

# NICE Citizens Council



**The attitude of the public to the use of patient information obtained from medical records by the National Confidential Enquiries**

4<sup>th</sup> Meeting of the NICE Citizens Council

13<sup>th</sup>-15<sup>th</sup> May 2004, Brighton

The Citizens Council meeting has been facilitated and this report drafted on behalf of the Citizens Council members by Vision 21. In this report we've tried to indicate where a judgement might be a majority view, so that NICE can see the weight given to certain views by the Citizens Council. However, we also thought it was important to give space to explain the reasons behind the judgements of those who were in a minority.

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## SECTION ONE

### The topic for the NICE Citizens' Council – May 2004

#### The topic to be discussed

NICE would like to know the attitude of the public to the use of patient information obtained from medical records by the National Confidential Enquiries.

#### Background

##### What are National Confidential Enquiries?

- 1.1 NICE funds three organisations that undertake research into the circumstances surrounding either the deaths, or very serious events, of patients, in order to identify ways of improving the quality of care in the future. These organisations are known as National Confidential Enquiries, or "Enquiries" for short.
- 1.2 NICE took over funding the Enquiries in 1999 – before that they were managed by the Department of Health.
- 1.3 The Enquiries have historically concentrated on patients who have died in order to identify preventable causes of death.
- 1.4 Each Enquiry undertakes research in different areas:
  - a. **The Confidential Inquiry into Suicide and Homicide** (CISH) examines the care of people who commit suicide or murder who have been in contact with mental health services within the previous year.
  - b. **The Confidential Enquiry into Maternal and Child Health** (CEMACH) researches the care of a) women who die as a result of pregnancy and childbirth; b) babies who are born dead (stillbirths) or who die during the first year of life; and c) children who die.
  - c. **The National Confidential Enquiry into Patient Outcomes and Death** (NCEPOD) examines the outcomes of patients who die within 30 days of undergoing an operation or other treatment within a hospital.

##### What is the Enquiry process?

- 1.5 The Enquiry process involves looking carefully, and in detail, at the medical records of patients (including both hospital and GP records); and the doctor who was in charge of the patient at the time of death is usually asked for his/her comments.
- 1.6 The form and nature of the Enquiries is changing. First, there is an increasing tendency to look at not only those patients who have died but also those that might easily have done so (so-called "near

misses”). This is because some deaths have become so rare that they are too few for statistically reliable results to be generated.

- a. One example is deaths during and after pregnancy where the numbers are now becoming so few (around 100 per year) that statistically reliable information is becoming hard to acquire. In this instance “near misses” might (for example) include pregnant women admitted to an intensive care unit but who survived.
- 1.7 The second change is that, in order to see whether particular circumstances really are associated with such serious adverse outcomes as near misses or death, the Enquiries are now also starting to look at information from some patients who have had a good outcome. The Enquiries then compare the care received by patients who have had different outcomes in order to understand what effect care has on patients and identify “risk factors”.

### **What results have they had?**

- 1.8 The National Confidential Enquiries (“the Enquiries”) have a long tradition in contributing to improvement in patient care. Previous findings from the Enquiries include:
- a. Showing, in the 1950s, that bleeding was the commonest cause of women dying during pregnancy. This led to better arrangements for care such as ensuring that labour wards were sited in places where there was rapid access to resuscitation facilities
  - b. Showing that babies are more likely to develop “sudden infant death syndrome” if put to sleep face down rather than on their sides or back.
  - c. Showing the serious consequences of not having a dedicated operating suite and staff for undertaking emergency surgery.
  - d. Showing that patients in mental hospitals used shower curtain rails as points from which to hang themselves.
- 1.9 Some of these results (for example bleeding to death during labour) were used to persuade people (the government, health care professionals, patients, local communities) that isolated maternity hospitals were unsafe; and that investment in alternative facilities would save lives.
- 1.10 Other results, such as the benefits from putting babies to sleep on their sides or backs (rather than face down), have been a surprise because they challenged what was considered to be best practice at the time. The publicity campaign generated as a result of the finding about how to best to put babies to sleep has led to a very substantial (possibly two-thirds) reduction in “sudden infant deaths”.

### **Do they investigate individual deaths on behalf of relatives who want to know what has happened?**

- 1.11 No. The Confidential Enquiries analyse anonymised data about relevant deaths that have been collected at a national level, rather than investigating individual patient deaths. The Enquiries make recommendations about how systems of care should be organised, not about the care of any individual patient or the conduct of any one clinician.
- 1.12 The Enquiries are not a substitute or alternative to referral to a Coroner, or to legal action where a patient's family seeks damages for medical malpractice.
- 1.13 Rather, they are research studies to identify factors (sometimes called "risk factors") that may be associated with deaths either because facilities are generally not good enough, or because there are factors (previously not recognised as being "adverse") or where care (for many other reasons) may not have been good enough.

### **Is the information used by the Confidential Enquiries anonymised?**

- 1.14 NHS organisations are generally not able to supply the data in a non-identifiable or anonymous form. And, anyway, the Enquiries need to know the identity of individual patients so that records from different sources can be linked together. The records are then anonymised before a team of independent clinical scrutineers reviews them.

### **Do individuals give their consent for their medical records to be used by the Confidential Enquiries?**

- 1.15 No. The Enquiries face three problems which makes it difficult, in practice, to seek consent:
  - a. A typical Enquiry study might include several thousand patients from hospitals throughout England, Wales, and Northern Ireland. Information is typically collected some time after the episode of care in question. Thus the resources, time and infrastructure needed to acquire informed consent from each patient or their representative make the exercise practically very difficult, if not, impossible.
  - b. There is an even greater problem in relation to people who have died or who have suffered a serious adverse event. One interpretation of the law is that consent would be needed from their next of kin.

### **What's the problem?**

- 1.16 The Data Protection Act 1998 heralded an increasingly firm stance about the use of identifiable patient information in research. The

common law of confidentiality has always been that identifiable patient information should not be used without the consent of the patient.

- 1.17 The Health and Social Care Act 2001 further strengthened the legal position on the use of identifiable patient information. However, Section 60 of the Act provides powers to ensure that, subject to strict safeguards, patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The Department of Health states “the power can only be used to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative, and where anonymised information will not suffice”.
- 1.18 The Enquiries need to collect patient identifiable information and, in practice, they believe it is impractical to seek consent from individual patients (or their next of kin).
- 1.19 The Enquiries apply for Section 60 support to allow them to collect patient identifiable information. However, Section 60 support is intended to be granted only for an interim period, and must be reapplied for annually.

#### **What’s the question for the Citizens’ Council?**

- 1.20 Should the National Confidential Enquiries be required to seek prior consent from every patient and next of kin whose identifiable data are used in their research?
- 1.21 In answering this question the Council will need to consider, amongst others, the following questions:
  - 1.22 Are the Enquiries making an important contribution to health?
  - 1.23 Is gaining patient/next of kin consent impractical and (for next of kin) too intrusive, or not?
  - 1.24 Are the Enquiries’ current arrangements for ensuring patient confidentiality adequate?
  - 1.25 Is the balance between the desire to gain consent offset by the benefits to the public of the Enquiries, or not?

#### **Use of the Council’s answers**

- 1.26 The Council’s answers will:
  - 1.27 Influence the strategic approach taken by the Board on the conduct of the Confidential Enquiries. In developing its final position, the Board will necessarily seek the views of the Confidential Enquiries Advisory Committee and the Enquiries themselves; and
  - 1.28** Influence the Enquiries’ approach to their responsibilities under Section 60 of the Health and Social Care Act 2001

## SECTION TWO

### Key findings

- 2.1 We think the Confidential Enquiries make an important contribution to health care.
- 2.2 Most of us don't think the Confidential Enquiries should be required to seek prior individual informed consent before using medical records for their research.
- 2.3 More than two thirds of us felt strongly that the arguments for gaining consent is offset by the benefits to the public of the work of the Enquiries.
- 2.4 Most of us accept that it would be impractical to require the Confidential Enquiries to seek such consent: we feel it could compromise the quality of the research, place an unsustainable burden on the Enquiries, and divert resources from other parts of the NHS.
- 2.5 Most of us accept that it is currently impractical to require the hospitals to completely anonymise the data at source, and overall most of us are satisfied as to the security and confidentiality of the psuedo-anonymised data used by the Enquiries.
- 2.6 Generally speaking, our objections to requiring the Enquiries to seek individual consent from patients or next of kin are on the grounds of impracticality not because it would be intrusive to the individuals concerned. Although it would not be an easy conversation to have, we felt that medical professionals deal with sensitive situations all the time, and most people accept that in the event of a death of a loved one, some things are essential even if they are distressing.
- 2.7 A minority of us believe it is essential that the Enquiries seek consent on the grounds that it is not right to make use of information about individuals without the individual's express permission. Even if there is a good case for the NHS needing that information in the interests of the greater good, some of us felt strongly that it is not acceptable to assume that it can be used without reference to the patient or their next of kin.
- 2.8 Although on balance, therefore, we supported the case put by the Confidential Enquires that they should not be required to seek individual informed consent, we also felt that there are a number of important culture changes that need to take place – both within the Enquiries and the NHS as a whole.

- 2.9 Firstly, all but one of us was unaware of the existence of the Confidential Enquiries before we were asked to discuss them. This is a matter of concern, and we would like to see NICE, the Confidential Enquiries and the NHS do much more to make the public aware of the Enquiries, their use of patient records, and the impact of their results on the development of health care in the NHS.
- 2.10 We felt that once the public knew about the work of the Enquiries, they would be more likely – not less – to support the use of their records for developing better practice and for learning from and addressing system failure. Although they undertake good work, it is not acceptable that the public doesn't know that this is happening.
- 2.11 Regardless of where any of us stood on the need to gain informed consent from individuals for the use of their own medical records, we all felt that it is vital that the public as a whole is better informed that these processes take place.
- 2.12 Some - though not all - of us thought that it would be possible to avoid the need to seek individual informed consent by undertaking a widespread publicity campaign to ensure that the public is made aware of the work of the Enquiries and the use that some patients' medical records might be put to in the pursuit of this work. In this way, general consent could be assumed to have been given, unless an individual chose to 'opt out' and have their medical records marked as such. We understand that the introduction of the electronic patient record might make this easier in practice, but some of us feel that it might be possible to do even now.
- 2.13 It's fair to say that all of us support the concept of a learning NHS. We understand that in order for each of us to benefit from ever-improving healthcare, there need to be systems in place that encourage honest disclosure of events. But we also think that this is not just a matter for health professionals, and the systems should be continually reviewed to do more to encourage patients and the public to be involved in helping improve the National Health Service. It may be that this could be part of a culture change from paternalism to partnership. Often during our discussions we referred to the responsibilities and well as the rights that patients, the public as a whole, and health professionals all have.
- 2.14 Much was made during our discussions of the reciprocal arrangements assumed between individuals and a national health service. As one Council member said: "We take a great deal from the NHS – why not say thank you by putting something back?" But there was some debate between us as to what is implied as a result of this, and whether some of this should be made more explicit as part of the patients charter. People need to know more about how the NHS works, and what their role is in relation to it. Regardless of our individual views on whether individual consent is required in this

instance, all of us would like to see a greater culture of openness and of trusting the public, to become the norm within the NHS.

- 2.15 Secondly, we are aware of the history and the context in which relationships between the public and the medical profession have developed over the years. Some of us were not entirely convinced that when we are told something is 'impossible' or 'impracticable', it isn't actually just because the professions think it is 'difficult' or 'inconvenient' for them. Many of us would like to see a more 'can do' attitude in relation to finding ways to involve the public in making decisions about how their data is used and about healthcare right across the board. It is not so long ago that patients were told it was impossible to see their own medical records.
- 2.16 Most of us felt, therefore, that we would like the chance for us as a Citizens Council – or the public as a whole - to revisit the situation in the future once the use of new technology such as the electronic patient records opens up new possibilities for the storage and sharing of information. Our views may change in the future, should new technology make alternative arrangements possible. A review should not necessarily be limited to a time when there is an integrated IT system within the NHS.
- 2.17 Next, we are convinced that informed debate amongst the public can only strengthen the support that individuals give to the system of collective provision that is the National Health Service. Some of us felt very strongly that we couldn't expect as individuals to opt out of one part of a system, and then expect the system as a whole to be there for us when we need it.
- 2.18 Even those of us who supported the idea of people being able to 'opt out' on an individual basis hoped that this option would be exercised only in a tiny proportion of cases. While a minority of us thought that the individual right to withhold consent is an important principle to safeguard for others, none of us said we were likely to exercise it for ourselves.
- 2.19 Finally, a number of us noted that the NHS has changed substantially since the Confidential Enquiries started, and there are now a number of other organisations – not least the National Patient Safety Agency – that have been set up to help the NHS learn and improve. While we support this work, some of us suggested that it's possible that some of the difficulties involved in 'sharing' data might be avoided if the NHS acted as more of a coherent whole where possible.

## SECTION THREE

### Our comments in detail

- 3.1 **We were asked to consider whether the Confidential Enquiries are making an important contribution to healthcare. Unanimously, we thought so.**
- 3.1 As one of us said: “I feel there is ample evidence for this – decline in maternal deaths, decline in infant mortality and cot deaths, changes in the care of patients with mental health problems.”
- 3.2 Many of us agreed that: “This kind of information is vital to improve future patient care and develop new ideas and procedures to the benefit of the service.”
- 3.3 As someone else pointed out: “They have the opportunity to identify areas of concern that need investigation without alarming patients whose records they investigate.”
- 3.4 Several of us took note of some of the examples we were given by the staff from the Enquiries, and from the staff from the local NHS Trust who came to discuss with us. “The Enquiries are making an important contribution to health, as evidenced by the statistics presented to us by the expert witnesses we have heard. I’m particularly thinking of the two thirds reduction in cot death due to the highly publicised Back to Sleep campaign arising from the CEMACH enquiry.”
- 3.5 Another said: “The example of reducing maternal deaths from 400 to 30 per year is proof that using medical records in research is beneficial to society as a whole, and many more examples exist.”
- 3.6 And the Enquiries can perform another function too – as well as identifying general lessons, they can raise cases that give rise to cause for concern with specific Trusts if necessary. “They have the opportunity to identify areas of concern that need investigation without alarming patients whose records they investigate.”
- 3.7 We agreed that it’s important that the lessons learned through the Enquiries are acted on, although one Council member explained their views on this: “The point that some problems are recurrent (eg lack of High Dependency Unit beds) does not mean that they are not being advanced, and it is good that the Enquiries are still flagging up such deficiencies. Every medic who has given evidence has spoken highly of the Enquiries’ role.”
- 3.8 Several of us welcomed the contribution of the Enquiries, even though we would also question the way in which they currently

approached the issue of patient consent for the use of records: “Any improvement to the health service, no matter how costly or time consuming is a good thing. I have no problem with the Enquiries going ahead, I do however feel that the public have a right to know what’s happening.”

### **3.9 We were also asked to consider if gaining patient or next of kin consent is impractical or not.**

#### **3.10 18 of Council**

3.11 Most of us thought it would be impractical because it would tie up so many resources that could be used elsewhere. Some of the reasons we gave are explained as follows:

3.12 “This for me is the main issue. The cost in money and man-hours at a time when the NHS is so under-resourced is just too great. Not only that, but the requirement is so huge that the cash and staff should be directed towards front line health needs. The situation in the overall NHS probably won’t materially improve for a generation.”

3.13 Someone else said: “Is the patient or next of kin going to be subjected to extra distress? How easy is it to find next of kin? What if the siblings disagree? What extra resources would be needed, and what other services could be lost as a result?”

3.14 Another Council member agreed: “It is hugely impractical, mainly because of the consumption of NHS resources that would better serve the public interest if used for care and improvements to practice.”

3.15 Others of us were worried about being able to get hold of the right people, in cases where the patient had died:

3.16 “It is impractical because of the cost implications of trying to trace the next of kin – people move house or relationships change. Even if next of kin are easily traceable, they would still need the resources to contact, visit and interview the next of kin, which is time consuming.”

3.17 Another Council member pointed out: “Not only is it insensitive to ask a grieving relative but also not everyone has families or homes, while identifying next of kin is harder than before as the dynamics of families have changed.”

3.18 And some groups within the population might be particularly hard to get in contact with: “Certain groups, such as homeless people, refugees, next of kin are beyond the scope of being traced and their assent acquired on some occasion.”

- 3.19 “After the death or near miss – yes, it is impractical. There may be hard to trace next of kin or at risk groups, who may be upset by the approach for consent. The numbers concerned – i.e. 25,000 per year for NCEPOD – are unrealistic. And rather than seeking individual informed consent, if you went instead for a general consent before treatment, this could not be done on a proper, informed basis for 55 million people.”
- 3.20 A couple of us were concerned about the pressure this extra request would put on the time of those health professionals involved in routine care: “In a seven to 10 minute time allotted during a GP visit the patient wants to concentrate on his or her current problem. Also, busy wards in hospitals cannot accommodate long explanations about consent.”
- 3.21 One person said that at the moment, they thought it was impractical, “But I think the new IT system should make it possible, and should be used as soon as possible. “
- 3.22 But another disagreed that this would provide any answers: “Even after records are totally computerised, gaining consent would still be very difficult and very costly. But it would still be nice to be asked. (No pun intended.)”
- 3.23 However, seven of us thought that there were practical ways of seeking individual informed consent.**
- 3.24 For us, these objections on the grounds of ‘impracticality’ simple reflected an attitude: “It can be seen as being impractical until it is chosen as a priority – as many things in history have been, for example they used to say that you can’t employ women as it is impractical to provide a separate toilet!”
- 3.25 Another Council member agreed: “It’s not impractical – our only constraints are medical people saying it’s difficult. Every situation is different but we must remember that in dealing with such a large organisation we are also dealing with individuals. Elements such as cost and manpower need to be made available to ensure that where possible consent is gained.”
- 3.26 One suggested doing it differently: “A lot of consent could be gathered at the ‘point of sale’ – at doctors’ surgeries and hospitals, in a totally practical way. It would be impractical to contact every person in the country – you’d never get all of them replying anyway and the cost would be exorbitant. There is lot of talk about the cost of gaining consent but no-one would hazard a guess at what it would be!”
- 3.27 Another Council member reminded us that we’d heard of occasions where it had been done: “The gaining of each and every individual’s consent may seem impractical, but if one diabetic practice could

contact and get consent from 2,000 people off it's own bat, it is not impossible."

- 3.28 And some suggested that although not easy, it matters enough to try: "It does appear to be a difficult exercise, but just because it is, does not make it impossible or unnecessary. Empowerment and self-governance, autonomy is the positive way forward."
- 3.29 A few Council members, including those who thought consent should be gained and those who didn't, suggested seeking consent in advance of any incidents – just in case.
- 3.30 One explained: "The way consent is asked for may or may not make it impractical. Asking a grieving family member or a confused or worried patient is impractical. By informing all of the population, including those who don't go to hospital regularly and offering the chance to have a note put on records declaring an opt out is practical."
- 3.31 Another said: "It is not easy, but the importance of doing so outweighs the impracticability. To leave asking until tragedy strikes is not a good way of going about things. Consent to the use of data is important, but not as important as consent for treatment. Therefore to inform the public about the good work of the Enquiries and giving the option of being on an opt-out register would satisfy the need for consent."
- 3.32 This Council member went on to say: "Some individuals may have highly sensitive reasons for wanting to keep their medical history secret to themselves, and a small number of medical professions associated with them. It is not for us to judge that they do not have the right of refusal. Enquiries have at times sought consent for the use of records amongst diabetes patients, and very few opted out, so I do not think that it would harm their work. If they received everyone else's data their work might be improved."
- 3.33 They continued: "We learned at an earlier Council that everyone has the right to refuse treatment so it seems strange, in an age of choice and patient partnership that we cannot refuse to have our data used if for example we have received a termination of pregnancy or if we have a disease such as HIV. It is kinder and less intrusive to ask. It is better if the person themselves gives consent. Some people with severe mental health difficulties may not be able to opt out and in such circumstances, however difficult this may be, the next of kin needs to be consulted."
- 3.34 We were also asked our views on whether we thought that gaining patient or next of kin consent was too intrusive or not.**

- 3.35 Eleven thought it was, although many of us were less concerned about this than about the sheer impracticality of the exercise, with several people commenting “I don’t feel it would be intrusive, just impractical.”
- 3.36 “People would be unnecessarily worried and may be suspicious of the reasons for data being provided,” said one Council member. “It may be too intrusive in some circumstances.”
- 3.37 “For instance,” explained another, “when a patient is too ill, or mentally incapable of receiving information about consent. And also when grieving relatives are not in a position to make a considered decision.”
- 3.38 A few of us were concerned about the expectations that may be raised by talking to an individual or their family about a process that is primarily designed to discover system failure. “I have a particular concern that it may raise expectations that there has been malpractice, when this is true in only 10% of cases. Such consent may also carry the implication of feedback as to what had been discussed by the Enquiry: unrealistic in all but ‘cause for concern’ cases. Do some people seriously think you could call 25,000 people per year to ask for consent?”
- 3.39 A number of us were worried about the effect this might have on grieving relatives and next of kin. “In certain circumstances I would consider consent to be intrusive and insensitive, especially when a request for consent runs a severe risk of interrupting and in some cases setting back the grieving process.”
- 3.40 Another Council member agreed: “If next of kin are grieving then it would be extremely insensitive to seek consent for the Enquiries to use their medical records for research – but when would be the best time? It may also cause extra stress and worry which could be avoided because data is anonymised anyway.”
- 3.41 According to another: “Death is caused in many different ways - suicide, suddenly, or suffering for an amount of time. People also grieve in many different ways and to expect that there would be a willingness to discuss is wrong.”
- 3.42 And one person pointed out the difficulties in finding the appropriate time to seek consent: “In many cases I think it can be very intrusive. Arnold could not really address the question of the best time to ask for consent. For example, in the case of cot deaths – should it be before the baby is born, just in case it dies? Or immediately after it occurs? Or six months later when it is all forgotten? Similarly, these difficulties apply to suicide cases.”

- 3.43 But others of us felt that: “If it is necessary it does not matter how intrusive it is.” Another said: “It would be highly discourteous not to ask.”
- 3.44 Several Council members commented: “Health professionals are extremely sympathetic in dealing with sensitive issues.”
- 3.45 And another person said: “I think that a lot of bereaved people would be only too happy to allow research done via records if it was done by the right sympathetic approach and person and advised that it was being done to stop the same things happening in the future. They could then be given the results, if any.”
- 3.46 One member was adamant: “Consent for the use of your medical records in the event of an adverse incident could be gained in advance on a blanket basis either when registering with a GP, dentist or on admission to hospital. It is intrusive NOT to gain consent.” And another suggested: “Ask the general public while they are not in trauma how they think about it.”
- 3.47 A number of us really weren’t sure, and said it would depend on the circumstances:**
- 3.48 “Obviously this depends on particular circumstances, how the approach is made and when – but this issue is dwarfed by the sheer practicality and size of the NHS population count.”
- 3.49 Several people pointed out: “After deaths of loved ones there are already many legal notifications and requirements. Giving information about what might happen to data and medical records need not be that much more intrusive. But I accept that it is not the best time.”
- 3.50 Another Council member said: “Consent has to be obtained, quite rightly, for clinical intervention, and far from being intrusive, the vast majority of patients would regard this as their right. I would assume that patients would be happy to consent to their data being used. The intrusiveness would arise in the event of death when families would be grieving and could resent such follow-ups.”
- 3.51 A colleague agreed: “Again we are all individuals. For some it would be too intrusive. For others, they have had discussions with their next of kin as to how they want to be treated after death or if they cannot take decisions for themselves, and this needs to be taken into account. Some individuals would be very helpful.”
- 3.52 We were asked if we thought the Enquiries current arrangements for ensuring confidentiality are adequate?**
- 3.53 Twenty thought so: three were not convinced.

- 3.54 Most Council members felt comfortable after hearing about the Confidential Enquiries' arrangements:
- 3.55 "The staff are extremely professional and understand the importance of their work and the evidence to back that up is that there has been no breaches of confidentiality in the 52 years they have been working."
- 3.56 "From the information given to us I would say yes, there have been no reported breaches of security or any dismissals for negligence."
- 3.57 "From the evidence heard it would seem they are adequate and professional and have a good track record. While not enshrined in law there is the ever present threat of job dismissal if confidence is breached."
- 3.58 Another Council member commented: "I am entirely happy with the arrangements as described by PIAG and the Confidential Enquiries. It instils enough confidence in me personally, that my records are safe."
- 3.59 Several of us pointed out that we have far more to worry about in terms of security of our information at other points in the NHS:
- 3.60 "Absolutely. The PIAG idea of pseudo-anonymising the data at the source hospital has advantages, but the current level of security is far higher than in any hospital or GPs surgery. The Enquiry staff go to an insane amount of care and should be applauded."
- 3.61 "It's more secure than our local hospital and GPs filing cabinets! (Which desperately needs to be addressed.)"
- 3.62 "There is possibly more risk at a GPs surgery or the hospital itself for information to be misappropriated."
- 3.63 Several Council members wanted to make sure that the Enquiries remain vigilant about their handling of patient records: "From the evidence presented to me I would assume that the current arrangements are adequate. Encryption, with the tie back/link back in the hands of one person would seem to ensure this. However, there should be strict inspection and audit to ensure adherence to the appropriate BS ISO17799 and any case studies should be very carefully anonymised."
- 3.64 Another also said: "After 52 years with no known leaks I think so, but beware complacency. I would be more concerned about my data getting out of other bits of the NHS than the Confidential Enquiries."
- 3.65 One or two people were confident that the records were kept confidential, but didn't think this removed the need to gain consent for

their use: “As the data is still theoretically identifiable it becomes all the more important that consent is sought.”

- 3.66 For those who were worried about the arrangements to keep the records secure, it was often due to the fact that they had to be physically transferred from one place to another.
- 3.67 “I don’t think they are adequate arrangements. Details are still on patient records when they are sent to the Enquiries. Never mind that the Enquiries remove them – they shouldn’t be sent without the patient allowing the hospital to do so. What if these records were lost in the post still with the details attached? Look at the recent exam paper fiasco, for example.”
- 3.68 Another Council member agreed: “Third parties may be involved, transport of medical records, records filed in public areas, more electronic data required.”
- 3.69 And some of us had general worries that “nothing is 100% safe. The more people who are involved, such as third parties, the less safe it is.” Another person said: “If someone wanted to break it, it could be done. After all, MI5 and MI6 are penetrated. Journalists will stop at nothing.”
- 3.70 One person said: “Fifty years ‘without a hitch’ does not mean that there will be another 50. Everyone has their price and details can get into the wrong hands.”
- 3.71 We then discussed where the balance lay – on the one hand, the desire to gain individual consent for the use of patient identifiable records. On the other hand, the benefits to the public of the Enquiries. Is the work of the Enquiries so important that it removes the need to gain consent?**
- 3.72 Eighteen of us said, yes: the value of the work of the Enquiries outweighed the desire to gain individual consent.
- 3.73 For several of us it was clear: not much was being asked of individuals, compared with the gains to future patients and the public as a whole:
- 3.74 “The benefit to the public is great in terms of lives saved. The privacy of the individual is not invaded, because the information is used in a pseudo-anonymised form. Because the individual loses nothing, and the society gains a lot, there is, to me, no need for consent. There may be a legitimate expectation that one be informed that this will be done, to protect your safety as a patient and improve care overall.”

- 3.75 Other Council members agreed: “The benefits obtained by the research carried out by the Enquiries exceed all the problems associated with obtaining consent and it seems to me negates any obligations to informed consent. Considering that the only information used will be anonymised.”
- 3.76 “Currently the balance is about right – a bias towards the public benefit through vital research.”
- 3.77 “Considering the impracticality of explaining what consent means to every individual – even providing they can be found, i.e. homeless, refugees, travellers etc - weighed against the huge amount of progress that the Enquiries have made I feel that these benefits far outweigh the need for consent. The risks involved in asking every individual to the Enquires could be detrimental.”
- 3.78 “The benefits from the Enquiries far outweigh the need to gain consent. If saddled with the need to gain consent it would result in corrupt data due to the numbers of people who hadn’t been willing or able to give consent, and the conclusions would be useless. In many cases, it is the groups from whom consent may be difficult to obtain that would benefit most from the work of the Enquiries.”
- 3.79 One of us quoted a surprising figure in support of his argument: “The need of many outweigh the needs of a few’ – so says Mr Spock, Starship Enterprise.” This Council member went on to explain: “The most important factor for society should be the help we can all give to one another - not your personal desires or fears over who will read your notes and discover insignificant details. I feel this issue about consent is paranoia or vanity.”
- 3.80 Another restated their case: “To gain consent from patients and next of kin would be expensive and time consuming and would avoid being too intrusive.”
- 3.81 For some of us, it was simply a case of the greater good of the majority taking precedence: “The benefits to the public far outweigh the desire to give consent. The majority rules in an election, so therefore the benefit of the majority must over-ride the rights of an individual.”
- 3.82 “I think there is a vast difference between the need to gain consent for clinical treatment, and the use of data about patient treatment in a statistical, anonymous form. The individual has little to lose from this. He or she is not directly physically affected, as is the case with clinical treatment, yet there is a real contribution back to all members of the public and to future generations. We all have individual rights, but of necessity those rights are part of a balance between individual rights and the rights of fellow citizens, i.e. society.”

- 3.83 This idea that the individual can only benefit because of what others put in was mentioned by many of us: “I believe that it is desirable to gain consent but having stated above how difficult and often impossible it is, the benefit of the Enquiries to the public has the greater importance. Healthcare must keep moving on to achieve greater benefit to society as a whole, and it is only through research of case histories that mistakes need not be repeated, and trauma and near misses can be reduced.”
- 3.84 One Council member gave this concept slightly qualified support: “If it was a question of balancing one against the other I would accept that the benefits are more important. I still have some concerns about the idea that ‘the road to hell is paved with good intentions.’ The benefits of the work of the Enquiries are huge. But there must be a major move towards awareness of their existence, what they do, and the information they use.”
- 3.85 However, some members – four of us - didn’t see that the work of the Enquiries provided enough of a reason not to ask for consent.**
- 3.86 “Just because the Confidential Enquiries have achieved good things there is no excuse for people not to be informed that their data may be used. They have had free access to medical records for many years and in this day and age it is unreasonable not to ask. Just because a person has died, they are no less entitled to respect and confidentiality. We should show some respect for the deceased. When someone has died, to be blunt, they are not fair game for having their notes looked into for whatever information may be useful, without their prior say so. Two wrongs don’t make a right. It is wrong for privacy to be invaded but it is still wrong for benefits not to be gained from learning from other people’s experience and thereby avoiding tragedies in the future.”
- 3.87 “Why the secrecy?” another Council member asked. “By informing people, they will question what’s going on, and that seems to be what the Enquiries are scared of,” said one Council member. “Individual rights need to be respected as individuals should be respected. By having the courtesy to ask, the general public would support the Enquiries and the NHS and the work they do.”
- 3.88 A couple of Council members thought that the Enquiries would gain from involving patients or next of kin more in the discussions about their research: “The benefits to the public of the Enquiries are very high – assuming their recommendations are taken on board. But, knowledge of them is low, and people need to be made aware of them and given the chance to opt out. A couple having experienced a cot death would be truly grateful to know that sleeping their next baby on its back would reduce the risk of another cot-death. They’d learn

the answer more quickly by being aware and having consented to their child's data being used in the Enquiry. They'd be most interested in its outcome."

- 3.89 Some felt straightforwardly: "The privacy of the individual should be paramount."
- 3.90 And one member was a bit sceptical about the benefits claimed by the Enquiries for their work: "It would seem that the Enquiries are the only people who know about the research and its results as the majority of doctors don't get to know about it. Once again, the desire to gain consent is paramount as it is the fundamental right of the individual to be informed. The majority of people would be only too happy to consent to their records being used. The benefits to the public can only be presumed – the two examples of their success would appear to be almost a matter of commonsense – a lot of the peripheral information could be gained from close relations, etc."
- 3.91 Another wasn't sure: "I believe as much information as possible should be given to people about what the Enquiries need, but I also believe this work is vital and getting consent on an individual basis could disrupt some of the results."
- 3.92 One Council member felt they were having a false choice put to them:
- 3.93 "I feel very strongly that you can have both. You can have a system of informed consent and the benefits of the Enquiries. It could also be argued that a system of individual informed consent could improve the work of the Enquiries by gaining the patient/public perspective."
- 3.94 We were asked to come to some conclusions. In light of all our discussions, should the National Confidential Enquiries be required to seek prior consent from every patient and/or next of kin whose identifiable data are used in their research?**
- 3.95 The majority of us – 18 - said no, the Confidential Enquiries shouldn't be required to seek prior informed consent from individuals. We said why we thought so:**
- 3.96 "It is for the good of us all, as this will provide valuable information on health trends without having to approach next of kin."
- 3.97 "Their work has real public benefit. We are all beneficiaries."
- 3.98 "Their attention to confidentiality is already far in excess of many other organisations and in many cases patient identifiers are not even used. The lack of true data should consent be required would

corrupt the results to such an extent that the research would not be worth doing.”

- 3.99 For some people, it isn't a question of balancing individual and collective needs anyway: "Individuals as well as the public as a whole benefit from their research." Another said: "I would rather have my records put to a good use, knowing that someone out there would benefit from them."
- 3.100 For quite a few of us, as long as it's not easily identifiable, there's no need to ask our permission to use our medical records:
- 3.101 "As far as is practical they should try to anonymise the data as much as possible."
- 3.102 Another said: "The data is only identifiable in a narrow legal sense. It is pseudo-anonymised, and that is sufficient."
- 3.103 "I believe the Enquiries have produced trustworthy reports in the previous 52 years by respecting patients' confidentiality. They have obtained identifiable medical records and encrypted or anonymised the data so as to facilitate their research – but also enabling them to go back to the hospital or doctor if a cause for concern should arise when carrying out research. They advised that 20 out of 1800 may be cause for concern and in such cases the identity of the patient is gained in order to improve future practice. They require identifiable data so that improvements can be made – if data was not identifiable it would defeat the whole purpose and prevent improvements from being carried out."
- 3.104 For many Council members, the problem has arisen in the first place because so few people are aware that their records are being used to help the NHS improve its systems. "For the next three years they can get by on Section 60. By then, a big publicity campaign with an opt-out opportunity for the public would be an exit strategy. I do not see the NHS IT system being in place for another 10 years, so absolute anonymity is a long way off. That said, people have a right to know what's going on. I'm only aware of one member of the Citizens Council who'd known of NCEPOD etc before we started this discussion. That's just one out of 30 people who are interested in the NHS."
- 3.105 But one Council member at least couldn't understand what all the fuss was about: "I can understand why some people fear secrecy but as far as I can understand this organisation is not a secret. If people wanted to find out about it they could have. Just because it hasn't been brought to their attention does not make it bad or unjust. If we all accept help from the NHS we should be morally obliged to give help back, even something as insignificant as our written records. We

are not talking about the NHS removing limbs or organs secretly, just looking at our notes.”

- 3.106 Some of us were concerned about the effect that seeking consent would have on the quality of the work – and also the expectations that would be raised amongst those approached in this way. “Asking for consent after the incident is insensitive and will raise agitation that there may have been malpractice. It would be a major economic drain, would not get 100% return, and would lead to a biased return, which would lead to a loss of professional respect.”
- 3.107 We had a real worry about what would happen if people were asked, but refused to give consent. “This could cause bias in the available medical records which could be used by the Enquiries in their research. People refusing could be the very target group identified as requiring research in order to establish reasons for concern. The example of a questionnaire being put to the public about suicide was a good example. More women completed the questionnaire, when in actual fact it was young men’s opinions which were more relevant, because they were more likely to commit suicide – but they didn’t complete the questionnaire.”
- 3.108 One Council member said that asking for informed consent just didn’t make sense: “It is impossible to gain consent for something that is not determinable. Not knowing the cause of death that would be investigated in advance makes asking for consent in advance meaningless. As I said before the risks to the work that the Enquiries do are not worth it. Considering the enormity of the task it would take an unlimited amount of time, unlimited cost. There is the risk of loss of data, and a possible unwillingness by the public to be motivated to consider what is being asked.”
- 3.109 Another Council member said: “I do not consider that there is a need for prior informed consent to be gained from every patient or their next of kin. Although the data is identifiable, this is only made so in those cases where the Enquiry needs to trace back to obtain further information, or to highlight cases of concern with individual Trusts.
- 3.110 But they went on to explain a point of view shared by a large number of Council members:
- 3.111 “However, although I think it would be costly in terms of resources, sometimes impractical and sometimes insensitive to obtain informed prior consent to the use of data, I do think that there is a very strong case for making a real effort to inform the general public about the use of data for audit and research purposes, since I do feel that the public have the right to know. This is not the same as informed individual consent and does not involve the same cumbersome procedures. Should this happen, I feel that most people would have a

positive attitude to the Confidential Enquiries. A publicity campaign should ideally be aimed at the general public rather than patients at the point of delivery, since some patients arrive in hospital and subsequently die and are not able to be informed. Informing a third party such as next of kin would be more difficult. I realise that an extensive publicity campaign would have its own difficulties – for example, look at the problems of informing the public about benefits. It might also make possible an opt out system which could be an answer for those who want some form of consent.”

- 3.112 Several other Council members shared this view: “At the moment, no. But the public at large needs to be much more aware of what goes on, and who and what the Confidential Enquiries are. The benefits need more publicity. The relationship between the Confidential Enquiries and the NHS should be clearer and more carefully explained. The outcome of the Confidential Enquiries’ investigations using people’s data should be given to them in some form.”
- 3.113 This idea that the Enquiries should inform the next of kin, and not just the Trust, where they have identified a ‘cause for concern’ was shared by a number of Council members:
- 3.114 “The cases which the Enquiries refer back to the hospital trusts because of concerns that they have with the treatment received should be relayed to patients or next of kin. I realise this may alienate the very people who report to the Enquiries, but patients or next of kin need to be informed.”
- 3.115 “If it never becomes feasible to get consent in every case, it should at least be possible to inform in every case. I for one see nothing to fear from the Confidential Enquiries, as long as we keep looking over their shoulders.”
- 3.116 One member explained how their views had changed: “I have strong views on the rights of the individual to privacy, however two things over the last three days have led me to believe these rights do not apply in this instance. Firstly, the question was posed: ‘do the ends justify the means?’. The answer is an emphatic yes. Secondly, the speakers from the local health trust were fully supportive of the Enquiries. They were very sceptical of their ability to function if informed consent was required. These were people at the sharp end of the Health Service with nothing to gain. I thought they gave an honest appraisal of the value of the Enquiries.”
- 3.117 Although most of us felt able to say exactly what we thought, for one Council member at least it wasn’t an easy decision: “Clearly there is no one right or wrong answer. There are valuable arguments on the human rights side, which deserve respect and consideration. However the sheer size of the task of seeking consent from every

patient must point to the answer no. The implied bargain between a citizen/patient and the NHS leads to the conclusion the Confidential Enquiries should NOT have to take the prior consent route. The overall public health good is best served by not imposing on the Confidential Enquiries the heavy, almost impossible task of seeking informed consent.”

3.118 One Council member wanted to point out that: “I’m happy with the National Confidential Enquiries using medical records as the circumstances in which they operate means it’s sensible to use anonymity instead of individual consent – but this information shouldn’t be used for any other purpose within the Health Service or public sector unless informed consent is gained.”

**3.119 Although it was a minority, seven of us felt strongly that the Confidential Enquiries should be required to seek informed consent before they gained access to patient records.**

3.120 In several cases, this was because of a view about how the NHS culture had changed over recent years – and how it needed to change even further in its attitude towards patients: “Only by seeking informed consent can the use of identifiable data be seen as valid. If the NHS wishes to be seen as a transparent organisation, they need to work in partnership with their patients and staff. The Enquiries would benefit the public by having individuals who were open to research and to contributing to that research. This would encourage ownership and partnership again in how individuals care for themselves and their health. Surely this will impact on the health service for the good of everyone?”

3.121 One Council member pointed out: “It is able to be done in other difficult situations such as when sectioning someone under the Mental Health Act – they have to contact the next of kin. It fosters a culture of trust and goodwill. It could play a part in shifting the culture of paternalism to partnership and inclusion.”

3.122 One person said: “It seems to be that the law is moving in the direction of consent always being needed to store or use information about us. If we gave consent we would have a better idea that our records were being used for X, Y or Z. Not to seek consent destroys goodwill and trust.”

3.123 Another Council member said: “I think that consent should be required where identifiable data is wanted. I would suppose that vast amounts of the research done could be achieved by accessing unidentifiable data, but where recognisable information is used consent should be required. I think if carte blanche for medical records is given it would enable liberties to be taken. This might never happen, but the ability for it to happen would be there. If the

records of deceased people are required, it would be more acceptable to access them without consent than to access the records of people who are still alive. It is surely only courteous to ask a person if you could access their records before steaming ahead and doing it arbitrarily."

- 3.124 And a colleague agreed: "It would be a culture change but the public and professionals involved in the Enquiries would become used to it in time. We all know the consequences of not asking for permission to use human tissue in research, and this is a less serious parallel position. I can understand that it would be convenient for the Enquiries to keep the status quo but anyone else would have to ask us to use data about us so why shouldn't they?"
- 3.125 "It seems to me that the Confidential Enquiries are frightened of asking for consent whereas if properly explained, I think the vast majority would happily give it. I know I would," said one Council member. "As a boy aged 11 I was admitted to St Mary's Hospital London (a teaching hospital) but whenever the surgeon or consultant came round with a group of medical students, even at that age, I was asked first if all may examine me. What can be easier than that?"
- 3.126 A Council member acknowledged: "In practical terms this might prove very costly, but patients rights should not be taken away from them."
- 3.127 One Council member was adamant: "I am NOT a civil libertarian. It is my liberty that has been removed without consent. For Civil – read Civility. Ask!"
- 3.128 "You can't make up someone else's mind for them that it's not necessary to seek their consent," explained one Council member. "I can waive my own right to be asked for my consent, but I can't waive others' rights on their behalf."
- 3.129 Another of the Council members was worried about the effects of this Council meetings itself: "My concern is that as a result of this meeting and the fact that the majority have voted in favour of not seeking consent – that the Confidential Enquiries will cease to anonymise data because they feel they have been given the go ahead to use data without consent and therefore not see the need to anonymise. Richard Congdon assured us that the Enquiries would continue to anonymise data and that all staff would respect patient confidentiality as they have done for the previous 52 years. I hope that is a true reflection of the Enquiries teams."
- 3.130 Is there a different way of gaining the consent of the public?**
- 3.131 Some of us wanted to suggest an alternative way of doing things – informing the public of the work of the Enquiries; assuming from that general knowledge that people automatically gave consent for their records to be accessed if necessary by the Enquiries; but accepting

an individual's right to explicitly 'opt out' of giving consent, and having their medical records marked as such:

- 3.132 "I believe that there should be an "opting out" system available – backed up with a brochure that contains full information on what the patient information will be used for. The provision of the option and the availability of the information would go some way to reassuring people and reducing the number that do opt out."
- 3.133 Another Council member explained: "For the sake of the greater good I believe the National Confidential Enquiries should have access to case histories as required. But in cases where consent has formally been refused, that should be respected."
- 3.134 Said another: "They need to make a concerted effort to inform everyone about their work, their procedures, and what their achievements are, and continuing developments. Look into ways in which people can give their consent in easy ways, with the opportunity to opt out, without costing the loss of information or increasing the workload and cost of carrying out the Enquiries."
- 3.135 "This is a very important question which has two answers," one Council member said. "The valuable contribution made by the Confidential Enquiries to the health of the nation must be maintained, but not at all costs. The privacy and human rights of everyone is sacrosanct and that is why I feel the general consent and the individual's right to opt-out is the only answer to a very large problem."
- 3.136 Another also asked: "Could not general consent be assumed if an opt-out is permitted after public awareness is raised? I feel the risk of an opt-out affecting the work of the Enquiries is diluted because the take-up of the opt out would be very small."
- 3.137 One Council member explained how it could work: "Most of the public would be happy for their data to be used, if they knew it was happening. When informing the population you have to take into account those people who do not regularly visit the hospital. For example, I myself haven't been to the doctor or the hospital since I was about seven or eight years old. If I was in an accident tomorrow and needed emergency surgery, it would be fair to say I would be unable to read any leaflets stating that my data may be used. If I was to die a week after my operation without ever regaining consciousness, my details will automatically be sent to NCEPOD without me ever knowing. I would not want my family going through the indignity of being asked for my consent. Therefore, the only practical and moral and ethical way is to make sure every member of the public 1) knows this goes on, 2) knows it is anonymised, 3) knows what effect the results have already had on the NHS, and 4) is offered the chance to opt out now, ready for the future, if they really

do object to their data being used. It is practical to not ask for individual consent – it is moral and ethical to make sure people know this is going on, and to have the choice.”

3.138 Someone else said: “The benefits of the Enquiries far outweigh the desire to gain consent. I feel public awareness is of great importance and some form of opt-out would negate the need for individual informed consent.”

3.139 Another Council member commented: “There is scope for discussion about how informed consent can be implemented and this should not be dismissed but investigated further. In an ideal world, it will always be preferable to uphold, wherever possible, the individual’s right to choose what happens to private information about themselves. Any avenue that makes this possible – even if it’s initially on a limited scale – should be seriously considered. Respect and discretion should be applied regarding information that reveals a patient’s personal health, lifestyle and preferences. Individual choice is important, and I feel inclined to defend the right of the individual to opt out of having their records used if necessary. Could we have a sticker applied prominently to the outside of medical notes for those who definitely refuse and are offended by the idea of their notes being used? This could easily be sorted on admission to hospital.”

3.140 Another member said: “I also think that one should be able to opt out or not – and that the majority would not opt out. I think that the rights of the individual would far outweigh the cost involved. This cost would be a one off cost only until a fully computerised system was in place.”

3.141 But not all of us agreed with this suggestion: “Prior consent at the point of joining the Health Service is unrealistic,” said one member. And a fellow Council member added: “I am not an advocate of the ‘opt out’ idea. If you take out of the system you should put back in.”

3.142 Another said: “An opt-out, following a publicity drive, may be appropriate. For me, however, you should not have the right to opt out as you are a beneficiary of the accumulated pool of past Enquiry data. How easy would it be to keep an ‘opt out’ register or to flag medical notes that someone had opted out in this way? For me the solution would be ‘inform – not informed consent’.”

3.143 A fellow Council member said that as fair as they were concerned: “ I wholly agree that the public should be informed of the work of PIAG and the Confidential Enquiries. I agree that in time, and if practical, some form of opt-out could be agreed. But at this current time, I feel that the work of the Confidential Enquiries is both valid and beneficial and that asking for individual informed consent is completely impractical. Therefore my personal recommendation would be to continue granting Section 60 support, until such time as positive

moves towards informing the public in general or inviting people to opt out if they truly wish to do so.”

3.144 And one Council member said: “It’s impractical, a waste of time and money. It will worry people. It will give people the chance to be selfish without just cause. It would even promote a class divide with wealthy or nobility being the articulate and pushy ones who want their records kept away from lower classes, or private health organisations cherry picking patients.”

**3.145 During the course of our discussions, as well as answering the specific questions that NICE put to us, we also identified some points we felt were important to note:**

**3.146 Publicise the work of the Confidential Enquiries more**

3.147 “I feel quite passionately that the NHS – in general, and in each part of it – must start to publicise their work a lot more.”

3.148 “Whichever route is taken there is an obvious need for an effective and sustained publicity campaign to inform the general public to ensure that the NHS’s bad reputation is not damaged further. The Confidential Enquiries have a good track record and a story to tell. The popular media and the broadsheets must be interested.”

3.149 “Perhaps more effort should be put into spreading the gospel as far as patient numbers are concerned.”

3.150 “Shout about your achievements. When you are recruiting lay members to the Confidential Enquiries, why not use that as an opportunity to inform the general public – as NICE did when it used Breakfast TV to recruit us to the Citizens Council? “

3.151 “It’s very important for NICE or the NHS to invest more time and money to promote their organisation more to inform people of their research. Maybe looking at what they are doing, how they carry out their research in order to change people’s perceptions. Steps need to be taken to ensure that information is communicated using different mediums.”

3.152 “The consent/opt out procedure should be put before the public in a way that is ‘in their faces’. I understand that there is some reference to the procedure in an NHS handbook but that is not enough. While the AIDS TV warnings some years ago were dramatic warnings I know, I believe some media information is necessary to ensure the public know about NCE and its work on our behalf.”

3.153 “Confidentiality is not an issue for myself – but lack of public awareness is.”

- 3.154 “I feel strongly that the Enquiries should go ahead with their work, however the method at the moment is slightly immoral. The cost of implementing an advertising campaign may be high, but if it is needed, it should be done. “
- 3.155 “People still have rights over how their information is used. Maybe if the public is more aware of the Confidential Enquiries this question would not have been raised.”
- 3.156 “It is important that as many of the general public as possible are made aware through as many different sources as possible (including all methods of free advertising, shout your achievements from the rooftops, hospital open days, radio interviews, etc) of what the Enquiries do and the benefits they bring.”
- 3.157 There may be benefits to be gained from more openness**
- 3.158 “Discussing the Confidential Enquiries work with next of kin may bring added benefits – relatives may be able to add something to the Enquiries that the hospital records might not show.”
- 3.159 “I think general support would be high if the public knew about the work of the Enquiries – and so the number of people choosing to opt out of allowing their records to be used would be small.”
- 3.160 “The reservations that may be held by some regarding lack of consent could be negated by good public relations informing the public that these Enquiries do take place and the benefits they provide. Having established the credibility of the Enquiries and their attention to confidentiality, the need for permission for exemption from bodies such as PIAG would be unnecessary.”
- 3.161 “A good publicity campaign explaining the need for and benefit of the Confidential Enquiries should be possible. The thought that they are unknown to the public makes them sound secret!”
- 3.162 The uncertainty around the question of individual consent is unhelpful**
- 3.163 “A change in the law is needed. End Section 60 and put the Confidential Enquiries’ entitlement to pseudo-anonymised information on a permanent footing.”
- 3.164 “It bothers me that the Government cannot or will not just legislate this problem away. To some extent it is too trivial to be overly concerned about. I also have concerns about how the Data Protection Act is restricting the application of ‘common sense’, either intentionally or by misunderstanding.”
- 3.165 “I can’t help thinking that the Enquiries are getting desperate because they know the rug is going to be pulled out from under them and they need to rationalise this before it happens.”

**3.166 The Enquiries work is valid only if they are taken seriously and their findings are taken note of**

3.167 “Reporting to the Enquiries is not compulsory, and therefore data is already biased.”

3.168 “Make reporting to the Confidential Enquiries a statutory obligation.”

3.169 “NHS hospital trusts should be mandated to contact the Confidential Enquiries.”

3.170 “I think an interesting point about ‘bias’ was raised by Arnold Simanowitz when he said that by making it not compulsory for all details of incidents to be sent to the Enquiries, the results are already biased. It should be compulsory for all those who do not opt out to have their details sent to the Enquires – so it should be the patient or next of kin who is allowed to decide not to take part, not the health professionals involved in the incident who decide not to forward the case.”

3.171 “Professionals must take note of the recommendations that the Enquiries make.”

**3.172 If individual patients have an obligation to co-operate with the Enquiries, then equally the Enquiries have an obligation to individual patients**

3.173 “Require the Confidential Enquiries to contact the patient or next of kin if the Enquiry reveals a ‘cause for concern’.”

3.174 “Absolutely anonymised data wouldn’t allow for any track back to hospitals to check or clarify issues.”

3.175 “Cause for concern cases should be notified to the next of kin.”

**3.176 There is a difference between using the records of those who have died, and those who are still alive**

3.177 “I’m quite comfortable about the use of dead patients’ data, but people still alive – near misses and good outcomes – is another matter altogether.”

**3.178 Get the different parts of the NHS working better together**

3.179 “I have been amazed by the number of organisations that seem to exist for the protection of patients – PIAG, NPSA etc. None of them seem to be doing a brilliant job.”

3.180 “Bring the Confidential Enquiries legally within the NHS and end the nonsense that even different trusts or GPs and hospitals can’t disclose to each other because they are all seen as third parties.”

3.181 “I do not think the Enquiries should be a ‘third party’ as far as the rest of the NHS is concerned.”

3.182 “I also think that National Enquiries should not be a third party.”

3.183 “The overlapping of resources and the duplication of reporting and analysis by all these different NHS organisations needs to be cut. Why can’t the NHS legislate for this?”

3.184 “Could the Confidential Enquiries be incorporated into a national health audit body with clear aims and rights given by statute? I think our discussions over the three days have already had an impact on the people who have talked to us.”

3.185 “When the Enquiries were set up there were fewer other organisations seeking to improve care, such as the NPSA. Is now the time to look at this overall?”

**3.186 New technology – in particular the introduction of electronic patient records – might open up new possibilities**

3.187 “The present system should continue into the future, at least until the NHS becomes totally IT orientated and acquires (hopefully) the flexibility to allow for opt outs to be effectively registered. This would be the time to open up the discussion once again.”

**3.188 This issue should be discussed again, because circumstances change**

3.189 “I would like to see the issue of the need for informed consent reviewed in five years time. This would ensure that the National Confidential Enquiries are not given ‘carte blanche’. This meeting also highlighted the need for a real push to a national electronic information system for the NHS. Although it would not necessarily be the whole answer to this issue, it would open up possibilities around consent.”

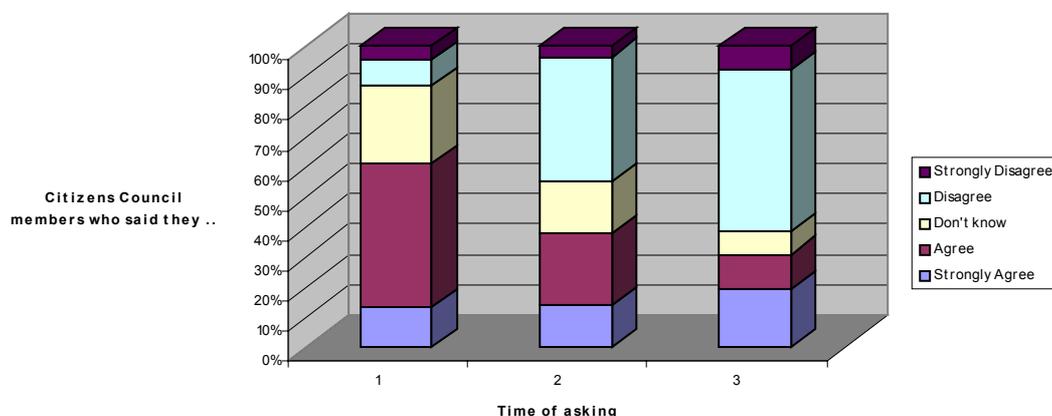
3.190 “Any method of doing anything needs reviewing and renewing. By relying on the fact that the Enquiries have worked this way for so long, we may be closing our eyes to a better way of doing it. “

### 3.191 Our views on statements about patient records ...

3.192 Over the course of the three days, as well as holding discussions and debates as a full Council and in small groups, we also filled in a questionnaire that asked for our responses to twelve statements. We did this three times, and so were able to see how our views changed or were reinforced as a result of our discussions. Below we describe how we responded to each statement.

#### Q1. Patients have a fundamental right to confidentiality and any use of information about their healthcare must only be with their consent.

Patients have a fundamental right to confidentiality, and any use of information about their healthcare must only be with their consent

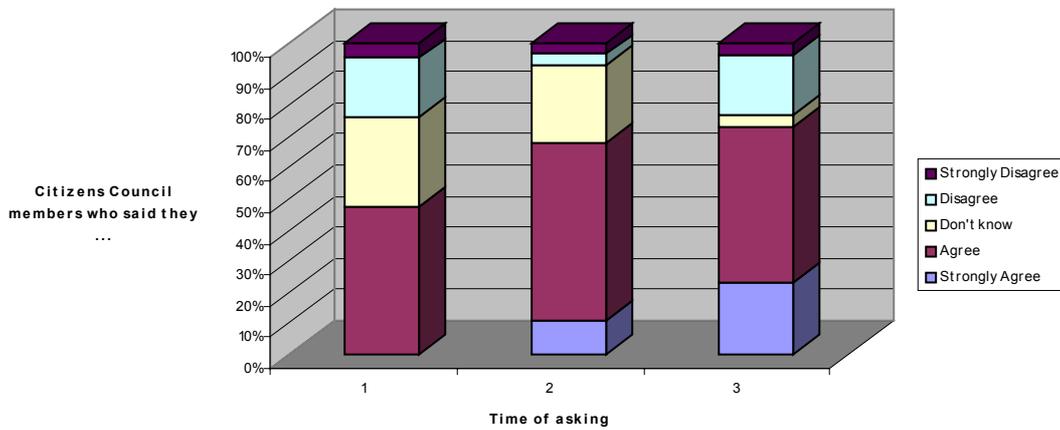


3.193 Over the three days, we saw a move away from general agreement to general disagreement with this statement.

3.194 When we were first asked about this, on Thursday morning, more than 60% of us agreed with this statement, with only about 10% disagreeing, and the rest of us being unsure. By the next day, less than 40% of us agreed with this, and about 45% now disagreed. Fewer of us – about 15% - were now not sure. By the end of Friday, our views had shifted further. By this stage, fewer than 10% of us didn't know what we thought about this statement. About 30% of us agreed (half of those who originally did so) that patients have a fundamental right to confidentiality – although within this 30% those of us who felt strongly rather than just expressing agreement had increased from about 10% to almost 20%. By now, in an almost complete reversal of our initial position, more than 60% of us disagreed with this statement.

**Q2. The benefit to future patients from research findings outweighs the need to seek consent to the use of medical records.**

**The benefit to future patients from research findings outweighs the need to seek consent to the use of medical records**

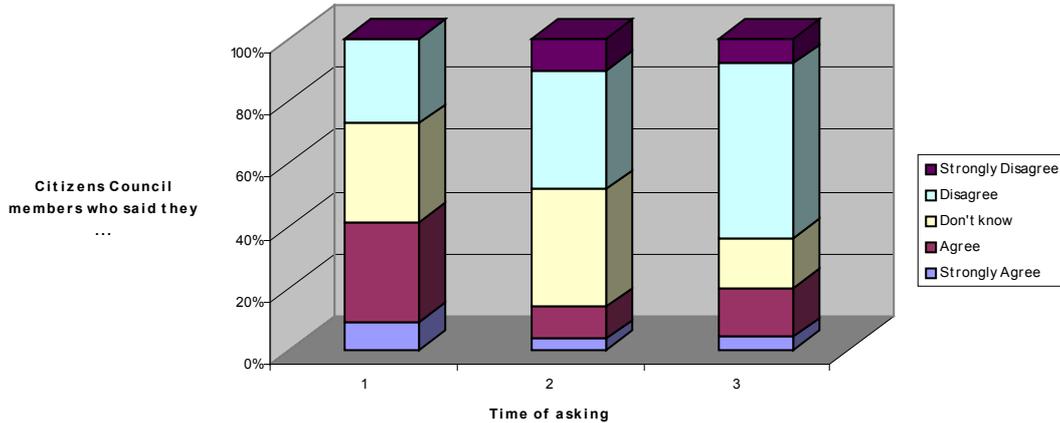


**3.195** Consistent with the shift of attitudes to the first statement, our opinions on this statement also moved significantly during the Council meeting so that by the end of Friday, more than 75% of us agreed with this.

**3.196** At first, half of us agreed with the statement (although none of us expressed 'strong' agreement the first time we were asked). The second time we were asked, almost 10% of us felt that we strongly agreed, with another 50% agreeing. The proportion of people who were unsure moved from 28% to 24% to just 4% by the end of Friday. Those who disagreed went from 20%, to just under 10% on Friday morning, and back to just under 20% by the end of the day. So those who disagreed at the beginning were also likely to disagree with this statement at the end – while those who were initially unsure were more likely to agree with it having heard the discussions.

**Q3. Respect for the rights of individuals is more important than possible future benefits for patients.**

**Respect for the rights of individuals is more important than possible future benefits for patients**

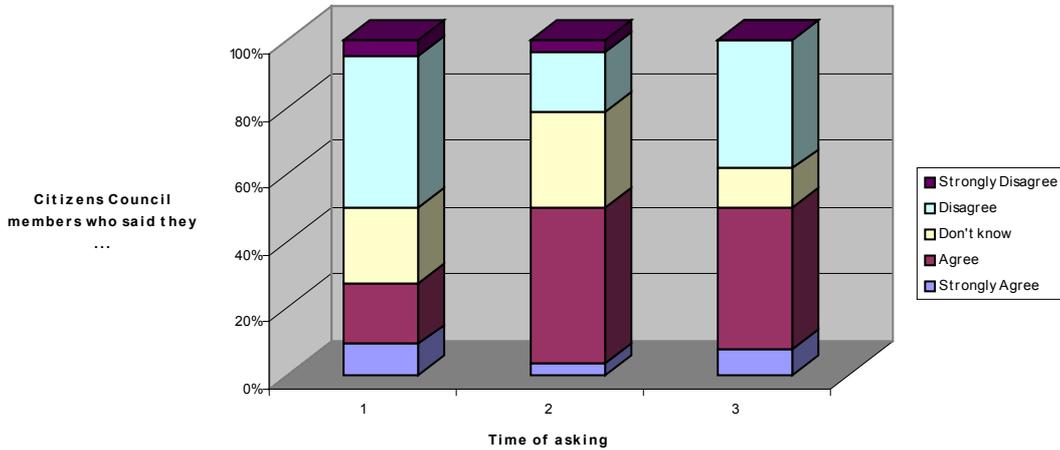


**3.197 During the course of the meeting, there was a move away from supporting this statement, with a fall in those agreeing from an initial 40% to 15% to an eventual 20%.**

3.198 At first, about 35% of us weren't sure if we agreed, and about a quarter of us disagreed – but no-one disagreed strongly. By Friday morning, even more of us were unsure – almost 40% - and far fewer of us (just 10%) agreed that respect for the rights of patients is more important than possible future benefits for patients. The strength of feeling against the statement had also grown. By now, half of us disagreed with this (double the number who'd disagreed the day before), with about 10% of those who disagreed saying they felt strongly about it. By Friday evening, most people had made their minds up, with just over 10% still unsure. Only 20% of us now agreed with this statement – with 65% of us disagreeing.

#### Q4. The right of patients to confidentiality reduces after their death.

The right of patients to confidentiality reduces after their death

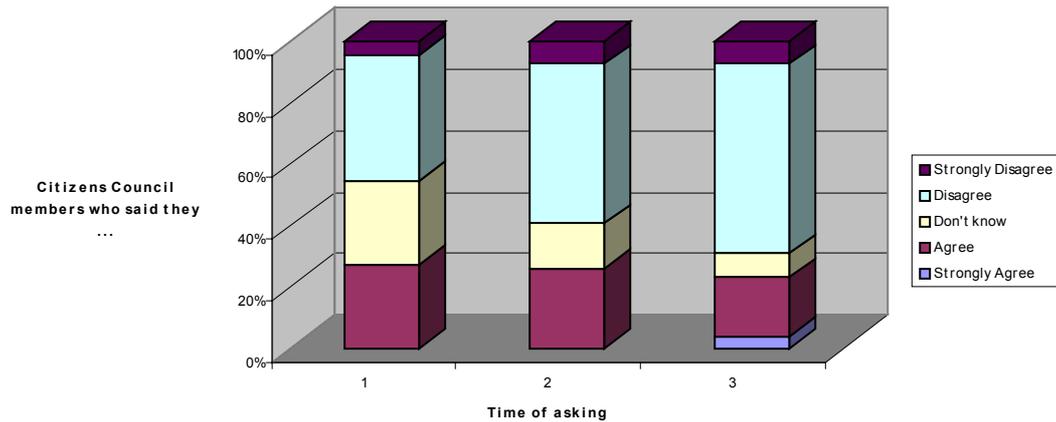


3.199 As we discussed the topic, more of us came to agree with this statement – although as a group we ended up fairly polarised in our views.

3.200 On Thursday morning, half of us disagreed with this, but just under a quarter weren't sure, and just over a quarter of us agreed with it. By Friday morning, the proportion of us disagreeing had dropped to about 20%, and by Friday evening it ended up with almost 40% disagreeing that the situation would change after death. By contrast, throughout Friday over half of us agreed with this statement, and only about 10% still being unsure.

**Q5. If patients have not consented to the use of their medical records for research purposes before they die, then the records must not be used.**

**If patients have not consented to the use of their medical records for research purposes before they dies, then the records must not be used**

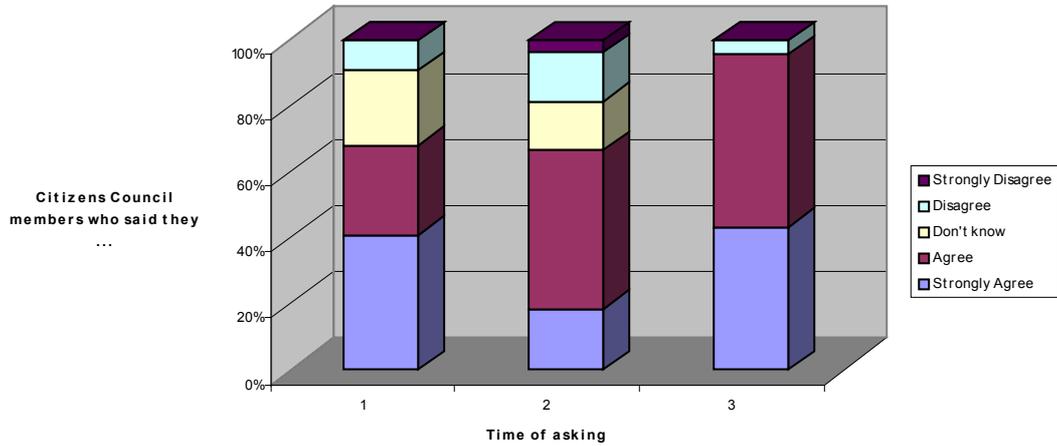


**3.201 At the beginning of the meeting, just under 50% of us disagreed with this statement and 25% agreed with it. By the end of the meeting, nearly 75% disagreed with the statement.**

3.202 On the Thursday morning, 5% of our group strongly disagreed with the statement, just over 40% disagreed, 30% didn't know and the remainder agreed. No one strongly agreed. The percentage of us who strongly agreed did not increase significantly over the period of the meeting. However, the number of our group who didn't know fell from 30% to 10%. The percentage of people who agreed rose by over 20% during the course of the meeting. By the end of the meeting there were nearly 5% who strongly agreed with the statement.

**Q6. Confidential enquiries should protect the identity of patients and doctors.**

**Confidential Enquiries should protect the identity of patients and doctors**

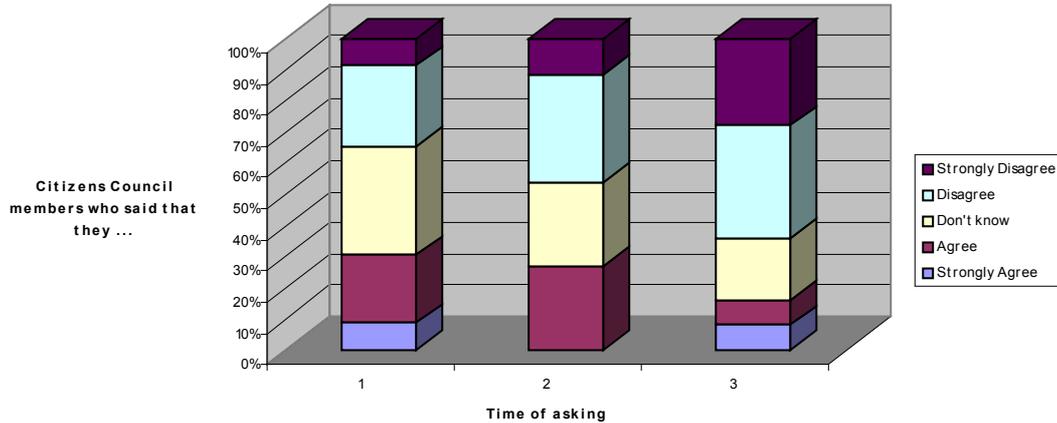


**3.203 At the beginning for the meeting, approximately 70% of the group agreed or strongly agreed. By the end, the change in those of us who strongly agreed was an increase by a couple percent, but those who agreed had increased by 25% so that 95% of us agreed or strongly agreed, and there was no one who said they didn't know.**

3.204 At the time that we answered the second questionnaire, the percentage of us who strongly agreed fell by about 20% whilst the overall percentage of those agreeing or strongly agreeing did not vary considerably. We did not agree as strongly at this interim point, but the figures for those of us agreeing strongly did increase to slightly over their original point, come the end of the meeting. At this interim point, there were about 5% of us who strongly disagreed with this statement, but by the Friday, none of us strongly disagreed.

**Q7. Confidential enquiries should protect the identity of patients but not of doctors.**

**Confidential Enquiries should protect the identity of patients but not of doctors**



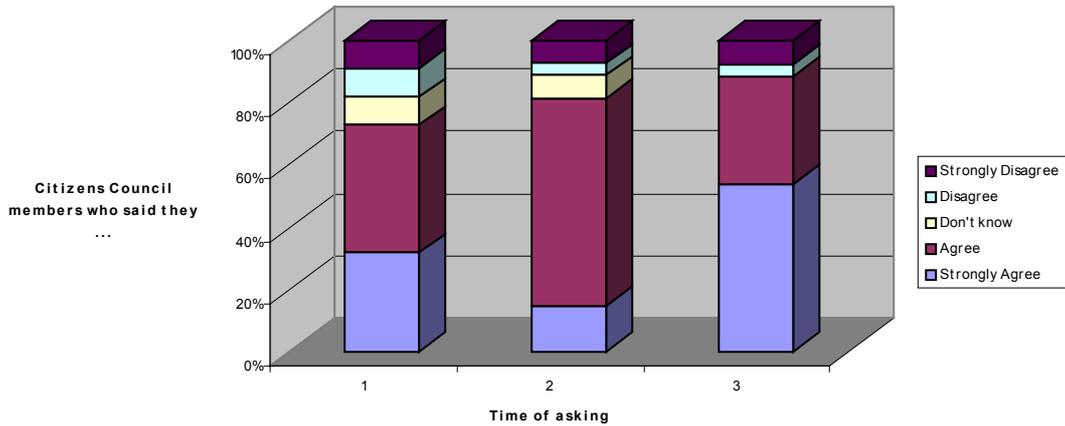
**3.205 When we were first asked this question, the group was divided almost into three – those who agreed, those who disagreed and those who didn't know. Over the period of the meeting, there was a shift amongst us to disagree with the statement.**

3.206 At the three points we were asked these questions, the number of us who didn't know dropped from about 30% to 25% and finally down to 20%. The percentage of us who agreed nearly halved during the course of the meeting, with those who strongly agreed fluctuating from 10% to zero and back up to 10%. Over the period that the question was asked, those that strongly disagreed rose from the original 10% to nearly 30%

3.207 The shift in opinion towards disagreement with this statement was accompanied by a number of statements that were concerned with the covering up of malpractice. One member of the Council pondered upon the case of Harold Shipman and whether this would have been different, had there been more openness.

**Q8. Patients cannot expect the best possible treatment in the future if they do not allow the NHS to have the information it needs to learn lessons.**

**Patients cannot expect the best possible treatment in the future if they do not allow the NHS to have the information it needs to learn lessons**

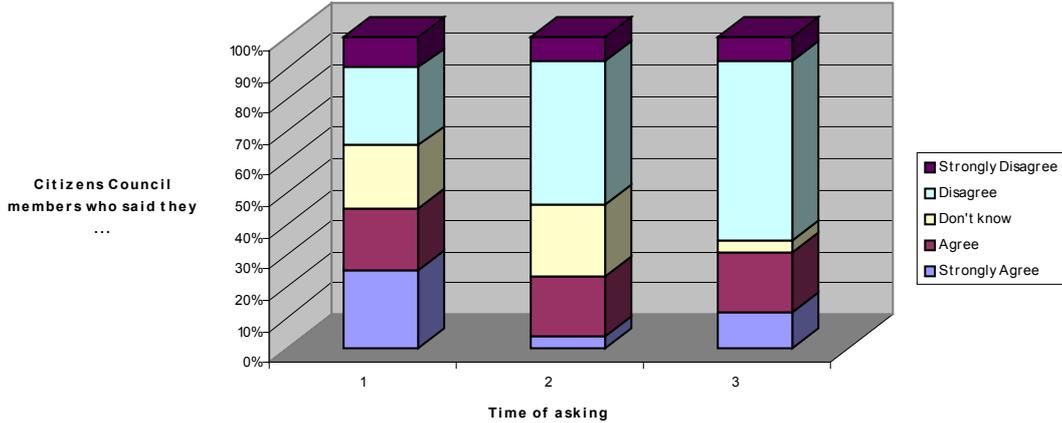


3.208 The answers given to this question followed a very similar pattern to those given to Question 6, however, we were less indecisive with only 10% answering 'don't know' when first questioned, less than 10% at the second asking and everybody making a decision one way or the other at the third time of questioning.

3.209 The number of the group who agreed grew from 70% to 80% to over 85% by the end of the Council meeting. The number of people who strongly disagreed only varied by a couple of percentage points over the period. It is interesting to note that the percentage of us in the group who strongly agreed with the statement dropped from an initial 30% to an interim 15% and then at the final time of questioning rose to about 55%. This final gain was mainly at the expense of the people who agreed, but also from those that had previously not known. As the discussion went on, the group appeared to be able to make up their mind, and as they did, they agreed with the statement.

**Q9. The NHS must always show its respect for patients' views by seeking consent, even if the information is anonymised.**

**The NHS must always show its respect for patients' view by seeking consent, even if the information is anonymised**

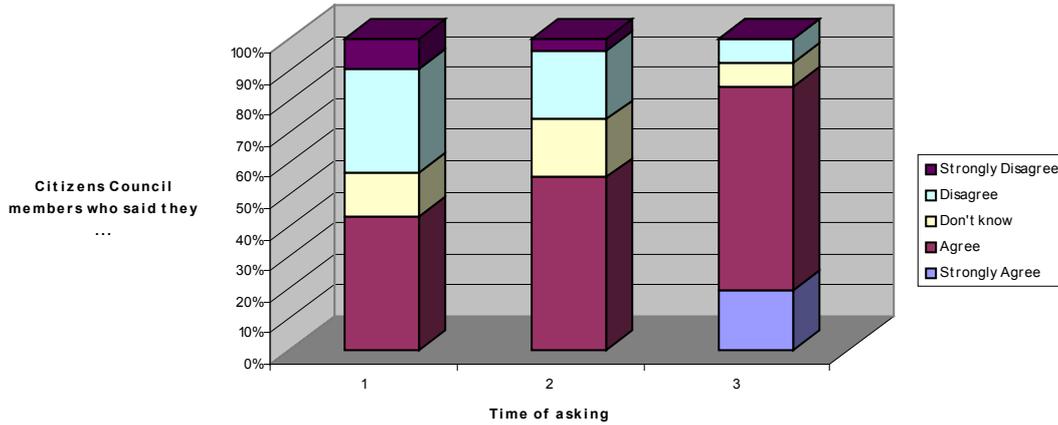


**3.210 Initially 45% of the group agreed with this statement and 20% didn't know. By the third time of questioning, the people in agreement had dropped to 30% and only 5% did not know.**

3.211 The number of members of our group who strongly disagreed with this statement dropped by a couple of percentage points over the period, but the total of us who disagreed and disagreed strongly rose from 35% to 55% to a final 65%. The percentage of those who agreed strongly dropped from 25% to 5% at the second asking, but then rose to just over 10% in the final reckoning.

**Q10. Patients should not be concerned about the use of personal information as part of a confidential enquiry.**

**Patients should not be concerned about the use of personal information as part of a Confidential Enquiry**



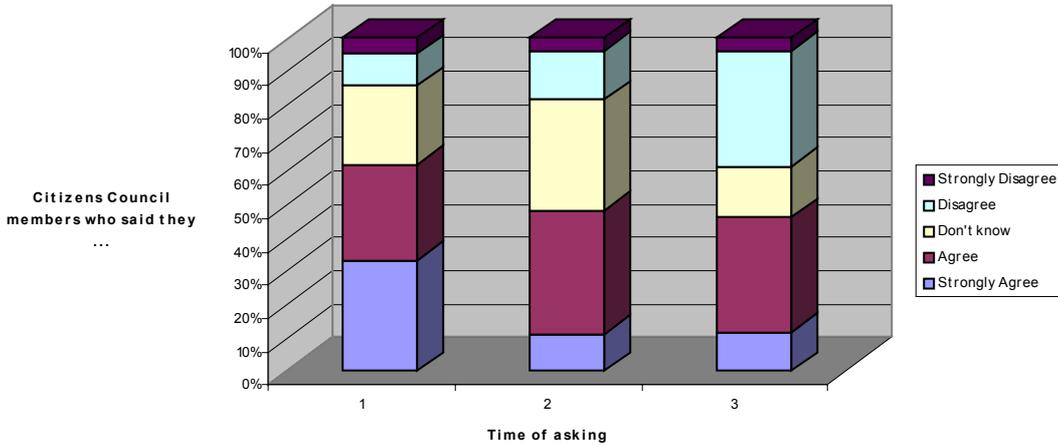
**3.212** On the Thursday when questioned, 15% of us didn't know and the remaining 85% were split equally between agreeing and disagreeing. By the third round of questions, 15% disagreed or didn't know and the remaining 85% agreed with it.

3.213 In the first two rounds of questions, there were no members of our group who strongly agreed but 10% and 5% who strongly disagreed. By the time the group were asked for the third time, nearly 20% strongly agreed with the question and nobody strongly disagreed. There was a large shift of opinion on this question during the course of the Council meeting.

**3.214** Two of the many reasons given by us for this shift in opinion were that there should be confidence in the system and that if it leads to better health for others, it should be done without concern.

**Q11. Patients have a right to withhold consent, so it must never be assumed.**

**Patients have a right to withhold consent, so it must ever be assumed**

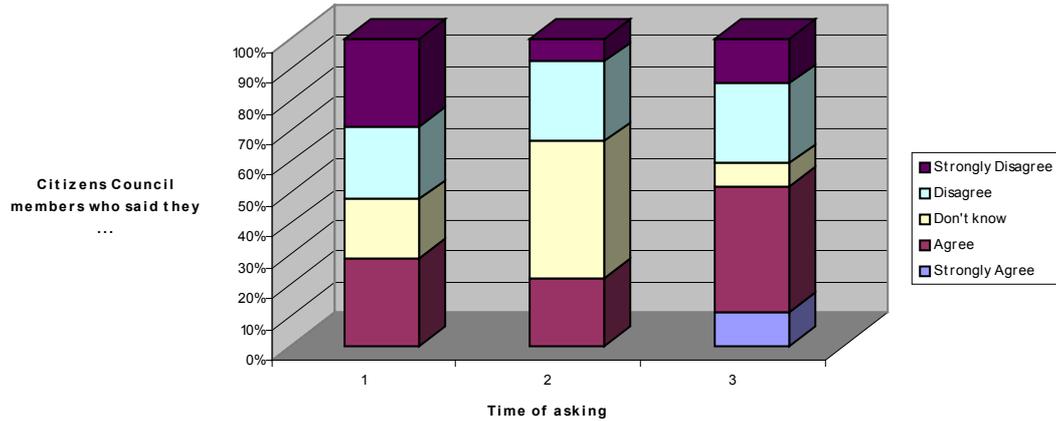


**3.215 At the beginning of the meeting, 60% of us agreed or strongly agreed with this statement, 25% didn't know and the remainder disagreed or strongly disagreed. There was shift of opinion during the meeting that left under 50% agreeing and strongly agreeing.**

3.216 On Thursday morning, 25% of us were not sure, but during the discussions this percentage rose to 35% before dropping to 20% when the group answered for the final time. There was a fairly constant 5% of our group who strongly disagreed with this statement throughout, but those who strongly agreed dropped from 35% at the initial questioning to just over 10% for the remaining two times.

**Q12. Patients do not own their medical records, so they cannot control their use for research purposes.**

**Patients do not own their medical records, so they cannot control their use for research purposes**



**3.217 Whilst just over 30% of the group of us agreed with this statement on Thursday morning, by Friday this had risen to nearly 50% who agreed, including 10% of us who agreed strongly.**

3.218 The number of people who said they don't know what they think about this statement went from 20% at the beginning to 45% during the discussions, to just below 10% by the end of Friday. There were none of us who strongly agreed with this statement until asked for the third time, when about 10% strongly agreed. The size of the group that strongly disagreed shifted from 30% to less than 10% and then finally to 15%.

## **APPENDIX ONE - How the Citizens Council makes its decisions**

The National Institute for Clinical Excellence's Citizens Council was formally established in November 2002 following a comprehensive recruitment process to attract members of the public to fill the 30 places. Over 35,000 enquiries were made for the Citizens' Council, of which 4,327 people eventually applied. The final 30 members of the Council – stratified to reflect the wider public – were confirmed at an induction meeting in London on Friday 1<sup>st</sup> and Saturday 2<sup>nd</sup> November 2002.

The first full Citizens Council meeting took place on the 21<sup>st</sup>, 22<sup>nd</sup> and 23<sup>rd</sup> November 2002 in Salford and the report on the Citizens Council members' conclusions and recommendations on the topic set for them at this first meeting ('What should NICE take into account when making decisions about clinical need?') is available on NICE's website [www.nice.org.uk](http://www.nice.org.uk).

The second and third Citizens Council meetings were held as part of a two-stage discussion on the issue of "age".

The second Citizens Council meeting was held at City Hall in Cardiff on the 8<sup>th</sup>, 9<sup>th</sup> and 10<sup>th</sup> May 2003. The third Citizens Council meeting was held at the Hilton hotel in Sheffield on the 20<sup>th</sup>, 21<sup>st</sup>, 22<sup>nd</sup> November 2003. The report of these meetings, and the Council's deliberations on the topic of "age" can also be found on NICE's website.

After the November 2003 meeting, 10 of the original members of the Citizens Council retired. Two of them chose themselves to retire, and eight others were chosen by lottery undertaken by Vision 21 staff in the presence of a solicitor. Ten new members of the public were chosen to become members of the Council, from the database of those who had originally applied in August 2002. Using a similar process to the first recruitment round, Vision 21 chose ten people, who, when added to the original twenty Council members, between them reflected the demographic make-up of the population of England and Wales.

An Induction was held for the new 10 members in London in March 2004, and the fourth Council meeting was held in Brighton between 13-15<sup>th</sup> May 2004. At this meeting the Council was asked to consider the Confidential Enquiries.

The process followed during the three days of the Citizens Council meeting in May 2004 can be summarised as follows:

- Briefing on the topic by Professor Sir Michael Rawlins, chairman of NICE and Andrew Dillon, Chief Executive of NICE.
- Presentations from, and formal and informal discussions with a range of expert speakers.
- Regular surveys of Council members views, to track opinions on key value statements, over the course of the three days.
- A debate involving speakers and Council members.

- Deliberative sessions to discuss and identify key issues to come from the evidence presented.
- Sessions during which Council members set their own agenda and decided which aspects of the question they wanted to pursue in more detail.
- Informal discussions amongst Council members during the course of the event.
- An opportunity to write down key points that individuals wanted to include in the report.
- Workshops to finalise the Citizens Council's conclusions and recommendations.

The information that the Citizens Council members receive from the speakers is only one of the things that influences them – their discussions about their own experiences and the values that they themselves hold are crucially important.

The Council meetings are facilitated and managed by Vision 21, media relations activity is co-ordinated by NICE, and the process is continuously evaluated by staff from the School of Health and Social Welfare at the Open University.

As a result of feedback about the first, second and third meetings from the Citizens Council members themselves, from the independent evaluation team, and from Vision 21, changes are made at each Citizens Council meeting to try to improve participation and deliberation. The most significant of these are:

- Citizens Council members are now given the topic well in advance;
- Council members are able to comment on and have some involvement in setting the wording of the questions;
- Council members are involved in making suggestions about which speakers are called;
- The minimum term of office of Council members has been extended from one year (two meetings) to at least three meetings, in recognition of the steep learning curve involved in taking part in this initiative.

One of the Council member said of this meeting: "I feel the people we have had to speak have not presented a balanced view. The vast majority have had a very strong vested interest in maintaining the status quo. I would have preferred a witness with a more 'can do' mentality about how we can get round the issue of it being impractical to get informed consent."

But another said: "We've had the chance to hear from a variety of perspectives. Many of them felt similarly, but that seems to reflect a broader view in the NHS – and we've had plenty of opportunity to put our own opinions forward." And one Council member said: "Thank you all of you for giving us the opportunity and privilege of speaking up and participating in the meetings. The respect shown to each individual is greatly appreciated and is what I want to see more and more of, in the NHS and in society."

Further feedback will be collected from the Council members in order to review and improve the arrangements for the next Council meeting, to be held in November 2004.

### **Speakers who attended the Citizens Council meeting in May 2004**

#### **Dr Julia Budnik**

Senior Clinical Effectiveness Facilitator, Brighton and Sussex University Hospitals NHS Trust.

#### **Richard Congdon**

Chief Executive, CEMACH

Richard joined the NHS through the National Management Training Scheme in 1975 and his later experience includes eight years as an NHS Trust Chief Executive. He was appointed Chief Executive of CEMACH in April 2002 with his initial brief to bring together the two existing enquiries into stillbirths and deaths in infancy (CESDI) and maternal deaths (CEMD) to formally establish CEMACH from April 2003. With a background in the NHS at a local level, Richard is committed to ensuring the continued relevance and impact of enquiry work for NHS Trusts and other NHS bodies in the field. His current focus is on setting up a new enquiry into child health whilst continuing to develop the maternal and perinatal enquiries

#### **Marisa Cullinane PhD**

Marisa Cullinane joined NCEPOD as Project Manager in November 2002. Prior to this Marisa had worked as a medical researcher in London teaching hospitals for 8 years, on a variety of projects into the prevention of stroke.

#### **Sarah Danko**

Clinical Effectiveness and Audit Manager, Brighton and Sussex University Hospitals NHS Trust.

#### **Hannah Godfrey**

Hannah is a junior barrister of Lincoln's Inn. She trained in London at a set of chambers specialising in human rights and civil liberties, her early practice being made up of a combination of criminal, social welfare and immigration tribunal work. She now practises from Cloisters Chambers, in the Temple, and is developing a specialist practice in the areas of personal injury, employment and discrimination.

#### **Christobel Hargraves B.Sc. RGN DipHSM MBA**

Mrs Hargraves is the Chief Executive of the National Confidential Enquiry into Patient Outcome and Death. She has been in post for 3 years following various roles in the Health Service, the private sector and most recently as a Senior Manager at the Audit Commission. Her career to date has involved nursing, information technology and management and she has a special interest in health service information systems.

#### **Dr Nav Kappur**

Assistant Director / Senior Lecturer in Psychiatry.

Nav Kapur is a Senior Lecturer and Honorary Consultant in Psychiatry at the Centre for Suicide Prevention, University of Manchester. His research interests include service provision for suicidal behaviour and the aetiology of illness behaviour.

### **Sean Kirwan**

Sean Kirwan is Digital Policy Development Officer at the Department of Health and Secretary of the Patient Information Advisory Group.

### **Madeleine St Clair**

Assistant Director Clinical Governance, Brighton and Sussex University Hospitals NHS Trust.

### **Arnold Simanowitz OBE**

Arnold Simanowitz was a partner in the solicitors' firm of Simanowitz & Brown until 1981 when he became involved in the founding of the charity, Action for Victims of Medical Accidents of which he was Chief Executive until December 2002.

He is a trained mediator, and was a member of the Department of Health's Working Party on mediation in medical negligence cases. He was also a member of Lord Woolf's Working Group on medical negligence and then the Lord Chancellor's Department Working Group. He was also a member of the Legal Services Commission's London Regional Legal Services Committee. He is a non-executive Director of the National Patient Safety Agency and a Commissioner on the Commission for Patient and Public Involvement in Health. He is also a co-opted member of the Professional Conduct Committee of the GMC and a member of the Chief Medical Officer's Advisory Group on Clinical Negligence Reform.

In 2001 Arnold received the Association of Personal Injury Lawyers (APIL) Award for Outstanding Achievement and an OBE for services to victims of medical accidents.

### **Karen Thomson**

Karen is User Involvement Manager at Diabetes UK, one of the largest patient organisations in Europe, Vice-Chair of the Patients' Forum, and has been a member of the Patient Information Advisory Group since December 2001.

### **Dr Charles Turton**

Medical Director, Brighton and Sussex University Hospitals NHS Trust (and Caldecott Guardian)

### **Dr Kirsten Windfuhr PhD**

Senior Project Manager.

Kirsten joined the Centre for Suicide Prevention in January 2002, as the project manager for the 'sudden unexplained death in psychiatric in-patient study'. In December 2003, she took on the post of senior project manager for the National Confidential Inquiry into Suicide and Homicide. Her research

interests include suicide, particularly among the young, and sudden death in patients under the care of mental health services.

Citizens Council members wish to express their gratitude to all those speakers who gave up time in their busy lives to attend the meeting and help debate the question NICE set the Council. Without exception, they provided the Citizens Council with food for thought and with stimulating discussions.

## APPENDIX TWO

### List of Citizens Council members

- **John Baldwin** - an electrician who lives in Widnes, Cheshire
- **Auriol Britton** - a singer working towards a diploma, who lives in Bristol, Avon.
- **Brian Brown** - an electrical engineer, from Chester-le-Street, County Durham.
- **Jennifer Brown** - a clerical officer who lives in Derby, Derbyshire
- **Sylvia Brown** - a retired local government officer who lives in London.
- **Rod Crowshaw** - a store assistant who lives in Castle Bromwich, West Midlands.
- **Trevor Davison** - a supervisor scaffolder, who lives in Lincoln, Lincolnshire.
- **Geraldine Fost** is a retired careers guidance manager, who lives in Hungerford, Berkshire.
- **Lorna Girling** lives in Norfolk, and is a part time philosophy student and a housewife and mother of one.
- **Susan Glendinning** - a part-time actress and clerical assistant who lives in Cardiff, Glamorgan.
- **Marie Goorun** - a dressmaker and part-time French tutor who lives in Gillingham, Dorset.
- **Terry Hamer** lives in Southampton. He works on the cruise ships at the terminal.
- **Mark Handley** - a project manager who lives in Kingston-upon-Thames, Surrey.
- **Robert Jones** works as a warehouse operative and is a football referee in his spare time. He lives in Cwmbran, Wales.
- **Arun Jotangia** lives in Bolton. Arun currently works for Manchester Airport.
- **John Mahoney**, who lives in London, is a former foreign editor for the BBC and for ITN News at Ten.

- **Melanie McClure** - a mother of one who lives in Hebburn, Tyne and Wear.
- **Susan McNeill** - a secretary who lives in Market Harborough, Leicestershire.
- **Tony Messenger** - an insurance broker who lives in Windsor, Berkshire.
- **Sharon Morgan** - a milliner who lives in Birmingham, West Midlands.
- **Linda Moss**, currently unemployed, trained as a TEFL teacher and now lives in Todmorden, West Yorkshire.
- **Bob Osborne** - a retired former pilot who lives in Horsham, West Sussex.
- **Paul Pendlebury** - an assembly worker, who lives in Preston, Lancashire.
- **Lisa Pompeo** lives in Bradford, and is a communications operator for the police.
- **Heena Sabir** worked for a while in human resources, and has recently moved to Huddersfield, where she is looking for suitable work.
- **Ian Simons** - a taxi driver, who lives in London.
- **Paddy Storrie**, a secondary school Deputy Headteacher, lives in Harpenden, Herts.
- **Fiona Taylor** - a legal assistant, who lives in Sidbury, Devon.
- **Peter Thomas** - a teacher, who lives in Rhondda, Cynon Taff.
- **Judith Ward** - a wood turner, who lives near Stoke on Trent, Staffordshire.

## The demographics of the Citizens Council

<b>Population (England &amp; Wales)</b>	<b>Criteria</b>	<b>Panel No's required to match population statistics</b>	<b>Actual Panel Members meeting the criteria</b>
10%	under 25 years	3	4
20%	over 60 years	6	6
12%	disability	3 or 4	4
5% (10%)	ethnic minority	3	4
13%	home, student, unemployed	4	4
19%	partly skilled/unskilled	6	5
25%	skilled manual	7	7
26%	skilled non-manual	8	7
14%	managerial & technical	4	4
3%	professional	1	1 <i>(plus 2 retired)</i>
49%	male	15	15
51%	female	15	15
95%	live in England	28	27
5%	live in Wales	2	3
7.9%	East Midlands	2	1
10.2%	East	3	3
4.8%	North East	1	2
13%	North West	4	4
15.2%	South East	2	2
9.3%	South West	3	4
10%	West Midlands	3	3
9.5%	Yorks & Humber	3	2
15%	London	4	3