, organisation, frequency and new methods of detection are needed.* For example, the use of the tumour marker CEA (carcino embryonic antigen) as an indicator of local recurrence is being assessed, and optimal post operative colonoscopy screening intervals need to be determined. Colorectal specialisation would encourage the inclusion of patients in trials with systematic follow-up protocols.

Measuring outcome

The standard medical assessment of outcome that concentrates on survival, disease free interval and recurrence may under or over estimate the benefit of treatment. Patients, however, are extremely concerned about the quality not just the quantity of life. Valid standardised tests of quality of life which assess the impact of treatment on psychological, social, occupational and sexual functioning are available and have proved useful in the treatment of other types of cancer. *These tests have not been used in trials of colorectal cancer therapy and must be used routinely in the future.*

Better information

There is wide spread ignorance about colorectal anatomy, function, disease and treatment. Good information about services, treatment outcomes and quality of care is essential if patients are to be able to make informed choices. The full range of cancer information agencies have an important part to play here. As quality assurance prompts hospitals to publish results of treatments and outcomes, patients and their general practitioners will begin to change referral patterns which could reinforce specialisation. *It is critical that measures of outcome are properly audited, and made available to the general public.* Regional cancer registries provide invaluable information and should be supported.

Question 4: What is the direction for future research?

Research

There are gaps in our knowledge about the natural history of colorectal cancer and the effects of treatment. At present only 2 per cent of colorectal cancer patients are entered into clinical trials. The resource implications of new screening or treatment approaches must be carefully considered. *In addition to those areas highlighted already we wish to recommend that research efforts be directed towards the following:*

1 The natural history of the adenoma, dysplasia and cancer, and the effects of intervention.

2 The molecular biology of colorectal cancer.

3 Hereditary factors — the evaluation of the practical and social implications of surveillance of high risk families.

4 The development of more sensitive tests of the physical and biological activity of tumours in order to facilitate the accurate pre and post operative staging of colorectal cancer.

5 The development of new treatments to improve survival and quality of life.

6 The use of validated quality of life measures in all clinical trials of colorectal cancer therapy.

7 Studies which will provide insights into the patients' experience of colorectal cancer, its treatment and the impact on their lives.

Panel members:

Professor Ross Anderson (Chair), Professor of Clinical Epidemiology and Social Medicine, Chairman of Department of Public Health Sciences, St George's Hospital Medical School, London; Dr Priscilla Alderson, Researcher in the Sociology of Healing, Department of Child Health, Westminster Children's Hospital, London; Professor Tim Cooke, St Mungo Professor of Surgery, Glasgow Royal Infirmary; Dr Alan Davison, District General Manager, North East Essex Health Authority; Dr Lesley Fallowfield, Senior Lecturer in Health Psychology, London Hospital Medical School; Mr Hugh Gravelle, Reader in Economics, Queen Mary and Westfield College, London; Dr Susan Huson, Consultant Clinical Geneticist, Churchill Hospital, Oxford; Dr Margaret Lloyd, Senior Lecturer in General Practice, Royal Free Hospital School of Medicine, London; Dr Kath Melia, Lecturer, Department of Nursing Studies, University of Edinburgh; Mr Neil Mortensen, Consultant Colorectal Surgeon, John Radcliffe Hospital, Oxford; Dr Robert Newcombe, Senior Lecturer in Medical Statistics, University of Wales College of Medicine; Ms Fedelma Winkler, Director of Service Planning and Service Development, Barking and Havering Family Practitioner Committee.

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Consensus conferences are an increasingly accepted means of synthesising available information and of producing a widely agreed view of the value of medical techniques and advances. In the UK the King's Fund initiated their use, and developed them beyond their original purely professional focus. This book describes this development and identifies the advantages and disadvantages of the approach, with the lessons learnt.

The subjects addressed by the conferences are wide ranging, from the role of asylum, to the application of genetic screening. All eight statements produced by the King's Fund to date are reproduced in the appendix.

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