NICE Citizens Council

“Only in research”

25 – 27 January 2007
Ela Pathak-Sen, Brendan Turner, Helen Bidwell and Jessica Abell of Vision 21 facilitated the NICE Citizens Council meeting. Geoff Watts wrote this report on behalf of the Citizens Council. For further information please contact:

Brendan Turner  
Vision 21  
213 Ducie House  
Ducie Street  
Manchester  
M1 2JW

or

Clifford Middleton  
National Institute for Health and Clinical Excellence  
MidCity Place  
71 High Holborn  
London  
WC1V 6NA
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td>4</td>
</tr>
<tr>
<td>What we were asked to consider</td>
<td>5</td>
</tr>
<tr>
<td>The conclusions we reached</td>
<td>5</td>
</tr>
<tr>
<td>How we worked</td>
<td>6</td>
</tr>
<tr>
<td>What we heard, and what we did</td>
<td>7</td>
</tr>
<tr>
<td>How we view OIR recommendations</td>
<td>18</td>
</tr>
<tr>
<td>Appendix 1 Tracking questionnaires</td>
<td>20</td>
</tr>
<tr>
<td>Appendix 2 Question</td>
<td>26</td>
</tr>
<tr>
<td>Appendix 3 Agenda</td>
<td>32</td>
</tr>
<tr>
<td>Appendix 4 Speakers</td>
<td>35</td>
</tr>
<tr>
<td>Appendix 5 Council Members</td>
<td>40</td>
</tr>
</tbody>
</table>
Foreword

The National Institute for Health and Clinical Excellence (NICE) exists to advise clinical and public health professionals on promoting good health and preventing and treating ill health. The Institute and its advisory bodies base their conclusions on the best available evidence. In doing so, however, they also have to make scientific and social value judgments.

The Institute and its advisory bodies are well qualified to make scientific judgments but have no special legitimacy to impose their own social values on the National Health Service (NHS) and its patients. These, NICE believe, should broadly reflect the values of the population who both use the service (as patients) and who ultimately provide it (as taxpayers). NICE therefore established a Citizens Council, in 2002, to help provide advice about the social values that should underpin the Institute’s guidance. Their views are incorporated into a guideline for NICE’s advisory bodies: *Social Value Judgements*.

The members of the Council reflect the demography of the English and Welsh populations. They serve for three years with one third retiring annually. They do not represent any particular section or group in society; rather they are a cross-section of the population with their own individual experiences, attitudes, preferences and beliefs. The Council meets twice a year.

At the January 2007 meeting of the Council, members were asked to consider the following question: In what circumstances is it justified for NICE to recommend that an intervention is used only in the context of research? The Council’s report will be available for public comment before it is presented to the Institute’s Board in July 2007 with a view to incorporating the Council’s conclusions into the next edition of *Social Value Judgments*.

Once again, the Institute is extremely grateful to the Council for its continuing help in developing NICE’s social values.

Professor Sir Michael Rawlins

Chairman
What we were asked to consider
In what circumstances is it justified for NICE to recommend that an intervention is used only in the context of research?

The conclusions we reached
These are the circumstances that we think should be taken into account when NICE considers whether or not to make an “only in research” (OIR) recommendation. Most of us felt that all but one of these was uncontroversial.

Many of our conclusions were unanimous; where there was a division of opinion the voting figures are recorded.

1. Whether at least one appropriate, relevant study is either:
   - planned (e.g. the study will definitely start within 6 months of the guidance publication date);
   - in progress (e.g. recruitment to the study is open, and is expected to last at least 1 year beyond the guidance publication date); or
   - could be established quickly.

2. Whether the question addressed by the study will contribute to reducing the uncertainties identified during the preparation of NICE guidance.

3. Whether the research is feasible (in terms of numbers of patients, recruitment etc.) and is likely to deliver results within an appropriate time period.

4. Whether the study will be multi-centre with broad coverage of the relevant geographical area and population to ensure that as many eligible patients as possible can realistically access the technology within a study setting.

Agree: 21
Disagree: 4
Don’t know: 2

5. Whether further research is good value for money.

6. Whether a fully supportive decision would lead to significant irretrievable fixed costs of implementation.

7. Whether a fully supportive decision, instead of an “only in research” recommendation, would lead to the termination of research in progress or prevent new research from beginning and thus have a negative impact on future collection of relevant information.

8. Whether it is realistic to hope that research can be carried out to the satisfaction of NICE. Factors to be considered include: the timeliness of the research; potential number of patients able to participate in research; the pace of the current research; the precise nature of the questions to be answered.

In addition to this list of “circumstances” we wish to add the following:

9. An OIR decision should not be used as a way of ducking the need to say “no” to interventions that are excessively costly.
10. NICE should resist the attempts of patient groups, the media and other bodies that may wish to pressurise it into choosing an OIR decision when a "no" decision is the more appropriate response.

11. Patients already receiving a treatment should continue to do so even if that treatment is then categorised as OIR.

12. When making an OIR decision NICE should define the questions it wants answered through research, and also prescribe the methodology to be used.

13. NICE may wish to consider how OIR could be used as means of encouraging innovation.

   Agree 23
   Disagree 4
   Don’t know

14. With treatments for life-threatening conditions where there is no other remedy available, NICE should consider granting it the “benefit of the doubt” with an OIR decision rather than a “no”.

   Agree 25
   Disagree 1
   Don’t know 1

15. NICE should be mindful of the risk of discriminating against groups perceived to have a low quality of life as measured by the QALY system.

   Agree 22
   Disagree 1
   Don’t know 4

16. NICE should do what it can to ensure that the findings of research are fed back to the clinicians who can benefit from them.

17. The AIR (“also in research”) option proposed by one of the speakers should not be adopted.

   Agree 24
   Disagree 2
   Don’t know 1

The Citizens’ Council would also like NICE to note one other topic on which we voted. By a large majority (24 out of 27 voting) we felt that the assessment of cost-effectiveness and the use of the QALY system should be the subject of a future Citizens Council meeting.

How we worked
Twenty seven of the 30 members of our Council were able to attend the meeting, held from January 25 to 27 at the NICE headquarters in London. Following a brief welcome from Andrew Dillon, Chief Executive of NICE, the first day began with an introduction by Professor Peter Littlejohns, NICE’s Clinical and Public Health Director. We then heard presentations by a health economist and by an ex-clinician
with an interest in the importance of evidence in judging the value of medical interventions.

At this point we completed the first of four tracking questionnaires, each of which comprised a series of questions. (We completed further questionnaires at the finish of the first and second days, and at the end of the meeting.) The tracking questionnaires have dual functions; they are used by the facilitators to follow the trend in the our thinking at various points during the meeting and are intended to elicit our views on some of the implications and consequences of NICE making an OIR recommendation. (See Appendix 1) The forms completed, we went on to hear further presentations about the importance of data registries, randomised controlled trials (RCTs) and systematic reviews of accumulated evidence

For our first exercise we divided into groups to explore how NICE and some of its stakeholders confront an issue on which a decision is required. Four experts reviewed some of the ethical and economic issues raised by the case, and added some further thoughts on decision-making by NICE. The day finished with another straw poll and a presentation on NICE’s interventional procedures programme.

The morning of the second day was filled with brief presentations from eight more experts who then responded to our questions on the implications of an OIR recommendation. In the afternoon we discussed what we had heard, and began trying to reach some initial conclusions.

Our final morning was devoted to a discussion of the recommendations, and our collective assessment of their importance.

We were able to question all the experts who spoke to us, and the meeting was punctuated with regular discussion – informally among ourselves, or together in our plenary sessions.

**What we heard, and what we did**

**Our initial response - and some warnings**

Following his words of welcome, Andrew Dillon emphasised the importance of the issue we were meeting to consider. As he pointed out, any decision to designate a treatment OIR inevitably means that, for a period at least, patients who have not already begun to receive it as part of a research study will be denied the benefits it may eventually confer. Mr Dillon said that a decision to apply this status has both ethical and practical consequences, and cannot therefore be taken lightly.

Before further discussion, or the opportunity to hear any evidence, we were asked for our gut response to the question when we had first read it. Should there even be such a category as OIR? Or is it never an appropriate recommendation on the part of NICE? Our response was unanimous; OIR is indeed a ruling that should be available to NICE. We were ready to begin our task: to consider the circumstance in which it might appropriately be used.

In his introduction to the OIR concept, Professor Peter Littlejohns commented that some of us might feel we were being asked an essentially technical question with a correspondingly technical answer. This, he said, was not the case: an assertion that became abundantly clear to us over the next two days as we began to grapple with the difficulty of making decisions when confronted with uncertain evidence, and evidence of uncertainty. What at first appear to be technical decisions are soon revealed as incorporating all sorts of value judgements.
As we learned, although the OIR option has always been available to NICE, it has been used sparingly: some 15 times since the body was created. Most NICE judgements have been an unvarnished “yes” or “no”. One danger of OIR is that some stakeholders might be inclined to take it as a coded refusal to adopt a technology: as a way of avoiding the tough decision. This charge would be particularly difficult to rebut if there were no trials of the technology already underway, and no prospect of any being set up. Professor Littlejohns then went on to outline some of the implications for those with an interest in NICE decisions if it did not make an OIR decision where it should have done.

- If NICE rules “no” when it should have said OIR:
  - patients will be denied access to the treatment
  - there will be delays in building an evidence base
  - innovation will be hampered

- If NICE rules “yes” when it should have said OIR:
  - unproven and possibly ineffective procedures will be in use
  - research will be hampered and questions of effectiveness may never be answered
  - a poor value innovation will have been encouraged
  - the NHS will incur unnecessary costs
  - NICE will lose credibility by having to change its mind

We questioned Professor Littlejohns. Surely, one of us asked, wherever there is any uncertainty about an intervention, NICE has a duty to classify it OIR? That, we were told, depends on what you mean by uncertainty – a thought we were destined to find ourselves wrestling with for the rest of the meeting. Any drug - though not necessarily some other form of intervention such as a surgical procedure - will already have been judged safe and efficacious by a licensing authority. But this will be in the constrained and specific circumstances of a clinical trial: often quite unlike those of routine clinical practice. Moreover the licensing authority does not judge a new technology’s cost effectiveness under everyday circumstances.

Another Council member persisted: why not classify every procedure and intervention an OIR? Splendid though this idea might be in principle, we were told, issues of commitment and funding render it currently (and foreseeably) impracticable. The closest to it at present is the post-marketing surveillance to which drugs may be subject. Other matters discussed at this stage were the likelihood of commercial or other pressures being brought to bear on NICE, and the extent to which the severity of an illness ought to influence an OIR decision.

Health economics: a crash course
The next hour saw Professor Karl Claxton making a spirited and engaging attempt to compress a term’s worth of health economics teaching into 60 minutes. Despite the difficulties, several things did become clear to us. First, there is a methodology for judging the cost effectiveness of treatments. It relies on measurements of increased life expectancy and/or of changes in the quality of the patient’s life following treatment. These can be combined to calculate what is known as the “quality adjusted life year” or QALY. Second, knowing what any particular intervention costs the NHS, NICE can estimates its cost-effectiveness. This is measured as the cost per QALY: the financial cost of each extra QALY conferred by the treatment. Third, because the NHS operates within a finite budget, NICE has to have a threshold above which new treatments are judged not to be cost-effective. ‘This has been set
at around the £20,000/QALY mark. All other things being equal, treatments costing this or less are deemed acceptable; treatments costing more are not.\footnote{NICE’s Guide to the Methods of Technology Appraisal, available on the NICE web site at http://www.nice.org.uk/pdf/TAP_Methods.pdf, states:  ’Below a most plausible ICER of £20,000/QALY, judgements about the acceptability of a technology as an effective use of NHS resources are based primarily on the cost-effectiveness estimate. Above a most plausible ICER of £20,000/QALY, judgements about the acceptability of the technology as an effective use of NHS resources are more likely to make more explicit reference to factors including the degree of uncertainty surrounding the calculation of ICERs, the innovative nature of the technology, the particular features of the condition and population receiving the technology [and] where appropriate, the wider societal costs and benefits. Above an ICER of £30,000/QALY, the case for supporting the technology on these factors has to be increasing strong.’ - NICE}

Judgements of this kind can never be precise. The evidence may be incomplete; what there is may be less than perfect. This observation moved Professor Claxton on to a further set of questions. Is the available evidence sufficient to justify making a judgment? What would it cost to collect more or better evidence? How much more reliable will that judgment then be? Does the extra reliability justify the cost of collecting the additional evidence to make it so? And so on…

It was already becoming clear to us that, for all the technical nature of the calculations, many fine value judgments also had to be made. The presentation prompted one of our members to raise an issue that was to come up several more times: the potentially discriminatory nature of QALYs. ‘Used without care – and some would say even with care – QALY assessments tend not to favour the elderly and the disabled.’

Our next presentation came from Sir Iain Chalmers, co-ordinator of the James Lind Initiative, an organisation that promotes attempts to study and reduce the uncertainties inherent in many treatments, old and new. Sir Iain gave us four telling examples of failure to confront uncertainty: the use of antibiotics in measles; the best sleeping position to prevent sudden infant death; the systematic use of steroids in acute brain injury; and the kind of fluid used to resuscitate people who are critically ill. In each case the failure to garner firm evidence had led to wasted money and lost lives.

Clinicians, managers and patients, he argued, all have a responsibility to contribute to advancing our knowledge. In practice this means organising clinical trials, paying for them, and volunteering to take part in them. NICE, he added, should resist pressure applied by special interests, ensure that evidence is made public, be open about uncertainties and – mostly relevant to the OIR issue – “be more ready to recommend that, when there is insufficient information about the effect of treatments, they be used by the NHS only within the context of research to reduce the uncertainties”.

Sir Iain went on to tell us of his regrets that more patients do not have the opportunity to take part in clinical trials. Responding to one of our questions about the quality of trials, he added the caveat that not all trials are appropriate or well designed. Not all the benefits being measured are what patients themselves, or their carers, would regard as most important. Researchers should find out what patients most need from a drug or a procedure, and ensure that this is taken account of when judging its effectiveness. When we asked how the extra research prompted by an increase in OIR decisions would be paid for, Sir Iain pointed out that the knowledge gained can sometimes turn out to save money.
Means and methods
The afternoon began with a further learning session on methodology. Dr Sarah Garner, a technical adviser to NICE’s Centre for Health Technology, explained the principles of a disease register, and how it can be used to record information about people who have something in common. Registers of interest to NICE are predominantly those that list the details of people who have all taken a particular drug for the same illness, undergone the same medical procedure, or who have been fitted with a particular device such as an artificial joint. Provided the information stored on the register is regularly updated, researchers can use it to assess how well the drug or procedure is performing.

NICE finds data of this kind useful for a number of reasons. Registers are valuable in assessing the benefits of new procedures; in accumulating information that can be used to resolve uncertainties; and in generating insights of the kind that are helpful when producing and reviewing clinical guidance statements. At various times NICE has used data from existing registers, recommended the submission of new data to existing registers, or encouraged the establishment of new ones.

Not everyone is happy about the use of registers. Some patients don’t like the idea of information about them being stored other than in their personal medical record; they may have fears about confidentiality, for example. This prompted one of us to ask who manages databases. The answer is that all sorts of organisations, ranging from industry to academia, collect information. Particular problems of confidentiality and use may arise if the organisation concerned is a commercial one. Another member was curious about the sheer quantity of data stored; is there a danger of accumulating too much, and virtually drowning in it? It seems there is. The remedy, Dr Garner explained, is to decide in advance exactly what information is needed to answer which particular questions.

Other research methodologies important to NICE are systematic reviews and randomised controlled trials or RCTs, the latter often being described as the gold standard, particularly in the case of drugs. Dr Mike Clarke of the University of Oxford, whose task it was to explain these techniques to us, suggested that their use was intended to answer three questions. These, he said were “How can we become more sure about things we are unsure about? How can we be sure that we are right to be unsure? And how can progress be made towards becoming more sure?”

Taking the examples of midwife- versus consultant-led care in pregnancy, and two alternative methods of handling burst blood vessels in the brain, he showed how the RCTs can be set up to make direct comparison of their respective advantages and drawbacks. He also explained why allocating patients to one or other alternative at random avoids subconscious bias, and makes the comparison a fair one. He then moved on to systematic reviews and the manner in which they can be used to pull together the findings of several or even scores of trials carried out on the same issue, so reaching more reliable conclusions. Even so, he concluded, uncertainty may remain. Scientists and doctors often round off their reports with the phrase “More research is needed”. Sometimes, he added, it has to be “only in research”.

Council members followed up Dr Clarke’s presentation with several practical questions. Can patients approach trial organisers and, if suitable, volunteer to take part? (Yes, and more would be welcome.) How can patients find out about available trials? (With difficulty; patient-friendly information about trials in progress is not easy to find.) Who initiates trials and chooses the topics? (Academic, charitable and commercial bodies. But, in spite of this variety, better ways of canvassing the views
of patients on what research should be done are still needed.) Is there a risk of trial
organisers reaching a decision too quickly about the best treatment and then
abandoning an alternative which, given further time, might actually prove superior?
(In theory, yes. In practice, “winning” treatments seldom wholly displace “losing” ones
entirely, so the door remains open.)

**New drug X: a case study**

During the next hour we split up into three groups, each with expert help, and
became members of a NICE appraisal group, dermatologists working in the NHS, or
patients suffering from a serious form of skin cancer. This case study was designed
to help us begin identifying some of the issues that are relevant to discussions about
the assessment of a new product. After 20 minutes of discussion in our groups we
reconvened to report back. The background to the exercise was as follows:

*Drug X has been licensed for use in patients with melanoma (the most serious type
of skin cancer) for the last 4 months. It has been hailed as the new ‘wonder drug’ in
the US. The drug is not cheap but as it has fewer side effects than other medication
and seems to have better results; dermatologists are prescribing it more and more.*

*NICE has been asked to appraise the drug. The Appraisal Committee having
considered all the available evidence is leaning towards an ‘only in research’
recommendation.*

The members of the Citizens Council are divided into three groups.
Each group is asked to work on the questions below

**Group 1:** NICE Appraisal group
[Experts: Dr Sarah Garner/Professor Karl Claxton]

*Put yourselves in the position of the Appraisal Committee. You are about to publish
the first draft of the guidance in which you say this drug should only be made
available as part of a research study.*

*What is the evidence you have seen or discussions that you have had is causing you
to go down this route? Why can’t you make a straightforward ‘no’ or yes’ decision?*

*What are all the things you would have considered before making this decision?*

*Which do you think are the most important and why?*

In the feedback session that followed, this first group reported that they had been
trying to balance the cost-effectiveness of the drug against the level of remaining
uncertainty about its clinical performance. Their considerations included the
following:

- The human consequences of a wrong decision
- The need to monitor long term effects
- The size of the test population
- The fact that, so far, it only “seems” to have better results
- The clarity and certainty of the information currently available
- The impact that a “yes” verdict would have on the NHS budget
- The possibility that clinical practice in the USA (where there is most
experience of the drug) may be different from that in the UK

**Group 2:** Dermatologists working in the NHS in England and Wales
[Expert: Professor Richard Lilford]
You know about the so-called effectiveness of this drug; in fact only a week ago the drug company hosted a conference on its benefits. From the information published by the company you know that this drug is more effective than its present counterpart for patients with advanced melanoma, and causes fewer side effects. You learn that NICE is considering an OIR recommendation.

What is the evidence/information you have received that causes you to believe that this drug is as effective as it claims?

What problems do you foresee for yourself and your patients if NICE makes an OIR recommendation?

The group considered two scenarios. In the first it supposed that the available evidence included controlled studies of a large number of people for sufficient time to judge survival rates, that there had been an adequate comparison with alternative drugs, and the cost-effectiveness data suggested that the drug would be good value for money in the NHS. Under these circumstances, an OIR decision would be inappropriate.

In the second scenario the group imagined that the studies were uncontrolled, with all sorts of selection biases. The blanket acceptance of the drug at this stage might hamper the development of something better. Under these circumstances, an OIR would be appropriate.

The group then tried to imagine how patients might be affected by an OIR decision. Not all would or could take part in a trial. Some might feel deprived. Some might attempt to get the drug privately.

Group 3: Patients
[Expert: Professor Tony Hope]

You are a group of patients suffering from this serious form of skin cancer, your disease ranges from just diagnosed to advanced. Some of you have been prescribed this drug in the last few months. A few of you took part in a clinical trial before the drug was licensed. You learn that NICE is likely to make an OIR recommendation.

What are the issues that concern you? Why do you believe NICE is taking this decision? What reassurances would you need?

Among the issues that preoccupied this group:
- Will the drug work?
- Will I be getting the best treatment?
- Will there be a post-code lottery?
- What side effects will I experience
- What feedback will I get during and after any trials?
- How robust and accurate has previous research been?
- Will some patients be scared and simply demand the drug
- Will patients who are already taking the drug be able to continue to do so if becomes OIR?
- Why is NICE taking this decision? For safety reasons? To keep down costs?
- Patients will need reassurance about the trial protocol, and the source of the finding
- Patients’ responses will be partly determined by whether not they are able to take part in the trial
A second straw poll – and more presentations

Following a discussion of some of these ideas we held a second straw poll. This time we were asked to imagine that we, or a close relative, had a melanoma. Given this intense personal interest, did we still think there could be circumstances under which it would be fair for NICE to restrict a new drug to the OIR category? Twenty of the group voted yes. At this stage it seemed that a substantial majority of us still felt OIR to be a valid type of recommendation. We had yet, of course, to begin tackling the key issue: the circumstances under which it should be used.

The next hour was taken up with four more presentations. Richard Lilford, professor of clinical epidemiology at the University of Birmingham and a member of one of NICE’s appraisal committees, revealed how techniques such as decision analysis and Bayesian thinking contribute to rational decision making. Tony Hope, professor of medical ethics at Oxford, addressed the ethical basis of an OIR recommendation. In denying a treatment to some patients, at least for a period, it may be a source of inequity. Although inequity is something to be avoided, he said, this imperative may be overridden if the intention is to seek a greater overall or longer term gain.

Professor Karl Claxton stressed that while NICE has to be clear what it still needs to know when issuing an OIR, it should not define the research or how it should be done. Dr Sarah Garner also made a second appearance, reminding us that NICE had made relatively few OIR recommendations, and arguing that it should continue to use them sparingly.

Mindful, perhaps, of the number of expert views we had already heard – and that there were more to come – one Council member commented that we were supposed to represent the views of the public. We should be careful, she reminded the rest of us, not to find ourselves simply regurgitating the opinions of the experts.

Another member wondered how it is that a new treatment can go all the way through development and licensing – processes that take many years and require vast amounts of study – and yet still not satisfy NICE that they are worth purchasing by the NHS.

We also discussed the need - as one of us put it - to “challenge” the public over participation in clinical trials. Only if we take part in trials will subsequent generations, or even ourselves in future years, benefit from the improved treatments they can bring.

The day finished with a presentation from surgeon Professor Bruce Campbell, chairman of the NICE’s Interventional Procedures Advisory Committee. Compared with drugs, he said, research on interventional procedures is thin on the ground. For all sorts of reasons, from a lack of commercial sponsors to the inherent difficulty of doing rigorous research into procedures, many innovations in this field enter routine practice without proper assessment. (Indeed, surgeons sometimes try out variants of existing procedures or even develop new ones within their routine clinical practice, and without any attempt to assess their value except on the basis of their own experience and judgement.) When NICE has assessed a procedure it can rule it “safe and efficacious enough for use with normal arrangements”, or it can issue cautionary guidance limiting use of the procedure to circumstances under which its results will be monitored through the use of registries or databases.

Council members then questioned Professor Campbell about the different regime that seems to govern procedures as opposed to drugs. Is it correct, one of us asked,
that registries are recommended in preference to the RCTs that would be expected in
the case of drugs? Professor Campbell confirmed that this is indeed so, spoke of the
methodological difficulties of doing RCTs on procedures, and added that registries
were also a lot cheaper. One sceptical member suggested that registers were
preferred because they offered clinicians fewer constraints on their cherished
freedom to do what they wanted in the way they wanted. Another wondered if the
preference for registries was just a way of getting round the lack of funds for
research. Professor Campbell denied both suggestions. In some cases, he claimed,
RCTs were simply not appropriate; in others it could be difficult to, for example, find
surgeons without a preference for one or other of two very different procedures, and
with sufficient skill to perform both.

Some queries – and some more experts
Day two began with Professor Littlejohns tackling some of the more general
questions that had been prompted by what we had heard on day one. In response to
a query about the extent to which NICE can influence the research agenda,
Professor Littlejohns told us that although the organisation had no research budget of
its own, it did have good relationships with the main funders, and could use its
influence to encourage what it saw as important work. He also referred to proposed
changes in the arrangements governing medical research in Britain. The outcome of
a report published last year by Sir David Cooksey, these changes are intended to
provide an overarching strategy for health research in the UK and, among other
things, make it easier and more productive to carry out research within the NHS.

The morning was taken up by a “question time” session with a panel of eight experts.
First to speak was biomedical ethicist Professor Richard Ashcroft. He pointed out that
when there is substantial uncertainty about the effectiveness and safety of a
treatment, offering it within the context of a trial is ethically the best thing to do
because it gives doctors and patients a way of dealing with the uncertainty.
Sometimes, he added, the issue is not about whether the treatment works, but
whether it is cost-effective. This, he suggested is a value judgment, not one to be
decided by research. OIR decisions should be taken if the clinical facts are in doubt,
not the cost-effectiveness estimates.

Hazel Thornton, a lay and independent advocate of quality in research and
healthcare, agreed. It’s important to determine the degree of uncertainty that still
exists, she said, particularly with early findings, by offering those interventions only in
the context of research. Health services researcher Professor Nick Black
contemplated the possibility of a time when patient data collection and monitoring
would allow even the most routine treatment to contribute more to our knowledge of
the safety and effectiveness of medicine. Glasgow writer and GP Margaret
McCartney described her own experience as a doctor involved in a trial, commenting
on, among other things, the difficulty that even she experienced in trying to find out
what trials were in progress; John Sitzia, an NHS research consortium director,
argued the case for patients having an input into the design of trials; and City
University Head of Midwifery, Dora Opoku talked of her experience of the committees
that oversee the ethics of research.

The remaining two panellists expressed some doubt about NICE’s OIR option. Brian
Buckley, a researcher in primary care who is also a lay and patient advocate, spoke
of the ethical implications of effectively inducing patients to take part in research, and
of the creation of new types of inequality. He also wondered if OIR research would
have much use beyond the satisfying the immediate requirements of NICE. Dr Tony
Whitehead, UK medical director of the drug company Sanofi-Aventis, suggested an
alternative to NICE’s OIR ruling: an AIR or “Also In Research” category. Under these
circumstances NICE would be approving an intervention for general use, while also making it clear that it would also like to see research continuing.

When the presentations were over we broke into small groups for 20 minutes to discuss what we had heard and to formulate questions for the panel. The first issue of concern to us was the possibility that a radical increase in OIR decisions might overload the research capacity of the NHS. This prompted Professor Black to a further mention of the Cooksey report and the Government’s intention to make the NHS more user-friendly for doctors and scientists wishing to carry out research projects. This in turn lead him to amplify a previous comment in which he envisaged the NHS of the future as a vast learning organisation, geared up to scrutinise everything it does, and taking more account of the views and experiences of the non-professionals within it. It’s the way that many organisations are nowadays developing, he said. Data are being collected all the time by the NHS, but mostly not used for research. In his vision, much of the cost of doing research would disappear; it would be a product of the routine running of the system.

Someone else asked about data protection issues. Real enough, Professor Black conceded. But much information can be anonymised while remaining useful. Professor Ashcroft was slightly less sanguine. Can the NHS be organised in a way that will guarantee the appropriate use of information while retaining confidentiality? He felt there might be two opposing principles here: on the one hand social participation and the common good; on the other confidentiality and the power of the state. People can, of course, volunteer their data. But, as Brian Buckley pointed out, they may not be a representative cross-section of the community.

We went on to discuss the AIR (“also in research”) suggestion that had been floated by Dr Tony Whitehead. He argued that it would give a range of data in real word circumstances as opposed to the idealised conditions of a clinical trial. Several members were sceptical; once a drug was on the market, would there be any inducement (least of all on the part of its manufacturers) to organise more research?

We were also less than happy to hear about the somewhat haphazard arrangements for ensuring that doctors and nurses know about research findings. Part of the difficulty stems from the sheer quantity and uncertainty of quality of new findings that become available every year. It seems there are still lessons to be learned when devising ways of putting policy into practice.

Questioned about research ethics committees, Dora Opoku admitted that there is an inevitable risk that people applying for permission to do research - including those working for drug companies - may not reveal enough of their plans. Dr Whitehead pointed out that a company has a great many hurdles to cross before it can get a study approved. In response to a further question he said he really had no idea why so many people continue to view the pharmaceutical industry with suspicion. Replying to a question on whether drug companies make their databases available to other researchers, Professor Black claimed that in his experience they didn’t.

Is all research actually worthwhile, we wondered. Dr McCartney and Professor Black said not. Studies may be badly chosen, or badly designed, or ask the wrong questions. Professor Ashcroft added that there is a bias in favour of research into new interventions, even though many old ones still merit it. John Sitzia added that the proposed new arrangements for research in this country, together with the work of the national co-ordinating body, the UK Clinical Research Collaboration, should improve matters.
One of the closing questions was posed to all members of the panel: in what circumstances do you think that an OIR decision is justified? Professor Black gave the first answer: when rigorous appraisal has been done, but uncertainty remains. Hazel Thornton, Dr McCartney, John Sitzia, and Dora Opoku all agreed. Dr Whitehead added the proviso that a research methodology other than that already used would be most appropriate. Professor Ashcroft offered two more caveats: that a method must exist to answer the question; and that this method must be ethically acceptable. Only Brian Buckley found himself unable to give even qualified endorsement to Professor Black’s answer.

The very final query concerned the additional delay imposed by an OIR decision; it could, thought Professor Black, be around five years.

**Initial conclusions**

To begin clarifying our ideas about the circumstances in which it would be right for NICE to reach an OIR decision we picked seven factors that should, directly or indirectly, influence the thinking of the appraisal committee. The members who first suggested each of these factors wrote the core idea on a flip chart. During the next half hour we gathered round them, holding small group discussions, and fleshing out the original thought.

1. Uncertainty. Information about a new intervention suggests it **may** be important; so this uncertainty would merit an OIR decision. We need to review all available information and research.
2. Cost-effectiveness. Resources are limited: a fact of life. QALYs are unpopular but necessary – unless someone can invent an alternative system. We shouldn’t use research as an opt-out just because a new intervention is too expensive; if it’s too expensive, we should say so. We should make the public more aware of the costs of drugs. The Government should come up with additional research founding; the cost of research should not have to be met out NHS funds.
3. Extra research. Is it feasible to carry out the extra work to the satisfaction of NICE? Will it happen? How much will it cost? NICE needs to be prescriptive about the information required. NICE should be kept informed of the progress of research. Properly controlled trials should be favoured, even in research on interventional procedures. The danger of an OIR is that it can be seen as a “no” in disguise. What happens if OIR recommendations are not acted upon?
4. Resolution of uncertainty. If NICE feels that neither “yes” or “no” is appropriate it must be certain that a more definite answer is obtainable in reasonable time; that the missing facts are potentially discoverable; and that the work will yield a wide benefit to a large population, or a great benefit to a smaller one. Being honest about uncertainty and addressing it should boost peoples’ confidence in the NHS.
5. Media pressure. Faced with a drug backed only by uncertain evidence, should NICE be swayed to an OIR decision by media pressure? Or by the politically difficulty of saying “no”? NICE needs to keep the media on side to ensure that its messages get across to the public. Avoiding “no” rulings helps to show NICE in a positive, “fluffy” and caring light, and perhaps reduce the likelihood of being taken to court by an aggrieved drug companies. BUT, does this justify NICE bottling out of hard decisions, and so wasting resources and raising false hopes? Coming up with too many OIR decisions would make NICE look indecisive: not good for a body created to make hard choices.
6. Research design. Following an OIR decision, should NICE collaborate with the committee that designs the protocol of the additional research? If it did, researchers would know exactly what evidence they needed to supply. This would involve greater transparency, more communication, and encourage NICE to be more proactive.

7. Researchers' intentions. All sorts of factors may drive the work ranging from self-interested careerism to altruism, and from academic interest to commercial gain.

We then discussed some of these circumstances. Many of us had already found that to decide which should be deemed relevant is far from easy. We were mindful of the fact that when NICE does its appraisals early in the life of a new intervention – something it is being encouraged to do – effectiveness may be even harder to judge.

At this point we repeated the previous small group discussion exercise with a further set of possible circumstances and factors that NICE might want to bear in mind.

8. Measuring uncertainty. Appraisers can never be 100 per cent certain. So how uncertain is uncertain enough?

9. Other treatments. What alternative treatments are available for the condition? Is this treatment the only hope for people with the illness?

10. Life-threatening conditions. Even if an uncertain treatment is for a life-threatening condition, should NICE still be prepared to OIR it rather than say "yes"? Arguments for doing so include honesty, consistency, the need to avoid wasting resources, and the importance of good research data not just to present but to future patients. Arguments against include patient choice and the avoidance of legal and other pressures.

11. Interventional procedures. There is a need to prevent new procedures being introduced into the NHS without a sufficient evidence base.

The final session of the day comprised a question and answer session with Professor Littlejohns and Dr Kalipso Chalkidou, NICE’s associate director for R&D. The aim was to clarify a few of our remaining uncertainties about research, and the significance of an OIR recommendation. Points emerging from this session included the following:

- doctors may receive a financial inducement to do research; this can be direct or indirect, in cash or in kind.
- the research specified in an OIR recommendation could be an RCT, the creation of a register, or something else – provided, in each case, that it receives ethical approval and is based on a formally agreed protocol.
- anyone can submit a question to NICE if they feel it to be an issue that merits attention. These are prioritised and passed to Ministers, who make the final decision about the topics to be examined.
- 'not all OIR decisions are identical. They represent varying degrees of enthusiasm on the part of appraisers.' They may be implicitly or explicitly encouraging or discouraging. They generally say precisely what sort of further research is required, and the questions that should be answered – but not how. Appraisal committees are not research commissioning bodies.
- people chosen to serve on appraisal committees represent the full range of stakeholders.
- with more drugs coming to market that have been tailored to the needs of smaller groups of people, it seems likely that OIR decisions will become more common.
Final day, final thoughts
Before taking a final vote on the circumstances under which an OIR ruling might be appropriate, we held one more group discussion on the issue. One of our number, dissatisfied with the imprecision of the term “uncertainty”, would have liked to quantify the precise degree of uncertainly that might (or already does) justify a NICE appraisal committee categorising an intervention OIR. This is not how NICE currently proceeds, and some of us were doubtful that such mathematical precision is achievable. Another member wondered if setting out the circumstances in which an OIR should be granted might be the forerunner of the systematic appraisal of all NHS interventions. Whether resources would allow any such development is a moot point – but no-one at the meeting was prepared to rule it out.

A couple of members were firmly of the view that NICE should not use OIR purely as a means of controlling cost. Honesty requires that if a new intervention is too expensive for the NHS, these should be the grounds on which it is ruled out. There was support for Professor Ashcroft’s statement that if further research can make no difference to the assessment of an intervention’s cost-effectiveness, then it would be dishonest to make an OIR rather than a straight yes/no decision. There was also general agreement that NICE should be precise about the extra information required; it would be wasteful and unfair to send researchers off on a wild goose chase.

One member pointed out that our provisional list of recommended circumstances included some that were repetitive, or unclear, or could be grouped together. The list was shortened and reordered and, when we were not unanimous, we voted on a show of hands.

How we view OIR recommendations
The results of the straw polls - along with the votes we took on the first eight of our conclusions - make it clear that most of us view OIR recommendations as acceptable in principle. As the remainder of our conclusions reveal, we also have a number of caveats and reservations.

In some areas where we were generally agreed on the likely effects of an OIR recommendation, the strength of our agreement seemed to become distinctly firmer during the course of our meeting. These areas included:
- the possibility that patients would be reassured to know that clinicians and the healthcare system in general could face up to uncertainty, and were confident enough to deal with it in a mature, scientific way, and avoid wasting money on unproven technologies [Charts1 & 2]. “All the public really want is the truth,” wrote one member in the comment space on the questionnaire. “Honesty would be appreciated,” wrote another. “I don’t think there is much confidence left”, was another and rather mournful view.

On other issues where we generally agreed, there was more of a drift toward certainty. These included:
- the opportunity that an OIR offers for patients to share responsibility in evaluating benefits, harms and cost effectiveness [Chart 3]. “But would they wish to share responsibility,” wondered one member. “\( I \) think they should; they may not agree,” said another.
- the possibility that health professionals and managers would accuse NICE of sitting on the fence [Chart 4]. “NICE has suffered worse allegations,” was one cheery comment. “It’s up to NICE to put its case strongly,” was another.

In other areas there was a drift towards greater uncertainty. For example:
- the possibility that NICE saying “yes” rather than OIR would cause current research programmes to be halted [Chart 5]

In some areas of majority agreement there was little change. These included:
- the unfortunate fact that some patients would, for a time, be denied a therapy that eventually proved to be beneficial [Chart 6]. Comments included, “Unavoidable and inevitable”, “A fact of life”, and “Especially if the research takes a long time”.
- the encouragement of an understanding that many interventions have not been adequately tested and may in fact be poor value for the NHS [Chart 7]
- a perception that the NHS is rationing care [Chart 8]
- the risk of an OIR fostering the view that patients are forced to be guinea pigs [Chart 9]. “A risk that should however be manageable.”
- the speed of recruitment of patients into clinical studies [Chart 10].

Because the public might feel that an OIR decision is all about cost cutting, we felt that NICE had a duty to explain clearly to the general public at large and patients in particular what the benefits of an OIR recommendation could be. Included in this was the need to explain that resources in the NHS are finite and therefore NICE has to make sure that anything it recommends represents good value for money [Chart 11]. “NICE should be able to educate the public”, “NICE must correct this perception”, and “The common perception is already one of the NHS as cost-driven”, and “The public must be realistic. The NHS can only fund so many things at once.”

Some members felt that when a treatment has already been available and is then categorised as OIR, there should be the ability to feed findings from the research into these newly categorised OIR treatments to key organisations; that those already receiving the treatment should be part of any new research programme.

Our feelings shifted somewhat in the course of the meeting but in the end we felt that OIR decisions had the potential to increase patient safety [Chart 12]. “Most people would realise the dangers of inadequate research,” commented one member.

It was clear from many of our comments that we recognise the difficulty NICE has to face whenever it makes a recommendation that runs counter to vested interests, or annoys industry, or upsets particular groups of patients. We are virtually of one mind in stressing the importance of communicating with the public and the media, explaining the logic of difficult or contentious decisions, and putting effort into ‘transparent and effective PR.’
Appendix 1 Tracking Questionnaire Results

Below are some implications, or consequences of NICE making an 'only in research' recommendation. The Citizens Council was asked to indicate to what extent they agreed with each one. They were given the questionnaires on four occasions throughout the three-day meeting as indicated in the agenda in Appendix 3 in order to track any changes over the course of the meeting; at the beginning and end of day 1, the end of day 2 and at the end of the meeting on day 3. The results are set out below.

CHART 1 Patients re-assured by honesty of clinicians and the healthcare system in general about the issue of uncertainty

CHART 2 Confidence that the NHS confronts uncertainties in a mature, scientific way and avoids wasting money on unproven technologies
Below are some implications, or consequences of NICE making an ‘only in research’ recommendation. To what extent do you agree or disagree with each one?

**CHART 3** Opportunity for patients to share responsibility for evaluating benefits and harms, and cost effectiveness of interventions

**CHART 4** NICE could be accused of sitting on the fence by professionals and managers who need to make a decision
Below are some implications, or consequences of NICE making an ‘only in research’ recommendation. To what extent do you agree or disagree with each one?

**CHART 5** If NICE says ‘yes’ rather than ‘only in research’ this will cause current research projects to be stopped

**CHART 6** Patients may feel prevented from accessing a therapy which may prove to be beneficial
Below are some implications, or consequences of NICE making an ‘only in research’ recommendation. To what extent do you agree or disagree with each one?

**CHART 7** Encourage understanding that many interventions in common use have not been adequately tested and they could be poor value for the NHS, providing no benefit or even doing harm

**CHART 8** NHS is seen to be rationing care
Below are some implications, or consequences of NICE making an ‘only in research’ recommendation. To what extent do you agree or disagree with each one?

**CHART 9** Risk of perception that patients are ‘forced’ to be guinea pigs or else won’t receive treatment

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire 1</td>
<td>8</td>
<td>5</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Questionnaire 2</td>
<td>13</td>
<td>2</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Questionnaire 3</td>
<td>1</td>
<td>14</td>
<td>5</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Questionnaire 4</td>
<td>1</td>
<td>13</td>
<td>3</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**CHART 10** More rapid recruitment of patients into studies/trials

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire 1</td>
<td>1</td>
<td>19</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Questionnaire 2</td>
<td>19</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Questionnaire 3</td>
<td>20</td>
<td>5</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Questionnaire 4</td>
<td>2</td>
<td>18</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Below are some implications, or consequences of NICE making an ‘only in research’ recommendation. To what extent do you agree or disagree with each one?

**CHART 11** The public may feel that patients are being prevented from accessing a therapy and that the aim is to cut costs

**CHART 12** Improved patient safety
Appendix 2 Question

Uncertainty and ‘Only in Research’

NICE’s Question

The Citizens Council is asked the following question:

“In what circumstances is it justified for NICE to recommend that an intervention is used only in the context of research?”

Background

NICE exists to develop guidance for the NHS and the wider public health community, based on the available evidence. However, there are often “gaps” in the evidence that NICE reviews. Such gaps may exist because:

- too few studies have been undertaken of the intervention NICE is considering;
- the studies that have been undertaken have not looked at relevant questions;
- unreliable methods have been used in the studies;
- the studies have been too small;
- the studies have investigated inappropriate patients;
- the quality and/or reporting of the available studies have not been good enough.

Irrespective of the causes, the consequences of such “gaps” in knowledge are the same: uncertainty about the effects of the intervention under consideration.

Such uncertainty is unavoidable and NICE cannot reject the use of an intervention just because there is some uncertainty about its effectiveness. The Institute expects the members of its advisory bodies to use their judgement in deciding whether the uncertainties make it more or less likely that an intervention is effective. Indeed, NICE has been able to recommend to the NHS, most of the interventions it has considered despite some gaps in the evidence. Such gaps are usually identified in a set of ‘Recommendations for Further Research’ which follow the main guidance.

However, as well as making recommendations for further research of interventions which it supports, NICE has sometimes recommended that interventions only be available in the NHS as part of a research programme (i.e. “only in research”). The additional evidence gathered by this research will then be used when NICE reviews its guidance. This approach has been used when promising interventions have not yet been supported by sufficiently robust evidence to justify an unqualified recommendation.

The “only in research” approach has also been applied in the context of the NICE Interventional Procedures programme (IP). This programme evaluates the safety and efficacy of interventional procedures, such as surgical operations or laser treatment for eye problems. IP guidance is different to the rest of the NICE products as it does not recommend the use of...
an intervention; instead, it assesses whether the intervention works and is safe to be used on
patients.

The ‘only in research’ option

The phrase “only in research” covers two types of studies:

- Use only if patients agree to participate in a randomised controlled trial;
- Use only if patients agree that their relevant clinical details are collected for later
  analysis (in a so-called data-base or registry).

Randomised controlled trials

In 2000, NICE recommended that removal of cancerous bowel by laparoscopic (keyhole)
surgery should only be done as part of a randomised controlled clinical trial. At the time,
there was uncertainty about whether this approach to treating bowel cancer was as safe and
effective as conventional (open) surgery. Although laparoscopic colectomy reduces,
considerably, the time spent in hospital after the procedure, the technical demands produced
uncertainty about how effective it might be in routine practice.

The Medical Research Council was, at that time, in the process of conducting a randomised
controlled trial comparing the outcomes of patients treated by keyhole surgery with those
treated conventionally. In this trial, patients with bowel cancer were allocated “randomly” –
and with their fully informed consent – to one of the two procedures.

The effect of NICE’s recommendation was that only those NHS patients who agreed to take
part in this MRC trial had the opportunity to be treated by the new “keyhole” procedure. And
even then, only half would be treated in this way: the other half would be treated using the
conventional surgical method. Patients who did not agree to take part in the study were
treated by the conventional surgical approach.

NICE’s decision encouraged recruitment to the Medical Research Council’s trial. The results
of the study showed that keyhole removal of the cancerous bowel was as effective, and as
safe, as conventional surgery. This provided the necessary evidence to support a NICE
recommendation that this intervention be introduced in routine NHS practice.

Patient registries

In 2003 the Interventional Procedures Advisory Committee investigated whether uterine artery
embolisation, for heavy periods due to fibroids, was safe and effective enough for routine use
in the NHS. Heavy periods due to fibroids are normally treated by surgical removal of womb
(hysterectomy). In this new technique the blood supply to the womb is blocked by injecting
very small particles into the blood vessels taking blood to the womb and the fibroids shrink.

This new procedure (called “uterine artery embolisation”) is done under sedation, rather than
general anaesthesia, and women need stay in hospital for 24 hours rather than 7 days after a
conventional hysterectomy.

The Advisory Committee was uncertain how effective the procedure was; and they were
concerned at its possible complications. They therefore recommended that patients should
only be treated under the NHS, using this new procedure, if they agreed to allow their relevant
details to be entered into an electronic database.

Recommendations such as these are now found not only in appraisals and interventional
procedures but also in clinical guidelines and, since April 2005, in public health guidance.
Indeed, in one of the first pieces of public health guidance published by NICE in March 2006,
three of the four interventions considered were recommended only in the context of research
Almost half of NICE’s recommendations in its interventional procedures guidance (which advises on safety and efficacy of surgical procedures) fall in the category of “cautionary guidance” and are recommended only with additional requirements for consent, audit and, occasionally, for more formal research. This is a way of encouraging responsible introduction of procedures without restricting them to “research only”.

**Consequences of using the ‘only in research’ option**

The potential risks and potential benefits to various types of stakeholders of using the ‘only in research’ option are summarised in the table below.

<table>
<thead>
<tr>
<th>Potential benefits</th>
<th>Potential risks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
<td></td>
</tr>
<tr>
<td>Greater clarity about health care uncertainties, leading to a decrease in variation in practice</td>
<td>Patients may feel prevented from accessing a therapy which may prove to be beneficial</td>
</tr>
<tr>
<td>Patients re-assured by honesty of clinicians and the healthcare system in general about the issue of uncertainty</td>
<td>Patients feel concerned about their doctors’ knowledge or ability if they express uncertainty.</td>
</tr>
<tr>
<td>Patients feel that they are part of the decision making</td>
<td>Patients may feel “coerced” into participating in research</td>
</tr>
<tr>
<td>Opportunity to share responsibility for evaluating benefits and harms, and cost effectiveness of interventions</td>
<td>As it is unlikely that the trials can be accessible for all, patients may feel that this is another example of variation in care</td>
</tr>
<tr>
<td><strong>Public</strong></td>
<td></td>
</tr>
<tr>
<td>Confidence that the NHS confronts uncertainties in a mature, scientific way and avoids wasting money on unproven technologies</td>
<td>The public may feel that patients are being prevented from accessing a therapy and that the aim is to cut costs.</td>
</tr>
<tr>
<td>Encourage understanding that many interventions in common use have not been adequately tested and they could be poor value for the NHS, providing no benefit or even doing harm</td>
<td>Patients feel that all possible interventions should be available to them, regardless of conventional scientific evidence of benefit.</td>
</tr>
<tr>
<td>Foster a sense of contributing personally to a better NHS</td>
<td>Patients feel that personal access to treatment should not be impeded by need for research</td>
</tr>
<tr>
<td>Potential benefits</td>
<td>Potential risks</td>
</tr>
<tr>
<td>-------------------</td>
<td>----------------</td>
</tr>
<tr>
<td><strong>The NHS</strong></td>
<td></td>
</tr>
<tr>
<td>Faster accumulation of useful evidence to inform practice; less chance of the NHS funding ineffective or harmful technologies for decades</td>
<td>NHS is seen to be rationing care</td>
</tr>
<tr>
<td>Reduces risk of NHS will reversing previous decisions and thus compromising its credibility by wasting valuable resources, for example, when money is invested in equipment no longer recommended</td>
<td>Risk of perception that patients are ‘forced’ to be guinea pigs or else won’t receive treatment</td>
</tr>
<tr>
<td><strong>Researchers</strong></td>
<td></td>
</tr>
<tr>
<td>More rapid recruitment of patients into studies</td>
<td>R&amp;D resources spent on research prioritised by NHS/ health professionals rather than on that being decided by researchers themselves</td>
</tr>
<tr>
<td>Greater chance of the result influencing clinical practice</td>
<td></td>
</tr>
<tr>
<td>Minimising the risk of a positive NICE recommendation causing current research projects to be stopped</td>
<td></td>
</tr>
<tr>
<td>Better quality, more relevant research questions developed by consensus of researchers with patient/public input</td>
<td></td>
</tr>
<tr>
<td><strong>Funders of research</strong></td>
<td></td>
</tr>
<tr>
<td>More rapid recruitment of patients into trials</td>
<td>Reduced control on research agenda</td>
</tr>
<tr>
<td>Greater clarity about clinical research priorities</td>
<td></td>
</tr>
<tr>
<td>Greater chance of the results influencing practice</td>
<td></td>
</tr>
<tr>
<td>More influence on health problems of most importance to patients</td>
<td></td>
</tr>
<tr>
<td><strong>Health professionals (Doctors, nurses, public health specialists etc.)</strong></td>
<td></td>
</tr>
<tr>
<td>Faster accumulation of useful evidence to inform practice and to improve shared decision-making of patient with doctor</td>
<td>May find it difficult to be honest when discussing the degree of uncertainty of effectiveness / safety about a treatment or intervention with their patients</td>
</tr>
<tr>
<td>Greater clarity and publicity about where clinical uncertainties lie, making it easier to discuss these uncertainties with patients</td>
<td>Uncertain about what OIR means in practice if no access to a suitable study</td>
</tr>
<tr>
<td>Potential benefits</td>
<td>Potential risks</td>
</tr>
<tr>
<td>-------------------</td>
<td>----------------</td>
</tr>
<tr>
<td><strong>Manufacturers of drugs or devices</strong></td>
<td><strong>Concern that the market for their product will be limited while the trial is underway</strong></td>
</tr>
<tr>
<td>- The opportunity to acquire evidence rapidly about the cost effectiveness, safety etc. of their technology in NHS settings</td>
<td></td>
</tr>
<tr>
<td>- To be able to cite reliable evidence to support their claims</td>
<td></td>
</tr>
<tr>
<td><strong>NICE</strong></td>
<td><strong>Could be perceived by patients to be unnecessarily rationing care</strong></td>
</tr>
<tr>
<td>- Reduced risk of having to reverse earlier decisions</td>
<td></td>
</tr>
<tr>
<td>- Maintenance of technical rigour while addressing the challenge of timeliness</td>
<td></td>
</tr>
<tr>
<td>- Development of evidence-based clinical and public health guidance</td>
<td></td>
</tr>
<tr>
<td>- Support innovation and patient access to new and emerging technologies and techniques</td>
<td></td>
</tr>
<tr>
<td>- Improved patient safety</td>
<td></td>
</tr>
<tr>
<td>- Improved control of public funds</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Could be accused of sitting on the fence by professionals and managers who need to make a decision</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Could be accused by companies of stifling innovation</strong></td>
</tr>
</tbody>
</table>
Circumstances that may matter

It has been suggested that there are some matters that might affect the appropriateness of an ‘only in research’ recommendation:

1. Whether at least one appropriate, relevant study is either:
   - planned (e.g. the study will definitely start within 6 months of the guidance publication date);
   - in progress (e.g. recruitment to the study is open, and is expected to last at least 1 year beyond the guidance publication date); or
   - could be established quickly;

2. Whether the question addressed by the study will contribute to reducing the uncertainties identified during the preparation of NICE guidance;

3. Whether the research is feasible (in terms of numbers of patients, recruitment etc.) and is likely to deliver results within an appropriate time period;

4. Whether the study will be multi-centre with broad coverage of geographical area and population to ensure that as many eligible patients as possible can realistically access the technology within a study setting;

5. Whether further research is good value for money

6. Whether a fully supportive decision, would lead to significant irretrievable fixed costs of implementation; and

7. Whether a fully supportive decision, instead of an “only in research” recommendation, would lead to the termination of research in progress or prevent new research from beginning and thus have a negative impact on future collection of relevant information.

Additional parameters may also have to be considered, such as the precise nature of the intervention/treatment; the potential number of patients able to participate in research; the stage of evaluation an intervention might be at, and the ‘pace’ of that research.

The Council is invited to consider these issues, as well as other relevant ones that may arise, and advise the Board.

Professor Sir Michael Rawlins  Professor Peter Littlejohns
Chairman     Clinical and Public Health Director
## Appendix 3 Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Who</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Thursday 25th January</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.00am – 9.15am 15 mins</td>
<td>Welcome from Vision 21</td>
<td>Ela, Brendan, Helen, Jess, Geoff.</td>
</tr>
</tbody>
</table>
| 9.15am – 10.00am 45 mins | Welcome from NICE  
Introduction to the question  
Setting the context for NICE  
What happens now, why is this question significant?  
Tracking Questionnaire 1 | Andrew Dillon  
Peter Littlejohns  
Kalipso Chalkidou |
| 10.00am – 11.00am 60 mins | Introduction to Health Economics / ‘Only in Research’ and the Value of Information | Karl Claxton                                   |
| 11.00am – 11.15am 15 mins | **BREAK**                                                             |                                               |
| 11.15-12:00. 45 mins | The importance of the issue of ‘Only in Research’                    | Sir Iain Chalmers                              |
| 12.15-12:45 30 mins | **LUNCH**                                                             |                                               |
| 12:45 – 2:00pm 1hour 15 mins | Research                                                             | Mike Clarke  
Sarah Garner  
Mike Clarke |
| 2.00pm – 3.00pm 1 hour | What are the implications of an OIR recommendation?  
Part 1 | Experts to facilitate  
1. Representative of Appraisal Group – Sarah Garner  
2. Doctor/clinician Richard Lilford  
3. Tony Hope – ethical, perspective  
4. Karl Claxton – health economist |
<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Who</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BREAK</strong></td>
<td>Will be taken during the exercise</td>
<td></td>
</tr>
<tr>
<td>3.00 - 3.30pm</td>
<td>Feedback to Expert Group</td>
<td></td>
</tr>
<tr>
<td>30 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.30pm – 4.30pm</td>
<td>What the Experts say</td>
<td>Each expert will have 15 minutes to present their views.</td>
</tr>
<tr>
<td>1 hour</td>
<td></td>
<td>1. Richard Lilford</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Tony Hope</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Karl Claxton/Sarah Garner</td>
</tr>
<tr>
<td>4:30 pm – 5:00 pm</td>
<td>‘Only in research’ and NICE’s Interventional Procedures Programme</td>
<td>Bruce Campbell</td>
</tr>
<tr>
<td>30 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.00pm – 5.30pm</td>
<td>Reflection tracking questionnaire 2</td>
<td>Peter Littlejohns/Kalipso Chalkidou to come in to answer any technical questions</td>
</tr>
<tr>
<td>30 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Friday 26th January</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.00am – 9.30am</td>
<td>Recap</td>
<td>Ela and Geoff Watts</td>
</tr>
<tr>
<td>30 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.30am – 1.00pm</td>
<td>What are the implications of an OIR recommendation?</td>
<td>Tony Whitehead</td>
</tr>
<tr>
<td>incorporating half hour break</td>
<td></td>
<td>Hazel Thornton</td>
</tr>
<tr>
<td>3 hours 30 mins</td>
<td>Part 2</td>
<td>Nick Black</td>
</tr>
<tr>
<td></td>
<td>Question Time Panel</td>
<td>Richard Ashcroft</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Margaret McCartney</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Brian Buckley</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dora Opoku</td>
</tr>
<tr>
<td></td>
<td></td>
<td>John Sitzia (INVOLVE)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair: Ela Pathak-Sen</td>
</tr>
<tr>
<td>1.00pm – 2.00pm</td>
<td><strong>LUNCH</strong></td>
<td></td>
</tr>
<tr>
<td>2.00pm – 5.00pm</td>
<td>Initial Conclusions</td>
<td>Peter Littlejohns/Kalipso Chalkidou to come back in (3pm)</td>
</tr>
<tr>
<td>3 hours</td>
<td>Tracking Questionnaire 3</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>Title</td>
<td>Who</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>Saturday 27th January</strong></td>
<td>9.30am – 12.00pm 2 hours 30 mins</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drawing conclusions and deciding what goes into the report.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tracking Questionnaire 4</td>
<td></td>
</tr>
<tr>
<td>12.00pm</td>
<td>Close and Thanks</td>
<td>Peter Littlejohns</td>
</tr>
<tr>
<td>12.30pm</td>
<td>LUNCH</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4 Speakers

**Professor Richard Ashcroft**
Richard is Professor of Biomedical Ethics at Barts and the London School of Medicine and Dentistry, which is part of Queen Mary, University of London. Before joining Queen Mary in May last year Richard was head of the medical ethics unit at Imperial College London. He is a deputy editor of the Journal of Medical Ethics, and a member of the ethics committee of the Medical Research Council and the Gene Therapy Advisory Committee. Richard has published a number of papers on ethics in clinical trials, and is also interested in genetics and in public health. Richard is married with a young son, and when he can he likes to sail.

**Professor Nick Black**
Professor of Health Services Research.
His main research interests are the use of clinical databases for evaluation and audit of health services (particularly in the fields of surgery and intensive care), non-randomised methods of evaluation, the relationship between research and policy, and the history of health services. He is involved in several aspects of the NHS R&D programme and is Chair of the UK Health Services Research Network. In 1996, together with Nick Mays, he founded the Journal of Health Services Research & Policy, which they continue to edit. He has recently published *Walking London’s medical history*, an attempt to raise public understanding of health services and health care policy through seven walks through London.

**Brian Buckley**
Brian Buckley is a voluntary trustee and Chairman of Incontact, a UK charity providing support for and campaigning on behalf of people with continence problems. He has been a lay/patient advocate member of the Health Technology Appraisal Committee of the National Institute of Health & Clinical Excellence (NICE) since 2003.

Along with the James Lind Alliance, he is currently involved in establishing a Working Partnership betweenclinician and consumer organisations which will identify and prioritise issues relating to incontinence which are currently unanswered by existing research evidence in order to inform the research agenda.

Originally trained as a sculptor, he worked for many years as an artist and as a designer in theatre, film and television.

Brian Buckley now works as a researcher in Primary Care. His main research interests are people’s relationship with their health and with health services, and the involvement of patients in research and health care decision making. He is currently finishing his PhD, which is concerned with the secondary prevention of ischaemic heart disease. He is principal author on an ongoing Cochrane review of secondary preventive interventions for ischaemic heart disease.

He works with the Cochrane Collaboration Review Group at the University of Aberdeen, developing methods for identifying and incorporating patients’ perspectives in systematic reviews of research into incontinence. He is involved in several major multi-centre Randomised Controlled Trials of treatments of incontinence in the UK.

**Professor Bruce Campbell, MS, FRCP, FRCS.**
Consultant in Vascular and General Surgery, Royal Devon and Exeter Hospital. Honorary Professor, Peninsula Medical School.


*HTA*: (Health Technology Assessment programme of the NHS): Chairman, Therapeutic Procedures Panel - prioritizing research topics.
Clinical work: Elective and emergency vascular surgery.

Publications include: Varicose veins; Vascular Services; Consent and information for patients; Palliative care; Amputation.

Assistant Editor, Annals of the Royal College of Surgeons of England.

Kalipso Chalkidou, MD, PhD
Associate Director for Research and Development, NICE

Kalipso is responsible for the planning and delivery of a NICE research and development agenda to support the production of cost-effective clinical and public health guidance. She advises the Institute’s Senior Management Team and the Board on emerging challenges facing the Institute and has been actively involved in promoting organisational change within the Institute as part of the R&D team. Kalipso is the lead in a number of methodology and guidance projects across the different NICE Centres. Before joining NICE, Kalipso worked as a surgical trainee in Cambridge after completing a PhD in the molecular biology of advanced prostate cancer at the University of Newcastle Medical School. She is a graduate of the Athens Medical School.

Sir Iain Chalmers
Iain Chalmers is co-ordinator of the James Lind Initiative, which promotes public and professional acknowledgement of uncertainties about the effects of treatments and research to address them. He edits The James Lind Library (www.jameslindlibrary.org), a web-based resource containing material about fair tests of medical treatments; he is a co-author of Testing Treatments: better research for better healthcare, a book for the public published by the British Library; and he coordinates the Database of Uncertainties about the Effects of Treatments – DUETs (www.duets.nhs.uk), a resource to help prioritise new research in the UK. He was director of the UK Cochrane Centre between 1992 and 2002, and director of the National Perinatal Epidemiology Unit between 1978 and 1992.

Professor Mike Clarke
Director UK Cochrane Centre
The UK Cochrane Centre was established at the end of 1992, by the National Health Service Research and Development Programme, ‘to facilitate and co-ordinate the preparation and maintenance of systematic reviews of randomised controlled trials of health care’. The UK Cochrane Centre is now one of twelve Cochrane Centres around the world which provide the infrastructure for co-ordinating The Cochrane Collaboration. The Centre supports contributors to The Cochrane Collaboration in the United Kingdom, Ireland, Turkey and countries in the Middle East.

Tony Hope MA PhD MBBCh FRCPsych MFPH
Tony Hope is Professor of Medical Ethics at the Ethox Centre in the University of Oxford, and Honorary Consultant Psychiatrist.

He has carried out research in basic neuroscience and Alzheimer’s Disease. Since 1990 he has focused on clinical ethics. His books include: the Oxford Handbook of Clinical Medicine (editions 1-4); Manage Your Mind; Medical Ethics and Law: the Core Curriculum; and Medical Ethics: A Very Short Introduction.

Richard James Lilford

<table>
<thead>
<tr>
<th>Qualifications:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic</td>
<td>MB BCh</td>
<td>-</td>
</tr>
<tr>
<td>MRCOG</td>
<td>-</td>
<td>January 1979</td>
</tr>
<tr>
<td>MRCP</td>
<td>-</td>
<td>February 1981</td>
</tr>
<tr>
<td>PhD</td>
<td>-</td>
<td>July 1984</td>
</tr>
<tr>
<td>MFPHM</td>
<td>-</td>
<td>June 1995</td>
</tr>
<tr>
<td>FRCOG</td>
<td>-</td>
<td>July 1996</td>
</tr>
<tr>
<td>FRCP</td>
<td>-</td>
<td>June 1997</td>
</tr>
<tr>
<td>FFPH</td>
<td>-</td>
<td>June 2003</td>
</tr>
</tbody>
</table>
Born in Cape Town and educated in Johannesburg Professor Richard J Lilford is Professor of Clinical Epidemiology in the Department of Public Health and Epidemiology, in the Medical School, in the University of Birmingham. He was appointed Head of Division for Division of Primary Care, Public and Occupational Health of the School of Medicine for a three-year term in January 2005. He is also the Director of the Patient Safety Research Programme for the Department of Health in England and he is Director of the Research Methods Programme.

He is a member of the NICE Appraisals Committee and a past member of the MRC Health Services and Public Health Research Board. He is a member of the Research and Development Committee of NICE.

Richard Lilford is an investigator on the Engineering and Physics Council/Industry MATCH Programme. His role in this is in health economic and decision analytic modelling and statistics. MATCH is the Multi-disciplinary Assessment of Technology Centre for Health.

Richard Lilford has occupied his present post for three years. Prior to that he was, for five years, a senior civil servant. Before that, he was for eleven years Professor of Obstetrics and Gynaecology in the University of Leeds. He was also an executive director with responsibility for R&D of the United Leeds Teaching Hospitals.

Professor Lilford’s main interests are in Bayesian statistics, ethics and clinical trials. Professor Lilford has published over two hundred and fifty original research papers and he is an investigator on over seven and a half million pounds worth of government, industry and charity sponsored research.

**Karl Claxton**

Karl Claxton is a Professor in the Department of Economics and Related Studies at the University of York. He is also a Senior Research Fellow in the Centre for Health Economics, University of York. In 1997/98 he was a visiting Harkness Fellow at the Harvard Center for Risk Analysis, Harvard School of Public Health and since 1999 he has held an adjunct appointment at Harvard as an Assistant Professor of Health and Decision Sciences. His research interests encompass the economic evaluation of health care technologies. The key areas of interests include: Bayesian decision theory; the value-of-information analysis; setting priorities in clinical research and development; and the efficient design of clinical trials. He has served as a member of the National Institute for Clinical Excellence Appraisal Committee since September 1999. The committee meets monthly to appraise new and existing health care technologies and issue guidance for the NHS on the use of these technologies. More recently he has contributed to the Task Group which developed guidance for the appraisal of health technologies for NICE. He is also co-editor of the Journal of Health Economics.

Sarah Garner
Dr Sarah Garner is a pharmacist and is a Technical Advisor for the Appraisal's Team at NICE. Sarah has been with the Institute for over six years and her current role is quality assurance of individual appraisals and the development of new methodology including the use of disease registers. Sarah also specialises in broader aspects of pharmaceutical policy and is the lead for the Department of Health advisory committee on antimicrobial resistance and an editor for the Cochrane Skin Group.

Margaret McCartney
General Practitioner in Glasgow and columnist for the Weekend Financial Times.

Dora Opoku MBE
Dora Opoku is currently the Head of Department of Midwifery at City University, London, England. Her department works closely with 4 health Trusts where students from her department receive their practice education within some of the most diverse and economically deprived areas in England.

Dora has a strong interest in ethics which goes back awhile and influenced her area of further study in the early 1990’s when she read for her masters degree in Medical Law and Ethics at King’s College, London.

In 2002 she was a member of the Department of Health (England) Good Practice in Consent Advisory Group in 2001.

She combines her role of academic midwife with extra curricula community and church orientated activities. Dora currently chairs one of the 3 Research Ethics Committees of the East London and the City Health Authority.

John Sitzia
John is the Sussex NHS Research Consortium Co-Director. John is responsible for the overall management and strategic development of the Consortium. He is also Associate Director (R&D) at Worthing and Southlands Hospitals NHS Trust.

John is a member of INVOLVE. INVOLVE was established to promote public involvement in research, in order to improve the way that research is prioritised, commissioned, undertaken, communicated and used.

Hazel Thornton
Hazel was given the ‘breast cancer’ label following acceptance of the invitation to attend for population breast cancer screening for 50-64 yr. olds in September 1991. Her diagnosis of Ductal Carcinoma in Situ (DCIS) led to an invitation to join the U.K.DCIS Trial, which she declined. (See: Breast cancer trials: a patient’s viewpoint. Lancet 1992; 339:44-45) Numerous published papers, presentations and involvements followed.

In September 1994 she co-founded the Consumers’ Advisory Group for Clinical Trials (CAG-CT): a joint profession/patient working group. She now describes herself as an “Independent advocate for quality in research and healthcare.”

She has been involved in various research projects as: an adviser; steering group member; an applicant (successful); a referee of grant applications; a member of a breast cancer commissioning group; a co-author disseminating research findings; and as a member of (2) Data Monitoring and Safety/Ethics Committees.

Hazel is an Honorary Visiting Fellow in the Department of Health Sciences at the University of Leicester. In July 2002 she received an Honorary Doctor of Science degree at the University of Leicester for her contribution to medicine and patient care. She was elected a Fellow of the Royal Society of Medicine in December 2002.
Dr Tony Whitehead MB ChB FFPM
Tony Whitehead graduated in Medicine from Liverpool University in 1979 and worked in Hospital Medicine and General Practice before joining the Pharmaceutical Industry in 1984. He has worked for Solvay Healthcare and Pfizer, in the US and UK, and also within the Biotechnology sector. He has experience in a range of therapeutic areas including Cardiovascular Medicine, Metabolic Diseases, Urology, Oncology Gastroenterology and Psychiatry. Tony joined Sanofi-Synthelabo as Medical Director for UK Ireland in October 2002 and was appointed UK Medical Director for sanofi-aventis, following the merger in October 2004. He is a member of ABPI Medical Committee and NICE R&D Advisory Committee. He is active in several areas within the Faculty of Pharmaceutical Medicine involved in Higher Medical Education and Training.
Appendix 5 Citizen Council Members

Clifford Avery - an aircraft servicing engineer from Essex.

Jonathan Barwick – is a lecturer and trainer in hospitality and travel at a Further & Higher Education college in Norfolk.

David Batchelor – an engineer from Leicester.

Michael Beecroft – a self-employed driving instructor from Lincolnshire.

Andrew Callaghan – a gardener from West Yorkshire.

Steven Coad – an industrial safety engineer who lives in County Durham.

Tim Duckworth – a courier from Bury in Lancashire.

Freda England – works for the Citizens Advice Bureau and is from Lymington in Hampshire.

Ron Findley – a database administrator from London.

Geraldine Fost – a retired careers guidance manager, who lives in Hungerford, Berkshire.

Alan Garvey – an auto engineer who lives in Manchester.

Lorna Girling - lives in Norfolk, and is a part time literature student and a housewife and mother of two.

Terry Hamer - lives in Southampton. He works on the cruise ships at the terminal.

Meryl Hobbs – a retired teacher and farmer’s wife from Herefordshire.

Kelly Hughf – a veterinary nurse who comes from Bishop Auckland.

Susan Jackson – is a cabin crew member from Surrey.

Robert Jones - works as a warehouse operative and is a football referee in his spare time. He lives in Cwmbran, Wales.
Catherine Kaer-Jones – a student support leader working in a Bradford school.

Jack Kelley – is from Doncaster and worked in the construction industry but is now in security.

Claire Marshall – is a freelance writer from London.

Tina McDonnell – a trainer with a High Street bank from London.

Freda McEwan – a witness liaison officer for the Metropolitan Police, from London.

Christine Minton – a retired community service unit manager for the Probation Service, living in Essex.

Linda Moss - currently unemployed, trained as a TEFL teacher and now lives in Todmorden, West Yorkshire.

Patricia Roberts – an accounts assistant from Flintshire.

Heena Sabir - worked for a while in human resources, and has recently moved to Huddersfield, where she is looking for suitable work.

Mohammed Shakil – is from Rotherham and training to be an accountant.

John Shephard – a technical author from Derby.

Rebecca Sparling – a full time university student living in Birmingham.

Paddy Storrie - a secondary school Deputy Headteacher, lives in Harpenden, Herts.