Health & Social Care Data:
Report on User Engagement Workshops

Prototyping Feedback

This report has been produced for the Department of Health following a series of 6 workshops conducted with patient representatives and professionals from health and social care services prior to the publication of the Caldicott Review.

July 2016

Contents

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1. Introduction

In spring 2016 the Department of Health (DoH) commissioned a series of workshops on the proposed new consent model for health and social care data arising from the review led by the National Data Guardian Dame Fiona Caldicott.

The purpose of these workshops was to get feedback from patient and healthcare professionals on a series of prototypes for presenting the outcomes of the Caldicott Review before publication, in order to refine and improve how the new model could be presented to the public, thereby reducing risk early on.

Policy Lab worked with the DoH to develop a range of low-tech prototypes designed to test a number of different elements including:

a. **Language:** do the public understand how the consent model is explained? What impact does language have on people's choices?

b. **Visual presentation:** how do the public and health professionals react to different visual forms (e.g. text-based option buttons, text-based opt-out, visual model, video description)?

c. **One or two question:** which model works best?

d. **When and where:** what is the best time for people to be asked the questions (e.g. in person after a health intervention, online when people are finding out information)

e. **Who:** who is best to deliver the message (e.g. another patient, a health-care professional) and what materials do these groups need in order to do this?

The workshops were designed and facilitated by the Government's Policy Lab and independent dialogue experts Involve. This report presents the findings from these workshops.

2. Overview of the workshops

Six full day workshops were held between the 10th and the 23rd June 2016, in a range of locations across England chosen by the Department of Health (DoH). The Department was also responsible for recruiting participants for the workshops.

The workshops were designed to last 4-5 hours and involve a mix of a mix of small group discussions and plenary sessions to capture both initial reactions and then deeper thought about the range of prototypes:

- a morning session with health and social care professionals to provide feedback on the models; and
- an afternoon session where they would be joined by patient representatives to explore the best ways to present information and support the public to be able to provide informed consent.

In practice none of the workshops were delivered in this way (as described below), with most becoming combined sessions including both professionals and patient representatives.

In total 92 people attended the workshops: 70% coming from the health and social care professions and 30% representing the public[1], who generally came from organised patient and/or carers groups. It should also be noted that the vast majority of the public representatives were quite 'professionalised' i.e. already heavily involved in policy discussions around health and social care planning and practice.

The workshops

Morcambe – 10th June 2016
Facilitators: Simon Burall (Involve) and Cat Drew (Policy Lab), supported by DoH staff.
This workshop was delivered as a combined full-day workshop for public and professionals together. There were 12 participants, most of whom were employed within the healthcare system.

Manchester – 13th June 2016
Facilitators: Simon Burall (Involve), Laurence Grinyer (Policy Lab) and Kaela Scott (Involve), supported by DoH staff.
20 people attended this full-day combined workshop, with a high proportion employed within local authority social care services.

London, Wellington House – 14th June 2016
Facilitators: Laurence Grinyer (Policy Lab) and Kaela Scott (Involve), supported by DoH staff.
The 10 participants in this workshop were all professionals, with most involved in health sector research, and as such were generally already well aware of the issues around data sharing and the proposals likely to emerge from the Caldicott Review. At the outset of the workshop they expressed their disappointment that there were no members of the public present as this was the main reason many of them had chosen to participate. Despite this there was a good discussion of the prototypes, however the workshop ran for the morning only.

[1] Of the public representatives however over 70% attended the single workshop in Leeds, with the remaining 8 participants attending one of the other 5 workshops.

London, NW London Pioneer – 16th June 2016
Facilitators: Kaela Scott (Involve) and Cat Drew (Policy Lab), supported by DoH staff.
There were 10 participants in this combined full-day workshop from the North West London health and care system (most of whom had already spent a number of years working together to implement an objections systems and data sharing across their own local health and care economy). In addition to people working in predominantly clinical settings this workshop also included the active participation of 2 people invited as observers and 2 lay partners from GP practices.

Leeds – 17th June 2016
Facilitators: Kaela Scott (Involve) and Cat Drew (Policy Lab), supported by DoH staff.
This workshop was the only one in the series that was delivered as a morning session with professionals (14 attending) and an afternoon session where they were joined by patient representatives (20 attending). Unfortunately only 3 of the professionals from the morning session stayed into the afternoon so their role had to be revised and they tended to participate throughout the afternoon as observers / advisors, able to answer questions about existing practice in the area.

London, ADASS – 23rd June 2016
Facilitators: Kaela Scott (Involve) and Laurence Grinyer (Policy Lab), supported by DoH staff.
Despite 14 people having confirmed to attend this workshop a combination of flooding in central London and the fact that it coincided with the EU referendum meant that the workshop was actually delivered to a very small group of 5 social care professionals from London Councils. Given the size of the group the workshop also finished early. A single patient representative arrived towards the conclusion of the workshop and her feedback was collected separately.

3. Overview of findings from the workshops

3.1 In general people found the consent model confusing and difficult to understand.

3.2 Many people found the description of the standard / current setting to be very different to their understanding of how health and social care information about them is already shared.

3.3 There was general agreement that the implementation of this consent model needed to be proceeded by a wide reaching information and awareness raising campaign.

3.4 Further that any information campaign needed to make clear that this was designed to replace and override existing consent systems and create a unified, nationwide system that would make people's interactions with the health and social care systems better.

3.5 This campaign also needs to focus on how this will be of benefit to people, individually and collectively, to encourage them to be generous with their information as the impacts on the system could be quite significant if high numbers of people choose not to provide wide consent.

3.6 Participants generally felt that a big, nationwide launch, with a letter sent to everyone and a timeframe to reply was the best method to introduce the consent model.

3.7 This should be supplemented with options to respond online and include signposting to sources of support and further information.

3.8 There was considerable concern about this being an opt-out model - particularly given that the default position, if people did not respond, was to assume consent to the widest level of sharing.

3.9 Most workshop participants felt that being asked for consent should require an active response i.e. that an 'If you agree do nothing' option was neither practical or legitimate.

3.10 In general people favoured the 3 different choices regarding consent, however they did not all necessarily agree that they should be cumulative i.e. that by agreeing to share information for research purposes you also had to agree to share information for planning purposes.

3.11 There will need to be considerable attention paid to the language used to ensure a clear, consistent and accessible message is delivered.

3.12 There will need to be much wider consultation and prototype testing, reaching out beyond stakeholders to include members of the public, before implementation or even wider discussion.

3.13 The workshops have also identified a range of Frequently Asked Questions that will need to be answered/answerable at the start of any implementation process.

4. Wider issues and concerns raised in the workshops

There were a range of general issues and concerns raised in virtually all of the workshops that had an impact on the discussions that took place. In some cases the time given over to explaining, debating and clarifying these matters significantly limited the time given to consideration of the prototypes and methods for presenting information.

4.1. **People wanted to debate the model itself**

Inevitably, many of the participants came expecting the workshop to be an opportunity to consider and debate the relative merits of the proposals and recommendations that were to be included in the Caldicott Review. It is sensible to assume that this will be the case when the model is rolled out and highlights the need for an effective communications campaign.

4.2. **Why this is happening? and Why now?**

There were repeated questions asked about why there was a need for this, particularly in areas where there has already been significant work done to develop and integrate consent systems across regional areas (often involving much more detailed categories of consent). There was an initial assumption by many that this system would exist alongside local/regional models and simply add another layer of bureaucracy and/or confusion i.e. that this would risk becoming another 'care.data'.

It therefore needs to be made clear from the outset that this is being developed as a nationally standardised system that will be supported by legislation and will override and replace existing systems i.e. that once implemented patients will not have different levels/forms of consent registered in different places. It must also be noted that there was also some resistance to this from professional groups who have already spent considerable time developing consent systems that, in some cases, they thought were better than the model proposed.

4.3 **Difficulties in understanding that the consent model only applied to personal, identifiable information.**

Many people, including professional participants not already actively engaged in consideration of data sharing protocols, did not understand this when they initially read the information. It did not seem enough to state that existing systems for sharing anonymised data would remain as they are. Even by the end of the workshops, despite the facilitators best efforts to clarify, a surprising number of people were still making comments that demonstrated they thought they were being asked to opt in or out of non-identifiable data being shared.

4.4 **Lack of clarity about how health and social care data is currently shared**

There was a general lack of clarity, from many of the professional as well as the patient representatives at the workshops, about existing data-sharing, and in particular the regulations for the sharing of data between health and social care systems. Further, the significant anomalies in relation to the official position on data sharing in the delivery of direct care (based on a presumption of sharing) and the reality as people experience it tended to add to this confusion. It also suggested to many that, even at the most limited level of sharing put forward in the Caldicott

model, they were being asked to give consent to much wider sharing than was currently the case.

In this context, describing the baseline position for all of the consent options under discussion as currently being one in which *data is routinely shared between health and social care systems for the provision of care* seemed disingenuous to many participants. Perhaps at best this can be described as the aspiration.

For others there was also significant concern that their health records were already being shared this widely. This resulted in numerous discussions about the idea that there needed to be an option for people to withdraw their consent to automatic sharing of information for direct care.

4.5 **Real public concern about sharing data with social care**
Throughout the workshops there was a clear sense that while most people were happy to have their information shared within the health service, and looked forward to a situation where this would be done more consistently and effectively, many were very hesitant for their data to be shared with the social care system. Most of the concerns seemed to stem from a lack of trust in the professionalism of local care providers (especially outsourced services), the security of data within local councils and a general sense that, if data was shared it would become an 'open book' accessible at any time by anyone within the system. There was very little understanding of the professional protocols relating to data being accessed on a need to know basis.

5. Method of asking for consent

In the workshops participants were asked to consider a range of ways in which the public may be asked for their consent including:

- by letter;
- though a conversation with their health or social care provider;
- on-line.

Preferred method for asking consent:

5.1 Across all of the workshops there was general agreement that **a letter, sent to all people registered within the NHS and social care system**, was the preferred method for asking for consent. While it may be seen as antiquated by some, it is a tried and tested method used regularly within the health and care system.

5.2 **Reasons for this preference included:**

- A standard letter to all people ensured a consistency of information provided.
- An official letter will emphasise the importance of the decision.

- If everyone receives it at the same time there is an assumption that people will then be more likely to talk about it with family and friends and hopefully assist with response rates.
- The request for consent should not be linked directly to an interaction with health and social care system as this could promote insecurities ('What do they know about me?' 'Why do they want my information?'), result in people feeling pressured to respond in certain ways ('If I don't consent will this affect my treatment?') or lead to ill informed decisions if people are sick, injured or in crisis.
- It is neither practical or viable for the initial approach for consent to be made by health and social care professionals during a consultation or scheduled contact. The task of introducing and explaining a complex consent model was not seen as a good use of the time of professional's who are widely recognised to be already under pressure in terms of delivering care and treatment.

5.3 **Recommendations for asking for consent by letter:**

- A standard letter should be sent to everyone at the same time.
- This must be preceded by a nationwide information and awareness raising campaign so that people are expecting the letter.
- The letter should be clear and simple (see section 6).
- It should be accompanied by an information leaflet giving examples of what the different levels of data sharing mean in practice.
- It should provide links to further information on-line.
- It should sign-post people to where they can ask questions or seek advice.
- It should give a clear date for responses to be received (although acknowledge that people can change their level of consent at any time).
- It should provide an option to complete the consent process on-line.

Further considerations related to asking for consent by letter

There were a number of other factors relating to asking for consent by letter that generated considerable discussion within the workshops but for which there was no clear preference expressed overall.

5.4 **Who should the letter come from?**

Within the workshops there were a variety of suggestions made as to who the letter should come from:

a. The NHS – many people felt that the letter should come from the NHS as people generally have trust in this organisation and existing confidence in its ability to securely hold and use their health information. A counter argument made to this however was that, given the consent being asked for includes data sharing with the social care system, an NHS branding may be misleading.
b. Individual GP Surgeries – Some participants felt that a letter from their own GP practice might be more likely to be prioritised by the public, as it was

more meaningfully linked to their own care than a general nationwide request.

c. The Department of Health – While for many this option seemed both more inclusive and more 'official' there were equally concerns that people may be less inclined to share their information if it was perceived to be a request from a government department, or alternatively that it was too remote from people's general understanding of the health and care system.

5.5 **Consent relating to minors**

While in discussion there was a general assumption made that a parent/guardian would be asked to give consent regarding the information shared about minors under their care, it was however one of the first questions asked by many people and therefore needs to be explicitly addressed. The question was also raised as to whether people deemed Gillick competent are able to give their own consent and how this would be implemented.

5.6 **Ongoing process for triggering letters asking for consent**

Once all people in the system at a certain date have been contacted questions were raised regarding how new entrants to the system would be asked to give consent. The most popular suggestion appears to be that it should become part of registering with a GP, with the letter either directly given to patients or sent immediately following registration. It was also suggested that a letter should also be automatically sent to people on their 16th birthday to ask for their individual consent.

5.7 **Professional's role in providing information and clarification to the public**

While the was general opposition to direct health and social care providers being the primary route for asking the public for consent, there was also a recognition that they will be the most likely to be approached by people seeking further information and/or advice. In this case they need to be prepared and well briefed. While most found the model Healthcare Conversation, as presented in the workshops, to be unwieldy and unhelpful there was a sense that a glossary of terms / stock phrases / choices of vocabulary could be useful.

Regarding signposting patients towards sources of support it was felt that as much as possible this role should be delegated to support staff e.g. practice managers and receptionists or other organisations e.g. CAB's or patient groups, with direct care providers only becoming involved if an individual member of the public had specific concerns in relation to their own personal/medical information.

6. Methods of giving consent

Throughout the workshops participants were shown a range of different prototypes for presenting the choices people will have regarding how their personal information is shared. The purpose of this was to test how public[2] and professionals responded to the different choice formats, uses of language and varying layouts and to identify preferred options.

There were 4 distinct prototypes presented:

1) Your health and social care information – a 3 option tick box format offering a choice between Standard, Limited and Restricted settings.
2) My health and social care information profile – a 2 option tick box format offering a choice between Standard and Restricted settings.
3) Your health and social care information – an explicitly opt-out format presenting 3 levels of choice: for direct care, to also plan for services, to also support research.
4) My health and social care information profile – an explicitly opt-out format presenting 2 levels of choice: for direct care only or also to run the NHS and improve treatment.

Many of these options were then also presented with icons and/or in an online prototype.

Overall observations

Before moving on to a more detailed commentary on what came out of the workshops in relation to the language and layouts used in the prototypes there are a number of observations that need to be noted from across the series of workshop.

6.1 In general people found the choice they were being asked to make **confusing and difficult to understand**.

6.2 Participants had to be consistently reminded by the facilitators that it was **personal / identifiable information** they were consenting to share or not share (and that anonymised data is shared by default).

6.3 There was general concern that the **premise of implied consent** could mean there was no real way of knowing if people had given consent, ignored or forgotten the request or not answered because they had not understood what was being asked.

6.4 There was considerable concern, particularly among public participants, that there was not an **option to not share personal information by default even for direct care**. Many felt this needed to be consented to on a case-by-case basis, particularly when sharing outside of the NHS.

Areas of general agreement:

6.5 That, in contrast to what is being put forward in the Caldicott review participants generally agreed that **giving consent should require an active response** (i.e. that a 'If

[2] While there was a distinct lack of public participants at most of these workshops it is important to note that, during this section particularly, the professional participants were encouraged to (and generally did) also respond in a personal capacity – thinking about how they, their friends and families might react to the information provided.

you agree do nothing' option is not preferred). While it was acknowledged that this would result in additional administrative cost, and potentially lower consent rates, it was generally felt that it was the only way to ensure consent was based on a decision, rather than omission.

6.6 That the question **asking for consent should be framed in an affirmative way** (similar to prototypes 1 and 2) – i.e. 'I agree to my data being shared for this purpose', rather than 'I do not agree to my data being shared for this purpose'.

6.7 Despite favouring the process of giving consent requiring an active choice (prototypes 1 and 2) most groups **preferred the language of prototypes 3 and 4**.

- Liked the conversational and logical flow of the questions
- Liked the less formal / more real world titles at each level
- Liked that it illustrated what the headings meant
- Liked the inclusion of who you should speak to if you were not happy with the existing sharing between those providing your care

6.8 While it was recognised, particularly among professional participants, that the preferred outcome for the system was the highest level of consent being given by the highest number of people many were very **uncomfortable with the idea that a non-response would be taken as implied consent for full sharing**. Several groups suggested instead that a non-response should be defaulted to the most limited setting.

6.9 That once a system is instituted there is **a role for professionals at next point of contact to raise the question of consent with patients/clients who have not indicated a preference** and direct them to sources of information and the ways they can register their choice.

6.10 That any **online option for giving consent must use the same language and structure as printed materials**.

6.11 That any **online mechanism should be linked to existing secure systems** - e.g. patient records or the Government Gateway otherwise you risk creating a situation wherein the public is being asked to provide personal information in order to verify their identity and generate a new online account in order to indicate that they do not want to share their information.

Categories of Consent – 2 or 3 options?

6.12 Many groups were initially drawn to the 2 option versions (prototypes 2 and 4) due to their simplicity. In discussion however almost all groups ultimately **preferred the 3 option model.**

6.13 The main reason for this, particularly from professionals, was the belief that the **binary model would result in higher opt out rates** i.e. that that people who were concerned about research but otherwise happy to share their data for planning purposes would all then opt out.

6.14 Some groups however also had **concerns about the cumulative nature of the consent options** as expressed in prototypes 1 and 3 i.e. they wanted the option to be able to consent to information being used for medical research but not for planning services.

This concern was particularly evident from groups who had already demonstrated hesitancy about information being shared with the social care system.

6.15 One concern raised about the 3 option model however was that people might be tempted to **go for the middle option**, thereby withdrawing their consent for their information to be shared for research purposes, just 'to be seen to be doing something' / taking some control of their information.

7. Presentation of information

A key conclusion drawn from across the workshops is that the language used to communicate the consent models to the public must be as clear and simple as possible; that is was already a complicated and confusing topic without using unfamiliar language unnecessarily.

To assist in simplifying the presentation of the topic there were a number of general recommendations made regarding language and content:

7.1 **State clearly that this consent relates to personal identifiable information** –the prototype letter caused a lot of confusion by referring to what is not included i.e. anonymised or de-personalised data.

7.2 There needs to be a clear upfront statement of **why sharing this data is of benefit.** The letter (or whatever format is decided) needs to emphasise the benefits to individuals and to the wider system from the outset.

7.3 The choice people are being asked to make should be **presented in an affirmative way** – 'I agree to my information being used for….'

7.4 **The language used needs to be person focused** – 'you' and 'your care', 'me' and 'my information'.

7.5 **Simple examples are useful in the letter and form.** This was one of the key reasons that people generally preferred the language in prototypes 3 and 4 e.g. 'Local health and care planners will know what services people need in your area'. There was concern however that they must be carefully chosen, with many people objecting to the use of 'cancer' as an example throughout because they thought it was too emotive and an attempt to manipulate people's responses: as one participant stated *"Who wants to say that they won't help treat and prevent cancer? You may as well add in children and puppies!"* Instead it was suggested that a range of illnesses could be listed e.g. 'to improve how diseases such as heart disease, cancer and diabetes are treated and prevented'.

7.6 The language, images and logos used throughout must be **consistent and inclusive of social care.** (see section 8)

7.7 That any **on-line presentation must use the same language and structure as printed materials**.

The Use of Icons

7.8 In general people found the use of icons to be **helpful and aided clarity.**

7.9 Most people felt that when the **icons were used to cumulatively illustrate** the different types of consent included in each of the options this was particularly helpful.

7.10 There was concern however that they must be used judiciously in the design of materials of there was a **risk of it becoming cluttered**

7.11 **Feedback on the specific icons**

- The Stethoscope - Most people found the stethoscope clearly related to direct care provision. There was concern however that it was not inclusive of social care and therefore could be misleading. An alternative suggestion for this icon was an image of a person receiving care.
- The Hospital Building – This clearly identified a wider institutional setting for people and seemed a suitable representation of system planning. There was a suggestion however that the '+' used in the image should be replaces with a standard 'H' hospital logo.
- The Microscope – This was widely endorsed as a clear symbol for research, even though in reality the research under question was much more likely to be data based.
- The Heart – this was seen as very confusing and quite meaningless when used to try and symbolise the research and planning options.

Leaflets / Information Cards

The leaflets/information cards were widely agreed to be very useful in principle however:

7.12 They need to be more realistic and written by people with a clearer understanding of the health and social care systems.

7.13 They need to explicitly emphasise the difference that the sharing of data has made.

7.14 Many of the examples used in the prototypes, particularly in relation to the use of shared data in planning do not actually related to data sharing, rather just identify good practice.

7.15 The case studies, even in the planning level, should relate to identifiable benefits to people rather than the system itself (i.e. not about recharging but being able to have better facilities in the right places)

8. Language

The workshop process also identified a range of preferred terms, alongside those that should be avoided.

8.1 **Use 'Information'** rather than 'data' *i.e. 'How your health and care information is used'*
Not only is data a more technical, bureaucratic word that can alienate some people, but media reporting of data scandals has made people very cautious. It was also raised in at least 2 of the workshops that HSCIS had done some previous research that concluded people were more comfortable with the term information (as something given) than with data that was perceived as something that was taken from them.

8.2 **Use 'Care'** rather than 'social care' *i.e. 'How your health and care information is used'*
For many people the term social care is quite meaningless or is specifically related to social work services. For many in the workshops it took some time to realise that the term covered a range of other care services including care homes.

8.3 **Use 'treatment and care'** rather than 'direct care' *i.e. 'People providing you with treatment and care…'*
People tended to find the phrase direct care quite clinical and felt that it emphasised care provided in a medical setting. There also needs to be an explicit explanation of who could be included within those providing you with care – GP's, nurses, midwives, care home staff, social workers, dentists etc.

8.4 **Use 'relevant information' or 'the information they need'** rather than 'some information' or 'a certain amount' *i.e. 'People providing you with treatment and care will be able to see the information they need…'*
People found the use of vague terms like 'a certain amount' to be off putting and made them suspicious that all information would be made available to everybody as an open book. It needs to be clear that people involved in providing treatment and care will have access on a need to know basis.

8.5 **Use 'people'** rather than 'patients' *i.e. 'personal and identifiable information about people…'*
People who are not actively using the health and care system need to know that this is still relevant to them and encouraged to register their level of consent.

8.6 **Use 'identifiable'** rather than 'confidential' *i.e. 'personal and identifiable information about people…'*
In general people reacted particularly badly to the idea of confidential information being shared as it seems contradictory. In general, this was seen as a simpler and clearer way of explaining what information was being shared. There was also a call for examples of the type of information that would and would not be shared in relevant contexts, for example social care services routinely hold information about people's financial situation and ability to pay and there was concerns raised that this would be shared with GPs and specialists.

8.7 **Avoid using terms like 'anonymised' and 'de-personalised'**
While there are different legal definitions of anonymised, pseudonomised, de-personalised etc. the public mainly care whether they can be identified from the data.

8.8 **Avoid using 'permission'**

Aside from the fact that there are statutory or safeguarding conditions that could override the 'permission' given, it was felt that being asked to 'agree' or give 'consent' to information being shared was a simpler question for people.

8.9 **Use 'choosing'** rather than 'deciding' or 'setting' *i.e. 'choosing how my health and care information can be used'*
Deciding or setting implies a sense of permanence and people need to be made aware that they can change their choice at any time.

8.10 **Avoid using 'checking'** *i.e. 'The NHS and social care system will not be able to use your information to plan care or check the quality of care you receive'*
Some people found this phrase quite threatening and took it to mean that if they did not give consent to share at this level no one would monitor the individual care they received. Perhaps 'planning services and monitoring the quality of care provided' would be a better choice of words.

8.11 **Avoid using the phrase 'care planners'** in the context of consent to use data in wider service planning as it has a specific meaning in a social care planning context.

8.12 **Avoid using 'setting' to name the different consent levels** i.e. Standard, Limited, Restricted Settings as in prototypes 1 and 2.
Many people found this wording confusing, taking it to apply to a physical setting or place. It was suggested that if these categories are used to denote the different consent levels they should be renamed as Standard Sharing, Limited Sharing and Restricted Sharing.

8.13 **Avoid using 'Standard'** i.e. *the 'Standard Setting'*
Because Standard can be taken to read average it could be considered an attempt to bias the public towards this being the expected, reasonable response. It also implies that it is the current situation and, while it may be the official position, in reality it is not and people could be misled to agreeing to a status quo as they currently experience it.

8.14 **Use 'treatment, care and prevention'** rather than 'cures' *i.e. 'this information can be useful for other purposes, such as planning better services and researching better forms of treatment, care and prevention.'*

8.15 **Avoid using the word 'Charities'** without further explanation
The statement that charities would having access to identifiable information instigated serious concerns for many participants – with many instantly thinking of cold calling and questioning why charities would need this information, what types of charities and what they would do with it. Perhaps this could be avoided if charities were simply included within a list of research organisations that would have access to the information including those within the NHS, Universities, Pharmaceutical companies etc.

8.16 **Avoid using the word 'Marketing'** without further explanation i.e. *'It will never be used for marketing or insurance purposes'*
This statement also caused confusion for many people as they took it to be a guarantee that the information would never be used for market related purposed (i.e. commercial purposes) rather than restricting it from marketing (i.e. promotional) purposes.

9. Frequently asked questions

The workshop process highlighted a range of questions and issues that will need to be clarified and /or publically clarified at the very start of the implementation process.

9.1 There needs to be recognition that the level of sharing implied by the current / standard setting is aspirational, and that the goal is presumably to have mechanisms in place that allow this level of sharing as routine by the time of implementation.

9.2 There needs to be clarity about the default position if there is no response made by individuals – that as it stands this is an explicitly opt-out model with a non-response defaulting to the widest level of consent.

9.3 Needs to be much wider understanding that there is no explicit consent required for sharing directly related to the provision of care, and that this includes sharing with the social care system.

9.4 People need to be clear that this consent relates to personal identifiable information and in order to be clear on this, they need to know what types of information could potentially be shared in different circumstances.

9.5 People also felt much more comfortable with the idea of sharing their information if they were also able to have access to the information held about them. Will people have access to their own records as part of this system?

9.6 There needs to be clarity regarding consent given for minors and when/if this is automatically withdrawn when they reach 16.

9.7 There needs to be clear list of the types of people/professions that will be included in having access to personal and identifiable information, and that this could include private companies and charities contracted to provide care services.

9.8 People need to be reassured that the ability to access information is managed by a range of professional codes of conduct etc. that ensure access is only given to relevant information when needed to deliver safe and effective care.

9.9 People need to be aware that there are cases where, even if they choose the most limited sharing setting, their data may be shared without their permission e.g. safeguarding situations or public health emergencies.

9.10 There needs to be very clear information available on where / how this data will be held, how access works in practice and the relevant security standards and data controls.

9.11 The public need to be informed about how data is accessed for research – including that research access is unlikely to be to a full medical history but rather a specific data set, requested for a specific purpose that will require approval by an ethical advisory board.

9.12 It needs to be very clear that, while you can change your mind at any time, as records are held digitally this will remove your information from future use, but not lead to it being extracted from data sets that are already produced and in use for planning and /or research.

10. Recommended next steps

Following the workshops these are our recommendations to ensure that the new consent/opt-out model for data sharing proposed in the Caldicott Review is presented in a way that enables people to make an informed decision about how their personal confidential data will be used to inform health and social care provision.

10.1 That the Department of Health takes note of the issues with understanding the model raised in this report and considers re-framing how it is presented to the public.

10.2 That a revised set of prototypes are produced drawing on the language, methods of presentation and preferences identified in this report.

10.3 That a further series of iterative testing workshops are held with a diverse cross section of the public who are specifically recruited for this purpose.

10.4 That the staff involved in facilitating these workshops are briefed to be able to provide clear and consistent answers to the FAQs (highlighted in section 9 of this report) in order to be able to maintain focus on testing the prototypes.