



## **Report on NICE Citizens Council meeting**

### **Patient Safety**

**7 – 9 June 2007**

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## 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 June 2007 meeting of the Council, the key question for the Council was as follows: Does the Citizens Council accept that it is appropriate when developing "patient safety solutions" that NICE take the costs, as well as the benefits, into account? The Council's report will be available for public comment before it is presented to the Institute's Board in November 2007.

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 NICE asked us to consider**

The Institute has been asked to develop solutions to reduce or prevent harm to patients while under the care of the NHS. It is, currently, the intention of the Institute to take account of cost effectiveness, as well as clinical effectiveness, when developing patient safety solutions.

1. Does the Citizens Council accept that it is appropriate when developing “patient safety solutions” that NICE take the costs, as well as the benefits, into account?
2. If the answer to question 1 is ‘yes,’ what principles of cost-effectiveness should apply?
3. If the answer to question 1 is ‘no,’ what criteria should NICE apply in deciding whether or not it should recommend a particular safety solution to the NHS?

### **The conclusions we reached**

In response to the first question put to us, a substantial majority of the Council agreed that it is appropriate for NICE to take account of costs as well as benefits when developing guidelines on the improvement of safety.

We are aware that the methodology currently used by NICE – and which is also likely to be used in developing safety solutions - relies on the QALY. However, a substantial majority felt that the QALY methodology did not lend itself well to making decisions on cost effectiveness in the area of patient safety. This is because the QALY does not include certain costs including litigation, cost to carers and those left behind following a death.

However, mindful that the QALY continues to be widely used in work of this kind and that currently there is no other adequate cost effectiveness tool, most of us also felt it would not be helpful to NICE simply to dismiss QALYs out of hand. So, with this absence of a suitable alternative, we would suggest that if NICE is to use QALYs in assessing safety solutions, it does so with a degree of flexibility greater than is normally the case when setting a threshold figure above which expenditure for a particular purpose is judged unacceptable.

While we recognise that departing from a single standard threshold creates problems of its own - not least in consistency - we are also aware that NICE does on occasion move outside its own self-imposed limits when particular circumstances seem to justify such action.

What circumstances might be relevant when making decisions on the cost of equipment or practices intended to avoid error? We envisage a sliding threshold limit. Factors that might contribute to the case for moving a threshold include:

- the severity to an individual of any likely injury or harm resulting from the error;

- the wider cost to society of coping with the aftermath of the error - cost to those left caring or bereaved, cost of litigation;
- the extent to which the error is unique to the medical environment (falls can happen anywhere; only in operating theatres do people have the wrong kidney removed); and
- the possibility that failure to address the safety issue in question could have a severely damaging effect on public confidence in the NHS.

### **How we worked**

The Citizens' Council met from June 7- 9 at the NICE headquarters in London. Twenty two of our members were able to attend the meeting - which began with an introduction to the topic, why it matters, and how NICE hoped we would be able to help in formulating its thinking on guidelines for assessing safety procedures in medicine. We heard evidence on the extent of medical error in the NHS, on the case for and against taking cost-effectiveness into account when designing new measures, and how this can be done in practice. We heard from patients' representatives, doctors, nurses, health managers and economists. We considered three case studies in which risk reduction was needed or had been attempted, and we performed exercises intended to put us in the position of those whose task it is to make and justify decisions on what should be done.

Our two and a half days included time for questioning the experts and expressing our own ideas, and sessions in which to discuss the issues among ourselves, either collectively or in small sub-groups. We also completed tracking questionnaires at the beginning and end of our meeting, and twice during its course, to monitor changes in our response to NICE's basic questions.

### **What we heard and what we did**

#### Our introduction to safety

Michael Rawlins and Peter Littlejohns began the day by outlining the problem of accidents and errors within the NHS from MRSA to the administration of the wrong drug. In 2000 the National Patient Safety Agency (NPSA) was set up to co-ordinate action on reducing errors. NICE has been asked to become involved because of its reputation for developing guidelines based on solid principles and drawn up by independent advisers. To this end it has already launched two pilot projects: one on drug reconciliation; the other on patients who develop Ventilator Associated Pneumonia (VAP) whilst in hospital Intensive Care Units.

Although both these pilots will involve analyses of cost-effectiveness, we were told, this assessment criterion is not yet a given. Hence NICE's wish to hear the views of the Citizens' Council. The dilemma, of course, is the usual one: ensuring the NHS gets value for money for any of the recommendations that NICE makes recognising that if you increase spending in one area you have to reduce spending in another.

One Council member pointed out that, in many circumstances, employing more staff would be an obvious way of enhancing safety. But those staff members would almost certainly contribute to more than just safety in their workplaces. Professor Rawlins agreed that it would be necessary in such cases to try to apportion the time spent in different tasks if one was to make realistic cost calculations. But not all changes, he added, are necessarily costly. Some may require nothing more than redesigning or re-ordering our processes. We also raised the question of litigation: an issue that came up many more times over the next two days.

In the next presentation Sir Liam Donaldson, the Chief Medical Officer, brought home the reality of medical mistakes by telling us how a tragic error came to be repeated 25 years later because the relevant lessons had been learned, but not satisfactorily applied. In 1975 Lee Duggins, an eight year old with leukaemia, was treated with a powerful drug called vincristine that is intended for injection into a vein. But there was a mix-up, and Lee's drug was injected into his spine. Six days later he died. It was recognised at the time that this error could be repeated - but the precautions taken have not proved sufficient to prevent recurrences. Hence the death in 2001, for the same reason, of 18 year old Wayne Jowett. Worldwide this error has been recorded more than 50 times.

Sir Liam went on to outline the "Swiss cheese" model in which all the weaknesses (the "holes") in a set of precautions designed to prevent error occasionally line up and allow a generally avoidable mistake to be made. These precautions include supervision, training, physical barriers to error, and proper procedures. Common sources of error range from dose miscalculations when giving radiation, through to the surgical removal of a wrong organ or limb. While aviation, he added, has done much to improve its safety record, medicine lags far behind. In a 30-year career the skills of an airline pilot may be reassessed 100 times. This is not so in medicine, where any call for periodic reassessment is seen as a threat. It was pointed out that whilst the culture in the airline industry is more safety focussed, those performing procedures, i.e. the pilots, are likely to suffer the consequences of their actions more directly!

Sir Liam gave us further shocking figures. For example, while there is a one in 3 million chance of dying in an airline accident there is a 1 in 300 chance of dying in hospital - although not all these deaths are due to safety issues. This certainly focussed our minds on our task over the next three days.

Sir Liam brought up the issue of the price of shifting the culture. Although there is literature that says that a safe culture does cost less there is uncertainty as to how to put a cost to it; the information on the methodology is not yet available. Therefore we need to ascertain whether the methodology NICE uses can be applied to safety guidance/solutions.

In subsequent questioning Council members suggested that the discussion of safety issues should figure more prominently in the NHS, both generally in

training and specifically during the handover procedure when staff are changing shift. Sir Liam agreed with this, and also with a subsequent suggestion that there had to be something better than the threat of litigation to persuade medical authorities to reveal what had gone wrong during an incident.

On a show of hands it became clear that, at this early stage, the overwhelming majority of us felt that safety should be a top priority for the NHS, and that the cost-effectiveness of proposed interventions needed to be taken into account.

### First reflections

Having acquired an outline of the nature and extent of the safety problem, we were invited to offer our first thoughts on it, and what might be done to improve matters.

One member pointed out that the top priority in the NHS has to be saving lives; an excess of attention to safety might divert unacceptable amounts of money away from treatment. Another member drew a parallel with education in which an obsession with health and safety considerations had led to a reduction in educationally valuable enterprises such as school journeys abroad. In similar vein, someone else talked of the drawbacks of smothering the world in bubble wrap, much as we tend now to do with the lives of children. On the other hand, if the risk of going into hospital is seen to be unacceptably high, people may be deterred from agreeing to it.

Error can never be entirely eliminated, so the goal must be to find a balance between the inevitable risks of treatment and the need for safety. The real issue is *avoidable* risk. This prompted someone else to comment that any successful treatment should surely be taking routine account of safety. A reasonable level of safety should be integral to the system.

By this stage many of us had begun to sense an odd contradiction: that while the purpose the NHS is to make people better it seems traditionally to have been relatively negligent about safety. This, it would appear, has sometimes been viewed less as a core part of the enterprise than as a kind of optional or bolted-on component. Among our members are people who have worked in industry, and as employers. They expressed surprise that the Health Service did not behave as most employers now have to: routinely incorporating safety considerations in the everyday running of the business. One member referred to the nuclear industry in particular where a culture of health and safety is woven into everything it does, and where the level of precaution to be taken is graduated according to the perceived level of risk. The same member also queried the assumption that safety measures should automatically increase the cost of a procedure.

Someone else mentioned the importance of training: many problems could be avoided if properly trained people simply followed the instructions they have been given. And could patients also play a part? How would doctors and

nurses respond if patients regularly enquired when they had last washed their hands? This might be one way of helping to implant a culture of safety.

The wisdom or otherwise of a culture of blame also had a brief mention. It was prompted by one member who queried the responsibility of those in the NHS: how often are staff sacked for safety errors? This in turn triggered someone else to point out that blame cultures don't make for openness and improvement. People have an interest in covering up their mistakes.

Money, of course, kept re-emerging as an issue. Everything, including safety, is subject to limits on spending. But several members were keen to emphasise that successful safety measures have a cost-saving as well as a cost-incurring component. If you fall out of bed and break both legs, the cost of treating them might exceed the cost of some piece of kit that would have prevented the accident. And there are also longer-term costs in being negligent about safety; these include compensation to victims, and knock-on effects in employment and much else.

### Patients' voices

We next heard presentations from two people with a "professional" role in promoting the interests of patients. Harry Cayton is the Department of Health's national director for patients and the public. He pointed out that the more effective medicine becomes, the more potentially dangerous it is. He also reminded us of the "conspiracy of silence" that long existed between doctors and patients, with neither group liking to admit the existence of these dangers.

Not only does he believe that safety has to be paramount in the NHS, but also that safe systems are efficient and cost-effective. He takes the view that where costs are incurred, they are outweighed by savings in litigation and other costs to society, and that we should be focussing on how to understand, control and share risk rather than concern ourselves with cost.

The other speaker in this session, the Patients' Association trustee Edwina Currie, was not so optimistic as Harry Cayton about the cost-free nature of safety enhancement. But she quoted the airline executive who said that if you think running a safe airline is expensive, you should try trying running an unsafe one. She also brought up hospital cleanliness (the state of which leaves her generally unimpressed) and said she was puzzled that hospital authorities seemed surprised by the level of hospital-acquired infections in the UK. She feels that health authorities looking for increased safety have three possible strategies when considering the balance between costs and patient benefit: to choose the lowest cost solution; to choose the solution that's most likely to be complied with; or to allocate a portion of the budget to safety and then ask how it can best be spent. In her view there is already enough money in the NHS, but much of it is being wasted!

In the subsequent discussion one of us argued that politicians have been guilty of suggesting to the public that they can have a deluxe service for little money, so making people think they can have their cake and eat it. Mrs Currie

disputed that this was what politicians did. Other matters we debated with the two speakers included the possibility of designing safety into equipment and systems, the extent to which it is appropriate to compare safety in the NHS with what happen in other industries, and whether there was sometimes a reluctance among NHS staff to take full moral responsibility for their actions.

#### Case study I: microbes on the ward

The issue of hospital acquired infections returned to our attention in the afternoon as the subject of our first case study. Dinah Gould, professor of health care research at the London's City University, itemised the main microbial culprits and what they do. We were then given a list of possible solutions, and asked to choose the three that we each thought would be most valuable. Most of these options can be found operating in some UK hospitals, and some are national policy. Some solutions are those that the general public think are appropriate. The purpose of this exercise was to get us to think about the various factors that come into play when making this kind of decision (For the list of possible solutions, and how we distributed our votes, see Appendix 1.)

The option that picked up the most votes was the introduction of ward housekeepers who would have responsibility for cleanliness. We were then asked to say briefly what had motivated our choices. The factors that most of us had been bearing in mind were practicability, simplicity and cost. A couple of us had been motivated by personal observation or plain common sense.

In discussions with Dinah Gould we talked about the role of antibiotic misuse in spreading resistance to these drugs, the quality of cleaning staff in hospitals, whether contracting out cleaning tended to reduce its thoroughness, and whether understaffing contributes to the rise in infections. With reference to the last of these issues, Dinah Gould told us that while anecdotal and circumstantial evidence pointed to that conclusion, the link had not been proved. It seems that our hospitals are generally dirtier than those in other European countries; although infection control nursing was invented in the UK, it is used more effectively elsewhere.

#### Case study II: new variant CJD

Dr Kalipso Chalkidou, associate director for R&D at NICE, described the great difficulty of sterilising surgical instruments contaminated with the abnormal prion proteins responsible for causing CJD. She then outlined the advice that NICE had given on the matter: in a nutshell, that a small proportion of exceptionally high risk surgery should be done using single-use instruments or with sets kept together and used only for specific procedures. NICE had rejected the widespread adoption of single-use instruments on grounds of cost or because suitable instruments were not available or not up to the required standard.

Dr Roger Eglin, head of microbiology at the National Blood Transfusion Service, followed with an account of the interventions - from donor selection to leucodepletion - by which he and his colleagues try to keep blood free of any contamination. They are currently studying a device for filtering prion material

out of blood; but at this stage, he admits, some small unquantified risk of prion transmission via blood still exists.

Lester Firkins, father of 25-year-old Ellis who had died of CJD, then described how he had been a lay member of the NICE committee that drew up the guidelines on CJD and instrument sterilisation. Many of us were impressed by the extent to which he had risen above his personal tragedy to support guidelines that, by his own admission, will probably allow a handful of people – perhaps half a dozen over the next decade – to die from CJD. This is the price that will have to be paid for making realistic recommendations. As Mr Firkins added, one of those deaths could be of another of his own sons. Whatever decision you take you must be prepared personally to accept the consequences.

In discussion it emerged that if circumstances change, so may the recommendations. Disposable instruments, for example, may become more readily available and cheaper. One Council member remarked on the safety of transfusion compared with many other procedures in medicine. The reason, we learned, is that nearly all stages of the process are carried out under controlled conditions in controlled environments. Such cannot always be the case in medicine.

In the subsequent discussion we returned again to the issue of hospital cleaning. There was much concern among Council members over the paucity of hard facts that had been available to underpin those fundamental changes which had overtaken the running of hospitals during recent decades. The most obvious is the contracting out of cleaning services. Cost had clearly been a major if not *the* major factor in these decisions. But had anything else been taken into account?

We ended the day with a swift run down of the things that had to be borne in mind when responding to the question of what patient safety is all about. Our list included: systems; training; physical barriers to error; protocols; awareness; supervision; motivation (staff and patients); control of people and the environment; accountability; experience; and prior risk assessment.

#### The case for (and against) cost effectiveness

Friday morning began with a brief but sobering discussion of the previous day's account of the 25 year long failure to solve the problem of vincristine administration in the treatment of leukaemia. We contemplated options such as engineering out the problem by making the syringes impossible to use in the wrong site. But if you can't rely on a doctor to read an instruction that's clearly written on the side of a syringe, said one member despairingly, what can you do?

We then listened to four presentations on cost-effectiveness. Peter Walsh of Action Against Medical Accidents, the only charity devoted to patient safety and seeking justice for people who'd been so injured, argued that when NICE was framing guidelines for safety, it had to take account of considerations that wouldn't normally influence cost effectiveness decisions. These include public

confidence (the number of people wanting something done and for how long they've been demanding it), fairness, and staff morale. Such things may conflict with a more conventional balance sheet approach. NICE should also prioritise the elimination of known preventable errors over research into methods of detecting and minimising currently unavoidable ones, said Mr Walsh.

Joan Higgins, chair of the NHS Litigation Authority, described its role in defending unjustified claims, settling justified ones, providing incentives to reduce accidents and running a risk pooling scheme into which Trusts pay annual contributions ranging from £15K - £8.6 million according to the types of service they provide, the size of the Trust and so on. She reported that the cost of all claims for the period 2006/7 had amounted to £613 million. But handling large sums of money had not persuaded her that the threat of punitive damages is either a good or an effective means of trying to improve medical practice. She prefers health providers to rely more on improved training, more patient empowerment, and a greater emphasis on acting ethically.

Professor Graham Loomes of the University of East Anglia offered us an economist's take on cost-effectiveness. Three questions, he argued, are crucial. Are some kinds of safety worth more than others? How much is patient safety worth? And should we think of it as preventing deaths or saving life years? Whether you like it or not, he said, all decisions have monetary values. The aim must be to think clearly about the financial implications of what is being decided. For this purpose he felt the QALY to be useful. And if we wished to put a premium on the prevention of risk, we should decide how to weight the decision, and by how much. We should also be conscious of opportunity costs: that within a finite pool of resources, spending money for one purpose means not using it for some other.

The remaining two speakers were from the National Patient Safety Agency (NPSA). Peter Mansell insisted cost-effectiveness needs to be made explicit; unless this is done, he said, the merits of a decision cannot be argued. And if we disliked cost-effectiveness we would have to choose some other criterion – such as the greatest benefit for the greatest number. He personally believed in using a range of criteria that he saw as representing fairness (transparency, clarity, inclusiveness, evidential, consistency, accountability and impartiality) and practicability (autonomy, realism, testability and timeliness as well as cost effectiveness). He also reminded us that preventing an error saves the cost of later remedying it or paying compensation for its consequences.

One of the points made by Tara Lamont, also from NPSA, was that some safety interventions are cheap: persuading all hospitals to use the same emergency call number, for example. She also said that while it may be relatively straightforward to calculate the cost of intervention, estimating the costs saved by reducing harm is often tricky.

The discussion that followed these presentations revealed several differences between the experts. Peter Walsh argued that QALYs should be used not by

themselves but in conjunction with other considerations including ethical values such as the importance of preventing the NHS from doing harm. In fact he said that in NICE's guidance on vCJD, QALYs had not been used. Graham Loomes argued that, from an economic perspective, to speak in these terms was simply to duck the issue. If you are going to give "appropriate" weight to this or that additional factor you have to have a systematic means of doing so. He was quite happy for people to suggest that certain factors should carry a premium; but you still have to decide how large it can be. He added that forums such as ours were one way of finding out what the public wants, or feels to be acceptable. But in the end there has to be a means of translating that feeling into practice.

One of us mentioned the power of the media as a driver of action. But whether this is for good or ill remains debatable. Is it better for policy to be made by journalists or by a more reflective public consultation? Another of us suggested that if the NHS is spending the amount of money on litigation mentioned by Joan Higgins, analysing the types of accident involved and preventing them would save the money paid out in premiums.

Other topics discussed were the extent to which there is already a safety culture in the NHS, the importance of making decisions transparently, whether or not the QALY is as suitable for safety purposes as for its current use, how otherwise you make decisions about moving resources from one use to another, and the extent to which qualitative judgments can be pinned down by quantitative evaluators.

The discussion continued after lunch. One Council member suggested that waste in the NHS was sufficient to bear the cost burden of introducing extra safety measures. Another dismissed this claim by pointing out that, true or not, NICE discussions are based on the assumption of a fixed pot of money. The central question, he ventured, is what to do when a tragic risk is potentially avoidable, but only by paying a premium to do so. Should this premium be funded? Answering his own question he said it should – and floated a figure of up to three times the standard NICE threshold of around £25,000 per QALY.

This was clearly a concrete proposal, and it was suggested that we vote on it. We did so, and all but two of us backed the idea (though not specifically the x3 factor) of paying a premium for improved safety where the only solution available required a disproportionate allocation of resources. In fact the proposer himself later withdrew the x3 factor on the grounds - accepted by most of us - that putting a definite figure on it was not wise.

Another of us voiced the concern that if we started playing around with the formula too much we would make the structure of the model so loose that it might no longer have any validity or integrity.

This took us on to further discussion of the QALYs: a system about which a number of Council members continue to harbour doubts, or even severe reservations. In deciding how resources should be used we should not be

bound by formulae that don't take account of our gut feelings or our sense of justice. Some members though, irrespective of their view of QALYs, felt that because this was the means of assessment already in use by NICE it would be unhelpful simply to reject any thinking based on it.

### Case study III: preventing falls in hospital

Our third case study was an exercise in how best to prevent falls in hospital. The problem, and a range of possible solutions, are shown in Appendix 2. Our task – for which we divided into three sub-groups – was to select the combination of measures we thought most appropriate, and to explain our reasons.

Although we found some similarities in the thinking that underpinned our respective suggestions for tackling the problem - practicability, the impact of the changes on staff, evidence of effectiveness, cost effectiveness, getting as many staff members as possible involved etc – the packages we compiled were not identical. Indeed, one group decided to put all its money into a single intervention: employing more nursing staff. This exercise brought home to us that even when the money is available to implement change, deciding how to do it can be far from obvious.

We went on to discuss our proposals with Mala Karasu, a matron at Guy's and St Thomas's Hospitals in London, and with Kate Bryce of University College Hospital, a nurse who specialises in the prevention of falls. Talking of their own experience, the former emphasised the importance of using a combinations of approaches, of assessing elderly patients for their risk of falling when they were admitted to hospital, and of training staff to appreciate the different needs of different patients. Kate Bryce described the anti-falls strategy that she has implemented at UCH, and the extent to which it has succeeded in curbing the problem – a 40 per cent reduction. Although it seems to have reduced falls, she admitted that her hospital's emphasis on clinical efficiency and cost saving targets did not make her task any easier.

The discussion then widened to cover several topics including the possible drawbacks of removing experienced nurses from the wards to implement and oversee projects such as a falls prevention scheme, and the importance of ensuring that the lessons of experience are fed back into a system to improve it.

### Effectively refreshed

Dr Joanne Lord completed the afternoon's presentations with a refresher course on cost effectiveness. It's necessary, she said because of limited resources. But which costs to include? NICE's remit is to focus on NHS and personal social service costs and savings, both immediate and long term. NICE does occasionally stray beyond them – but not into individual patients' productivity or loss of it.

She outlined the difference between cost-effectiveness (the price of obtaining a unit gain of whatever is being measured) and cost utility – which allows treatments to be compared by means of the QALY. This makes it possible to

trade off quality of life against its length: one year of 100 per cent healthy life equals two years of 50 per cent healthy life, and so on. The NICE threshold for accepting or rejecting a treatment – not set in stone – is £20,000 to £30,000<sup>1</sup>. Factors that might influence the decision to depart from it include the certainty of the data, the social value of the treatment, the practicalities of implementation, and legal or policy restraints.

We went on to discuss how well this approach might work in relation to safety issues. Several of us pointed out that errors in health care may incur a litigation cost, and wondered if this should be incorporated in any cost-benefit assessment that NICE might make of a proposed new safety measure. We realise that this is not something that NICE assessments have so far had to take account of; but many of us felt strongly that it had to be brought into the equation.

### The really important issues

We finished the day by compiling a list of those issues we felt to be most important. Although many of us (but not all) thought that the cost-effectiveness of any proposed safety intervention would have to be taken into account, few of us felt that this was, by itself, sufficient. Other factors that merit consideration include: the importance of maintaining public confidence in the NHS; the need to develop more of a culture of safety in the Service (“safe systems save money”); a new model for making cost effectiveness estimates, or agreement that there should be exceptions to the QALY threshold; a need to take account of saved litigation costs; more emphasis on training for safety; more accountability; that safety might be seen as akin to “rule of rescue” circumstances under which exceptional measures requiring exceptional resources are justified; the prioritisation of the importance of safety interventions; the need for more accountability; and a consideration of how the addition of a safety brief to NICE might eventually impact on NHS costs more widely.

One member argued that, in many cases, paying more attention to safety issues will, by definition, save money. Hospital managements, for example, have such an interest in reducing the number of falls among elderly people moving through their corridors. The real problem, he added, lay in trying to prevent the more exotic risks that are unlikely to generate savings in the longer term. He felt that these risks - some of which, such as having the wrong kidney removed, are alien to everyday life - merit special consideration, including, perhaps, a two or three times greater QALY threshold than that generally used by NICE.

Another member summarised her thoughts in these words: “A patient using the NHS for treatment should be able to hope that, unless terminally ill, they

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<sup>1</sup> In general, NICE considers that treatments costing less than around £5,000 to £20,000 per increased quality-adjusted life year (QALY), or life year gained, are usually cost effective. NICE expects its advisory bodies to explain explicitly, however, their reasons for recommending – as cost effective – those treatments costing in excess of £20,000 to £30,000 per QALY or life year gained.

will finish that treatment without being further damaged by accident or negligence.

“A patient must accept that there may be some element of risk to them as there is any area of life.

“The NHS should aim to eliminate any damage to patients that can reasonably be foreseen, and should organise its working practices so that negligence is less likely. It cannot foresee and provide for all eventualities.”

### Final morning

In our opening discussion of the final day several of us began by raising or resurrecting some key issues. A couple of members who were inclined to answer “yes” to NICE’s first question were, nonetheless, worried that doing so might give the impression that every exercise in safety enhancement could be treated in the same manner. They wanted to emphasise the need for flexibility, from instance to instance, in the amount of money judged to be worth spending. In discussion, this view seemed to resonate with more of us. The likely severity of the outcome of an error, for example, could be allowed to affect any multiplier applied to the standard QALY threshold. This approach might also be relevant if a particular safety issue was found to be having a major effect on the public’s trust in the NHS. Under these circumstances an otherwise disproportionate spending on a safety measure might be justified.

Several members continued to express doubt that the QALY is the most appropriate yardstick to use when dealing with safety as opposed to treatment. Another member raised the question of fairness: is my safety worth more than yours? This prompted someone else to respond that treating people fairly does not necessarily mean treating them equally.

Members also used the discussion to emphasise two other points. First, that good training - in hygiene, for example - is important because if people do a job well, their risk of making errors will probably be reduced. This is something that NICE might wish to emphasise generally in its guidance. The second issue was prioritisation; it is important to decide which issues are most pressing.

For our final brainstorming session we divided into four groups to discuss how we thought NICE’s questions should be answered. We then reconvened to pool our thoughts. Much of this was a reiteration of views and ideas already expressed – not least the desire of some members to find an alternative to the QALY. But, working on the realistic assumption that the QALY had to be treated as the starting point, one of our groups began thinking about the factors that might justify a departure from the standard £25k threshold. These factors include: the severity to an individual of any likely injury or harm; the cost to society of coping with the aftermath of an error; the extent to which the error to be prevented is a unique product of the medical environment (falls can happen anywhere; only in operating theatres do people have the wrong kidney removed); and the possibility that failure to address the safety issue in

question could have a severely damaging effect on public confidence in the NHS.

The group that began to list these factors were, as they admitted, aware that adding more and more principles and qualifications to a model makes it ever more “sloppy”, and less useful as a firm framework on which to base guidelines.

#### Final considerations

Overall, while we were confident that our two and half days of discussion had helped to identify a number of concerns about a straightforward extension of the current NICE model into safety, none of us were under the illusion that the way forward was now clear. Further reflection, together with experience drawn from the pilot projects now in progress, will be required before NICE can reach a settled conclusion.

In reaching that conclusion we would want NICE to be mindful of a number of considerations. These include the cost to the NHS of litigation; the importance of striving for a sense of fairness in any proposed scheme; the need to create a culture of safety within the NHS; the practicability of any proposed guidelines; that costs to the NHS of safety procedures may avoid later (and even greater) costs in other areas of social spending, often coming out of separate budgets; that any health system which fails to take safety seriously is hardly worthy of the name; and that, ultimately, safety benefits everyone.

#### How our views developed: the tracking questionnaires

The results of the five tracking questions that had “agree/disagree” answers, shown in Appendix 3.

Q1. There was virtual unanimity throughout that keeping patients free of unintended harm is a top priority for the NHS. All that changed was the strength of our feeling: it dipped slightly, then returned to more or less what it had been originally.

Q2. Most Citizens’ Council members believed throughout that cost effectiveness has to be taken into account in developing safety measures. Our feeling strengthened during the meeting.

Q4. The results of this question mirror those of Q2. From the outset the majority of us disagreed that cost effectiveness should not be taken into consideration when enhancing patient safety – and this opinion firmed up during the course of the meeting.

Q6. Opinion on whether NICE should use the same cost effectiveness threshold for safety as for other guidelines was divided from the outset. We did not reach a consensus on this point. However views did change over the course of the meeting with the balance of opinion shifting from agreement to disagreement.

Q7. The trend here was clear. At the beginning of the meeting a majority of us felt that NICE should take account of all cost implications; by the end of the meeting that feeling – albeit to different degrees – had reached unanimity.

What follows are some of the comments that our members added to the first and last of the questionnaire forms that we completed. Overall there was little discernible qualitative shift of opinion between the beginning and end of the meeting. The only exception was in views of the suitability of the QALY. Having had only a few mentions in the first questionnaire, it attracted a good number of negative comments in the last one.

*Comments from the first questionnaire form.* (The numbers refer to those on the form; see Appendix 4.)

- 1) Safety “should be incorporated in the NHS agenda”. “Patients trust the NHS and their treatment quality. We need to do everything we can to safeguard that trust.” “Patient safety a priority. Very little point in replacing one illness with another.”
- 2) “There are limited funds, so available monies need to be spent in the most cost-effective way by tackling the most important issues that affect most patients.” “We cannot give carte blanche for spending, even for something as important as safety.”
- 3) “If a proven solution will have major beneficial results long term, the cost threshold should be exceeded.”
- 6) “It (QALYs) is a system that has been in use for a considerable time, and is most effective.”
- 7) Wider costs that need to be taken into account include litigation and negligence compensation, the cost of treating mistakes, the need to change the culture the NHS and the cost of retraining staff.

*Comments from the last questionnaire form.*

- 1) “Safety must be an integral part of any decision.”
- 2) We should take into account ethical issues, the bigger picture. “The money available is finite; if something gains, then something else loses.”
- 3) “Perhaps a new model should be looked for, as opposed to QALYs.” “The QALY could be used in a flexible way.”
- 4) “I’m not saying we should not use cost effectiveness, but I don’t trust the models on offer.”
- 6) “Not QALYs.” “The QALY system does not fit patient safety.” “I believe the QALY threshold should vary with patient safety issues.” “Patient safety is and should continue to be one of the cornerstones of NHS philosophy.”
- 7) Social costs such as the bereavement of a breadwinner etc should be taken into account. “While it is more difficult to assess human costs, they must be included.”

## **Appendix 1 Case study: some solutions to hospital acquired infections**

[The figures in square brackets indicate the number of votes cast for each option.]

- 1) Spot checks on hospitals to ensure compliance with the Health Act 2006: Code of Practice for the prevention and control of healthcare associated infections. [8]
- 2) Hospital Uniform policy that bans the wearing of uniforms outside hospital and Hospitals to provide in house laundry services so that bugs are not carried from hospital into the community and vice versa. [6]
- 3) All staff who work between wards to wear protective clothing when entering different wards thus reducing the risk of cross contamination and protecting staff from infection. [0]
- 4) A 'Clean Your Hands' Campaign which includes:
  - Alcohol hand rubs: placed close to where the patient is cared for e.g. by the bed head, or on the locker. Staff in specialist areas to be given own supply of alcohol gel.
  - Posters and badges with the slogans 'It's OK to Ask' encouraging patients to ask if staff had washed their hands. [4]
- 5) Computerised surveillance system alerting Infection Control staff that a patient has either developed an infection or has had an infection in the past. This helps ensure that these patients are managed and treated quickly and isolated if necessary. It can also show if there are 'pockets' of infection in the hospital. [1]
- 6) Screening for main bugs e.g. MRSA, TB, HIV for all patients entering hospital. [8]
- 7) Each ward should have a Housekeeper. The key role is to ensure cleaning of wards carried out to required standard by trained staff and not nurses. [14]
- 8) Limited visiting times thereby reducing the number of visitors who may bring infections in with them. [6]
- 9) Guidelines on the appropriate prescribing of antibiotics. [1]
- 10) All patients who can be are bathed and washed everyday. [0]
- 11) Learning through Action schemes. These use a tool called Root Cause Analysis that helps hospitals find out what factors or events led to infection and how to reduce the risk of this happening again. [6]
- 12) National standardised colour coding of hospital cleaning equipment and material to ensure items are not used in multiple areas thereby reducing the risk of cross infection. [0]

13) Re-design hospitals to increase the number of single rooms, thereby making it easier to prevent cross infection. All new hospitals to have single room wards with en suite bathrooms. [2]

14) National standardised measurable cleaning standards to be set for each hospital; with clear targets for reducing infection. Regular audits to be undertaken. [9]

## Appendix 2 Case study: preventing falls in hospital

The task: You are the Board of an acute hospital that has a rehabilitation ward for older people. You are concerned about the number of slips, trips and falls that occur on this Rehabilitation ward.

As a Trust Board you have set aside £300K to attempt to help prevent falls. You will now need to evaluate these proposals, decide which ones you feel are appropriate and why. Whilst you are doing so, you must consider the following:

- What criteria are you going to use to do this?
- What dilemmas, problems, issues does this raise?

In the last year, your Trust reported 1,300 falls across the hospital, and this is higher than the national average for most Trusts your size. Most of these falls happened on this ward. The manager for the ward says this is not particularly surprising because of the kind of patients cared for on the ward but is concerned because the trend is up.

The Trust has calculated that it is facing increased associated health care costs of approximately £120k per year. These are things like additional staff time, extra investigations, medication and surgical costs. This does not include any payments that arise out of litigation.

The manager has undertaken an analysis of the kind of falls and the impact this has had on the patients, their relatives and staff.

Kind of falls: (this seems to follow the national trend)

- 64% of the falls reported resulted in 'no harm'
- 30% resulted in low harm, cuts, bumps and bruises
- 4% resulted in moderate harm, wrist fractures especially for patients with osteoporosis
- 1% resulted in severe harm; patients suffered a fractured neck of femur and one patient died.

The Impact

Formal and informal complaints have gone up for the ward, relatives are angry because they believe that their loved ones have not been cared for properly. They perceive staff to be 'negligent'

Patients who have fallen, even though the fall may have resulted in no harm, are shaken, upset and tend to lose confidence. This slows down their recovery and rehabilitation and so they stay longer in hospital.

The family of the patient who died as a result of the fall is suing the trust and there has also been a report to the Health and Safety Executive.

Staff morale is low and whilst other factors do contribute to this, staff feel dispirited and cite the number of falls as one of the biggest problems their ward has.

Patients are more likely to be referred for residential and nursing care rather than return to their own homes.

As the Trust Board you have agreed to convert an old ward on the ground floor into a new rehabilitation ward. The management team for the Rehabilitation service has put together some proposals which have estimated costs alongside. They believe that these would reduce the number of falls on their ward. These proposals fall under 3 categories:

- Ward environment
- Services and systems
- Staffing

They have also highlighted the benefits and risks, where appropriate, of some of their proposals.

### Ward environment

PROPOSAL	COST	BENEFITS	RISK
Layout of the ward changed to increase the space around the beds and install a bathroom for every bay.	£300k	More space around the beds means space to manoeuvre and less risk of hitting oneself against furniture. A bathroom for each bay means a shorter walk to the toilet and therefore lower risk of accidents and slipping	Likely to lose 6 beds on the ward which means to get through the number of patients you need to in a year you will have to reduce length of stay
Cordless patient call bell system	£3K	No wires, call bells can be placed within easy reach, patient can take call bell with them to the chair	Call bell pads will get lost, also will need regular checking to ensure batteries are working.
New low impact, rubber flooring, like in gyms	£10K	If patients fall they are less likely to hurt themselves seriously	Not enough evidence to show this works
Improved lighting and hand rails in all corridors	£5K	Patients can see better and have support when walking up the corridors	
<b>COST</b>	<b>£318K</b>		

### Services and systems

PROPOSAL	COST	BENEFITS	RISK	OTHER CONSIDERATIONS
A falls risk assessment for every patient coming to the ward to highlight those patients most in danger of falling	Staff time, included in staff costs below	Able to target interventions to those most at risk	Additional work for already busy ward staff	
Specialised alarms and wrist bands to identify patients most at risk of falling	£3K	Patients easily identifiable, alarm sounds alerting staff when patient is mobile and therefore at higher risk of falling	Wrist bands not identifiable from a distance, could also be confused with other important patient identifier wrist bands Staff may not be available to watch and monitor patients when alarm sounds. An over reliance on staff monitoring means patients	

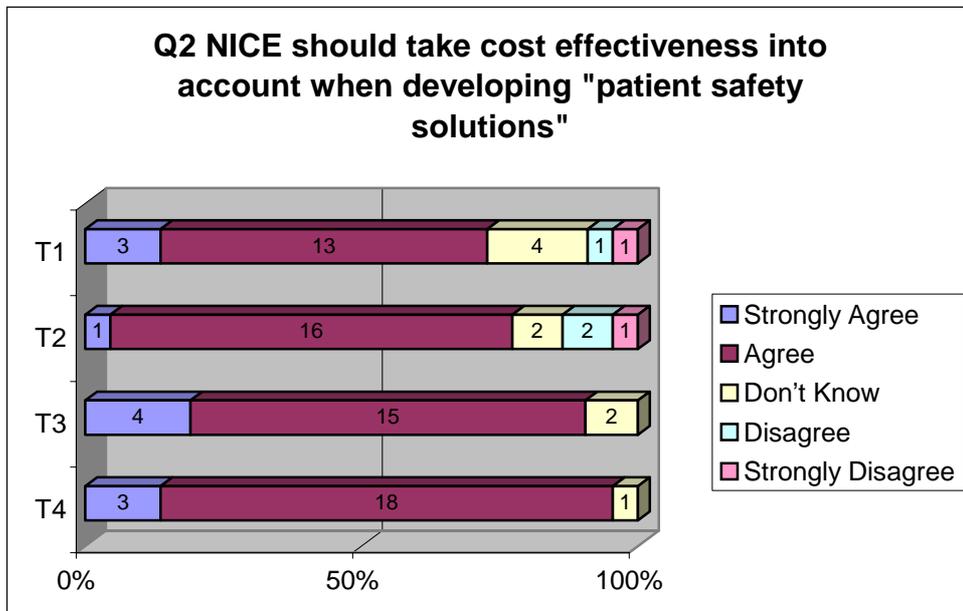
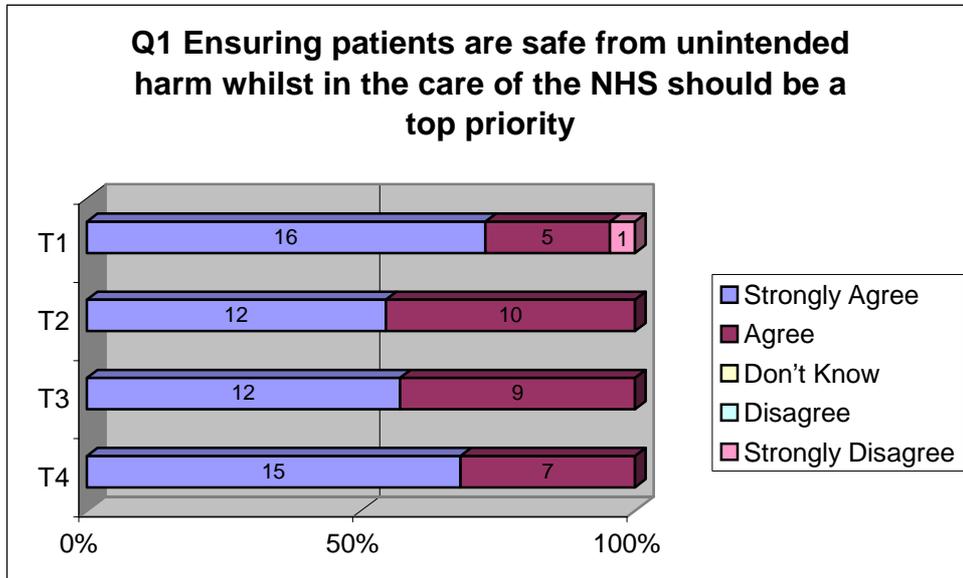
PROPOSAL	COST	BENEFITS	RISK	OTHER CONSIDERATIONS
			do not develop confidence and this slows down rehabilitation	
Develop and implement an appropriate policy on the use of cot sides	Staff time, included in staff costs below	Staff have clear criteria on the use of cot sides thus stopping indiscriminate use	Over reliance on a policy prevents staff from using their own judgement	
Increase in podiatry services to the ward.	£7K	Ensure the condition of patients feet are not leading to falls and that footwear does not cause problems	Over reliance on a specialised service may mean that podiatry issues are not addressed as part of the overall care on the ward.	
Increase in the ward domestic and portering contract	£10K	Ensure spills are promptly attended to, patient areas are kept clear of obstacles etc		
Rapid response medication review service for those identified at risk of falling	£75K	Patients on particular medication could be at higher risk of falling and need rapid review		
TOTAL	£95K			

#### Staffing

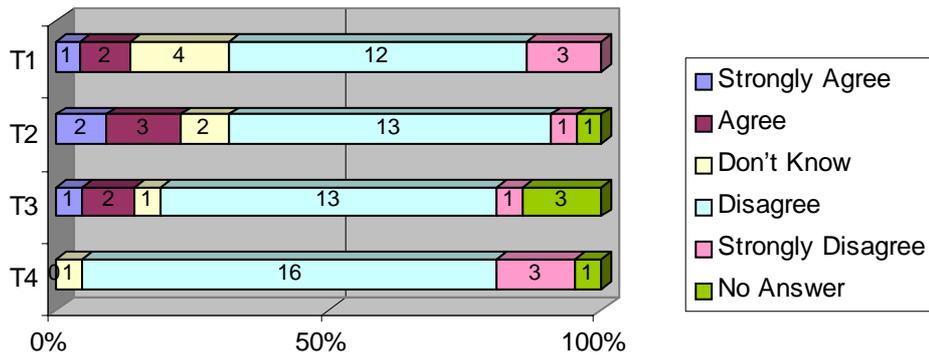
PROPOSAL	COSTS	BENEFITS	RISKS	OTHER CONSIDERATIONS
An increase in nursing staff on the ward: especially on the morning shift.	£100K	Risk assessments can be carried out Patients can be attended to promptly. For example accompanied to the toilet etc.		

### Appendix 3 Tracking Questionnaire Results

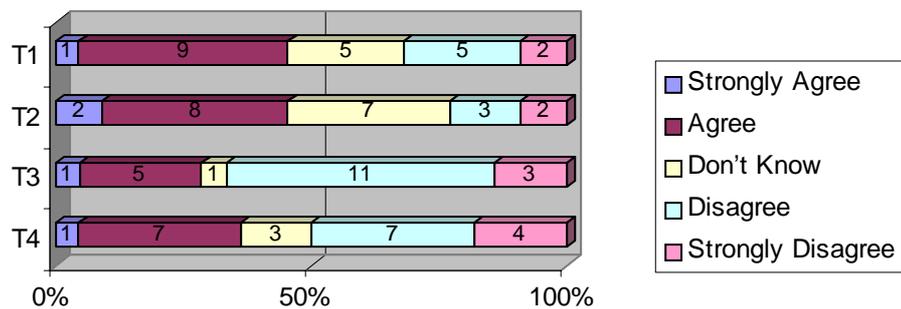
The Council were given a questionnaire to complete (Appendix 4) at the beginning of the meeting, the end of Day 1, the end of Day 2 and at the end of Day 3. The results of the closed questions are below.



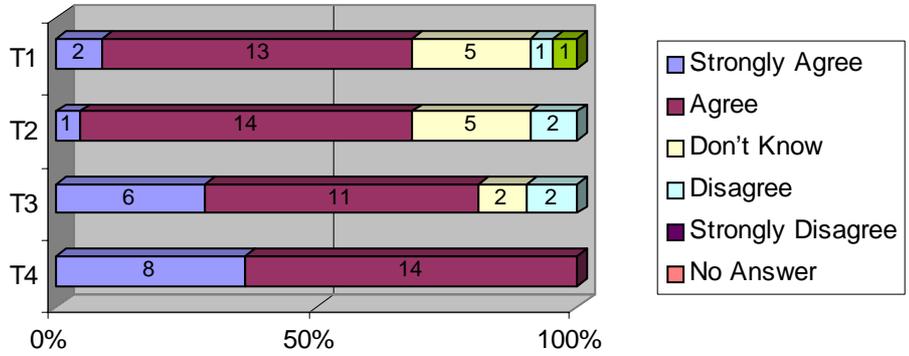
**Q4 Cost effectiveness should not be a consideration when NICE develops "patient safety solutions"**



**Q6 NICE should use the same cost effectiveness threshold when developing patient safety solutions as they do when developing any other guidance**



**Q7. NICE should take into account all cost implications when considering cost effectiveness for patient safety solutions**



## Appendix 4 Tracking Questionnaire

1. Ensuring patients are safe from unintended harm whilst in the care of the NHS should be a top priority.

Strongly Agree      Agree      Don't Know      Disagree      Strongly Disagree

Comments.....  
.....  
.....  
.....

2. NICE **should** take cost effectiveness into account when developing “patient safety solutions”.

Strongly Agree      Agree      Don't Know      Disagree      Strongly Disagree

Comments.....  
.....  
.....  
.....

3. If you believe NICE **should** use cost effectiveness, under what conditions should the cost threshold vary?

.....  
.....  
.....  
.....  
.....

4. Cost effectiveness **should not** be a consideration when NICE develops “patient safety solutions”.

Strongly Agree      Agree      Don't Know      Disagree      Strongly Disagree

Comments.....  
.....  
.....  
.....

5. If you believe NICE **should not** use cost effectiveness, what other criteria should NICE use to make a decision?

.....  
.....  
.....  
.....  
.....

6. NICE should use the same cost effectiveness threshold when developing “patient safety solutions” as they do when developing any other guidance.

Strongly Agree      Agree      Don't Know      Disagree      Strongly Disagree

Comments.....  
.....  
.....  
.....

7. NICE should take into account all cost implications when considering cost effectiveness for “patient safety solutions”.

Strongly Agree      Agree      Don't Know      Disagree      Strongly Disagree

What are the wider costs that NICE should take into account?.....  
.....  
.....  
.....

## **Appendix 5 The Question**

### **NICE's Question to the Citizens Council**

The Institute has been asked to develop solutions to reduce, or prevent, harm to patients while under the care of the NHS. It is, currently, the intention of the Institute to take account of cost effectiveness, as well as clinical effectiveness when developing patient safety solutions.

4. Does the Citizens Council accept that it is appropriate when developing "patient safety solutions" that NICE take the costs, as well as the benefits, into account?
5. If the answer to question 1 is 'yes,' what principles of cost-effectiveness should apply?
6. If the answer to question 1 is 'no,' what criteria should NICE apply in deciding whether or not it should recommend a particular safety solution to the NHS?

## 1. Background

1.1 While the safety of patients has always been at the heart of the work of health professionals this aspiration has not always been fully realised. Before the advent of modern medicine many traditional treatments were as likely to impede healing as they were to generate improvement in patients. However it was often non-professionals who raised concerns. The French playwright Moliere (1622-1672) suggested that “Nearly all men die of their medicines and not their diseases.”

1.2 When medicine started to become based on scientific principles, and the mechanisms underlying disease were better understood, concerns over patient safety became less of an issue. However, more recently, the issue has re-emerged as a key challenge to health care systems throughout the world.

1.3 In 2000 a report called “*An organisation with a memory*” produced by an expert group chaired by Professor Sir Liam Donaldson (the Chief Medical Officer for England) highlighted that patient safety was still a problem. The report suggested that in the UK:

- 400 people die or are seriously injured in adverse events involving medical devices.
- nearly 10,000 people have adverse serious reactions due to drugs
- around 1150 people who have been in recent contact with mental health services commit suicide.
- nearly 28,000 written complaints are made about aspects of clinical treatment in hospitals
- the NHS pays out about £400 million a year in settlement of negligence claims, and has a potential liability of £2.4 billion for existing and expected claims
- hospital acquired infections – around 15% of which may be avoidable – are estimated to cost the NHS £1 billion.

1.3.1 Even more of a problem was that relatively infrequent but serious specific adverse events happen time and time again. Enquiries and incident investigations determined that “THE LESSONS MUST BE LEARNED” but the evidence suggested that the NHS was not good at doing so.

1.3.2 The report highlighted a number of changes needed. In particular, there was a need to move away from a “blame culture” in which individual professionals were considered “at fault”, towards a culture in which individuals could feel comfortable in identifying where mistakes had occurred and the organisation as a whole could respond in order to find solutions. Implicit in this approach is the belief that the problem usually lies in organisations and systems rather than individuals.

1.3.3 The report concluded that key to this approach are arrangements to collect and collate information on adverse events and to use this data to find solutions.

1.3.4 Patient safety is not just a problem for the NHS. An American report “*To Err is Human*” showed a similar picture in America. Applying their findings to the UK would

suggest that 10% of all admission result in harm to patients costing (£2 billion a year in additional hospital stays alone).

1.4 As a result of the Chief Medical Officer's report, the National Patient Safety Agency (NPSA) was established in 2001. Its remit is to co-ordinate the safety efforts of all those involved in healthcare, and to learn from patient safety incidents occurring in the NHS in England and Wales. Initially it concentrated on establishing a National Learning and reporting system. This is a database comprising reports on adverse events submitted by individuals and organisations in the NHS.

1.5 Since 2005, the advice produced by the NPSA falls into 4 main areas: Safety Solutions, Safer Medication Practice, Nutrition and Cleaning and Design and Human Factors.

1.6 The NPSA, at the present time, has 54 active projects underway in their Safer Practice Department; 36% arise from the NPSA's prioritisation process using data from the National Learning and reporting System and other sources; 27% have been identified, by NHS organisations, as a local patient safety need; 20% were referrals direct from the Department of Health; with the remainder coming from a variety of other sources. There are 10 different outputs from this work, including alerts, notices and information bulletins. Examples of recent publications include:

**Patient Safety Alert: correct site surgery** – recommendations, prepared in conjunction with the Royal College of Surgeons, for marking the site of surgery; and a checklist for staff to confirm that arrangements to promote correct site surgery are in place. Immediate action was expected with dates for implementation.

**Safer Practice Notice: Right patient, right blood** – an initiative to promote short and long term strategies that will ensure that blood transfusions are carried out correctly. A number of deaths, and a larger number of adverse reactions, had been identified over an 8 year period as a result of the wrong blood type being given. Action was expected by NHS organisations with an specified completion date.

**Patient Safety Information** - advice for nursing staff on the need for awareness that in some people with established spinal cord damage are dependent on manual evacuation as their routine method of bowel care. Action was identified but without a specific date for completion.

1.7 Some NPSA advice forms part of the National Standards set for the NHS. These require individuals and organisations to comply with them immediately or within specified time periods. The key mechanism for monitoring compliance against the safety alerts and notices is the Department's of Health's Safety Alert Broadcast System. Local SABS liaison officers distribute the information and receive feedback on the action taken. A similar arrangement operates in Wales.

## 2. The Current Situation

2.1 In 2006, the Chief Medical Officer commissioned a review of patient safety in the NHS, which culminated in a second report, *Safety First*. This concluded that, although the profile of patient safety has been raised, it is not always given the same priority or status as other major issues (such as reducing waiting times,

implementing national service frameworks and achieving financial balance). In addition, the report found there is little evidence that data collected through the National Learning and Reporting System were effectively informing patient safety at the local NHS level. It concluded that the opportunities available to the NPSA to harness the expertise and commitment of other agencies involved in patient safety have not been realised. It also noted that an environment motivating and inspiring clinical and non clinical staff to ensure that all care is as safe as it can be had yet to be established..

2.2 As part of its recommendations *Safety First* suggested that NICE become involved in patient safety. Specifically it indicated that; *A pilot should be established to examine the option of NICE developing technical safety solutions.*

2.2.1 The rationale for this recommendation was that NICE has established a track record of success in providing national guidance on the promotion of good health and the prevention and treatment of ill health; and that it had been effective in engaging the wider health community, the healthcare industries and the public in developing its guidance. It considered that there may be opportunities to harness NICE's expertise to streamline the production and dissemination of safety solutions across the NHS.

### **3. NICE's approach to patient safety**

3.1 A Patient Safety Solution is identified as a system, design or intervention that has demonstrated the ability to prevent or mitigate patient harm arising during the process of healthcare. The NICE pilot will be in line with the Institute's core principles for the development of guidance.

3.2 As part of this pilot the Citizens Council is being asked about its views on incorporating costs into the identification of technical safety solution.

### **4. Assessing the costs of improving safety.**

4.1 NICE has always taken into account evidence about cost-effectiveness, as well as the clinical- effectiveness, in assessing clinical interventions and more recently public health interventions.

4.2 In general, in healthcare as in other fields such as aviation and rail travel, the rhetoric is that no cost can be put on making hospital, planes and trains safe. In reality of course cost always plays a role; and the benefits have to be assessed against the expense of safety initiatives.

4.2.1 When NICE was invited to develop guidance to the NHS on reducing the risk of transferring CJD (mad cow disease) it undertook an economic analysis and showed that not only that could it be done but that it also effected the conclusions. (See Appendix A for more information.)

4.2.2 In conducting the technical safety solution pilot mentioned above, the Institute proposes to perform a health economic analysis. The Council is being whether it agrees with this approach and, if it does, what principles should be applied.

## **Appendix A - NICE guidance on managing the risk of CJD transmission via surgery**

### **The problem**

Creutzfeldt-Jakob Disease (CJD) is an incurable brain disease that leads to dementia and death. There are different types of CJD. A new form of CJD was found in the UK in 1996 and is called variant CJD (vCJD). vCJD affects younger people, and is probably caught by eating food from cattle infected with BSE ('mad-cow disease').

All types of CJD are thought to be caused by prions, abnormal infectious forms of a protein found at high levels in brain and nerve cells. There is no treatment against prions, and unlike bacteria or viruses, prions cannot be killed or inactivated by normal hospital cleaning or sterilisation methods. If people who already have CJD have surgery or another medical procedure there is a small possibility that the instruments used could become contaminated with prions, and CJD could be passed to another patient. CJD that is caused by transmission during surgery or other medical procedures is called 'iatrogenic CJD'.

Since 1996 159 have died from this disease in the UK. Although the number of vCJD cases peaked around the year 2000 and has been declining since, the number of healthy people carrying the disease that could potentially contribute to transmission through surgical instruments is currently unknown. Recent reports on the likely transmission of vCJD by transfusion of blood products donated by three patients subsequently diagnosed with vCJD, have added to these concerns.

### **NICE's task**

In May 2004, the UK Chief Medical Officers asked NICE to develop and publish guidance to the NHS on how best to manage the risk of transmission of all types of CJD, including vCJD, via surgery.

Central to the development of the NICE guidance was ensuring that patients undergoing surgery and other medical procedures were protected both from contracting CD through contaminated instruments and from experiencing delays in their operations or complications due to low quality single use instruments. In issuing its advice, the Institute took account of the cost effectiveness of its guidance to ensure that the recommended measures represent good use of NHS funds.

### **The process**

To develop the guidance, the Institute convened a panel of experts who formed the CJD Advisory Sub-Committee (CJDAS or the Committee). CJDAS consisted of clinicians, scientists, epidemiologists, health economists, government agency representatives and a lay member.

A considerable proportion of CJDAS, including its Chair, were practicing surgeons. Practical input from frontline clinicians familiar with the operating theatre environment ensured the guidance was realistic and implementable in the current NHS setting. To assist the Committee in its task, NICE commissioned an independent academic group to undertake a systematic review of the literature and produce a risk assessment, that is, to try and quantify the risk of transmission of CJD via interventional procedures based on the existing evidence. This group also prepared a detailed cost-effectiveness analysis of the different possible recommendations.

### **The guidance**

Having reviewed evidence on more than 2,000,000 procedures, and based on the levels of risk and associated costs, the Committee decided to focus on those procedures that are considered to carry a high risk for CJD transmission: operations on retina and optic nerve and intradural operations on the brain, including neuroendoscopy. For these procedures, the Committee considered a range of different measures taking account both of the effectiveness of these measures in reducing the risk of transmission of the disease and also of the cost and practical difficulties of implementing such measures in the everyday NHS setting.

Its main recommendation was that appropriate measures are immediately put into place to ensure that all instruments stay together within their sets in high risk specialties.

The Committee also considered the option of introducing single use instruments for all high risk procedures. Using instruments once only and disposing of them after use is the only way completely to eliminate any risk of transmission of CJD via surgery. However, such a recommendation would have large cost implications for the NHS and would be practically hard to implement particularly where single use instruments are not available in the market. Furthermore, even in cases where single use instruments are currently produced, there are concerns regarding their quality. The introduction of single use instruments for tonsillectomies a few years ago resulted in a dramatic increase in complication rates such as bleeding. Therefore, CJDAS decided not to recommend the wide introduction of single use instruments for the majority of high risk procedures.

The NICE guidance on CJD was issued in November 2006. Work has already started to support the implementation of the NICE recommendations by a number of relevant groups in the Department of Health while the Chief Medical Officer has issued a letter to all NHS Trusts highlighting the importance of following the NICE guidance to protect patient safety.

## Appendix 6 The Agenda

NICE Citizens Council: Patient Safety Agenda		
Time	Title	Who
<b>Thursday 7th June</b>		
9.00am – 9.30am	Welcome and establishing the modus operandi	Ela and Brendan
9.30am – 10.00am	Welcome from NICE  Introduction to the question Setting the context for NICE What happens now, why is this question significant?	Prof Sir Mike Rawlins
10.00am – 11.00am	Patient safety in the NHS - How is it dealt with now? - Why go for a 'cost effective' approach?	Prof Sir Liam Donaldson – Chief Medical Officer
11.00am – 11.15am	<b>Break</b>	
11.15am – 12:00pm	Reflection	
12.00pm – 1.00pm	Patient Safety in the NHS - The voice of the patients	Edwina Currie – Trustee, Patients Association Harry Cayton - National Director for Patients and the Public
1.00pm – 2.00pm	<b>Lunch</b>	
2.00pm – 3.00pm	Case Study 1 Hospital Acquired Infection	Dinah Gould – Professor of Health Care Research, City University
3.00pm – 3.15pm	<b>Break</b>	

<b>NICE Citizens Council: Patient Safety Agenda</b>		
<b>Time</b>	<b>Title</b>	<b>Who</b>
3.15pm – 4.15pm	Case Study 2 Variant CJD	Dr Kalipso Chalkidou – Associate Director, Research and Development, NICE Dr Roger Eglin –National Blood Service Lester Firkins
4.15pm - 5.00pm	Any questions? Key thoughts	Prof Peter Littlejohns Dr Kalipso Chalkidou
<b>Friday 8th June</b>		
9.00am – 9.30am	Recap	Ela and Geoff Watts
9.30am – 11.30 am Break for coffee at 10.30am	The case for cost effectiveness or not	<ul style="list-style-type: none"> <li>• Peter Walsh – Chief Executive AvMA</li> <li>• Joan Higgins - Chair NHS Litigation Authority</li> <li>• Tara Lamont – NPSA</li> <li>• Peter Mansell – NPSA</li> <li>• Prof Graham Loomes – UEA</li> </ul>
11.30am – 12.00pm	Reflection	
12.00pm – 1.00pm	<b>Lunch</b>	
1.00pm-2.00pm	Case Study 3 Preventing Falls in Hospital	Kate Bryce – University College Hospital Marla Karasu – Guy’s and St. Thomas’ Hospital
2.00pm – 4.00pm  3.00pm – 3.15pm	Putting a price on patient safety  <b>Break for Tea</b>	Dr Jo Lord – Technical Advisor, NICE Facilitators
4.00pm – 4.30pm	Any questions	Prof Peter Littlejohns
4.30 – 5.00pm	Final thoughts for the day	Ela & Geoff

**NICE Citizens Council: Patient Safety Agenda**

<b>Time</b>	<b>Title</b>	<b>Who</b>
<b>Saturday 9th June</b>		
9.00am – 9.30am	Recap from the day before	
9.30am – 1.00pm	Drawing conclusions and deciding what goes into the report.	
1.00pm – 1.30pm	Close and Thanks	
1.30pm	<b>Lunch</b>	

## **Appendix 7 Speaker Biographies**

### **Professor Sir Liam Donaldson MSc, MD, FRCS(Ed), FFPHM, FRCP, FRCP(Ed), FMedSci**

Chief Medical Officer of the Department of Health from 1999. A public health physician by training, Sir Liam Donaldson (2002 New Years Honours List) was previously Regional Director, NHS Northern Region, and before that the Regional Medical Director of that region.

Liam Donaldson started his medical career in surgery and later trained in public health, holding senior posts in public health medicine and management. From the mid-1980s to the mid-1990s, he was Director of Public Health for Regional Health Authorities covering the North East and Yorkshire regions of the National Health Service.

From the early 1990s he combined the role of Director of Public Health with the post of Regional Director of one of the eight regional offices of the National Health Service Executive. His particular experience and interests have been in strategic management and planning, health policy, public health programmes, clinical governance, problems of poor professional practice and health services research. He has graduated from the universities of Bristol, Birmingham and Leicester and has been awarded honorary Doctorates by the Universities of Huddersfield, Bristol, Cranfield and Portsmouth. He also holds an honorary Chair of Applied Epidemiology in the University of Newcastle upon Tyne. He is co-author of a standard textbook of public health and has published widely on health and health service research subjects.

In 1998, Liam Donaldson became the 15th Chief Medical Officer for England succeeding Sir Kenneth Calman. In this role he is the Government's senior medical adviser. He has responsibilities for: policy development and implementation in improving the population's health (particularly reducing inequalities), protecting the public's health; and with the NHS leading on the implementation of clinical governance.

Since taking up the CMO post he has authored several major government reports some of which include: An organisation with a memory: report of an expert group on learning from adverse events in the NHS; Supporting Doctors, Protecting Patients; Stem Cell Research: Medical Progress with Responsibility; Building a safer NHS for patients, The Removal, Retention and Use of Human Organs and Tissue from Post-mortem Examination, and proposals for future specialist certification and revalidation of doctors.

In the 2002 New Year Honours List, Liam Donaldson received a knighthood in recognition of his achievements in health and health care.

### **Harry Cayton**

Harry Cayton is National Director for Patients & the Public at the Department of Health where he advises Ministers, senior officials and the NHS on the involvement of patients & the public, on improving patients experience and on building a patient centred health service. He continues to work one day a week in the voluntary sector to keep in touch with service users' issues and priorities.

He led the team that produced the white paper on choice, responsiveness and equity in the NHS *Building on the Best*. He has produced reports on the reform of dentistry, cosmetic surgery and information governance in the NHS and on the role of the arts

in health. He is chair of the Care Record Development Board which deals with policy and ethical issues in relation to the electronic patient record.

Before joining the Department of Health in 2003 he was chief executive of the Alzheimer's Society and before that of the National Deaf Children's Society. He is a trustee of the grant giving charity, Comic Relief.

### **Edwina Currie Jones**

Edwina Currie Jones was born and raised in Liverpool and educated at Oxford and London Universities. For some years she was a teacher and lecturer in FE and for the Open University. She served as a councillor in the City of Birmingham for 11 years where she chaired the Social Services and Housing Committees, and was a member of then Chairman of the local health authority. On her election to Parliament in 1983 she joined the Health Select Committee then was appointed a Minister in DHSS in 1986, with responsibility for public health and women's health. She resigned over food safety in 1988 and thereafter chose to remain on the backbenches, where she campaigned on issues including gay rights, the abuse of people with learning difficulties, Gulf War syndrome and the advent of vCJD through "mad cow disease". In the 10 years since leaving Parliament in 1997 she has become a well-known broadcaster, with her own programme on BBC Radio Five for 6 years, and has also published 10 books including 6 novels. She is Patron of the Reigate and Banstead Women's Refuge, Patron of the Human BSE Foundation, and appears before the Council as a Trustee of the Patients' Association.

### **Dinah Gould**

After graduating from Durham University, Dinah Gould trained as a nurse at St Thomas's Hospital in London. She was a ward sister at Chelsea Hospital for Women and an infection control nurse in St Mary's Hospital Praed Street before moving to a career in higher education. Her doctoral thesis explored nurses' performance of key infection control precautions (hand hygiene and blood/body fluid precautions) at a time when infection control was neither a popular topic for research or much taught to student doctors and nurses. Dinah helped to change this by publishing widely in scholarly and professional journals and introducing infection control as an important topic in the nursing and medical curriculum. In 1998 she gave evidence to the National Audit Commission during its first enquiry into infection control in acute hospital trusts and has explored the role of hospital matrons in promoting environmental cleanliness and hygiene. As Professor of Applied Health at City University in London, Dinah still conducts original research related to healthcare-associated infection, supervises doctoral students and is a member of the Hospital Infection Society and the Infection Control Nurses' Association. She has recently undertaken a Cochrane review to explore ways of increasing compliance with hand hygiene and the impact on hospital infection rates which attracted media attention around the world.

### **Dr Kalipso Chalkidou**

Associate Director, Research and Development, NICE

### **Dr Roger Eglin**

Head of National Transfusion Microbiology Department, National Blood Service  
England

### **EDUCATION:**

1970 B.Sc. (2.1) Medical Microbiology, University of Dundee

1971 M.Sc. General Virology, University of Birmingham

1974 Ph.D. Virology, University of Birmingham

## EMPLOYMENT HISTORY

2000 – present	Head of National Transfusion Microbiology Department, National Blood Service England
1991-2000	Head of Virology Department, Leeds PHL
1985-1991	Clinical Scientist Grade C, Oxford PHL
1983-1985	Clinical Scientist Grade B, Oxford PHL

## PUBLICATIONS

- 1: Leong HN, Tuke PW, Tedder RS, Khanom AB, Eglin RP, Atkinson CE, Ward KN, Griffiths PD, Clark DA.  
The prevalence of chromosomally integrated human herpesvirus 6 genomes in the blood of UK blood donors. *J Med Virol.* 2007 Jan;79(1):45-51.
- 2: Eglin RP, Murphy WG.  
Beyond leukodepletion: removing infectious prions by filtration. *Transfusion.* 2005 Dec;45(12):1836-8.
- 3: Warwick RM, Eglin R.  
Should deceased donors be tested for vCJD? *Cell Tissue Bank.* 2005;6(4):263-70.
- 4: Howell DR, Eglin R.  
Low-level hepatitis B viraemia. *Transfus Med.* 2005 Feb;15(1):63; author reply 65-6.
- 5: Barbara J, Eglin R, Mortimer PP.  
Towards the holy grail of the infection-free blood transfusion. *Commun Dis Public Health.* 2004 Mar;7(1):8-10.
- 6: : Gallimore CI, Green J, Lewis D, Richards AF, Lopman BA, Hale AD, Eglin R, Gray JJ, Brown DW.  
Diversity of noroviruses cocirculating in the north of England from 1998 to 2001. *J Clin Microbiol.* 2004 Apr;42(4):1396-401.
- 7: Eglin R.  
Implementation of genome amplification technology for HCV RNA detection. *Transfus Med.* 2002 Aug;12(4):265-73.
- 8 Barbara J, Eglin R.  
Genome detection and transfusion: setting the scene. *Transfus Med.* 2002 Aug;12(4):227-8.
- 9: : Reesink HW, Engelfriet CP, Tegtmeier GE, O'Riordan J, Eglin R, Barbara JA, Flanagan P, Lin CK, Rawlinson W, Muyille L, Wendel S, Biagini S, Lazar AE, Krusius T, Alitupa E, Grillner L, Preiser W, Doerr HW, Brand A, Zupanska B, Brojer E, Degre M.  
Prevention of post-transfusion cytomegalovirus: leucoreduction or screening? *Vox Sang.* 2002 Jul;83(1):72-87.
- 10: : Grant PR, Sims CM, Krieg-Schneider F, Love EM, Eglin R, Tedder RS.  
Automated screening of blood donations for hepatitis C virus RNA using the Qiagen BioRobot 9604 and the Roche COBAS HCV Amplicor assay. *Vox Sang.* 2002 May;82(4):169-76.
- 11 Eglin R.  
Enhanced arm cleansing, diversion of the first aliquot of donation, NAT and their impact on blood safety. *Transfus Apher Sci.* 2001 Dec;25(3):175.
- 12 : Hale A, Mattick K, Lewis D, Estes M, Jiang X, Green J, Eglin R, Brown D.  
Distinct epidemiological patterns of Norwalk-like virus infection. *J Med Virol.* 2000 Sep;62(1):99-103.
- 13: Cade A, Brownlee KG, Conway SP, Haigh D, Short A, Brown J, Dassu D, Mason SA, Phillips A, Eglin R, Graham M, Chetcuti A, Chatrath M, Hudson N, Thomas A, Chetcuti PA.
- 14 Randomised placebo controlled trial of nebulised corticosteroids in acute respiratory syncytial viral bronchiolitis. *Arch Dis Child.* 2000 Feb;82(2):126-30.

### **Lester Firkins**

For 35 years Lester Firkins worked within the UK Banking Industry.

In 2001, following the death of his eldest son, Ellis, to vCJD he embarked on a different road.

Initially, he chaired a Patient Charity – Human BSE Foundation – and this brought him into contact with the various statutory bodies involved with that disease.

He is currently Chair of the James Lind Alliance (Monitoring and Implementation Group) – an MRC / DH funded initiative aimed at supporting Patients and Clinicians within a Working Partnership to prioritise where they think Research Funding should be directed.

He also remains interested (naturally) with CJD and Co-Chairs the only Clinical Trial into the disease and is also Co-Chair (with Sir Michael Rawlins) on the MRC New Therapies Scrutiny Group.

Lester was a member of the NICE Committee considering the impact of vCJD on Surgical Instruments – and is currently a member of the NICE Appeals panel.

### **Professor Graham Loomes**

Graham Loomes is Professor of Economic Behaviour and Decision Theory at the University of East Anglia. His research is focused on the analysis of preferences and decision making, with particular applications to health, safety and environmental issues. This involves the use of experimental techniques to aid the development of theory and methodology, and the conduct of surveys and field studies to apply the principles and methods to practical policy issues such as the monetary value to be attached to health and safety benefits. He is the author of more than 50 papers in refereed journals and books (journals include: *American Economic Review*, *Econometrica*, *Economica*, *Economic Journal*, *Journal of Health Economics*, *Journal of Risk and Uncertainty*, *Oxford Economic Papers*, *Review of Economic Studies* and *Social Science and Medicine*). He has undertaken research for a number of government bodies in the UK and elsewhere, including Departments of Environment, Health and Transport, the Health and Safety Executive, the NHS and the National Institute for Health and Clinical Excellence. He has also received research funding from the Economic and Social Research Council and the Leverhulme Trust.

### **Peter Walsh**

Peter Walsh is Chief Executive of Action against Medical Accidents ('AvMA') - the independent charity which promotes better patient safety and provides information, advice and support to people affected by a medical accident. He took up his current position in January 2003. Peter has extensive experience of work on patients' rights, advocacy and health policy. Before joining AvMA he was Director of the Association of Community Health Councils for England and Wales. He had been Chief Officer of the Community Health Council in Croydon where he co-ordinated monitoring of local health services and took part in strategic planning, as well as supporting individuals with complaints about the NHS. Prior to that worked in the voluntary sector, mainly within Councils for Voluntary Service. This included development work with voluntary and community groups, including work on user involvement, community care planning, and developing advocacy projects for different groups of people. He also has experience of working in the private sector in the advertising and publishing industry. Peter holds a Masters degree in Business Administration ('MBA')

specialising in health service management from the University of Hull and a BA in English from the University of Leicester.

Other positions held:

- Trustee and Executive Committee member of *Clinical Disputes Forum*
- Editorial Advisory Board of *Clinical Risk* journal
- Member of the *National Patient Safety Forum* (chaired by the Chief Executive and Chief Medical Officer of the NHS)

### **Joan Higgins**

Joan Higgins was Professor of Social Policy at the University of Southampton and Professor of Health Policy at the University of Manchester. She is now Professor Emerita in Manchester. She was President of the European Health Management Association from 2001-3.

She has had a long career in the public sector, chairing Boards in the NHS. She was Chair of Manchester Family Health Services Authority and Manchester Health Authority and then Regional Chair in the NHS in the North West. She was Chair of the Christie NHS Trust, a specialist cancer centre in Manchester, from 2002-7 and left there to become Chair of the NHS Litigation Authority in April 2007. She chairs the Patient Information Advisory Group in the Department of Health, which provides advice to the Secretary of State on the use of patients' health records and ethical issues concerning confidentiality and consent and is involved in the implementation of the NHS electronic care record. She is also a member of the Queen's Counsel selection panel.

She was made a DBE in the 2007 New Year Honours List, for services to healthcare.

### **Peter Mansell**

Peter is the National Patient Safety Agency's Director for Patient Experience. His role is to provide the major lay contribution to the overall success of the NPSA through the development and implementation of effective lay participation and influence in NPSA's work.

Peter left school without any qualifications and worked in various manual jobs until becoming paraplegic at the age of 20, in 1978, through a road traffic accident. Peter then studied and gained a Degree in social policy and administration and a postgraduate Diploma in management.

Peter's injury led to an interest in health and disability and the social policy issues surrounding them, and to his working for many organisations in this field. Peter has been Chief Executive of both the Spinal Injuries Association and The Royal Association for Disability and Rehabilitation, as well as Chairman of the Royal National Orthopaedic Hospital Trust.

Peter has spent over three years as inpatient in hospitals and has experienced medical error and harm.

Peter is 49 years old and lives in south London with a wife Karen and his youngest son Alex (17). His other son, Greg, is at University in Hull studying German.

### **Tara Lamont**

At the National Patient Safety Agency (NPSA) for the last two years, Tara Lamont has led the process for prioritising safety solutions; produced a report on medication safety; and is now project developer for the major review of the national incident reporting system. Before then, she worked at the Audit Commission for eight years, leading three national value-for-money studies (and audits) of diabetes services; general practice resource use; and specialised services. She is familiar with health technology assessment methods, helping to set up the new NHS R&D Programme in

the early 1990s, prioritising research needs and acting as Secretary to the Standing Group on Health Technology. She has also worked for the British Medical Association, writing reports and books on diverse issues such as complementary medicine, hazardous waste and medical research funding.

**Dr Jo Lord**

Technical Advisor, NICE.

**Kate Bryce**

Kate Bryce was awarded a BSc (Hons) in Physiotherapy from Nottingham University in 1999; became qualified for non-medical prescribing in 2006 and completed a Diploma in First Contact Care for Falls in August 2006. Her interest in elderly care and falls management began in 2000 during time spent working in an Elderly Care Day Hospital. Kate move to London in 2001 and took a Senior Physiotherapy post at University College Hospital. She worked in acute care, specialising in admission prevention with a focus on older patients and the risks associated with a rapid discharge. Her case load regularly included adults suffering multiple health issues that influenced their well-being, life style and possibility of falling. The impact, assessment and treatment of falls rapidly became a special interest and Kate was prominent in work on the Trust's risk assessment, which culminated in the development and launch of a Trust wide Slips, Trips and Falls assessment tool in 2004. Kate has developed her interest and regularly represents the Trust on community Steering Groups. In 2006 Kate took over the lead of the Hospitals Rapid Response Team, overseeing the therapy assessment, treatment and discharge planning of patients attending accident and emergency and admitted to the acute assessment unit. As part of her Diploma she spent time working under the mentorship of Dr Rosaire Gray, where she completed the medical assessment and diagnosis of patients attending a falls clinic. She provides support and training across the MDT and established the Trusts Falls Steering group before taking a career break to have her first child. She returned to work as the Trust's Falls co-ordinator in March 2007. Her new remit is to lead the develop of the Trust's Falls Strategy. This must accommodate the needs of the seven hospitals within the Trust and balance the government targets with the practical application of an effective falls care pathway embracing medical assessment, risk minimisation and rehabilitation.

**Marla Karasu**

Matron, Geriatrics, Guy's and St. Thomas' Hospital.

## **Appendix 8 The 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.