

“What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and delivery of care?”

NICE Citizens Council

Meeting report: 10-11 November 2015

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Foreword

Once again, the Citizens Council has approached the meeting question with enthusiasm, this year examining the range of ethical and practical issues that relate to using data derived from personal care records for research and the evaluation of care interventions.

The use of personal care records is controversial and has been subject to much national debate. From NICE's perspective, we are looking to collect information with the consent of patients and service users to resolve uncertainties about the effects of interventions in order to produce national guidance. Whilst this approach is conceptually straight forward and is being explored as part of the Accelerated Access Review and refresh of the Cancer Drugs Fund it presents a number of challenges. Work is ongoing to address the methodological challenges; for example, it is difficult to identify cause and effect if sicker patients are given new drugs because they haven't responded to the older ones, or if patients are taking other medications.

The starting point for this Council meeting was therefore not *whether* care information should be aggregated and analysed, as this is a governmental policy, but what ethical and practical issues need to be considered *when* arrangements are put in place to collect data for analysis. In particular, we wanted to explore the Council's attitudes and beliefs underpinning issues of privacy and consent, the benefits of patients and service users contributing information for the good of society as a whole, and how all of this impacts on access to care.

This report from the 2015 Citizens Council meeting provides some interesting insight and highlights the complex and sometimes conflicting attitudes that exist. The Council's discussions reveal different attitudes depending on the context in which information is collected. There was a clear disconnect between members' concerns about the personal information that is collected by retail loyalty cards and internet browsing, which by default companies are permitted to sell-on, and that which is compiled in a health or care setting. Many of the Council's conclusions suggest that although they would be happy to contribute their own information, their concerns centred around the sufficiency and transparency of the control procedures in place when information is collected automatically by the system. The reasons for this dichotomy are not clear and could be explored further in order to more fully understand the underlying values guiding views on this.

As to be expected, Council members were concerned about the security and robustness of the data collection and analysis processes. They were particularly concerned about the raw data, however anonymised, being given or sold onto third parties who could then profit from it. The raw data were seen to be the 'crown jewels'; in one Council member's words "Once you've given your data, you can't get it back." There was less concern about the results of any requested analyses being made available. There was also limited awareness about how information from care records is currently used; many thought such data was already pulled together and analysed routinely by the health and care systems to improve care.

The biggest challenge, particularly when researching new interventions of uncertain benefits, is ensuring all patients can be safely monitored and the data collated as efficiently as possible. This would lead us to make data provision a condition of access. On this issue, the Council identified that factors such as how many people want to access the treatment and the type of organisation running the research would need to be considered.

There was an apparent tension between the 'social duty' to provide information, particularly given the interventions are being publically-funded, and the individual rights to privacy. Most council members felt that in a publically-funded system the 'greater good' should prevail as it would benefit all users. Freedom of choice should however be maintained which could be taken account of when choosing whether or not to receive that intervention.

The Council's discussion highlighted the need for NICE to be very clear about what its role is, whether that is as a receiver of analyses derived from care records, or receiver of data themselves. In either case NICE has a responsibility to ensure all necessary governance mechanisms are in place, either directly or through collaborators who provide analyses to NICE. It is also important to determine where the actual data should lie. For example, could a system be set up that allows data to be collected and held in one location, with specific analyses to be undertaken on request? Above all, this report of the 2015 Citizens Council meeting demonstrates that it is essential that any national plans take the public views into account.

Going forward, the Council's discussions and conclusions will not only feed into the development of methods and processes for NICE programmes, alongside scientific findings relating to the use of observational and real world data, but will also support the development of the NICE Observational Data Unit that supports NHS England's Commissioning through Evaluation work. Furthermore, this report contributes to broader debate within the health and social care system.

Thank you to the Citizens Council members who attended the two-day meeting to dissect and debate the question we set for them.

Sarah Garner
Associate Director
Science Policy and Research, NICE

Executive summary

Individual privacy, confidentiality of personal information, data protection, transparency, the public benefit of research and good scientific practice ensuring the accuracy and validity of research findings are key ethical concerns, according to the NICE Citizens Council, when it comes to the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care.

Complete transparency on how information from personal data will be used and who it will be shared with, effective informed consent procedures and strategies to ensure complete anonymisation of personal data, data security and research governance are needed if NICE uses information derived from personal care records for its work in the future.

These were the main conclusions and recommendations from the 2015 meeting of the NICE Citizens Council, a panel of 25 members of the public that provides NICE with a public perspective on challenging social and moral issues that the Institute takes into account when producing guidance. The Council met to discuss and answer the question:

What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?

This question was asked to explore the use of information from care records as part of the evaluation and research of new treatments and approaches to delivering care. This is an important topic of direct relevance to producing guidance in circumstances where research from more traditional sources, such as randomised controlled trials, is limited or absent, such as for new treatments to treat rare conditions, and to provide information on 'real world' populations.

The Council explored the question by thinking about the benefits and concerns in the collection and use of anonymised personal data in everyday situations and then in health and social care, before identifying ethical issues from the perspective of the care user/service user, the care provider, the research organisation and society as a whole. They considered whether there are circumstances when access to interventions being researched in care should be limited to patients consenting to share their data and finally weighed up how sharing personal care data for health and social care research fitted within the values of a social duty for the greater good and an individual's right to privacy.

At the end of the meeting just over half of the members of the Council said they would have no concerns about NICE using anonymised data derived from personal care records. The remainder had concerns about the use of such data, including its use by NICE. These concerns related to use of data from personal care records generally, regardless of the organisation using it for research.

They centred on transparency about how data is used and how it might be used in the future; the potential for data to be sold on to other organisations and used for profit and for purposes other than research; ensuring research is conducted according to good scientific practice and data is used to benefit society; and data security.

To ensure people fully understand use of data from personal care records for research the Council suggested that NICE should hold open days and provide information resources designed to ensure people understand what data is being used for, precisely how it will be used and providing reassurance that personal care data will not be passed on or sold to other organisations. Consent procedures should be audited and an ombudsman should oversee the governance of the use of personal care information for research. The Council recommended that appropriate systems and good working practices should be put in place to ensure a consistent approach to research planning, data capture and analysis.

Key outcomes from the meeting

The strengths and limitations of using information from personal care records for evaluating treatments

The Council considered a main strength of this approach may include better research outcomes because the effects of the intervention being tested are monitored by each patient or service user's regular care provider, who has greater knowledge of their individual circumstances. Other strengths included greater convenience and potentially lower cost to the patient; better continuity of care; and data being collected from a more representative population. Limitations identified were lack of time and research expertise among GPs and other care staff; risk of human error and lack of accuracy in data collection and entry; concern about security of data transfer and security; and concerns about the efficacy and safety of the intervention being researched.

The ethical issues that would need to be considered in order to collect and use information from personal care records

- **Confidentiality, privacy and data security** were identified as key ethical concerns, with questions around whether data from personalised care records can ever really be anonymised and who might have access to data.
- **Transparency** was considered a very important issue and that patients/service users should be informed about exactly what is being done with their data, what else might be done with their data, and what might happen in the future.
- The **public benefit of research** was identified an important ethical concern. The Council considered it essential to focus on research that makes the best use of resources and ensure that research is open to all members of society, with no discrimination.

- **Good scientific practice** was also considered an ethical issue, with concern about the accuracy and validity of research design and data analysis. The Council felt that research that does not produce any useful findings because it is not scientifically robust is a waste of time and resources.

Citizens considered there was a difference in the level of concern for these ethical issues, depending on the type of organisation doing research, with potentially more trust that the NHS or an academic group would have greater openness about the aims of research and more focus on research for public benefit than for-profit organisations. Protection and confidentiality of personal data should be a top priority for all types of organisations, the group agreed.

Circumstances, if any, in which it would be reasonable to allow access to a treatment not yet approved for routine use only to those patients or service users who consent for their data to be used as part of an evaluation scheme

Members of the Citizens Council were sharply divided on this issue. Some felt there should be no circumstances that would justify opting out of sharing data, mainly because to do so would limit the accuracy and validity of data collected as part of an evaluation scheme, which is of particular importance when monitoring the safety of new interventions. They also considered it only fair that people receiving treatment or care as part of research should provide their data to allow progress in care delivery. However, some felt that access to treatments or care being evaluated should never be restricted only to those consenting to share their data. They considered that this would be taking away people's freedom of choice and would be coercing people to take part in research in return for receiving treatment, which they felt was not appropriate in a care situation.

Reconciling a social duty for the greater good and individual rights to privacy

Citizens Council members considered social duty and the greater good was of much greater importance than individual privacy when it came to the use of data from personal care records for research. There was clear recognition that this was necessary to make advances in health and social care research and for the good of society as a whole. However, there was also a desire to maintain individual freedom of choice, which was also considered a mark of a healthy society.

Introduction and background

What is the Citizens Council and how does it contribute to NICE's work?

The Citizens Council is a panel of 30 members of the public that provides a public perspective on challenging social and moral issues that NICE needs to take into account when producing guidance. This is achieved through a two-day meeting usually once a year, focussing on answering a question that helps elicit Council members' views, opinions and concerns about a particular issue that NICE needs to understand in its work. The main findings are used to inform the principles set out in NICE's Social Value Judgements document and to guide specific areas of NICE's work.

The question addressed at the 2015 Citizens Council meeting was:

What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?

This question was asked to explore the use of information from care records as part of the evaluation and research of new treatments and approaches to delivering care. This approach to obtaining information is an important topic of direct relevance to producing guidance in circumstances where there is potential to develop recommendations that can enhance the efficiency and effectiveness of care but where research from more traditional sources, such as randomised controlled trials (RCTs), is limited.

Randomised controlled trials are considered the gold standard for establishing a causal relationship between a particular treatment or action and an outcome and for measuring the size of the treatment effect (efficacy) and assessing side-effects. RCTs that are well designed and carried out provide an accurate answer to the question they are setting out to answer within the group of people who take part (in research terminology, high internal validity) but they may sometimes be limited in the extent to which findings can be generalised to a wider group of people in 'real world' practice (external validity).

People in 'real world' care may be more varied in their characteristics, such as having a wider age range or more comorbidities, compared to those included in clinical trials. In these circumstances data from sources other than RCTs, such as from observational studies or anonymised data from care records, may provide useful information. However, care must be taken when interpreting outcomes from these types of data because it is less straightforward to minimise potential bias than in RCTs.

Most NICE programmes use evidence from RCTs to evaluate the effectiveness and cost-effectiveness of a treatment or approach to care but there are some situations where other types of data are required, such as extrapolating outcomes over a long period of time (many RCTs are

relatively short in timescale) or where there is a need to confirm that trial results apply to the 'real life' population for which a particular treatment or intervention is being considered. There are also circumstances where RCTs are not possible or no data are available or are very limited, for example with social care or for treatments for rare conditions where there are very limited numbers of patients.

Collecting and analysing data on how treatments and care work in real world settings can provide evidence that helps to reduce uncertainty about their effectiveness, as long as findings are analysed appropriately and care is taken to minimise potential biases. However, there is currently limited consensus about the role of these types of data and NICE, together with other organisations, is working to establish how to make use of these data and in what circumstances such data may and may not be useful.

How will NICE use outputs from the meeting?

The meeting enabled Citizens Council members to explore several questions on the use of anonymised data derived from care records that NICE needs to answer for its work. NICE is currently engaged in several activities to establish best scientific practice in the use of observational data and to understand its potential limitations. Deliberations from the meeting will enable developments in NICE methods and processes to take account of citizens' views and ensure these are integrated with other sources of information.

The ethical and other issues that need to be considered and resolved in order to use observational data to assess the effectiveness of interventions in real life is currently a key issue for the NICE Observational Data Unit and the NHS England Commissioning through Evaluation work that it is supporting. Citizens Council deliberations will inform governance arrangements and NICE's position in discussions with the numerous stakeholders interested in the use of observational data.

A particularly challenging and timely ethical question in this arena is whether there are any circumstances where it would be reasonable for treatments that are not yet fully approved and are being made available as part of an evaluation scheme to be available only to those patients who consent to their data being collected and analysed. There may be a greater role in the next few years for patient access schemes linked to recommendations contingent on further research to support earlier patient access to medicines addressing currently unmet need. It is essential that citizens' views are incorporated into adapting decision frameworks to take account of these developments.

Understanding more fully the issues involved in reconciling social duty for the greater good and individual rights to privacy and choice, is an issue of broad importance for NICE and other healthcare system partners. Outputs from discussions on this balance at the Citizens Council meeting will add to the understanding of citizens' views and support public engagement on the use of real world data in assessing health and social care interventions.

How did the Council explore the question?

The Citizens Council 2015 meeting was organised to guide Council members in a logical way through the different elements and issues underpinning the question being addressed: *What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?*

Council members started by considering their initial thoughts on the pros and cons of using anonymised data from personal care records. They then thought about the benefits and concerns for the individual and for the organisation in everyday examples of collection and use of anonymised personal data, such as store loyalty cards, before exploring examples in health and social care.

The group identified the ethical issues they felt were associated with use of data from personal care records, from four different perspectives: the care user/service user and his/family, the care provider, the research organisation and society as a whole, before suggesting practical solutions to solve these concerns. The Council then explored the implications of limiting access to interventions being researched in care to only those patients / service users who agree to their share data for research. As a last step they weighed up how sharing personal care data for health and social care research fitted within the values of social duty for the greater good and an individual's right to privacy.

Discussion encouraged Council members to think *why* they held the opinions they expressed and *what lay behind* their conclusions. Throughout the meeting members of the Citizens Council were asked to challenge themselves by asking why they held the views they expressed. Experts in research design and ethics, research participants and researchers involved in using personal care data shared background information, ideas, insights and personal experiences to provide further 'food for thought' for Citizens Council members to consider in their deliberations.

Understanding the meeting topic

Setting the scene

Maggie Helliwell, a non-executive director with NICE and previously a GP for 34 years, set the scene for what the Citizens Council members were being asked to consider by tracing how the collection of personal care data has changed since she first started working in general practice in 1981 and the opportunities and challenges offered by growing computerisation of patient records.

"I want to take you back to 1981," she said, taking Council members back to her surgery when GPs recorded information on each patient's paper notes. "There were no computers and no mobile phones. The computer was the GP's brain, where we collected and analysed information about each patient," she explained, adding that continuity ensured this knowledge built over time. "Times change. Patients' paper notes are now on computer. A patient's record is now continuously updated by GPs, other practice staff and by hospital clinicians," Dr Helliwell told the meeting. She traced developments in the use of routine care data for research and how this could add to what is provided by randomised controlled trials and the care of the individual patient. "Computerised patient care records provide an incredibly rich data source; a huge tapestry of information for every patient," she explained.

Recognising that people have concerns about the potential security and use of their data, she explained some of the processes in place for ensuring data is kept confidential, including her role as Caldicott guardian responsible for data governance and protection at her local hospital. Outlining some of the benefits of computerised data to individual patients, she noted that test results can be rapidly shared with clinicians managing their care to inform decision making and multidisciplinary teams, such as those caring for people for cancer, can share information easily and quickly.

NHS England's care.data project, in which all primary care data would be aggregated across the country and potentially made available to organisations other than those working in research, has changed the situation, Dr Helliwell suggested, adding that people would have to opt out of data sharing. She noted that a survey on this issue revealed a huge spectrum of opinions, ranging from people thinking data were already shared with outside bodies to those with concerns about data security and sharing.

"But we compartmentalise our attitudes to sharing data, using Facebook and Twitter with little thought of what happens to the information they collect," she challenged, concluding, "Where does that leave us with using care data for research? That is what you must consider over the next two days."

Introducing the question and its importance to NICE

Professor Sarah Garner, Associate Director for Science Policy and Research, NICE.

Professor Garner explained to the Citizens Council why NICE needs to consider the use of anonymised data derived from personal care records in its work and what these data would add to

the current evidence that NICE uses to make its decisions. “We are trying to look at where NICE needs to be in five years’ time. A ‘tsunami’ of data is being created by the NHS and social services. NICE needs to look at what we should do with this information and we are asking you for your advice on this,” she told Council members.

After recapping NICE’s role in providing national guidance and advice to improve use of health and social care, she underlined the fact that all NICE guidance is based on the best evidence available, including expert input and patient and carer involvement. She then introduced the question being addressed by the meeting – *What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?* – and defined key terms:

- **Anonymised information:** information that has had all personally identifiable data (such as name, address or full date of birth) removed.
- **Personal care records:** an official record of a person’s health or social care history, such as their patient record held by a GP or a record held by their social care provider.

Detailing how these data are used in research, she explained that anonymised information from many personal care records is gathered together into a separate set of data, which researchers then view without having full access to each individual care record.

Why does this matter to NICE? Professor Garner explained the importance of good quality evidence in reducing uncertainty about whether a treatment works and helping to manage risks and noted that evidence is created by collecting and analysing data. In the traditional ‘hierarchy of evidence’ randomised controlled trials (RCTs) are considered the gold standard but, although they have many strengths (careful selection of patients, random allocation to the new treatment being tested or the control and relatively straightforward analysis), there are also limitations, and other types of data can provide necessary supplemental information relevant to how the intervention is used in practice. RCTs are also not possible for testing certain kinds of treatment or interventions, for example surgery.

Is there another way? A lot of data is already recorded as part of routine care providing information on how people use and respond to treatments and interventions in real life. Analysis is more complicated than for RCTs but can be done. Professor Garner gave the Citizens Council members an example to illustrate the difference between using evidence from a randomised controlled trial and from observational data for a new drug to lower blood pressure during pregnancy.

Another way to collect data?

Imagine a new drug is being developed to lower blood pressure during pregnancy. Patients taking part in a randomised controlled trial are regularly monitored by researchers. In this case, this could include measuring blood pressure, carrying out urine and blood tests and checking the baby's heart rate. But research could also be carried out as part of the routine care process, with a woman's own doctor monitoring these things as part of her usual care.

This would be more efficient, less of a burden for participants and less expensive overall. But there are also drawbacks. This type of observational study may attract only the sickest patients who haven't responded to the usual treatments, which may potentially skew results. Other factors, such as other medications women are taking, may make it more difficult to interpret the effects of the new treatment and there are more chances of mistakes with entering data. Analysis of results is therefore more difficult than for an RCT, but it is not impossible.

The pros and cons of using data derived from personal care records

Using Professor Garner's example, the Citizens Council discussed the pros and cons of using data from anonymised personalised care records compared to those for a randomised controlled trial. Working in small groups they considered three different people's perspectives: the service user; the doctor caring for the patient; and the researcher.

For the service user, Council members focussed particularly on the burden to the individual, the quality of their care, individual privacy, data security and the validity of the research approaches. Potential disadvantages of taking part in an RCT included time, cost (including travel), having to take time off work and the difficulty of travelling in later stages of pregnancy. Potential advantages of taking part in research in usual care included 'no duplication of effort for the patient,' with all data being collected at routine visits. Discussion drew on personal experience of attending clinics during pregnancy and some people's experience of taking part in research studies that were not part of routine care.

In terms of quality of care, council members considered that an RCT might have a more specific focus than that achieved in usual care so a woman's blood pressure and the treatment she is given may be monitored more carefully. They also thought that any problems might be dealt with more quickly at a research centre and that a woman on a research study might receive better care overall. In contrast, they considered a potential downside of the new drug being tested in usual care was that the doctor would be checking other things in addition to blood pressure. Delegates were also concerned that doctors already have a lot to do, so research would be adding more to what is required in routine care. Another disadvantage was the lack of continuity in care, with patients seeing different doctors each time. There was also concern about whether the efficacy and

safety of a new drug would be properly monitored in routine care. In contrast, a potential benefit of research in usual care where a patient sees their own doctor regularly is that they will know more about them than an outside researcher.

Regarding confidentiality and security of data, some Council members were concerned about the privacy of taking part in research and whether this would be greater in usual care or within an RCT. One group member questioned whether data collected as part of usual care are “ever truly anonymised”. There was some concern about where data might potentially be transmitted.

“Are data collected as part of usual care ever truly anonymised?”

There was also some feeling that the quality of findings might be better with an RCT – “because it’s being done properly” – than with research conducted in routine care, where doctors may lack research expertise. However, council members also recognised a disadvantage of an RCT is the limited range of patients that can take part, particularly because “most people have more than one thing wrong with them.” “Trials exclude a lot of people,” one participant noted. There was some concern about the date of birth being removed in anonymised data and whether this might lose information that could be useful in interpreting the effects of the drug being tested.

“I think findings may be more accurate with a clinical trial because it’s being done properly. Doctors doing research in routine care may have less expertise.”

One group member had found taking part in a research study at a specialist centre very interesting but was disappointed not to have had any feedback on the eventual study findings. She said: “All that time and effort, considering I was so ill, and I have no idea what was found.” This comment underlines the value of ensuring research findings are reported back to participants, regardless of the research design used.

Council members also raised the positive effect of taking part in research in routine care that can potentially benefit other people: “You feel you are making a difference by being involved” One delegate recalled giving extra blood during her routine pregnancy care as part of a study on Down’s syndrome. “I never noticed it, after talking it through and agreeing to take part. If it can make a difference to other women by identifying Down’s syndrome earlier ... It took no extra time.”

From the perspective of the doctor caring for the patient, Council members focused largely on the quality of patient care and the reliability of research findings. They considered that research conducted as part of routine care could place extra time pressure on doctors and this may result in the quality of patient care being reduced. However, they recognised that the continuity of care achieved through the doctor having greater involvement in the research might also be associated with better quality of patient care. The development of an effective new treatment if an RCT proved positive was considered a further benefit of this approach. However, a potential downside

of an RCT is that important information about the patient collected during the research may not be shared with the patient's doctor, who would be providing care in the longer term.

In terms of the reliability of research findings, Council members considered that one advantage of research conducted as part of usual care is that a woman's GP would have greater involvement. However, potential negative factors included the increased workload for GPs and the risk of human error in recording research data.

From the researcher's perspective, Council members focussed mainly on the reliability, efficiency and cost of research and the security of data. They considered that an RCT offered the benefit of being conducted by experts in the field. Carrying out research using care records could potentially recruit more easily, drawing on the large number of pregnant women in routine care and so could be carried out more quickly and potentially reduce research costs. However, potential disadvantages of research using care records included the impact on doctors' workload, which may affect the quality of both patient care and the research, and concern about data security.

Summary

Each group then shared their top pros and cons for each research approach from the three different perspectives they had discussed. They generally considered there were more disadvantages than advantages for both types of research approach, particularly from the patient's perspective. The main themes that emerged in discussion were:

- the burden to the individual in terms of their costs and time, which were considered greater for taking part in a randomised trial than for research using data collected from routine care;
- the quality of care provided to the patient, which Council members thought may be higher in a trial centre than in routine care, although they considered the continuity of care and wider understanding of the patient/service user's individual circumstances would be better in routine care;
- individual privacy and data security, which the Council identified as important but were unsure of the differences between RCTs and research within routine care in how well these issues are addressed
- the reliability of research findings, with groups considering the accuracy would be greater in an RCT but findings would be more widely applicable in research using care records; and the efficiency/cost of research, with research conducted using data from care records being more efficient and avoiding the duplication of effort that may occur in an RCT where a person still needs to see their GP for aspects of their care other than that being studied in the trial.

Issues in data collection and use - everyday examples

The Citizens Council began to explore the issues associated with the collection and use of anonymised data from individuals by considering three everyday examples of systems that collect personal data:

- Supermarket loyalty cards – Information is collected up-front on: name, address, email, gender, date of birth, and (optionally) on the number in a person's household, their ages and specific dietary requirements. Data about shopping activity is also collected as the loyalty card and related coupons are used. The terms and conditions note that data will never be shared outside the group of businesses owned by the supermarket, but the company may use and share anonymised information outside the group.
- Healthcare retail loyalty card – This collects similar information to the supermarket loyalty card, including data about shopping activity for health related products. Terms and conditions say details will be shared only with businesses that process loyalty card information on their behalf and with companies owned by the same retail group.
- Price comparison website for home insurance – a website that asks for a wide range of information up-front (postcode, home ownership, value of home contents, previous insurance claims etc) to provide a person with quotation for home insurance.

The aim was to help people to start considering the issues in the collection and use of personal data using examples to which they could immediately relate. "We all give a lot of data away in everyday situations," explained the meeting facilitator Pete Spriggs. "We are going to think about the pros and cons associated with this before moving on to thinking about this for examples in care situations."

Concerns for the customer

Council members were generally much more focused on the concerns for the customer in these everyday examples and several groups started their discussions by thinking about these before considering benefits. Concerns sprang to people's minds more immediately than benefits and the list of concerns was much longer than that for the benefits to either the customer or the organisation. Meeting participants were generally surprised and concerned about the range of personal information that the organisations they discussed were able to collect about individuals.

Council members were particularly concerned about **information being shared with other organisations or sold to them** without the individual's knowledge or agreement. Although this was explained in the terms and conditions of the schemes discussed, people were concerned about the wide range of organisations that might gain access to their information, for example The supermarket might share a person's personal information with its mobile phone and insurance companies. They thought this might lead to being offered unwanted products and services as well

as having wider consequences, such as affecting insurance premiums. In their discussion Council members drew on examples of situations where they realised their information was being shared with other organisations or sold on. For example, one person recounted renewing their car tax online and automatically being asked to join the organ donor registry.

Several people expressed a general concern about loyalty cards **collecting potentially personal information without a person consciously giving it**. They realised that a customer's shopping information provided detailed information on what they bought, when and where, their spending capacity and habits and could reveal information about their family structure, diet and lifestyle.

"Big Brother is watching you by tracking your purchases."

One delegate said, "Big Brother is watching you by tracking your purchases." Another commented, "I stopped using a supermarket loyalty card a few years ago because I thought they had too much information on me." Information given to

an insurance site could be even more revealing about a person's life and circumstances and may affect their insurance in the future. There was particular concern about how information provided for one purpose, such as food shopping, could be used for another purpose, such as a loan application.

Council members were concerned about the **security of their data**, including how securely it was stored and transferred and who else may be able to access information collected online, particularly after recent cases of hacking. Some were also concerned about whether an organisation's employees could access an individual's personal information.

There were questions about **how information is anonymised**, and what is included in anonymised information when organisations share it with others. The underlying concern was that personal details might be shared much more widely with unforeseen results for the person who had simply signed up to a store loyalty card. There was also concern about whether information held about one person might be inadvertently shared with another if the loyalty card was in joint names. "Could your partner get information, such as on your smoking and drinking behaviour?" one Council member asked.

Several people were concerned about **who owned the information** that individuals supply to organisations and puzzled why they had to pay a company for supplying a copy of the information the company holds about them. One delegate asked, "Why should you pay when it's your information?" Council members wondered whether other organisations also charged people for copies of the information they held on them.

Benefits for the customer

Members of the Citizens Council initially found it easier to think of benefits for the customer than the benefits for the organisation.

One of the most useful benefits to the customer was being offered **tailored or personalised suggestions for products** to buy based on the information they provided and data collected on their shopping habits. This was seen as saving customers time. Another potential benefit was 'not being bombarded' with information and offers not relevant to them. **Receiving points and discounts** with store loyalty cards was one of the more obvious benefits of store loyalty cards to customers.

Price comparison websites for insurance give people **options that are personalised to their needs** and may save them money. They can be convenient to use, saving people time and also reminding them of renewal dates.

Benefits for the organisation

This was an aspect Council members hasn't really thought about before, but they quickly identified that such data collection systems provide an important way of **targeting customers** for particular products and special offers, with the aim of **increasing sales**. They suggested that a customer's shopping information provided detailed information on what they bought, when and where, their spending capacity and habits and could reveal information about their diet and lifestyle, which could all help organisations in targeting products to relevant customers. Shopping information can also **inform sales statistics**, charting trends and planning. Companies can profit from the information they collect by selling it to other parts of their company or outside organisations.

Several people considered that store cards provided 'good PR' for companies, suggesting that they are there to help save money and for members to feel part of the organisation, **building customer loyalty**.

Summary

Greatest concerns lay in the potential for sharing information with other parts of an organisations or selling it on, especially if this results in data being abused, for example using information on purchasing of alcohol or cigarettes to inform insurance premiums or staff having access to information on when a person routinely shops in a store to time a burglary at their home. People were particularly concerned that information they provided for one purpose may be used, without their intention or permission, for another purpose. Council members were concerned about data security and how data is anonymised before being shared or sold on. There was also a question over who owns the data – the individual who supplies it or the organisation that collects it.

"All of the pros to the companies collecting the data are the cons for us."

Council members were clear on the benefits to the customer of these everyday examples in helping to save them money and receive tailored offers and information, and to organisations where they facilitate customer profiling, potentially increase sales, support planning and build customer

loyalty. However, they considered there were more concerns for the customer than benefits for either the customer or the organisation in the everyday examples of data collection they discussed.

Summing up the balance between the benefits of data collection schemes to organisations against the potential concerns for customers, one Council member commented, "All of the pros to the companies collecting the data are the cons for us."

Issues in data collection and use – health and social care

Everyday systems collecting personal health information

Having considered the pros and cons of everyday examples of personal data collection, Professor Sarah Garner asked Citizens Council members to think about whether their attitudes towards data collection are different when it concerns health and social care than for other aspects of life. She explained that health related information is already being collected outside the NHS, outlining recent research showing that Google and Facebook are the commonest websites approached by third parties to obtain information provided by people in their searches on Google or in posts they make on Facebook. This can be very revealing, for example a Google search for information about a particular health condition can potentially be traced back to an individual by the IP address unique to their computer or mobile phone number if they search using a smartphone.

She asked Council members: “What is special about health or social care data? Is the important issue who enters the data or who holds the data? And is there something in particular that is special about health and social care records that we need to take into account?”

Examples of data collection in health and social care research

The Citizens Council then moved on to consider health and social care scenarios for data collection. The scenarios varied in terms of who was collecting the data, how it was collected, the purpose of the research and the type of health or social care need to which the research related. The aim was to tease out whether there was anything different about the collection and use of data in health and social care situations, and, if so, what these were and any potential benefits and ethical concerns.

1. A company that provides telecare equipment and services to support a person’s safety and independence in their own home, such as reminders to take pills or systems calling for help if they fall, is carrying out research to test the effectiveness of their products in supporting people with social care needs to live more independently. They are collecting anonymised data about when and how the telecare equipment is used and analysing this alongside anonymised information extracted from service users’ care records about how and when they access other social care support.
2. A manufacturer of e-cigarettes is carrying out research to test the impact of e-cigarettes on public health using a password protected online data registry where members of the public can sign up to give fortnightly information on things like: how and when they have used e-cigarettes, other nicotine replacement products or regular cigarettes; their levels of physical activity; levels of alcohol consumption; their general health.
3. A drug company is developing a new drug for the treatment of epilepsy, which has been shown to be safe but the full extent of health benefits and side-effects are not known. Research is

needed to test how well the new drug works before NICE can consider recommending it for use by the NHS. This will involve the drug company giving the new treatment to the NHS to offer to patients as part of their routine care and the NHS will give the company anonymised data from the health records of patients treated with the drug so they can analyse how well it works.

4. A new surgical procedure has been developed for treating a form of cancer that, although not rare, currently has few treatments available and most patients live less than 12 months. The procedure has been shown to be safe but the full extent of the health benefits and side-effects are not known so research is needed before NICE can consider recommending it for routine use by the NHS. This research will involve offering the new procedure to patients as part of their care and using anonymised data derived from their health records to analyse how well the procedure works.
5. A pharmaceutical company wants to better understand a very rare condition before it starts to develop a new treatment. Because there are very few people with the condition (around one in 60 000 people) it is hard to recruit participants for a traditional research study. So, instead, the research will use anonymised data derived from the health records of patients with the rare condition to analyse how it is experienced and managed in real life.
6. The National Survey of Health and Development has collected information from birth to the current date on the health and life circumstances of 5500 men and women born in March 1946. With study participants now in their late 60s, the survey offers a unique opportunity to explore the long-term biological and social processes of ageing. Participants take part in questionnaires, interviews and cognitive tests and information is also being automatically collected from their records, including hospital admissions, educational qualification, cancer diagnoses, blood samples etc.

Benefits and concerns for the patient or service user and his/her family

Citizens Council members generally found it much more straightforward to see the benefits and concerns of each research scenario from the perspective of the patient or service user and his or her family than from the point of view of the care provider, the researcher or collector of data, or society as a whole.

People drew on their own experiences and those of their family to consider the scenarios and there was some focus initially on the **practical benefits and concerns** of the interventions being tested in the research studies rather than the ethical concerns. For example, regarding the telecare equipment study, one group member considered that this type of support would be 'a reassurance to me' in the care of her mother who has Alzheimer's disease, including reminding her to take her medication. A couple of people felt that having access to this type of service through taking part in the study would help a person stay in their own home and support their independence. E-cigarettes

could help people to stop smoking and reducing passive smoking, and could also save individuals money they previously spent on cigarettes.

Citizen Council members immediately identified the benefit of taking part in research offering a new therapy or surgical treatment to the patient in **improving their health or extending their life**, particularly where treatment options are currently limited. In a terminal situation or where there are currently no treatments they felt patients had nothing to lose by taking part in research offering them options and potentially everything to gain, so the benefit of sharing their data outweighed any risk. A benefit for individuals contributing health data to an ongoing survey would be **feeling involved in something important**, that could potentially help them, their family and others.

When the group considered concerns for the patient/ service user they initially focused on the **practical issues or risks associated with the intervention** being tested in the study, such as whether a telephone reminder to take a tablet would be effective in getting a person to actually take their medication, the fire risk with e-cigarettes or whether their use might become a habit, and potential adverse effects of a new drug or surgical procedure.

Moving on to considering ethical concerns, a major concern was whether the patient/service user would **feel comfortable for information to be shared** about falls or other incidents, or about their personal habits, such as alcohol consumption or exercise. This was considered very personal information that should not be shared and there was concern that others could potentially use the information to their harm. **Data security** was a major concern. People were concerned about **what** was being done with the data collected, **who** the information was being shared with and **where** it might potentially go.

There was a tension between concerns that pharmaceutical companies potentially use data 'for their own ends' and the recognition that these companies are often necessary for the development of new treatments to meet unmet medical needs. Overall, people considered the benefit for people of having a new treatment outweighed their concerns about sharing data with companies.

One group member raised the issue of the **consent process** because they were unsure how this would happen for research carried out as part of usual care. There was also concern about **what the individual would get** from providing their data. "What do I get from this?" asked one participant. The group considering a new treatment for a rare condition were concerned that a patient might contribute to research by sharing their data but might **no longer have access to or be able to afford** the drug once it was approved and not available as part of a research study. Some Council members were concerned why so much **more information** was collected in some of the scenarios than seemed necessary to answer the research question.

Reflecting the **shift towards becoming more concerned** about sharing personal data expressed by several people during the meeting, one Council member said, "I've completely changed my mind. When I first started [the meeting] I thought 'yeah', but now all I can think of is cons." Another noted, "Once you've given your data, you can't get it back." The impression was that this was mainly in relation to concerns about data security and who else may have access to a person's data other than the researcher.

"Once you've given your data, you can't get it back."

Benefits and concerns for the care provider

Council members considered the benefits and concerns for the care provider in very practical terms based on the interventions being researched. Benefits included having **more efficient and improved care and treatment options** for patients. However, care providers might have concerns about whether innovations, such as telecare, resulted in **meaningful improvements for users**. They might also be concerned about the risk of **previously unrecognised side-effects** with drugs being researched in routine care.

Taking part in research as part of providing routine clinical could take up doctors' **time** and affect careers, either negatively or positively. There were also concerns about the **costs** of a new treatment or intervention and whether the service would be able to afford it.

Benefits and concerns for the researcher or collector of the data

Groups quickly identified the potential benefit for researchers of **making money and profiting** from a successful new development resulting from analysis of data collected, for example if e-cigarettes proved beneficial for public health or a new drug was effective. Participants felt that the company collecting data on e-cigarettes could also potentially use the database for **marketing** to target people with specific products and use the information collected during the study for promoting its products.

Organisations gain the benefit of a **valuable database of information** provided free-of-charge by research participants. They may have a **wider range of data** than collected in a randomised trial, which they could use for various purposes. In terms of research methodology, accessing data from care records would provide information on a **broader range of people more representative of the population** than in a randomised trial. Carrying out research using routine data from care records may be **cheaper** than a randomised trial.

A concern for the researcher was whether people were truthful in providing self-reported information, such as for the database on e-cigarettes and other health behaviours, or healthcare providers input data correctly, potentially affecting the **accuracy and quality** of data. "Would you say online how much alcohol you consume, or how much exercise you take?" asked one group member. Another asked, "How truthful are people when they asked to supply information about

habits such as smoking, and how might this affect research?" There was also concern about **how many** people would sign up to an online database and **how long** they would continue to provide information without an incentive. Voluntary research projects may provide **skewed data** because people taking part may not be representative of the population.

Benefits and concerns for society as a whole

At a society level a major concern was **transparency** in *what* is being done with data, *who* the data collected is being shared with, particularly the risk of it being sold to commercial organisations, and *how* it is being shared, particularly in terms of how carefully personal details are anonymised. **Data security** was also considered a major concern. Council members thought it particularly important to ensure **protection of vulnerable members of society**, such as the older people, by handling their data with added security so it is not used to their detriment or to target them for marketing. There was real scepticism about the security of data. "Nothing is every totally secure," suggested one group member, noting data leaks recently reported in the media.

"Nothing is ever totally secure."

Some Council members were concerned that for-profit organisations, such as pharmaceutical companies, might **manipulate data** to optimise their profits. There was also concerns about the **value to society of the research questions** that private companies might ask, with one participant questioning whether pharmaceutical companies could delay bringing out a new drug until an old one had ceased to be profitable to them. Some citizens questioned whether research with very expensive drugs in rare conditions might take resources away from treating more common conditions.

The main benefit to society in the care scenarios on data collection was considered to be **new knowledge** and **access to new interventions or treatments** being researched and its potential **public health impact**. For example, group members considered the telecare service, if successful, could help people to remain independent in their own homes and reduce the pressure on social services. E-cigarettes could potentially reduce smoking, and, in turn, passive smoking (particularly for children). Research programmes could **free up resources** for other patients and care users.

Summary

The main concerns that emerged in common for all health and social care scenarios were transparency about what is being done with the data and who has access to the data, how sharing their data might affect the individual (eg insurance premiums, family members, what may be done with their data in the future), data security and the accuracy and validity of data collected from care records. People could generally see more benefits than concerns for research aiming to

"If people have a rare condition, research will benefit them and others with the condition so we would be happy to allow access to their records for this."

find new treatments or interventions for conditions that are life-threatening, where there are currently no effective options or where a condition is too rare for a randomised controlled trial. One delegate commented, "If people have a rare condition, research will benefit them and others with the condition so we would be happy to allow access to their records for this."

However, there were concerns that even if the research found a treatment or care intervention was effective, it might not continue to be available after the research study has finished if its high cost means it is not cost effective to provide as routine care. This reflected a general concern about the cost to society of innovative treatments and how to fund them.

Is there a difference according to who is collecting the data?

During further discussion, Council members were asked to consider whether there different attitudes towards pharmaceutical or other commercial companies compared to other types of organisation carrying out research using data from personal care records, such as the NHS or academic researchers.

"We feel as a society we are at the mercy of pharmaceutical companies because they usually put profit before people."

At this point, the Council felt that there was a clear difference. This was due to a fundamental difference in the aims of these organisations, with pharmaceutical companies working to make a profit and operating in a competitive market, while the NHS and academic groups aim to improve people's health and care.

"Pharmaceutical companies hold a lot of power and the potential for life or death, and make huge profits out of life or death situations," one person suggested. Another said, "We feel as a society we are at the mercy of pharmaceutical companies because they usually put profit before people." There was a feeling that pharmaceutical companies had eroded trust in the past and one person asked a question about who oversees pharmaceutical companies. Several Council members considered they felt more positively about use of data from personal care records if a healthcare organisation was using it "to create more health for people".

"I can see the benefit of using data from care records if organisations are using it to create for health for people."

Research ethics and associated practicalities

Principles of research ethics

Dr Harriet Teare, DIRECT Project Officer at the Centre for Health, Law and Emerging Technologies (HeLEX), Nuffield Department of Population Health, University of Oxford.

Dr Teare introduced the Council to why it's important to consider ethical concerns associated with different research strategies and the different ethical considerations and key principles that may apply. "It's tempting to think that ethics is really just common sense and about 'doing the right thing'," she said, before explaining that it is more complex in practice and needs to take account of different people's perspectives.

International codes put the patient's wellbeing at the centre of any medical situation and Dr Teare explained four key values - autonomy, beneficence, non-maleficence and justice – that underpin decisions about ethics. However, these can conflict in some situations. For example, if an individual patient refuses essential treatment, following this wish (respecting autonomy) may be at the expense of making the patient better (beneficence) or avoiding further harm (non-maleficence). If not treating the patient leads to a worsened condition that is more costly to manage, then this also conflicts with making best use of resources for society as a whole (justice). "To improve treatment means we need to do research," Dr Teare pointed out, but the Declaration of Helsinki makes it clear that the rights of the individual are even more important. Considering the use of personal health data in research, she suggested that key measures to protect individuals in research aim to ensure privacy, confidentiality, good scientific practice, public benefit and protection of future generations.

Tools used to protect individuals in traditional research include informed consent and right to withdrawal at any point with no personal consequences. However, their use may be more complicated in research using data from personal care records. An individual may give consent to the initial research study but there be uncertainty about how the data might be used in the future. It may also be difficult to withdraw consent at a later date, with the individual unable to check if their data has been deleted. Other issues that may occur with this type of research include incidental findings, which have nothing to do with the research question but may have implications for the individual, and the question of whether anonymised data can be traced back to the individual.

Ethical issues in the collection and use of data from personal care records

The Citizens Council moved on next to explore the ethical issues that they felt should be considered in the collection and use of data from personal care records. To do this, the Council built on the concerns identified earlier in the meeting and considered the main ethical issues suggested by Dr

Teare: individual privacy, confidentiality, good scientific practice, ensuring no financial incentives to take part in research, public benefit, and the possible impact on future generations.

Groups considered whether their responses applied only to care situations or only to non-care scenarios before suggesting practical solutions that researchers / collectors of data could put in place to respond to the ethical issues identified.

Confidentiality, privacy and data security were immediately identified as key ethical concerns for the patient/service user, care provider, researcher and society, with questions around whether data from personalised care records can ever really be anonymised and about who might have access to data. People drew on other health-related situations to consider the potential implications of data not being kept confidential, such as sperm donors being traced in the future by offspring. These issues were not considered unique to health and social care situations and Council members considered there was no difference in the need to protect data and keep it confidential depending on who was collecting and using data. Protection and confidentiality of personal data should be a top priority for all types of organisations, the group agreed.

Practical solutions for ensuring confidentiality and data security suggested were **better regulation and auditing of data management**, for example by the Information Commissioner, and a requirement that all **staff should be trained in information governance**. Researchers should be accountable for ensuring they use **secure IT systems** for storing and analysing data and staff involved in data collection and analysis should be vetted. Data management systems and staff training need to be updated regulated in the face of new challenges to data security.

Transparency was considered a very important issue for the patient/service user, including having information on exactly what is being done with their data, what else might be done with their data, and what might happen in the future. There was concern about whether an organisation could keep data forever and whether they might use it for other purposes. Council members considered there was a difference in the type of organisation doing research, with potentially more trust that the NHS or an academic group would have greater openness about the aims of research than for-profit organisations.

Council members suggested that systems should be established to ensure that researchers are transparent from the outset, with **informed consent procedures** requiring them to tell study participants how their data will be used and who might have access to it (including whether their data may be sold to other organisations), how long data will be kept and what will happen to data once the research study has finished. **Explanations should be kept simple** to ensure study participants can understand and they should be given written information. Informed consent procedures should include information about what a researcher plans to do with data if they discover incidental findings about a participant's health and wellbeing. Citizens also suggested that **individuals should have access their own data** as part of ensuring transparency.

The **public benefit of research** was identified as an important ethical concern, with one Council member commenting, "I don't mind if research is helping people but if it's marketing I would decline." A potential solution that researchers could put in place to ensure public benefit of any research they carry out is **patient / service user involvement** in the design of research, which Council members considered particularly important if it could potentially affect their health or have wider long-term consequences. Council members felt that **researchers must think about the benefits to society** of their research, particularly if resources for a study are coming from the public purse. Research studies of greatest benefit to society should be prioritised and this should be **discussed transparently with the public**. Focusing on research that makes the best use of resources was identified as an important issue and ensuring that research is open to all members of society, with **no discrimination**.

"I don't mind if research is helping people but if it's marketing I would decline."

Good scientific practice was considered a concern for patients/ service users, care providers and researchers. Council members considered that researchers have a 'duty of care' for optimising accuracy of data and ensuring data are analysed correctly. **Appropriate systems and good working practices** should be put in place to ensure a consistent approach to research planning, data capture and analysis. Council members were concerned that there should be a **complaints process** in place for research study participants, overseen by an **ombudsman**. They felt there was no difference between different types of research organisations in this regard.

Different perspectives on using information from care records

To illustrate what research using anonymised data derived from personal care records might look and feel like in real life, the Council heard from a patient, a service user and a researcher who have each been involved in different research projects.

Patient / service user perspectives

Alan Campbell, a patient with diabetes and participant in research to test a new piece of monitoring equipment.

Alan Campbell, who has had type 1 diabetes for 22 years, told Council members about his experience of taking part in research studies involving the use of data from his personalised care records. He told them why he considers this is beneficial both to him as an individual and to society as a whole.

He is currently participating in a trial funded by Diabetes UK, to test an electronic detector that he wears in his shoes to monitor the pressure under his feet. The technology aims to reduce the risk of pressure ulcers, which can be a particular problem for people with diabetes. He explained that he has diabetic neuropathy, which reduces his ability to sense the pressure under his feet. The electronic detector alerts him via a monitor like a watch around his wrist when the pressure is too high. The research uses data collected from the device together with information from his patient records. This helps him and the study findings will also help others with diabetes. Alan's view was that if we don't share data, people won't get the care and attention they deserve and need, and that data saves lives.

Alan noted that an added benefit for him was that all 11 sets of health records (paper and electronic) previously held on him by his GP clinic and several hospitals were now collected together electronically. He felt it is essential that all clinical records about a patient are pulled together, explaining that in all the different sets of records held previously not one had a complete picture of him. When asked, around 60% of Council members had thought that personalised care data was already linked and shared by different healthcare providers and were surprised that this was not the case in many areas of the country.

Martin Rathfelder, a member of the public and participant in a national UK Biobank study

Martin Rathfelder explained why he is one of the half a million volunteers taking part in the UK Biobank study, hosted by the University of Manchester and supported by the NHS. His view was that sharing your data lets others learn from your experience. All participants have provided blood, urine and saliva samples for analysis, answered questionnaires about their diet and lifestyle and agreed to have their health followed using information from their GP healthcare records. Over the years this will build into a powerful resource that will help researchers to discover why some people develop particular diseases and others do not. He explained that unlike a lot of research, which studies people who are already ill, this study will enable researchers to follow what happens to

people who are currently healthy and what factors may be associated with conditions they develop over time.

Clinician / care provider perspective

Dr Sue Collier, Head of Medical Operations with the Salford Lung Study GSK (GlaxoSmithKline), described how the linked-up medical records between GPs and hospitals in Salford are enabling research into a new medicine given as part of usual care to patients with asthma or a type of chronic bronchitis (termed chronic obstructive pulmonary disease, or COPD). Data from their care records is being collected and analysed to assess the benefits and side-effects with the new treatment. The aim is to mix the robustness of a randomised controlled trial with a 'real world' approach and learn how we can use patient data in new ways to answer scientific questions, she explained.

A major advantage of this approach is that it can be more inclusive than a randomised trial, by including patients with asthma who smoke and those with chronic bronchitis and an abnormal ECG (which is common because most of these patients smoke) and by being available to patients who are housebound. Linkage of records means that safety monitoring can be performed in real time rather than with a time delay, which occurs in a clinical trial.

Seven thousand patients have been recruited so far, with a very good response rate, which Dr Collier considered had been achieved by individual conversations explaining why the study is being carried out. She noted that a lot of people had previously opted out of sharing their data but opted back in when the study was explained to them..

Professor Garner asked Citizens Council members what they thought about this type of research partnership between a pharmaceutical company and the NHS. One delegate said they had a 'nagging doubt' about any research that involved a company potentially making profit at their expense.

Other views on data sharing

Professor Garner explained to the Council that there are some extreme views on the use of anonymised data from personal care records and that speakers representing the 'middle ground' who would report factually on the relevant issues had been chosen for the meeting. To provide a wider perspective she gave Council members a handout giving examples of views expressed by members of the public through online comments in response to news articles about sharing data from care records under NHS England's care.data project. Some of the views opposed to data sharing included:

"If pharmaceutical companies want your data, their main interest is likely to be in their profits, not in your health."

"Has it occurred to you that unless you have personally verified that the GP medical history held about you is accurate then you will be forever be the one-eyed chain smoking, legless dwarf with a liver transplant that it says on your record. Try to get you head round the reality of GP records - before they kill you! Unless the patient checks the record this whole system is pointless."

"Once your data is digital it is distributable. Once it's distributable, it can be commoditised. Once it's commoditised, insurance companies will come sniffing... After that, don't be unemployed, sick or old."

"Under no circumstance should anyone outside of the NHS be using my health information... insurance companies will be able to charge more because they will know everything about you. In whose world is that 'the greater good'?"

"I have no issue with the collection of medical data for the purposes of research. However, the major point here is that the data is for sale. The data is for sale to those not only who will better health, but to those who will seek to profit from your ill health. Health is a human right, and it should never be for sale; especially to big pharma."

Implications on access to care for patients and service users

In the next stage of the meeting the Citizens Council considered the relationship between access to a new treatment or care innovation willingness to share data from personal care records.

Research that allows early access to treatments not yet fully approved

Professor Vikki Entwistle, Professor of Health Services Research and Ethics, Health Services Research Unit at the University of Aberdeen.

Professor Entwistle outlined the standard regulatory process for new medicines before explaining the exceptions underlying 'early access' or 'compassionate use' schemes. Such schemes allow 'early' use of medicines that have not yet been approved for patients with serious conditions and who have limited or no treatment options. There are obvious benefits for these schemes, particularly in providing treatments for people who previously had no or few options. However, there are also concerns, explained Professor Entwistle. In particular, there is a concern about the greater good. "We need medicines to be tested to demonstrate that they are effective and safe before being used by patients. Making exceptions in very rare cases does not compromise this regulation, but offering larger scale 'exceptional' access to unapproved medicines could undermine systems designed to ensure the safety of medicines," she pointed out. It could also discourage manufacturers from running trials and make it hard to withdraw drugs if the research conducted whilst 'exceptional' access is allowed shows the treatment to be ineffective.

Collecting data from personal care records for people prescribed a drug on an early access programme can produce additional information on the risks and benefits of the treatment that would otherwise be lost, Professor Entwistle suggested. Experience with a number of initiatives suggests "a large majority of people are willing to offer their data for the common good," Professor Entwistle reported. But she acknowledged that some people might have concerns about the privacy of their data. She concluded by asking the Citizens Council to consider whether participation in early access schemes should be restricted to those people willing to share their data. Would this be fair? And what kinds of conditions and protections are needed?

Implications on access to care for patients and service users

Members of the Citizens Council considered the practical and ethical issues associated with sharing information from personal care records as part of research and started to think about whether only those willing to share their data should be able to receive early access to care that is not yet routinely available.

Why an individual might not want to share information from their personal care record

Some Council members considered that people might not want to share data from their medical care records because of concerns about what might be done with the data in the future, or because

it might be shared with, or sold on to, other organisations. Others suggested that a person might not want to share information from their care record if they had a particular condition or treatment that they did not want others to know about, for example treatment for drug abuse. Some people commented, based on personal experience, that incorrect information may be in a person's care record and they would not want this shared.

Commonest concerns about sharing data were similar to those raised previously about the use of personal care record data generally: confidentiality of data (particularly information that could have future repercussions for the individual, such as affecting a person's insurance or employment), privacy, data security, and transparency. There was concern about a person potentially wanting to change their mind and withdraw during a study. "If you have given your data you can't take it back," noted one delegate.

Why it might be important to allow access only to those prepared to share data

Some Council members considered that allowing people to opt out of sharing data might undermine research. One person argued, "If people are not willing to share their information how can we go forward?" "You would end up with no study or not enough data to get a good study," another added. They considered that medical treatments available today have been made possible

"If people are not willing to share their information how can we go forward?"

only because people have shared their data and research for the future would be put 'in danger if people don't share their information'. There was also a concern that research data would be incomplete and vital data may be missed if not everyone treated with a new drug shared their data.

People recognised that an early access scheme is a 'special case' so some felt differently about data sharing compared to standard medical care. "If you are being treated with an unlicensed drug, all of your medical information is needed," one delegate suggested. Meeting participants considered that sharing data for new and unlicensed medicine is essential to ensure safety is carefully monitored, for the individual being treated and for other patients who might wish to receive that treatment in the future.

Reflecting on these discussions, the Council considered the most important reasons for making treatments or interventions not yet fully approved available only to those who are willing to share their data were:

1. Full knowledge of medical history is required before drugs can be prescribed to ensure safety and efficacy (which could be categorised as both benefit to society and personal benefit to the individual patient).
2. If the trial goes wrong the data and information need to be used to prevent harm to others (which can be classified as benefit to society and safety).

3. Safety for everyone because the drug is unlicensed (benefit to society, safety).
4. Helping people in the future (benefit to society).
5. Someone else who is willing to share their data could be missing out (individual benefit).

Other reasons given by the whole Council were: it's not cost-effective and doesn't add value if people don't share their data; to increase medical benefit to the patient (for example, how do you know the drug would suit you if you don't share data?); if you are going to benefit from trials you should be prepared to share your data; to have continuity of evidence; to ensure no missing vital data *such as* on side-effects; those unwilling to share their data are no use to the study; to get the best outcomes; commitment of patients; you will end up with no study if you don't get sufficient data.

In which circumstances, if any, would it be reasonable to allow only people who consent to use of their data to access the treatment or care being evaluated?

Council members worked in small groups to consider this question before sharing areas of agreement and points of disagreement. They were sharply divided on the issue. Some of the groups considered there should be no circumstances that justify opting out of sharing data because this would stifle research. They considered that if people were getting the benefit of a treatment they should be willing to share their data so others could benefit and research knowledge could move forward. "If you won't share your data, I would say you can't have the treatment," said one participant.

"If you decide to take part in research you should agree your data is used for research purposes that would eventually help others."

However, others felt that access to treatments or care being evaluated should never be restricted only to those consenting to share their data. Illustrating this divergence, one group said, "We all agreed if you decide to take part in research you should agree your data is used for research purposes that would eventually help others," while another group noted, "One suggestion is that there are no circumstances where someone should not be given access to treatment. The opposing argument is only in special circumstances or in dire need."

"You should be able to say 'no' otherwise you are taking people's rights away."

Some people considered that the requirement to share is a matter of fairness and of making most efficient use of available resources. "If there are limited resources for a new drug it should be prescribed firstly to those helping with sharing data," suggested one group member, with another adding that giving a drug to a person unwilling to share their data may mean that it's not available for another person who would. It was suggested that it was not cost-effective to give the drug to someone unwilling to share their data.

Others felt that people should be able to say 'no' because sharing personal data should be a free choice. "You should be able to say 'no' otherwise you are taking people's rights away. They should be able to say 'yes' or 'no'," a Council member suggested.

Council members also considered circumstances where it would be reasonable to allow access to a treatment that was being evaluated in research to those *not* willing to share data from their personal care records, rather than circumstances where access should be made available only to those sharing their information. These circumstances included: people needing urgent treatment; people who are terminally ill; children; vulnerable adults who can't give informed consent; people with certain religious beliefs (because they would not want their family to know they were receiving treatment); people with conditions they don't want others to know about; politicians and other people in the public eye (although one group member pointed out that data is anonymised so no-one would know who it had come from).

Overall, Council members generally felt it would be appropriate to make treatments being researched available only to people willing to share their data where a study was over-subscribed, so treatment should be given to those consenting to provide information, and where sufficient numbers are needed so that a study can be published and to ensure it is comprehensive. One person observed the tension between thinking about this issue as an individual patient and thinking about the benefit to the NHS / society as a whole. The Council went on to explore this further in subsequent discussion considering the public and private interests relating to social duty for the greater good and individual rights to privacy, in the context of sharing information from personal care records.

Does this depend on the type organisation that data is shared with?

Some Council members discussed the different types of organisations involved in research and felt that it made a difference whether the data were being collected for use by the NHS (in which case data should be shared) or by a profit-making organisation (where there should be a choice). Professor Garner asked the Citizens Council as a whole to consider this further and asked again about whether they had different views depending on the type of organisation wanting to analyse information from personal records. "Is there a difference between organisations such as NICE and academic groups compared to pharmaceutical companies and device manufacturers? And does it depend on whether organisations are paying for the data?"

The majority of Council members still considered there was a difference in the use of data from personal care records for research by NHS organisations compared to pharmaceutical companies. Themes that emerged at this point in the discussion were: the level of trust in an organisation, what an organisation intends to do with data and whether information is being used with the aim of making a profit or not. People generally considered that organisations such as NICE are trusted more than pharmaceutical companies. However, there was some uncertainty about what NICE

might potentially do with personal care data, with some group members questioning why it needs data if it's not developing new medicine. This might point to the need for further public education on how NICE uses data in its role of evaluating medicines and interventions for use by the NHS.

However, Council members were now divided on whether for-profit organisations should benefit from the use of data from personal care records. Some considered it was wrong for companies to make money out of information that patients / service users give as part of their NHS care. "If it's mainly for profit and not for medical benefit, then it's not right," suggested one Council member. But others felt this was not a clear-cut issue. Another Council member argued, "Drug companies are profit making, but they *have* to be. They are doing studies and doing work to bring new drugs. Without these companies there would be no new drugs so it's very important they have data."

There was recognition that organisations such as NICE need good quality data for evaluating medical treatments. "NICE needs full information – the more that is provided by trials, the better you can make decisions," one participant suggested.

"NICE needs full information – the more that is provided by trials, the better you can make decisions."

Several areas of concern emerged during this discussion. One issue (which had been raised previously) was the oversight and regulation of pharmaceutical companies. A new concern was what would happen if something goes wrong with a drug being tested by providing access in routine care, including liability issues. Professor Garner explained that this is currently 'a grey area.' A Council member said they would be "worried if the onus was put back on the patient even though they might not be aware."

Social duty for the greater good and individual rights to privacy

Introducing the underlying concepts

Professor Jonathan Montgomery, Professor of Health Care Law at University College London and Chair of the Nuffield Council on Bioethics.

Professor Montgomery introduced the concepts of social duty for the greater good and an individual's rights to privacy and choice. He explained that there is both a private interest and a public interest in each of these and introduced what this means in the context of sharing individual patient health data.

He outlined the three main ideas that need to be considered in this arena: privacy (the right to be left alone and the freedom to be yourself); public goods (common interests and the collective good) and social duties (living together in harmony or living well). While we all have a right to privacy, we are all affected by those around us.

Do our health records belong to us as individuals? Professor Montgomery pointed out that health information in our records partly comes from us and partly from the health system we interact with. Potential use of this information for research needs to be underpinned by a 'social contract' that sets out the fair ground rules, he suggested. Public goods include:

- common interests in which we all share equally, such as clean air and water, where there is no conflict
- collective (public) interests that may benefit each person differentially but with overall positive effects for the greatest good, such as health services
- personal (private) interests that we each hold independently, such as life and personal health, where they need to be constraints and /or trade-offs, balancing individual freedom against the good of society as a whole. He asked us to consider, whether there are some things that are so important to people that they should stop us sharing data, for example.

Moving on to consider social duties – to respect the rights and freedoms of others – Professor Montgomery explained the concepts of solidarity (making us all better off if we collaborate) and reciprocity (giving something back in return for what we have received) and how these might apply to sharing data from personal care records. He suggested we make judgements on the balance between how much a result is worth having, such as a new treatment in the future, against how far we are prepared to share our privacy. Summing up recent work by the Nuffield Council on Bioethics in this field, he argued the key elements in the use of data from personal care records for research are transparency – explaining to people why this is being done – backed up by accountability and governance, concluding that agreement of a social contract is needed in order to achieve this.

Reconciling social duty for the greater good and individual privacy

Citizens Council members considered the public and private interests relating to social duty for the greater good and individual rights to privacy, in the context of sharing information from personal care records. They considered a selection of statements representing different positions, voting on their importance and exploring the implications of prioritising each position over the others.

Ranking of statements as important/very important

Voting on these statements as individuals revealed that Citizens Council members generally considered social duty and the greater good of much greater importance than individual privacy.

1. Public interest for social duty/greater good

Everyone benefits when we all co-operate. We all have a responsibility to contribute towards improving the health and well-being of society as a whole.



2. Private interest for social duty/greater good

If we allow data to be collected now, it might improve the care and treatments that are available to me when I need them in the future.



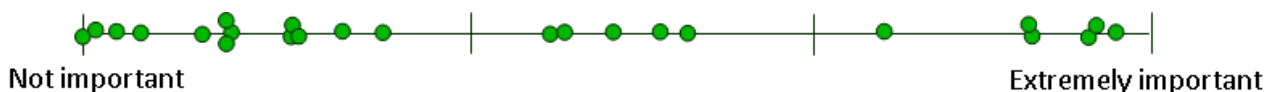
3. Public interest for individual privacy

A society that respects individual privacy is stronger because it gives people choice about whether or not to share their health and care information, and confidence that their choice will be obeyed.



4. Private interest for individual privacy

I want the right to keep my life private – my health and care information is part of what makes me 'me'.



Drawbacks of allowing one statement to trump the others or to be discounted

Council members then considered what the drawbacks would be if one of the four statements were allowed to 'trump' all others or if a statement were discounted.

Private interest for individual privacy

During group discussion, Council members considered the drawbacks of allowing this statement to trump all of the others would include a negative impact on research progress as a whole, with no data being collected and no developments in medical science. "There would be no cures for cancer and other serious diseases," one member pointed out, while another suggested it would slow research down and it would take longer. However, one delegate questioned whether this would be true: "We may just go back to randomised controlled trials," he suggested, although he noted that these are very expensive. Council members suggested there might also be negative consequences for the individual resulting from the lack of sharing of personal health information between different health agencies "so if you take ill away from home and need treatment they may not have information on you, such as medicine you should not take."

Groups generally agreed that discounting this issue would violate the individual's right to privacy. "I might want to keep my life private," one person pointed out. They also thought certain groups of people, such as those with impaired mental capacity who may be unable to give informed consent, might lose out from not being able to opt out of data sharing. There was concern that giving people no choice about sharing their data might reduce the number of people willing to participate in a research study and may also mean a sample is not representative of the population as a whole.

"I might want to keep my life private."

Public interest for individual privacy

A drawback of allowing this statement to trump others might be fewer participants taking part in research so it would more difficult and take longer to make progress in medicine. However, group members could see several problems in discounting this statement, including individuals feeling concerned about, or not agreeing to what their data might be used for. Some individuals may want the freedom to opt out of research, such as donating their organs, for religious reasons so group members considered it important to maintain individual choice.

Overall, several Citizens Council members considered it was important to allow individuals privacy and the right to choose to share their data because they considered this was important to society as a whole. They felt society was stronger if people had freedom of choice.

Private interest for social duty / greater good

Loss of individual freedom and feeling forced to take part in research would be major drawbacks of allowing this statement to trump others, group members suggested. Other potential drawbacks

might be a failure to focus on an individual's current health needs and the collection of 'too much data' that could be difficult to manage. But discounting this statement would stifle research and potentially limit treatments for individuals in the future.

Public interest for social duty / greater good

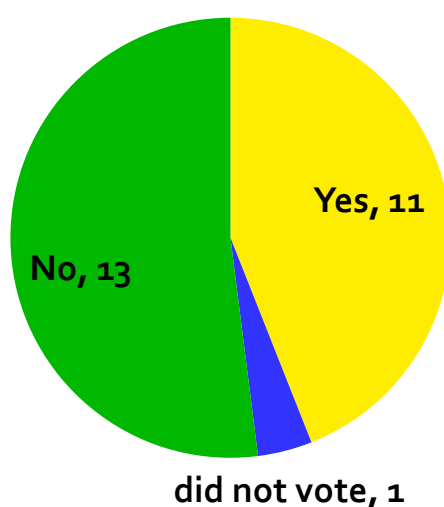
People would feel intimidated and forced to share their data and there would be no individual choice, Council members suggested when considering the drawbacks of allowing this statement to trump all others. It would mean people were not able to hold different opinions on this issue. However, Council members considered that allowing this statement to be discounted would be very damaging to society as a whole and to progress in research. "Society would break down," one group member warned. Others suggested, "We would be taking away faith and hope," and, "There would be less medicines."

Could NICE use anonymised data to fill gaps in evidence?

Bringing the discussions and insights from the two-day meeting to a conclusion, Citizens Council members were asked the question: 'If NICE was not getting enough evidence in the usual ways and so wanted to use anonymised data to fill the gaps, would you have any concerns?'

Opinions were fairly evenly divided, with **13 people voting 'no', 11 voting 'yes' and 1 abstaining.**

If NICE was not getting enough evidence in the usual ways and wanted to use anonymised data to fill the gaps, would you have any concerns?



People then shared their remaining concerns about the use of anonymised data from personal care records for research by NICE and considered practical ways in which NICE could respond to meet these concerns. Key themes that emerged were transparency and the potential for data to be sold on to other organisations and used for profit and for purposes other than research; good scientific practice and collecting and using data to benefit society; and data security.

Council members proposed that to address these concerns, NICE could ensure transparency through open days and information resources to explain what data is being used for, explaining precisely how it will be used and by giving reassurance that personal care data will not be passed on or sold to other organisations. Professor Garner explained that informed consent must be in place before a patient agrees for their data to be used in research and this should state how their information would be used and analysed.

The Council recognised the central importance of informed consent in ensuring transparency. Member recommended that informed consent procedures should be randomly checked by NICE, bearing in mind that they may be carried out by others (such as GPs) on their behalf and it was

suggested that consent should ideally be personalised, to ensure people fully understand what data they are sharing, who it will be shared with and how their data will be used.

Throughout the meeting members had raised the question about whether there was an ombudsman to oversee the governance of sharing personal care information for research. They suggested that an ombudsman should be considered to take on this governance role.

Conclusions and key outcomes

The 2015 meeting of the NICE Citizens Council set out to explore the question:

What ethical and practical issues need to be considered in the use of anonymised information derived from personal care records as part of the evaluation of treatments and the delivery of care?

In response to this question the Council considered that key ethical issues are:

- **Confidentiality, privacy and data security**, with questions around whether data from personalised care records can ever really be anonymised and who might have access to data.
- **Transparency** and ensuring that patients/service users are informed about exactly what is being done with their data, what else might be done with their data, and what might happen in the future.
- **Public benefit of research**, focussing on research that makes the best use of resources and ensuring that research is open to all members of society, with no discrimination.
- **Good scientific practice** to ensure the accuracy and validity of research design and data analysis. The Council felt that research that does not produce any useful findings because it is not scientifically robust is a waste of time and resources.

Citizens considered there was a difference in the level of concern for these ethical issues depending on the type of organisation doing research, with potentially more trust that the NHS or an academic group would have greater openness about the aims of research and more focus on research for public benefit than for-profit organisations.

Council members recommended that practical measures to meet these concerns should include complete transparency on how information from personal data will be used and who it will be shared with, effective informed consent procedures and strategies to ensure complete anonymisation of personal data, data security and research governance if NICE uses information from personal care records for its work in the future.

The Council considered a main strength of using information from personal care records for evaluating treatment may be better research outcomes. Other strengths included greater convenience and potentially lower cost to the patient; better continuity of care; and data being collected from a more representative population. Limitations identified were lack of time and research expertise among GPs and other care staff; risk of human error and lack of accuracy in data collection and entry; concern about security of data transfer and security; and concerns about the efficacy and safety of the intervention being researched.

Considering whether it would be reasonable to allow access to a treatment not yet approved for routine use only to those patients or service users who consent for their data to be used as part of an evaluation scheme, some Council members felt there should be no circumstances that would justify opting out of sharing data, mainly because to do so would limit the accuracy and validity of data collected. They considered it only fair that people receiving treatment or care as part of research should provide their data to allow progress in care delivery. However, some felt that access to treatments or care being evaluated should never be given only to those consenting to share their data because this would be taking away people's freedom of choice and would be coercing people to take part in research in return for receiving treatment.

Social duty and the greater good was of much greater importance than individual privacy when it came to the use of data from personal care records for research, the Council concluded overwhelmingly. There was clear recognition that this was necessary to make advances in health and social care research and for the good of society as a whole, balanced against a desire to maintain individual freedom of choice.

Final thoughts

Reflecting on the two-day meeting Citizens Council members felt they had travelled a long way in exploring and understanding the issues associated with the use of anonymised data from personal care records for research purposes. "Talking about sharing data has made us aware there are a lot more factors to consider," suggested one group, adding, "We all felt we learned something."

"Talking about sharing data has made us aware there are a lot more factors to consider."

While recognising the benefits to society of sharing personal data for research some Council members wanted to emphasise that they considered individual freedom remained important and individual rights should be respected by any system introduced to enable use of personal care data by NICE. "Individualism is still important and should be respected," suggested one participant. There was some remaining scepticism about whether people would be given a real choice about the use of their personal care data for research because some Council members felt that Government agencies could access whatever data they wished, with or without an individual's consent.

Some concerns remained about the potential for misuse of personal data, including the effectiveness of anonymisation of personal care data and whether it could be tracked back to an individual; what happens to data after it has been used for research; and data security as a whole. Measures to ensure confidentiality and data security are essential to reassure public concerns on these issues. Transparency and fully informed consent – achieved by explaining in a simple and easily understandable way how an individual's data would be shared and used for research – were

"Researchers should state exactly what is being done with data and make it simple for people to understand."

considered key measures to ensuring that people felt comfortable with research involving use of their personal care data. "Researchers should state exactly what is being done with data and make it simple for people to understand," Citizens Council members concluded.

Next steps

This report will be used to provide that National Institute for Health and Care Excellence with a public perspective on the ethical and practical issues that need to be considered in the use of anonymised information derived from personal care records as part of the Institute's work in evaluating treatments and the delivery of care. The report will be presented to the NICE Board and the conclusions and recommendations will be used to inform the principles set out in NICE's Social Value Judgements document. The information provided will also, where appropriate, be used to inform specific areas of NICE's work and be incorporated into the methods guides for individual programmes.

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Further information

Copies of the slides shared during the two-day meeting are available on request to:

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