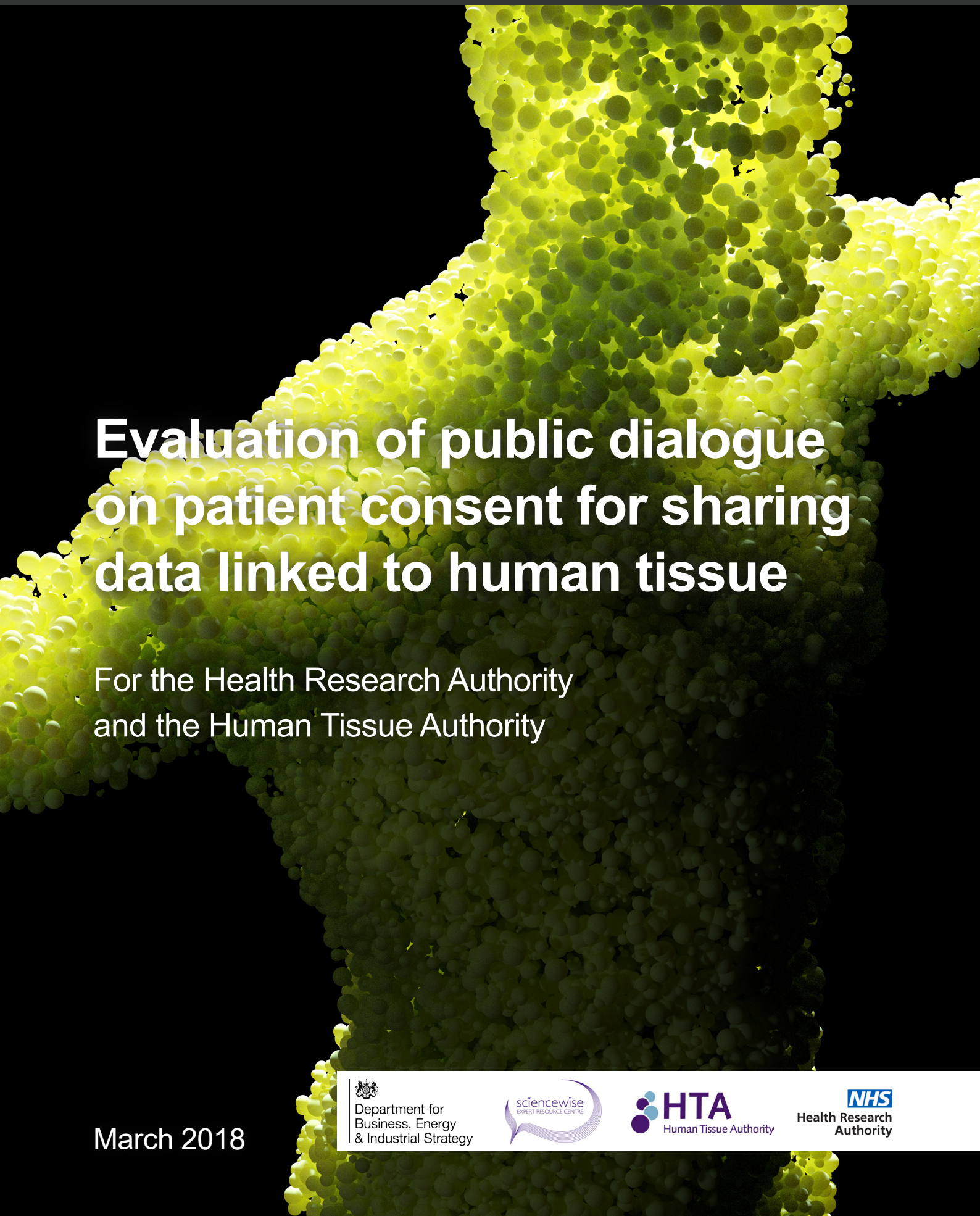

Evaluation of public dialogue on patient consent for sharing data linked to human tissue

For the Health Research Authority
and the Human Tissue Authority

March 2018

Department for Business, Energy & Industrial Strategy

sciencewise EXPERT RESOURCE CENTRE

HTA Human Tissue Authority

NHS Health Research Authority

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Executive Summary

This report sets out the findings of the evaluation of the Health Research Agency's (HRA) and Human Tissue Agency's (HTA) *Patient consent for sharing data linked to human tissue* dialogue conducted between September and October 2017. The dialogue was co-funded by the Sciencewise programme[1].

Context and Aims

The HRA and HTA, in conjunction with the Sciencewise programme, commissioned Ipsos MORI to design and deliver a public dialogue on the issues surrounding consent to use patient data linked to human tissue in health research. It was designed to engage members of the public in order to inform new HRA and HTA guidance for consent procedures that will maintain public trust, support informed consent, and facilitate better health research.

The dialogue built on previous public dialogues commissioned by the HRA in 2013, which focused on public views on the HRA's remit to streamline and simply the research approval process and transparency. And a 2015 public dialogue looking at how participants were recruited for health research. In both of these previous dialogues issues of consent were discussed.

Activities and Content of the Dialogue

The objectives of the dialogue were to:

1. To undertake a dialogue with the public and patients to discuss and explore the issues(aspirations and concerns) around sharing and storing patient data linked to tissue donated for research purposes.
2. To listen and understand public views towards how such issues can be covered in the broad consent process to maintain public trust.
3. To explore public views on the use of electronic dynamic consent for linking patient data on an ongoing basis to donated tissue.
4. To use the results of the dialogue to inform the HRA/HTA's new guidance on sharing donor data in relation to tissue for research.

To achieve these objectives there were two rounds of public dialogue workshops and an online community, with various activities, between the two rounds of workshop.

75 public and 11 specialist participants took part in the workshops. They were held in London, Sheffield and Birmingham between September and October 2017. Public participants were given incentives up to £150 for taking part in the workshops and online community.

[1] Sciencewise is funded by Department for Business, Energy & Industrial Strategy (BEIS). The Sciencewise programme aims to improve policy making involving science and technology across Government by increasing the effectiveness with which public dialogue is used, and encouraging its wider use where appropriate to ensure public views are considered as part of the evidence base. https://www.gov.uk/government/collections/sciencewise-public-dialogue-on-science-and-technology

Round One of the dialogue covered the issues presented by tissue donation and data linkage. Public participants were able to discuss the information and ask questions of the specialists present. The information covered:

- biomedical research and how it operates
- biobanks
- health data, anonymisation and data privacy issues
- safeguards

Between Round One and Round Two, participants in the on -line community reflected on their initial views, and took part in activities about the future of research and possible risks in tissue donation and data linkage.

Round Two of the dialogue was designed to identify and clarify participants views on different consent protocols. They were presented with consent forms (and some information sheets) to explore three types of consent - broad, hybrid and dynamic consent.

An Oversight Group (OG), comprising stakeholders from the health research and governance fields (including one patient), a Sciencewise programme representative and officers from the HRA and HTA, was brought together to support the HRA and Ipsos MORI (the delivery contractor) to design the dialogue process and the materials used, review the report and its findings.

Evaluation data

The data used to assess the public dialogue came from -

- Observations at three of the six workshops and a review of the materials and processes used
- Evaluation forms from six workshops, from 75 public participants and 11 specialist participants.
- Observations of two OG meetings and five project management meetings
- Interviews with OG members and the HRA and HTA Chief Executive Officers
- Ad-hoc interviews with participants in the workshops - both public and specialists
- An overview of email traffic (over 500 messages) between the HRA, HTA, contractor, Oversight Group and Sciencewise
- Documents produced by the process

Evaluation findings

The dialogue met all its objectives. It enabled the public to discuss and explore the issues around sharing and storing patient data linked to tissue donated for research purposes. It provided the space for the HRA, HTA and other stakeholders to listen and understand public views on the broad consent process; the use of electronic dynamic consent for linking patient data; and there are clear plans to use the results of the dialogue to inform the HRA/HTA's new guidance on sharing donor data in relation to tissue for research.

The dialogue also met the quality standards required by the Sciencewise programme. In short, it:

- was appropriately framed - consent processes need to be reviewed in this area

- had good governance - an active multi-party stakeholder Oversight Group to help shape the workshops and reflect on outcomes. And good project management.
- went through good design process - a good length of time to draft and review materials and workshop processes, with lots of input from the Oversight Group
- had engaging and various ways of enabling public and specialist participation
- has clear avenues to reflect on the results and inform further guidance on consent and links to tissue.

Key learning and successes

- Highly able delivery team - flexible in adaptations to design of materials and workshop processes. Used a variety of activities in workshops. Had excellent liaison with the OG, albeit with one small omission in design delivery. Used the same core facilitation team across the venues.

- Knowledgeable and highly able client - used their experience of what works and doesn't from previous dialogue and other social research approaches. Used their networks to gather a multi-stakeholder Oversight Group. And had good control of Project Management.

- Top management commitment - CEOs of both HRA and HTA were involved in high level planning and briefed and supportive of the project. And they were clear on the dialogue's objectives of influencing guidance.

- The Oversight Group provided multi-stakeholder input, with feedback from them helping to framing the dialogue workshop design and materials. They also provided specialist participants for the workshops. An OG meeting after the workshops helped inform the HRA and HTA's conclusions from the findings of the dialogue. One enhancement, suggested by an OG member, is to provide a mechanism so that OG members are clear on what they are being asked to comment on (in the design phase of the workshops), and have a central point to collate and file feedback to the contractor.

- There was excellent feedback on workshop delivery from both public and specialist participants.

- Impact on policy/guidance - there are current plans for a joint HRA/HTA meeting to reflect more deeply on the findings and then produce draft guidance for further consultation with stakeholders.

1. Introduction to the dialogue

In May 2017, Ipsos MORI was commissioned by the Health Research Authority (HRA) and the Human Tissue Authority (HTA), with support from the Sciencewise programme, to undertake a public dialogue to explore views of consent to use patient data linked to human tissue in health research. The dialogue findings will inform new HRA and HTA guidance for consent procedures that will maintain public trust, support informed consent, and facilitate better health research.

1.1 Background to the research

Biomedical researchers want access to the human tissue samples held by biobanks[2] and to link it with health data. Samples linked with health data can better support detection of the biological, genetic or behavioural factors which influence health outcomes and as result allow researchers to understand how diseases develop. Tissue in biobanks is currently underused however, as it can be unclear whether the necessary consent permissions are in place to allow the linking of human tissue and health data. This dialogue has looked at what the public think constitutes informed consent and whether current consent forms need to change in order to achieve this.

Alongside the traditional, face-to-face way of seeking consent using paper-based forms, dynamic consent provides opportunities for donors to give ongoing consent for their tissue and data to be used for specific purposes on an ongoing basis. Another aspect of this dialogue was to examine whether current consent is suited to emerging technological developments like genome sequencing[3], and whether this can be future-proofed given the aspiration to roll-out more widely.

Ultimately, HRA and HTA are looking to augment their current guidance to ensure that the best consent procedures are in place, so that donated tissue has the greatest benefit.

1.2 Types of consent

The types of consent explored are as follows:

Broad consent: consent taken at the point of donation. It records consent for a range of unspecified future research projects; in some instances, the intended use will be stated.

[2] Is a large collection of biological or medical data and tissue samples, amassed for research purposes.

[3] A genome is the unique sequence of DNA in an organism. Genome sequencing is the process of determining the structure of an organism's DNA. It is hoped genome sequencing will lead to better understanding of disease and ultimately, more effective, personalised medicine.

Dynamic consent: intended to give donor's greater control and ownership of their consent. The theoretical concept is usually associated with an online platform where donors can consent to specific research on an ongoing basis. In theory, is also creates an opportunity for researchers to provide feedback to the donor.

Hybrid consent: simultaneously seeking a dual consent for use of tissue in both research and treatment – for example, for research findings to be fed back to clinical teams and potentially inform a donor's treatment. This form of consent is used in the genome sequencing project run by Genomics England and the NHS, 100,000 Genome Project which has clinical and research aims.

1.3 Aims and objectives

The overall aim of the dialogue was to understand the public's views on consent for linking tissue samples and health data for use in research. Specifically, the dialogue considered:

- The information that should be included in broad consent and hybrid consent;
- What needs to be in place (e.g. accompanying information, assurances etc.) so that those donating tissue and sharing their data feel comfortable with that decision; and
- Attitudes to electronic dynamic consent for linking patient data to tissue with the opportunity to update consent on an ongoing basis.

1.4 Methodology of the dialogue

A public dialogue approach[4] was considered the best way to explore this topic. It helps participants to learn about the topic and allows them the freedom to express the issues that are salient to them and develop their views in the light of discussion with other participants and specialists

1.4.1 Approach and overall methodology

The design of this dialogue was informed by an Oversight Group (OG). The group initially met to refine objectives and scope for the project; for a second time, to develop the dialogue materials, and for a third time to discuss the findings of this

[4] The dialogue approach deployed in this study was informed by the Sciencewise programme: guiding principles (2018) – these principles can be found at https://www.gov.uk/government/publications/sciencewise-programme-guiding-principles.

dialogue and this report. Some OG members attended the events where they answered participants' questions and helped present some of the key concepts. [5]

Reconvened public dialogue workshops were held in London, Sheffield and Birmingham between 26th September and 21st October 2017. A reconvened approach allowed participants enough time to digest the information they received on the first day, and reflect on the topic outside of the workshop setting.

In total 75 participants were involved in the dialogue. They were recruited on-street using quotas for gender, age, socio-economic group and ethnicity, to ensure participation of individuals from a range of backgrounds reflective of the areas they came from and the broad diversity of the UK population. The demographic breakdown of participants is included in Chapter 4.7 of this report.

As a thank you for their time, and to cover any expenses incurred through attending the workshop, such as travel or childcare, participants were provided with an incentive payment: £50 for taking part in the first workshop, a further £80 for returning for the second event, and £20 for taking part in the online community (a total of £150 for taking part in all three).

There were 2-3 specialists[6] at each of the events (information about their area of work and which events they attended is included in the appendix of this report). The specialists described their work, answered participants' questions, and engaged in discussions about tissue donation, linking this with patient data, different consent procedures and biomedical research. The dialogue with specialists played a key role in helping participants to understand the different actors in the current system e.g. biobanks and researchers, the different issues at stake and the possible implications of their discussions.

Facilitators followed a discussion guide throughout the two events to ensure that the same topics were covered in all locations. All materials were reviewed by the OG at an early stage, and signed off after several iterations by the HRA and HTA.

1.4.2 Materials and data collection

The **first event** aimed to frame the issues presented by tissue donation and data linkage. In between, participants were able to discuss the information and ask

[5] Details of Oversight Group members are included in the appendix to this report.

[6] the word *specialists* is used to cover all the health research specialists who attended workshops. The specialisms covered included - researcher, ethicist, research manager, regulator, academic, biobank officer.

questions of the specialists. In order to engage participants in these discussions, they were given the following information[7]:

Information given to participants	When / how information given	Function of information
Introduction to biomedical research and the different actors in the biomedical system	After capturing participants' awareness and understanding of biomedical research at the outset of Event 1, there was a presentation from Ipsos MORI and a quiz on biomedical research.	Participants understand the possible uses of donated tissue and linked data, and that commercial companies are important actors in biomedical research. The different modes were used to account for the different ways people learn and digest information.
Overview of biobanks, and the different stages from gathering tissue to research study.	This information was given to participants through a presentation from Ipsos MORI, a film produced by a biobank[8], a filmed "talking head" of a biobank representative.	Participants understand the process of collecting tissue, storing it, and using it in research. The videos helped deliver key messages in a consistent way across locations.
Overview of health data, anonymization, and relevant issues like data privacy.	After capturing participants understanding of what constitutes health data, there was a presentation from Ipsos MORI on health data, the process of de-identifying it and what is then shared with researchers. After participants discussed this, they were then shown	Participants understand which data is shared with researchers and engage in discussion on the potential risks and harms of sharing health data and linking it with data derived from human tissue.

[7] The table illustrates the type of information given to participants and in the sequence this happened.

[8] Introducing Newcastle University's Biomedicines Biobank

	a filmed talking head from the data privacy campaign group MedConfidential.	
Safeguards	HRA representatives presented information on data protection, regulation and ethical approval.	To identify the extent to which participants think that current safeguards are fit for purpose / need to be explained in information provided to potential tissue / data donors.

The purpose of the **second event** which took place approximately 2-3 weeks after the first one, was to identify and clarify participants' requirements of different consent protocols. They were presented with consent forms to explore broad, hybrid and dynamic consent. Improvisational actors also worked with the content of the discussions to bring the debates to life in an entertaining and educational way.

Information given to participants	**When / how information given**	**Function of information**
Real world example of permissions sought / information provided in broad consent	After a quick re-cap at the start of event 2, participants were given an anonymised consent form and patient information sheet	Capturing spontaneous views, then going into detail on which issues are most important to people
Overview of DNA, the human genome, the 100,000 Genome Project which utilises hybrid consent	Participants were shown a video about the human genome[9] endorsed by Genomics England, Participants were shown a video about the 100K GP[10] endorsed by Genomics England	Participants understand genetic data and future developments in medicine which might be important in consent

[9] https://www.youtube.com/watch?v=sn3_FlEbe0U

[10] https://www.youtube.com/watch?v=jP45Xe9O8XE&feature=youtu.be

Real world example of permissions sought / information provided in hybrid consent	Participants were given the consent form the consent form used in 100K GP run by Genomics England	Capturing spontaneous views, then going into detail on which issues are most important to people
Overview of dynamic consent, its underlying principles, and the technology needed to support it	There was a presentation from Ipsos MORI on dynamic consent.	Participants understand how dynamic consent could work, then being able to deliberate on its potential pros and cons.

Between the events, participants took part in **an online community**. This online platform offered participants a chance to reflect on their initial views, and take part in activities about the future of research and possible risks in tissue donation and data linkage. Exercises encouraged participants to think about particular harms or benefits which might result from different donation and linkage practices.

1.5 Structure of the report

The remainder of the report is divided into the following chapters:

Chapter 2: Methodology: This chapter sets out how the evaluator approached their work.

Chapter 3: Context: This chapter sets out why this dialogue happened when it did, who the key players are and what they expected to get from the dialogue.

Chapter 4: Scope and design: This chapter looks at why dialogue was used; what the projects governance arrangements were; the influence of stakeholders and how the workshop processes and materials were designed with input from stakeholders.

Chapter 5: Delivery: This chapter looks at how the workshops were run and how the participants experienced them. It also has a short section on the on-line community used in the project.

Chapter 6: Impact: This chapter looks at how the findings from the dialogue will be disseminated; whether the objectives were met; how credible stakeholders found the project and the projects impacts on guidance and knowledge.

Chapter 7: Overall lessons: This chapter sets out the key learnings from each previous chapter on the processes used in this public dialogue project.

2. Methodology of the evaluation

This chapter sets out how the evaluator approached their work.

The evaluator was guided by the Invitation to Tender[11] (ITT) which stated the aim of the evaluation as:

"...to provide an independent assessment of the impacts and quality of the dialogue project, covering the outputs and impacts of the project as a whole as well as the design, delivery, reporting and governance of the dialogue activities, and to contribute to the wider effectiveness and use of public dialogue."

And the objectives of the evaluation:

"...to gather and present objective and robust evidence of the nature and quality of the impacts, outputs and activities of the project in order to come to conclusions, and to identify lessons from the project to support the wider development of good practice in public dialogue."

The outputs of the dialogue are intended to inform the HRA and HTA in the development of their guidance for researchers when dealing with a range of consent issues relating to patient consent for sharing data linked to human tissue.

The evaluation identifies both the impacts of, and lessons from the dialogue. Given the development time needed to reflect on the dialogue findings, consult stakeholders and produce draft guidance, this report reflects on the intentions of the HRA and HTA in using the product of the dialogue.

As requested in the specification it does not assess the personal performance of those involved. The evaluator provided some formative feedback, during the process, but this was minimal due to the quality of the delivery.

The evaluation covers four broad areas, derived from the Sciencewise Quality in Public Dialogue Framework[12], and acknowledged as the focus of the evaluation. These are -

- Context - including, was the timing right? What were the boundaries of interest?
- Scope and Design - governance arrangements, resources, involvement of senior decision makers and other stakeholders, was there a purpose and were there clear questions to be addressed?
- Delivery - quality of the processes used, type of participants, participant experiences, quality of outputs
- Impact - on policy or guidance developments, on the participants, on the stakeholders and their organisations.

[11] Evaluation of public dialogue on patient consent for sharing data linked to human tissue for research. Ref - UKSBS FWSWCR17036BEIS/HRA

[12] http://webarchive.nationalarchives.gov.uk/20170712122413/http://www.sciencewise-erc.org.uk/cms/assets/Publications/Quality-in-Public-Dialogue-March-2016-Final.pdf

All these themes were addressed in our data gathering methods to provide a mixture of quantitative and qualitative data.

Our approach

Phase	Main activity	Products
Baseline	Understanding the work (eg reading, attending inception meeting) Outlining report structure (choosing measurable indicators, sharing for comment) Sharing evaluation activities Interviews with seven Oversight Group members and HRA and HTA Chief Executive Officers (CEOs). Transcription, Analysis, Report writing	Evaluation Activities report Outline report structure Baseline Assessment interviews records Baseline Assessment report
Interim	Observing three dialogue workshops (one in Round 1, two in Round 2.) Analysing, compiling and commentary on evaluation forms from all six events. Split into public and specialist returns.	Evaluation Returns for all six workshops Compiled Evaluation results, with commentary, for Rounds 1&2 Early draft report on Context, Design and Delivery
Final	Feedback at final OG on delivery and likely impacts Interviews with HRA, HTA, three OG members and Ipsos MORI Analysis, drafting, iterations of final report	Partial Draft for OG Final Draft Report

Our data were derived from -

Observations	Project Management Meetings Oversight Group Round 1 workshop Round 2 workshop	5 2 1 2
Reading	Emails (for information, needing response, use in analysis) Draft materials, process plans	Over 520 Several iterations
Interviews*	For Baseline Assessment (7 OG,	9

	including HRA and HTA Leads and HTA and HRA CEOs) Ad-hoc during workshops Post workshop delivery (HRA and HTA leads, 3 OG, Ipsos MORI)	 14 6
Evaluation Forms	After each workshop for public and specialist participants	Round 1 - 76 public responses, 10 specialist Round 2 - 65 public responses, 11 specialist
Review	Ipsos MORI final report drafts	3

*Interviewees were chosen on the following basis:

- For Baseline Assessment - HRA and HTA Leads and CEOs; a range of other OG stakeholders to cover biobanks, researchers, ethicists. These are the main fields either directly affected by the dialogue (eg guidance for research is intended to be changed) or indirectly (eg an ethicist who is an academic writing about the field and influencing thinking).
- At workshops - randomly talking to people, with some regard to a mix of gender and ethnicity.
- Post workshops - HRA and HTA leads and three key, and crucially, available stakeholder on the OG representing researchers whose organisations would be impacted by decisions made by the HRA and HTA on the field of health research. And IpsosMORI to understand how they had, broadly, analysed the data and come to conclusions.

Illustrative quotes are used throughout (from both interviews and evaluation forms) to demonstrate the points made by participants in their own language. Where verbatim quotes are used, they have been anonymised and attributed by location or function, e.g. London or Oversight Group.

Key indicators from the Sciencewise Quality in Public Dialogue Framework were used to review the data, derive evidence and report on. They are placed in a box at the beginning of each section of this evaluation report. The indicators were chosen on the basis of:

- concision (eg it would be impossible to cover all the indicators in the Sciencewise framework with the budget provided; and some of them are not relevant to an evaluation);
- practicability (eg did it seem possible to get meaningful data given the shape of the project and available resources)
- meaningfulness (eg what would enable a reader to know that the project had been well managed and run; and had some intended impact that was relevant)

Additionally, readers should understand that the depth of evaluation against each indicator varies depending on the data available.

We have used a thematic approach to analysis, in order to make sense of the data collected. The report uses anonymised quotes from public participants, OG members and specialists, who attended the workshops, to illustrate points and characterise key findings.

3. Context

This chapter sets out why this dialogue happened when it did, who the key players are and what they expected to get from the dialogue.

3.1 Timing

Indicators

- Rationale for use of public dialogue at the specific time it was done
- Evidence that the dialogue was timed to feed into relevant decisions as early as possible, at a point at which the decision could be influenced by the dialogue

As it is comprehensively described in their business case[13] for funding from BEIS/Sciencewise, the HRA and HTA rationale for the use of public dialogue was described as:

Tissue banks or biobanks store human biological samples for future use for research. Linking healthcare records to biobanks allows researchers to monitor health outcomes and connect them to biological, genetic or behavioural factors and treatments. Participants must provide consent to allow the linking of their biobank data with existing and future health records. This is usually given as part of 'broad consent'. However, it is suggested that some tissue in tissue banks goes unused by researchers because it is not adequately linked to patient data or not linked to future health data.

Tissue without data is of limited value and is problematic for the ongoing viability of tissue banks. It is important 'adequate' broad consent is sought at the point of donation for research; however there is a lack of clarity as to what level of broad consent is optimal. Additional guidance would help to ensure that donated tissue can be used to the greatest benefit. Related to this, we would also like to explore a relatively new concept known as 'dynamic consent' – where patients and participants are able to give consent for their data to be used in relation to their donated tissue for specific purposes on an ongoing basis. Dynamic consent would also allow patients to change the nature and status of their consent over time.

And with regard to how the dialogue will feed into relevant decisions, the ITT says:[14] -

[13] Business case proposal, Section 1.2, p4, 2016. A business case is a document that states the need for funding and the context to which it applies.
[14] ITT - Mini Competition against an existing Framework Agreement (MC) on behalf of Health Research Authority and the Department for Business, Energy and Industrial Strategy (BEIS)

*1.2 For this project, BEIS will be working with the Health Research Agency (HRA). The HRA would like to gain a greater understanding of public views on the consent required for sharing patient data alongside tissue for research. The outcomes of this dialogue will inform the development of a new joint HRA and Human Tissue Authority (HTA) guidance on data derived from tissue and consent for sharing patient data for research which maintains public trust. The future guidance would support both publically (*sic*) funded and commercially funded research alike in clarifying what optimal broad consent should look like.*

1.3 As there are some services that are overseen by the HRA and the HTA, both organisations work together in cooperation to support tissue based research. As such, there is a need for best practice guidance covering data which is provided as a joint enterprise between the two regulators.

1.4 HRA and HTA plan to develop guidance for both broad consent and dynamic consent for ongoing links to patient data as it evolves over time, in order to support researchers and tissue banks in getting the consent procedure right at the outset when the tissue is donated and encouraging good practice.

In interviews[15] with the HRA and HTA CEOs in July/August 2017, for the Baseline Assessment, both said that they saw the drivers including - the growth in the use of data, a need to connect the consent process across the organisations, and the need to take the public with us in making these changes.

OG members (including the HRA and HTA Leads), in interviews for the Baseline Assessment, understood how these objectives would be useful for researchers:

- in understanding the public's views on consent and data usage,
- in having clearer guidance for tissue and data use (when linked), and
- informing their own Codes of Practice, guidance or frames of reference.

And as one OG member said:

> "*The timing is good – this all complements various reports being produced for genomic issues and should help deal with some resistance to the idea that something new is happening - results will show that there is something to learn from this public discussion*."

Conclusion

The rationale for the dialogue is clearly expressed in the Business Case and re-affirmed in interviews with key players; and it is clear that the output is intended to influence the production of subsequent guidance.

3.2 Boundaries of influence

Indicators

- Evidence of clarity and openness about what could be informed and

[15] Baseline Interviews were conducted with 7 OG members and the CEOs of the HRA and HTA.

influenced by the dialogue and what could not
- Evidence that there was potential for change, that decision makers were willing to be influenced

The HRA and HTA were clear from their business case about what could be influenced by the project. Discussions at the 1st OG meeting and subsequent email traffic helped to create the ways in which the objectives of the project would be discussed. The HRA and HTA were clear that the starting point was:

We have identified three areas for dialogue and exploration with the public:

1. *Issues around the storage and use of tissue-derived data.*
2. *What constitutes optimal broad consent, including the issues above and the need to share donor data alongside donated tissue, and the requirement or otherwise to opt-out of the data being shared (who with, and for what purposes?)*
3. *Dynamic consent and how this relates to sharing donor data on an ongoing basis, linked to donated tissue*[16]*.*

They were also clear that the findings of this engagement project would be used to inform the development of new joint HRA/HTA guidance, which will address gaps in current guidance and promote good practices for consent for the use and storage of donor data in relation to donated tissue.

It was also indicated in the Business Case and in interviews for the Baseline Assessment, notes of the first OG meeting and in email traffic, that the outcomes of this work should help inform both individual researchers and those managing tissue banks whilst maintaining public confidence.

In Baseline Assessment interviews, OG members and the HRA/HTA CEOs were clear about the HRA/HTA role in producing guidance as a result of the dialogue. The HRA and HTA also said that they were willing to be influenced in their decision making, by the OG, post dialogue, informing them on what was useful from the dialogue and how it would be conveyed and used[17].

The dialogue was framed to focus on the objectives in ITT case:

1. *To undertake a dialogue with the public and patients to discuss and explore the issues(aspirations and concerns) around sharing and storing patient data linked to tissue donated for research purposes.*
2. *To listen and understand public views towards how such issues can be covered in the broad consent process to maintain public trust.*
3. *To explore public views on the use of electronic dynamic consent for linking patient data on an ongoing basis to donated tissue.*

[16] Business case

[17] Baseline Assessment, section Decisions about recommendations for guidance, Governance

4. *To use the results of the dialogue to inform the HRA/HTA's new guidance on sharing donor data in relation to tissue for research*.

Conclusion

The intention to seek public views on the links between consent for tissue use and data is clear; and the HRA and HTA have been open about this with stakeholders. And the HRA and HTA have plainly expressed their intention to both review guidance and be influenced by both the dialogue results and stakeholders on the OG.

3.3 Context setting

Indicators

- Evidence that the issues being discussed were understood in relation to existing knowledge about public and political concerns on the topic

Public concerns in this area can be derived from two main sources - earlier work on consent carried out by the HRA and work carried out by the Wellcome Trust on attitudes to commercial companies accessing health data.

The HRA engaged the public on issues surrounding *Recruiting Participants for Health Research*[18] in 2015, which informed their work on their Policy Framework for Health and Social Care Research; guidance on proportionate consent for simple pragmatic clinical trials; and guidance on how people are identified and recruited to take part in health research, including the implications in terms of patient records and shared data[19].

The Wellcome Trust, commissioned Ipsos MORI in March 2016, to run a project on *Public Attitudes to Commercial Access to Health Data*[20]. This project reported issues surrounding public concerns with the sharing of data and conditions which needed to be met to make it acceptable. The Wellcome Trust also had a representative on the OG.

Wider political concerns, were cited by the HRA Lead Officer 's reflections on the care.data consultation, which as was reported in The Guardian[21] as -

[18] http://webarchive.nationalarchives.gov.uk/20170712122742/http://www.sciencewise-erc.org.uk/cms/hra-health-research-policy-public-dialogue-health-research-recruitment-data-use-and-consent/

[19] http://webarchive.nationalarchives.gov.uk/20170712122534/http://www.sciencewise-erc.org.uk/cms/new-guidance-being-developed-following-public-dialogue-on-health-research

[20] https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-wellcome-mar16.pdf

[21] https://www.theguardian.com/technology/2016/jul/06/nhs-to-scrap-single-database-of-patients-medical-details

"*The government's scheme to store patients' medical information in a single database, which ran into massive problems over confidentiality, is to be scrapped…*[T]*he decision...follows publication of two reports that support far greater transparency...and opt outs for patients..."*

And, as reported in 3.1 above, the HRA and HTA were aware of the need to review the consent processes when linking tissue and data. Because of the impact on biobanks' ability to enable research, and researchers' ability to do their work effectively.

Conclusion

There are drivers from public concerns, which have been elicited in the above mentioned HRA and Wellcome Trust dialogue and research projects. And wider political concerns are characterised by both the HRA and HTA's awareness of changes in their field, and a desire to avoid the failures experienced by the care.data project.

3.4 Lessons

There are no lessons as such to be communicated to the HRA and HTA, but their approach to the dialogue - building on previous work, a sound understanding of previous work, senior management buy-in, the support of multiple stakeholders and an ability to clearly articulate the frame of the work is an example of good practice to be shared with other dialogue projects.

The achievement of the indicators used to assess Context are **very well met**[22].

[22] Definition of assessments - Appendix 4

4. Scope and Design

This chapter looks at why dialogue was used; what the projects governance arrangements were; the influence of stakeholders and how the workshop processes and materials were designed with input from stakeholders.

4.1 Rationale for dialogue

Indicators

- Evidence that the rationale for using public dialogue (rather than any other engagement / research methods) was clear, including how the dialogue results were expected to be used alongside other inputs to decision making

Much of the evidence for using public dialogue is cited in Section 3 above. What is not explicit is why public dialogue was used, rather than any other research method.

The HRA has used public dialogue in a previous project, but has also been involved in a Citizens Jury project and Focus Groups at the University of Sheffield.

In their interview for the Baseline Assessment, the HRA Lead said that as well as informing guidance, the HRA will also use the results to:

- frame a consultation on emerging guidance; will
- share the findings with Ethics Committees;
- use press and journals avenues;
- speak to various interest groups (eg NHS England, a research forum, industry groups, patient fora); and,
- weave it into their internal learning and development programme.

Other wider uses of the dialogue were characterised in the Baseline Assessment as: "*The main other impacts that interviewees saw was the impact on how their respective organisations engage the public; one, in particular, saying it was good timing for the dialogue, as there are a lot of other issues coming up around public health and the disclosure and use of data on large scales; as this is key to wider understanding of the health of the nation. One interviewee also mentioned a possible impact on their grants programme; as the outcome of the dialogue might prompt further research on consent approaches.*"

Conclusion

Beyond the need to find out public thoughts on the issues being discussed, there is no clear explanation of the rationale for using dialogue, as opposed to other forms of engagement or research. The evaluator is unaware of any comparative research comparing the relative merits of the products of what the Sciencewise programme understands as public dialogue and other research methods. The HRA and HTA are clear about what they wanted the public dialogue to achieve, but not why they choose this method, as opposed to others.

4.2 Governance and Management

Indicators

- Rationale for the role and membership of an oversight group for the design and delivery of the project
- Evidence of effective engagement of any oversight group
- Evidence of effective input by any oversight group
- Evidence of clear roles and responsibilities being agreed and implemented, including how changes to the project design were discussed and accommodated.
- Evidence of clarity of ownership and ultimate responsibility for ensuring the project met its objectives, including sufficient allocation of time for this.
- Evidence of an appropriate and efficient internal management team for the day-to-day organising of the project

The HRA and HTA recruited an Oversight Group in advance of the project's commencement in May 2017. The OG comprised representatives from the HRA and HTA, Wellcome Trust, University of Sheffield, UKCRC Tissue Directory, Genomics England, Medical Research Council, medConfidential, UK Cancer Voices and Astra Zeneca. These bodies represent regulators, ethicists, researchers, biobanks, patient rights and legal perspectives. This diversity of organisation and practice enables the HRA and HTA to get perspectives on design, delivery and potential impacts of the dialogue. Organising a group of stakeholders in an OG, means that they can both discuss issues face to face (in the one of the three OG meeting held) and comment and contribute to the development of materials and workshop processes. In the absence of such a group, stakeholder involvement in the governance, design, delivery and consideration of findings would be more challenging.

The OG[23] Terms of Reference specified its role as being to comment on:

- *"Key questions to be addressed*
- *Background/stimulus materials (ensuring it is comprehensive, balanced and neutral and accessible to a lay audience)*
- *Communications strategy*
- *Outputs from the dialogue exercises including written reports.*

The OG was also tasked to act impartially, give advice and guidance to the HRA and HTA on project development and have an Ambassador role.

A project inception meeting was held on 19th May 2017 to discuss:

- the roles, responsibilities and requirements of the contractors, dialogue deliverer and evaluator;
- governance and financial arrangements; and

[23] Oversight Group Terms of Reference, HRA, May 2017. See Appendices.

- initial planning (key issues to be considered, purpose of the project, risks, workshop planning, OG composition and communications).

It was attended by BEIS, HRA, Ipsos MORI (the dialogue deliverer), 3KQ (the evaluator) and the Sciencewise programme dialogue and engagement specialist (DES) and lead evaluator.

A list of actions and notes[24] on risks was circulated after the meeting to guide participants on their responsibilities in the initial stages of the project, including Ipsos MORI's role at the first OG to share initial process ideas, sampling methodology, materials development and issues for inclusion in the dialogue.

The agenda for the first OG[25] was circulated by the HRA on 23/5/17. Documents circulated with the agenda included the tender documents from both Ipsos MORI and 3KQ and the business case submitted by the HRA and HTA to BEIS for Sciencewise funding. The agenda covered an explanation of the Sciencewise programme and role; the role and composition of the OG; and an introduction to both contractors and their role.

The minutes of the 1st OG were circulated on 31/5/17, along with a paper on the role of biobanks in maintaining trust with the public when asking their consent to use tissue, and a paper on the risks and opportunities highlighted by the OG in its discussions. This latter paper on risks highlighted, for example, that "*this (the dialogue) will support both research organisations and researchers to follow good practice in seeking consent to access both tissue and patient data and so lead to better quality research*[26]".

The OG also highlighted design issues for the dialogue, including - "*will be a challenge to give the right amount of detailed information - there are many different options for consent*", and "*ensure depth in questioning - ie not just do you want more information*...[need to know] *what are the implications?*".

The minutes of the OG include a note on the discussions around the role of the OG. The terms of reference[27] were agreed, its composition was agreed and it was agreed that materials should be signed off by a sub group, not the whole OG.

Subsequent email discussion of the notes of the OG included contributions from seven OG members. One OG member raised the issue of how consent will be presented to the public, as it is complex and can be, for example, for permission for tissue use as opposed to permission for ongoing use of data in a range of contexts. This prompted an email discussion on how the key question for the dialogue should be framed. Several people referred to the range of nuances in consenting issues; and as a result Ipsos MORI[28], referring to earlier work with the Wellcome Trust[29],

[24] email 19/5/17
[25] the 1st OG met on 26/5/17
[26] note from OG meeting 26/5/17 - OG risks and opportunities notes vs2
[27] see Appendix 4
[28] email to all OG members 15/6/17

suggested two ways the dialogue could be framed - as "*a dialogue that elicits participant's principles in the context of the acceptability of linking human tissue and patient data e.g. health records*", or "*Alternatively, a dialogue that explores the mechanics of how consent is obtained*". This prompted further exchanges and Ipsos MORI's action was to weave this into the next iteration of the workshop plans.

This pattern of circulating ideas and workshop plans for input from the OG continued through the project and is referred to in further sections.

At the beginning of the project a weekly project management group was set up, comprising the HRA, HTA and Ipsos MORI, with the evaluator and Sciencewise DES joining on occasion. The role of this group was to review process, manage logistics and agree on how the wider OG would be engaged. The HRA and HTA acted as the sign off authority for materials and processes to be used in the workshops.

Examples of the activities of this group include discussion of the timetable for events, the online forum, involvement of specialists in the workshops, the types of specialists needed and how consent issues would be conveyed to the public (project management call on 4/7/17). In a later project management call, on 26/7//17, following the OG on 14/7/17, the group considered the details of consent models and how these would be used to inform materials and processes used in the workshops.

Throughout the project the governance arrangements have been clear and opportunities for OG stakeholders to contribute to the design of the project; the materials used; and to reflect on the outputs of the dialogue; via the OG meetings, email and attendance at workshops, have been well communicated and provided for. There were regular interactions between the dialogue contractor and client in the project management group and meetings, and the roles and responsibilities of all parties were clear. This is evidenced through notes of meetings, email exchanges, Terms of Reference for the OG, and interviews for the Baseline Assessment and after the dialogue. For example, one OG member reflected on the diverse range of OG members and how it was good to not only have this range, but that it enabled the OG to work through differences of opinion on materials and processes to be used in workshops.

One OG member said that it would be good, on future projects, to have someone act as a summariser and moderator of OG comments on materials and processes; because they sometimes found it hard to know which version was which and would have appreciated some guidance on what specifically to comment on in any particular moment in time.

Conclusion

The rationale for the role and membership of an oversight group is implicit in its Terms of Reference; and these roles and responsibilities were agreed at its first meeting. Subsequent email exchanges and subsequent meetings demonstrate that roles and responsibilities were implemented, and that there was effective engagement and input with and by the OG.

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[29] https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-wellcome-mar16.pdf

Project management meetings, on a regular basis (once a week during the design phase) and a period of nearly four months for design of the dialogue meant that there was clear ownership of the project, sufficient time to design the workshops and efficient day to day management.

4.3 Resources

Indicators

- Rationale for the budget and timescale allocated to the dialogue, and the particular skills needed

Experience from previous projects (HRA and Sciencewise) about the likely cost of workshops, governance, evaluation and reporting created the frame for the costs. Sciencewise guidance, from ten years of co-funding projects, also informed the budget. The HRA Lead had to negotiate for funding internally, and both the HRA And HTA got senior management buy-in.

The total budget was £120,000. The Ipsos MORI quote was £87,708; the quote for evaluation from 3KQ was £9,000. The evaluator's bid was £3,000 under budget, which allowed Sciencewise and the HRA to negotiate the use of this to fund incentives for participants. The remainder of the budget was in kind costs and cash from the HRA/HTA in servicing the project management.

Sciencewise provided a grant of grant £90,000 (75% of £120,000)

The public dialogue is comparable in cost to other dialogues (eg Cabinet Office Dialogue on Data Science Ethics in 2016 cost £130,000; HRA dialogue on Recruiting Participants for Health Research in 2014 cost £132,000).

The skills required for the project delivery agent are set out in the ITT; the implied rationale being that a contractor would need to demonstrate and practice these skills to win the tender. These skills deriving from wider Sciencewise Guidance about the role of contractors in delivering dialogue projects. And the skills required by the stakeholders on the OG are considered in 4.2 above and listed on the OG Terms of Reference.

Conclusion

The rationale for the budget, timescale and skills needed from the contractors and OG were clearly articulated in the business planning for the dialogue, procurement and subsequent conversations with stakeholders in the OG.

4.4 Involvement of senior decision makers

Indicators

- Evidence that sufficiently senior decision makers were involved throughout the process to provide organisational support to the process and results in principle and practice, and that they were prepared, willing and able to use the dialogue results to inform their decisions
- Evidence that the appropriate decision makers were sufficiently involved in the framing, design and delivery of the dialogue to understand the nature of the process and be confident that the results could be used in decision making

In interviews with the HRA and HTA CEOs in late July/early August, they both affirmed that they supported the dialogue; among other reasons because it would "*protect public confidence*"; and that they had been involved in discussions with their respective policy leads on the need for the project and the resources needed to service it. They stated too that they were committed to using the results to inform guidance that their respective organisations produced.

Both organisations committed the resources of senior managers to run the project and provide logistical support. The HRA Lead, in particular, drove the project by leading the Project Management Group, convening Oversight Group meetings and acting as the lead commentator and conduit for the consideration of materials and processes by OG members and the HRA and HTA.

Decision makers from biobanks, the MRC and Genomics England were also involved in the OG and played an active part in both commenting on materials and processes used in the dialogue and in attending workshops as either observers or specialist participants in discussions with the public attendees.

Conclusion

A range of internal and external stakeholders was involved in the macro and micro planning and design of the public dialogue; and there is plenty of evidence (interviews and email exchanges) to affirm the view that the results are intended to be used in decision making on the production of further guidance for researchers and others in this field.

4.5 Clear purpose, topic focus and questions addressed

Indicators

- Evidence that the purpose was clear and agreed among relevant stakeholders, and that different motivations and expectations among those involved were articulated and understood
- Rationale for the main topics and issues to be covered by the dialogue, and what was included and excluded
- Evidence of how the main topics and issues to be covered by the dialogue were identified and agreed
- Evidence that the purpose and objectives were framed in a way that ensured that the dialogue would meet the required quality standards,

including informing specific decisions
- Evidence of plans for how, where, when and by whom the results of the dialogue were expected to be used in informing decisions

As mentioned in 4.2 above, the OG comprised a range of stakeholder organisations who both helped to shape the purpose and content of the dialogue - by reviewing materials and process plans and by participating in dialogues as specialists or observers. And in addition the HRA was influenced by ongoing work with stakeholders from other projects, for example the Wellcome Trust project on consent, a previous HRA dialogue, and liaison with researchers and biobanks.

The OG meeting on 14/7/17 discussed[30] recruitment of participants and the process plans and materials for events 1 and 2. As a result several OG members provided information for materials, helped to reshape the questions being asked, and provided specialist observers and participants at workshops. Following the OG there were iterations of commentary on both event 1 materials and process; and then event 2 materials and process. Email traffic during July, August and September illustrates the level of interest and engagement from the OG in the design of the workshops.

The main purpose and objectives were agreed before the dialogue in conjunction with Sciencewise and BEIS. These were set out in the HRA's business case, on the basis of which the BEIS/Sciencewise funding for the project was approved. Subsequent interviews with HRA, HTA and OG members confirmed that the objectives of the dialogue were sound. Interviewees noted too the addition of a further objective: *To use the results of the dialogue to inform the HRA/HTA's new guidance on sharing donor data in relation to tissue for research.* This objective focused on the use of outputs from the project.

The HRA lead made it clear, in an interview, that the HRA and HTA would meet in April 2018 to consider, in depth, the findings from the dialogue. Anticipated use of the fundings included shaping HRA and HTA guidance to researchers, Access Committees and Ethics Committees, and informing further lines of inquiry.

Conclusion

It is clear that both internal and external stakeholders were involved in shaping the materials to be used and processes used in the workshops, and the workshop purposes and objectives.

4.6 Participant influence

[30] Notes from OG group 14/7/17, HRA

Indicators

- Rationale for the extent to which public participants could influence the design, process and outputs of the dialogue
- Evidence that the nature of the expected relationship (including limits) had been explained clearly and agreed with public participants

The dialogue did not intend to allow the public to influence the design or process of the dialogue; but by definition their inputs in the workshop and on-line community form the bulk of the outputs from the dialogue in terms of raw data.

Participants were made clear in the recruitment process (see 4.7 below) of their role, and the role of participants was made clear at the beginning of each workshop - that they were convened to have a dialogue about a variety of topics relating to the linkage of human tissue to date for research.. And that their views would inform the HRA and HTA review and/or production of guidance for researchers in this field

Conclusion

The dialogue sponsors (HRA, HTA, BEIS, Sciencewise) did not ask for a dialogue process which co-evolved its design and process with public participants. And participants were briefed on how their contributions would be used to inform subsequent HRA and HTA decision making.

4.7 Type/numbers of public participants

Indicators

- Rationale for the overall approach to involving particular members of the public to meet the objectives
- Rationale for selection of participants to provide a credible diversity and mix of participants and the basis for inclusions and exclusions
- Rationale for whether and how special efforts were needed and made to ensure the inclusion of specific groups
- Rationale for and evidence of approach to maximising inclusion and avoiding unintended exclusion

In order to meet the need that a "*key feature of public dialogue is that it brings together members of the public, scientists and other expert stakeholders to deliberate, to reflect and come to conclusions on national public policy issues*[31]" the following recruitment quotas were used for the public to broadly reflect the demographic make up of UK citizens -

Quota	London	Sheffield	Birmingham

[31] Ipsos MORI paper on Recruitment, 9/8/17

Age	Min 5 18-30, Min 5 31-44s, Min 5 45-64, Min 5 65+	Min 5 18-30, Min 5 31-44s, Min 5 45-64, Min 5 65+	Min 5 18-30, Min 5 31-44s, Min 5 45-64, Min 5 65+
Employment status	Working min 16 Not working min 8	Working min 16 Not working min 8	Working min 16 Not working min 8
Social grade	Overall: Min 7 AB, Min 7 C1C2, Min 7 DE	Overall: Min 7 AB, Min 7 C1C2, Min 7 DE	Overall: Min 7 AB, Min 7 C1C2, Min 7 DE
Gender	Min 12 Female, Min 12 Male	Min 12 Female, Min 12 Male	Min 12 Female, Min 12 Male
Ethnicity	Min 4 BME	Min 4 BME	Min 4 BME
Total	**25**	**25**	**25**

And as a result of discussions with OG members and in Project Management meetings the following people were to be screened out -

- People who work in market research.
- People who sit on ethics committees.
- People who work in or use biobanks.
- People who work in scientific research.
- People who have taken part in a workshop or focus group in the past year.
- Professionals working in the pharmaceutical industry.
- NHS staff who work in a clinical role (doctors, nurses, consultants etc.) or research role (e.g. research nurse involved in clinical trials).

This was to reduce the bias from stakeholders with an interest in the outcome. The recruiter was also briefed to reassure people that they did not require any prior understanding of the subject and that the workshops would be fun and interesting.

In order to enhance participation, 27 people were recruited for each event, in the expectation that there would be enough drop out to ensure 25 attended.

Participants were offered £50 for attendance at the first event, £80 for attendance at the second event and £20 for participating in the online community. A total of £150 if they attended both events and took part in the online community.

The decisions on the types of participants, inclusions and exclusions were made by the HRA and HTA , with advice and input from Ipsos MORI and the OG, in early August 2017. This included adapting the employment criteria to include students and

retired and to increase the numbers of BME participants for London. A revised draft was then used by recruiters, taking these considerations in to account.

Conclusion

The type and range of participants followed established practice (in brief, a representative demographic mix, with exclusions of people with the specific interest in the subject). The public participant recruiter used these practices to recruit a wide range of people who broadly reflect the diversity of the people of England. To maximise participation and inclusion, participants were supported before and during the workshops (they were sent joining instructions, were met by the recruiter at each event, and given cash incentives). In addition, Ipsos MORI over-recruited to ensure attendance and exceeded their target of 25 participants per workshop.

4.8 Number and location of workshops

Indicators

- Rationale for number and location of workshops with public participants in order to meet the dialogue objectives

The number of workshops delivered by the contractor was determined by the ITT. There is no explicit rationale for using two rounds of workshops in three locations, but general Sciencewise practice (which would have been a prerequisite for funding) is for reconvened workshops across a number of locations.

The project was limited to England, and it was agreed to focus on urban locations for ease of recruitment, logistics and ease of participation by specialists. The following cities were proposed by Ipsos MORI, with input from the HRA and HTA - London, Birmingham and Sheffield. In an interview with Ipsos MORI, after the workshops, there was no suggestion that rural locations would have been a factor in differing public attitudes to this topic.

Conclusion

There is a rationale for the number and location of workshops to meet the dialogue objectives.

4.9 Specialist involvement in workshops

Indicators

- Rationale for the role of specialists in the dialogue events
- Evidence that specialists invited to provide information to dialogue events were adequately briefed and supported, to enable them to provide appropriate information at the right time and in the right way

In an email on 16/6/17, Ipsos MORI, in responding to an OG members comments on draft recruitment tools, reported:

> "...*HRA/HTA has asked us not to include patients as dialogue participants. As xx, xx and others have rightly pointed out they are likely to have very different experiences and attitudes when it comes to these issues and would likely influence the views of those who are less informed."*

At the OG meeting on 14/7/17, the group discussed participation from its member organisations and their potential roles as either specialists talking to the public or observers in the room.

In late July and August, Ipsos MORI, in conjunction with the HRA, recruited specialist participants for all six events, using a matrix to ensure a spread of organisations and interests in the topics being discussed. These roles were identified as -

- clinical researcher who works with tissue,
- representative of biobank,
- expert patient,
- medConfidential or equivalent,
- Genomics England,
- policy researcher,
- industry representative,
- HRA and HTA

This reflected the composition of the OG and provided opportunities for the public to speak to users of tissue and data, policy makers and those with an official or voluntary oversight role (eg expert patients and medConfidential).

After comments from the HRA, guidance for both observers and specialists attending dialogue workshops was circulated in advance of each event. The guidance[32] covered their role as experts (venue details, who else is attending, timetable, and their role on the day, for example:

> "*answer people's questions...there may be questions emerging as participants wrestle with some unfamiliar concepts. hearing from people who work with these issues can make a big difference to comprehension...*".

The guidance also asked specialists to project a "benign and positive neutrality"; so that people felt they could both engage with the them and be open to them asking questions of public participants.

During the workshops in London and Birmingham, the evaluator observed specialist participants provide information in a descriptive, non-partisan manner; ask questions of participants to develop an understanding of their perspectives; and refrain from influencing people to think in any particular direction; all of which was requested in their briefing.

Additionally, specialists were welcomed by the facilitation team and given a further briefing (or reassurance of their role) if required.

[32] Guidelines for Observers and Experts - Ipsos MORI, draft v1, 21/9/17

Conclusion

The evidence (for example emails, briefings for specialists, discussions of roles at OG meetings) shows that the role of specialists in the workshops as either observers or participants was well thought through.

4.10 Design of workshops

Indicators

- Rationale for and evidence of how the overall approach to the design of the deliberative workshops meets the agreed dialogue objectives
- Evidence that the methods were appropriate to enable open, creative and productive discussions at deliberative workshops including sufficient time for participants to receive relevant and useful new information, discuss and think about implications (ideally with a break between events) and come to conclusions

As previously mentioned the approach to the design of the workshops (multi-stakeholder input) was aligned to achieving the overall objectives of the dialogue; which encompass more than just the design of the workshops.

Objective 1 - To undertake a dialogue with the public to discuss and explore the issues (aspirations and concerns) around sharing and storing patient data linked to tissue donated for research purposes.
This was achieved. A diverse group was recruited for each of three locations; stakeholders were involved in the design and delivery of workshops; the public contributions shaped the conclusions of the dialogue; and, various types of consent were discussed in the context of data and tissue links.

Objective 2 - To listen and understand public views towards how such issues can be covered in the broad consent process to maintain public trust.
This was achieved. Public views were gathered in discussions on broad consent, and hybrid consent, and issues of trust and confidence in the health research system were explored in the workshops.

Objective 3 - To explore public views on the use of electronic dynamic consent for linking patient data on an ongoing basis to donated tissue.
This was achieved. Electronic dynamic consent and its implications were explored and discussed extensively in the second round of workshops.

Objective 4 - To use the results of the dialogue to inform the new guidance on sharing donor data in relation to tissue for research.
The intention to use the results of the dialogue are clear, but the evaluator cannot determine that they have informed HRA/HTA's new guidance.

In 5.1 an overview of the dialogue workshop processes is shared. The event plans included -

- clear processes to prompt discussion among groups,
- shared several aspects of consent (including dynamic consent) to allow participants to understand the complexity of the field,
- the role of biobanks,
- ethical issues with anonymity,
- concerns about impact on personal insurance,
- public/private interfaces in research and perspectives on commercial use of data,
- role of the Genomics England Project,
- how consent is currently derived and the complexities of this.

Conclusion

Sections 4.2, 4.4 and 4.5 above demonstrate further involvement in aligning the objectives to the workshop design and the overall project. For the design of the workshops to meet the need for a public dialogue, the project objectives had to be aligned to workshop activities. This was achieved during the design of the workshops and project, with OG support.

A dialogue project also has to allow time and space for participants to discuss and understand issues. The time to absorb information, talk about it, reflect between events and come to conclusions were designed in. Chapter 5 (see 5.2, 5.5, 5.6, 5.7 and 5.8) relays participants' perspectives on their experience of workshops.

The break between Round One and Two, and the opportunity to reflect on issues in the online community with public participants from other locations (see 5.12); summarising by the facilitators; reconsidering issues of consent by looking at different aspects of it, all contribute to the conclusions that the methods used allowed participants to absorb, reflect on and come to conclusions about what they thought. There was no intention to seek a consensual view from participants, so contention (and the inevitable time needed to resolve it) could be avoided.

4.11 Lessons

There are no lessons to be learnt as such from this project, but the evaluator recommends that future projects consider these key aspects -

- creating a variety of experiences at workshops - plenary discussions, presentations, videos, group and pairs discussions, Q&A sessions, using case studies and real examples. As these are all critical in keeping people's attention and building understanding of an issue.
- providing plenty of time for the influence of stakeholders on material and process design to be realised. And aligned to this, the lead organisation to create summaries and guidance to stakeholders about the input needed from them.
- specialist involvement in workshops can enhance understanding and bring real examples to workshops. A well briefed specialist will also further illuminate the understanding of the topic in conversations, both formal and informal, with public participants.

- in the design process, proposed activities and materials should be referred back to the objectives and the purpose of the dialogue to ensure the direction of travel is apt

The achievement of the indicators used to assess **Scope and Design** are **very well met**[33].

[33] Definition of assessments - Appendix 4

5. Delivery

This chapter looks at how the workshops were run and how the participants experienced them. It also has a short section on the on-line community used in the project.

5.1 General process used for workshops

After a design process involving inputs from the OG, HRA and HTA, the structure for events and the online community were agreed. As related in Section 3, amendments were made both between events and within events to respond to feedback or allow time for more discussions.

Round One was an evening session (6pm to 9pm) in all three locations (London, Sheffield and Birmingham) and covered the following, via presentations, group discussions and plenary sessions:

- Introduction - what public dialogue is, how the workshop will run, how the results of the workshop will be used to inform HRA and HTA guidance for researchers.

- Purpose - the key question, *How should researchers seek permission to link human tissue with patient data for use in health-related research?,* was shared, and participants were told they'd be asked to think about issues like trust, effectiveness, acceptability and the best ways to seek consent.

- Introduction to biomedical research - a discussion in groups of 8-10 people on *What do people understand by the term 'health research'?* And a following plenary to answer further questions and provide more information about how it operates in the UK.

- Information on biobanks - how they receive tissue, the consent process, how they manage data.

- Donating tissue - the process you might go through and what you expect to happen; and what you think the challenges and problems are?

- Privacy - what personal data do you think is in your records, is some more sensitive than others, what do you think about what is collected and how it might be used, how is data anonymised.

- Implications - what are the risks you see in using records, sharing them with biobanks and linking it to tissue samples? And applying this to different potential applications.

- Safeguards - what is in place to protect you, ethics, how you respond to what is in place?

- Review - what are your key messages?

- Next meeting - information on event 2 and its purpose, information on the on-line community.

Round Two was a day time session (10am-4pm) and covered -

- Review - check in from last time, a recap of what was covered in event 1 and feedback on what people had said in event 1.

- Purpose - to focus on what consent forms give permission for; the reassurances people need and what safeguards and protections they need. And a reminder that the work is to help the HRA and HTA produce guidance for researchers that is publicly acceptable.

- Experiences - in groups people were asked about particular issues, for example using data for marketing, ethical perspectives, fears of commercial use, what might make people agree to their tissue being used?

- Critique of consent form and patient information - for example, checking people understand them; what they think the implications of giving consent are; who they think they might be giving consent to; where your information might be used?

- Data confidentiality and safeguards - conversations on data privacy, who has access, what oversight mechanisms people expect.

- Consent form composition - given the previous discussions, what do people think are the important things to include on a consent form?

- Improvisation - a recap from some improvisation actors who had listened into discussions and then asked people for prompts to act out the issue.

- Genomics England - a presentation on their work and a discussion about what people think about it. Discussions at tables about the Genomics England consent form and its implications for data sharing.

- Other types of consent - introduction to dynamic consent and conversations at tables about peoples thoughts on the process and implications.

- Review - final plenary to capture key thoughts from the group, talk about next steps and complete evaluations.

5.2 Focus on objectives

Indicators

- Clear statement of project purpose and objectives, agreed with relevant stakeholders and shared with public participants; evidence of reasons for any changes in objectives
- Explanation of limitations of project in achieving the objectives and how these affect the interpretation of results

As characterised in Section 3, the purpose and objectives evolved from the HRA and HTA identifying a need for dialogue on tissue and data links in discussions with stakeholders, and these objectives were further refined with a multi-stakeholder OG.

Public participants were given broad information about the purpose of the dialogue when recruited ("*workshops will involve discussing views and opinions on different topics including human tissue, data, consent and medical research*[34]"). At the beginning of each workshop, participants were reminded of the purpose of the dialogue and the focus for that workshop on achieving the objectives and purpose. At the end of Round One, participants were told what the next workshop would be about.

In the workshops, participants were told the purpose of each session and how it would work. Small group facilitators reiterated the purpose and mechanism for each session and clarified activities when needed.

On the end of workshop evaluation forms, public participants, in response to the question - *To what extent did you understand the purpose of the workshop?* - scored:

In Round One

I did not understand it at all	I did not understand it very much	I understood it quite well	I understood it completely
0	**3**	**47**	**27**

In Round two

I did not understand it at all	I did not understand it very much	I understood it quite well	I understood it completely
1	**1**	**33**	**31**

A subsequent question - *To what extent did the workshop cover the topics you were expecting?* - scored:

[34] Ipsos MORI Recruitment instructions, 9/8/17

Round One

I wasn't sure what to expect **17**	Not at all as expected **5**	Partly as expected **18**	Mostly as expected **32**	Completely as expected **6**

Round two

I wasn't sure what to expect **9**	Not at all as expected **2**	Partly as expected **9**	Mostly as expected **24**	Completely as expected **21**

There is a marked increase in understanding both the purpose and topics to be covered between Round One and Two.

Specialist participants were asked the same questions. In Round One all ten said that they understood the purpose of the workshop either 'quite well' or 'understood it completely'; ten out of 11 gave the same score for Round Two.

And all bar one (in Round Two) said the workshops covered topics 'mostly as expected' or 'completely as expected'. Of the eight additional comments made to this question, across both events, three specialists said that they thought there would have been more about consent in terms of linking tissue to data.

Both the public and the specialist participants clearly understood the purpose of the workshops and were reminded of this in both recruitment (for the public), briefing notes (for specialists) and at the beginning and end of each workshop.

One flaw, identified once the first iteration of the Ipsos MORI delivery report was published, was the difference in expectation between one of the stakeholders and the dialogue delivery team. The process plan for Round Two clearly stated that an information sheet would be used in conjunction with a consent form, when the public were considering an example of hybrid consent. On the day, the information sheet was not used, and this led to conclusions being draw, which would not have been, had the information sheet been used at the same time. Despite this, the stakeholder said, *"Overall, however, there are many helpful findings in the report...*[35]*."*

Conclusion

The design of the project enabled stakeholder input to the process, enabled public participants to understand the purpose, and the odd oversight on Round Two content, illustrates the impact of omission on the final product.

[35] email to evaluator - 30.1.18

5.3 Fair and balanced

Indicators

- Rationale for managing the split of responsibilities between facilitators - whose role is to manage and protect the integrity of the process, on behalf of participants, and specialists - whose role is to provide technical information on the content of the topic

Aside from the public there were several other roles being fulfilled in the workshops -

- the facilitation team
- recorders
- specialist participants
- observers
- evaluator (at 3 out of 6 events).

The dialogue was designed so that the facilitators could focus on the process, and specialists could present information, both in plenary sessions (in person or via pre-recorded video) and as participants in smaller groups of eight to ten participants. This has the advantage of allowing the public to engage with people who are immersed in the subject being discussed and prevents the facilitator from being caught in discussions of content

The evaluator observed this separation of roles at all three events attended, but also noticed that the specialists also kept their interventions as descriptive, opting not to try and overtly influence public participants to think one way or another.

The preparation of and planning for specialist participation is covered in section 4.9.

Conclusion

There is a clear rationale for the division of responsibilities between participants and facilitators in the dialogue.

5.4 Numbers and types of participants

Indicators

- Detailed profile of the achieved sample (i.e. final numbers and types of participants involved), the extent to which the recruitment specification and target samples were met and the extent to which this was appropriate to the objectives of the project

The expected profile and appropriateness of different participants is set out in 4.7 above. The final numbers reported for each event are -

- London Round One and Two - recruited for 25, got 27. The evaluator noticed a visibly good mix of age, gender and ethnicity.

- Birmingham Round One and Two - recruited for 25, got 27 at event one and 26 at event two, again the evaluator noticed a visibly good range of age, gender and ethnicity.
- Sheffield Round One and Two - recruited for 25, got 27 at event one and 25 at event two. the evaluator was not present at Sheffield events.

Conclusion

The mix of participants was as planned for (see 4.7) and the numbers of participants required was exceeded.

5.5 Respect for participants

Indicators

- Evidence (including from participants) of how respect for participants was demonstrated in the dialogue events
- Evidence (including from participants) of honest and full communications with the public participants throughout the process
- Evidence from participants of satisfaction with the process

At the three events attended by the evaluator, participants were greeted by the local recruiter and then invited to take refreshments before the workshops began. Tea, coffee and non-caffeinated drinks were available with snacks; lunch was provided; and in the longer event there were two breaks.

Both the London venue (Ipsos MORI HQ) and Birmingham venues were light and airy and there was plenty of circulation space. After the first London workshop, feedback on noise levels in the London venue resulted in a wider separation of groups to aid hearing, for Round Two.

At the beginning of each workshop, when participants had been split into groups of eight to ten, all people at the table, including the facilitation team (facilitator and recorder) and specialists were asked to introduce and say something about themselves. The facilitators and specialists treated all the participants inputs with the same level of interest and value, as a couple of public participants said -

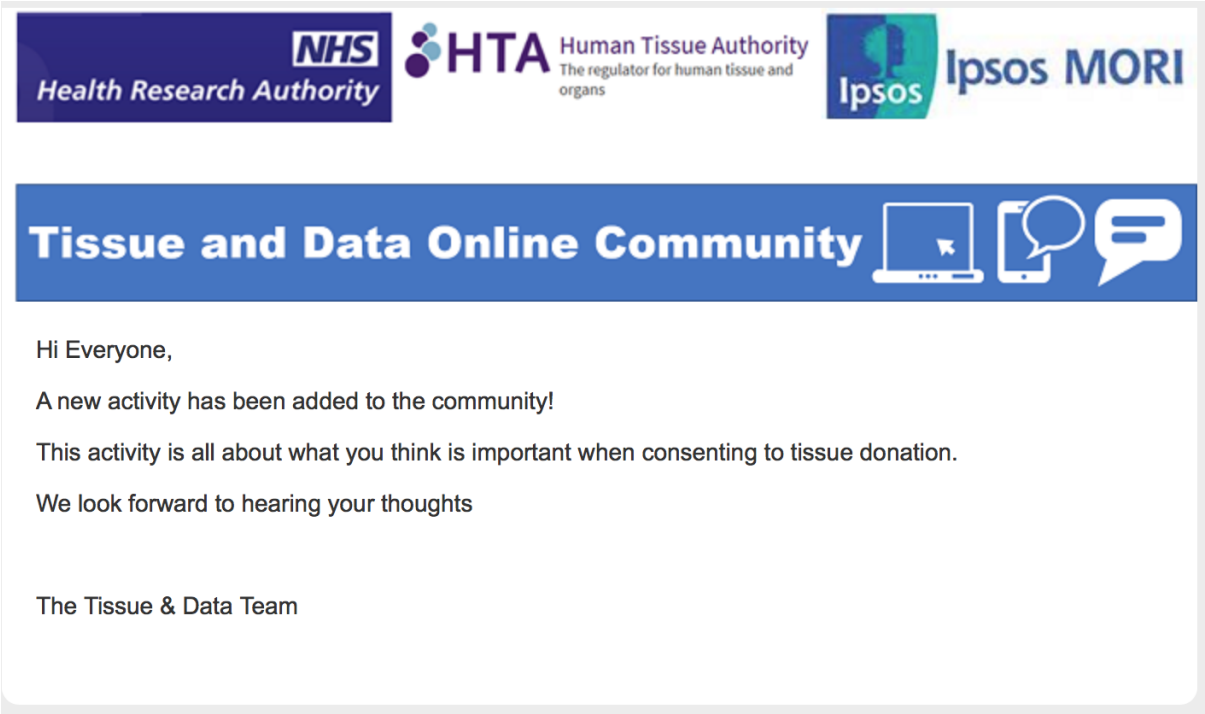
"a relaxed open platform to express your views"

"very good interaction with friendly staff"

The facilitation team was also clear and prompt about paying people their incentives and helping them with transport, if needed. They were also very prompt and helpful at dealing with a participant who fell ill in Birmingham.

Additionally, on the evaluation forms, none of the 78 public participants and 11 specialist participants said they thought they had been disrespected or badly treated in the dialogue.

Public and specialist participants received emails with joining instructions and were prompted about new activity on the online community with regularity, for example with this email from 3/10/17:



Levels of satisfaction reported by participants were consistently high. At each workshop participants (both public and specialist) were asked to complete an evaluation form (see appendix 1).

At Round One the combined scores for the public participants to the question - *How satisfied are you with the level of involvement you had throughout the workshop?* were:

Very satisfied	Fairly satisfied	Not very satisfied	Not at all satisfied
55	21	1	0

Comments included:

"I was very satisfied with how I was involved through the workshop"

"I thought there was a good balance between presentations and interactive activities"

In the *Other comments about this workshop* section, people referred to the knowledge they had gained:

"very informative, enjoyable and thought provoking"

"I found the workshop very beneficial and it has changed some of my opinions"

Some commented on the organisation of the workshops:

"very well conducted"

"well organised, friendly people, very informative"

Some made suggestions for improvements:

"room had no air - too hot"

"I would have liked more involvement in group activities"

And after Round Two the scores were similarly high:

Very satisfied	Fairly satisfied	Not very satisfied	Not at all satisfied
50	14	1	1

The comments were broadly similar to those from Round One. One of the two people who said they were unsatisfied said: "*not really possible as certain people liked to talk*".

Specialist participants were asked "*How satisfied were you with the level of involvement the public participants had throughout the workshop?".* They responded:

	Very satisfied	Fairly satisfied	Not very satisfied	Not at all satisfied
Round 1	9	2	0	0
Round 2	10	0	0	0

Specialists' responses to the question "*How else would you (and/or the public) have liked to have been involved?"* covered having more discussion time and smaller groups.

The evaluator observed high degrees of involvement in discussions. The facilitators encouraged people to speak, allowed conversations to evolve between participants, brought in specialists to clarify issues or talk about their work, and summarised conversations to build understanding of what was being discussed.

In ad-hoc conversations with both specialists and the public in breaks the evaluator got the impression that people were enjoying themselves, learning about the subject and felt that they had the time and space to contribute to the dialogue.

Conclusion

Participant scores and commentary in the evaluation forms after each event and the evaluator's observations, show that the public felt they were respected in how they were cared for (food and venue) and in how they were engaged with by both the facilitation team and the specialist participants.

5.6 Sufficient time

Indicators

- Evidence of and rationale for approach to ensuring there was sufficient time and support for participants to engage in deliberative discussions so that they could become informed about the topics, reflect on their own and others' views, discuss and explore issues in depth with other participants and come to considered conclusions

The evaluation form completed by participants at the end of each workshop asked "*How well were you able to contribute your views during this workshop?* "Three respondents mentioned time:

"time pressure was a factor, but event was well structured"

"more time"

"I think sufficient time was given"

This paucity of comments on time is reflected in the scores to the same question - *How well were you able to contribute your views during this workshop?* - eliciting -

Round One - 75/76 scoring "fairly well" or "very well"
Round Two - 65/65 scoring "fairly well" or "very well".

The process outlined in 5.1 above allowed participants to build up their knowledge on health research, tissue and how it is managed, data collection and usage and the range of issues around this over the two workshops.

This was achieved with a range of different inputs and processes in the workshops, and with the online community (see section 5.12). In Round Two, for example:

- participants discussed issues in groups both in Q&A sessions and between themselves;
- contributed comments and questions in plenary sessions;
- volunteered for vox pops;
- threw ideas into the pot for the improvised theatre;
- critiqued consent forms and information sheets;
- listened to videos and presentations, and;
- talked to specialists both in group sessions and in breaks.

As one public participant commented -

"Very interactive, good use of handouts, videos, comedy guys. Kept us from not becoming disengaged."

The evaluator observed the facilitator be clear about their role when they managed the first table discussion. They described their role as managing discussion and allowing all to speak. They demonstrated this by checking the perspectives of the less vocal participants, allowing participants time to talk between themselves and ask the specialists questions, but also be moved on when the facilitator summarised the discussion so far.

Conclusion

While any dialogue could have more time, participants overwhelmingly said that they were able to contribute their views. The evaluator also observed several conversations between members of the public and between the public and specialist present, in which the facilitator only intervened if they were headed off topic.

5.7 Feedback on facilitators from participants

Indicators

- Evidence (including from participants) that all the participants were able to have their say and that all those who wanted to give their views were encouraged and supported to do so
- Evidence that no single person or view was allowed to dominate and that diversity of views, multiple perspectives and alternative positions were supported in the discussions
- Evidence that the discussions were well structured, open, focused on the key issues, and that all the key issues were covered
- Evidence of attention to details of logistics, timing etc

These indicators are almost entirely dealt with in 5.2 to 5.6 above so this section will share points made by participants on the evaluation form's final question -
Do you have any other comments about this workshop?

From the public -

"very well conducted"

"friendly staff, most helpful"

"I like that the group split to allow more integration"

"very informative, well led and organised"

From specialist participants -

"well run workshop - genuine commitment to involving all participants"

"very well handled, think most people will have left feeling positive"

Conclusion

The evaluator also noted that the ambience of workshops was relaxed and encouraging. Good food and refreshments were provided and venues were comfortable and fit for purpose. A range of views was expressed by different members of the public, there was a high degree of participation and the pace of the workshops kept engagement focused, but not rushed.

5.8 Learning as process develops

Indicators

- Evidence of wash-up sessions after each event to immediately identify what worked well and less well, and what needed to be retained or changed in subsequent events

Wash up meetings were held immediately after each workshop; and issues were further explored in the regular Project Management meetings. As Ipsos MORI said[36] after Round One in London:

> "*I think the changes we've agreed with [the HRA lead] et al will address a lot of everyone's feedback, so we look good for Thursday in Sheffield.*"

Between the first London workshop and the first Sheffield workshop, amendments[37] were made to slides used in the process, as a result of reflections on the first workshop in a Project Management meeting, along with a revised discussion guide and a new activity. But as the HRA Lead said[38], "*I think we still need to be prepared to be flexible but that is fine*", acknowledging a trust in the Ipsos MORI team to make adaptations in the meeting as necessary. And as Ipsos MORI said[39], "*the catch up is happening all the time, rather than just in scheduled weekly calls".*

As a result of reflections from Round One, a revised process for Round Two was produced in late September and exchanges[40] between the HRA and HTA Leads, some of the OG and Ipsos MORI further developed the process.

The evaluator also returned collated participant feedback forms after each workshop (from both public and specialist participants) with comments on how either the participants or evaluator might enhance the process.

Conclusion

[36] email exchange between HRA, HTA, evaluator and IpsosMORI - 27/9/17
[37] Project Mgmt mtg and email exchanges HRA/Ipsos MORI - 27/9/17
[38] email - 28/9/17
[39] email - 3/10/17
[40] emails - 29/9/17 to 4/10/17

The wash up sessions, on conjunction with weekly project planning meetings ensured that learning was absorbed between workshops and the process used was adapted accordingly.

5.9 Recording

Indicators

- Rationale for the approach taken to recording and collecting data from the discussions and conclusions from the dialogue from the deliberative discussions at dialogue events

Ipsos MORI employed audio touch typists (with a minimum of 80wpm), with experience of social research, to record conversations in all the sub-groups at the workshops and in plenary sessions. The typists were briefed beforehand on the context of the work and told that they were expected to record all of the conversations. Additionally, a voice recorder was used to verify and clarify the record during transcription.

The purpose was to ensure a through record for subsequent thematic analysis in the reporting of the dialogue.

Participants were informed of this arrangement at the beginning of each workshop session.

Video and photographs were taken during sessions (participants were given the option to opt out of this) to enhance the understanding of how the process had worked and provide further evidence of discussions. The filmmaker also interviewed volunteers from amongst the participants, about their experience of the dialogue process and what they thought was key for consent and the current system for consent.

Conclusion

There is a clear rationale for the approaches taken to recording the events and the use of the data subsequently.

5.10 Agreement and uncertainty

Indicators

- Evidence of openness about where there was a lack of agreement and there remained plurality of views and how the rationales and implications of diverging views were recorded and reported so that reasons for disagreement were covered as fully as collective statements

In the events it was made clear by the Ipsos MORI team that there wasn't a right answer to discussions. All the public participants observed by the evaluator made at least one contribution to discussions at the workshops and contributions were recorded live by a note taker. In a post dialogue interview, Ipsos MORI said that their considered all the notes in their analysis of data. In their report, Ipsos MORI reflect the plurality of views. Examples of phrases in their report illustrate this include:

- "*Participants conceptualise health research as the...*"
- "*Overall participants thought that...*"
- "*Few participants had any...*"
- "*There was limited knowledge...*".

Section 5.11 below outlines how data was analysed and used. From both observations in the workshops and reading the Ipsos MORI report, the evaluator believes that agreement and uncertainties were both explored and tolerated in the workshops and that differences are indicated in the dialogue report. Ipsos MORI were also requested by the Sciencewise programme to include in their final report observations on the participants' journeys through the process and to provide more examples of where information provided had impacted on participants' views.

Conclusion

The report indicates different levels of support and illustrates the plurality of views on subjects. The process was not designed to seek a single conclusion on topics.

5.11 Reporting

Indicators

- Rationale for approach to analysis of data, and evidence of effective analysis

In conversation with Ipsos MORI[41] they said that they took all the transcripts (see 5.9 for method of recording) and applied a thematic analysis to the dataset. This was then compared to the objectives for the workshops and workshop sessions. The analysis was considered and refined in two internal analysis sessions (one attended by the HRA Lead) and then a report was drafted.

The use of thematic analysis[42] is widespread in the qualitative research community. In their draft report[43] for the OG on 19.1.18, Ipsos MORI point out that:

> "*qualitative research is illustrative, detailed and exploratory. It offers insight into the perceptions, feelings and behaviours of people rather than quantifiable conclusions from a statistically representative sample.*"

[41] follow up call after OG 19.1.18

[42] https://en.wikipedia.org/wiki/Thematic_analysis

[43] January 2018, internal and client use only

They go on to say that while the findings cannot be claimed to be statistically representative, the findings are useful, as they are about participants perceptions.

Conclusion

The approach to the analysis of data and its appropriateness followed good industry practice and the limitations are well framed.

5.12 Online community

Indicators

- Rationale for use and evidence of effectiveness in adding to value of workshops

An online community, called the Tissue and Data Online Community, was set up at the end of September 2107 to provide a forum for further discussion among participants of the issues addressed in the dialogue. The community website had a landing page with links to a blog, chat space, information about the project and spaces to further develop ideas for consent. One of the early posts, “Your thoughts on the first event” attracted 212 views and 31 posts from participants. A forum post on ideas for consent attracted over 500 views and produced 30 comments from participants.

When the online community was closed in October 2017, it had attracted -

	Views	Comments
Blog	154	10
Challenge	320	43
Forum	336	44
Stepboard	1760	803

The log in process and navigation of the site were easy to use and follow. Participants were emailed with notice of new activity on the site; the search function produced quick and clear results, and Ipsos MORI were active in moderating the comments and affirming people's participation.

Involvement by participants in the online community was not required, but an incentive of £20 was given to those who did.

In an interview in January 2018, Ipsos MORI highlighted the value of the online forum in maintaining interest between workshops, reinforcing learning, and further engagement with the themes in the workshops, but it did not impact on the findings of the dialogue. This is because there were no issues raised by the public on the

forum, that were not raised in dialogue workshops. The HRA Lead said she was, "*impressed by the inputs*[44]" from participants.

Conclusion

The online forum extended the engagement of participants and allowed them to see the thoughts of people from other locations. And this is the main benefit, as it did not add to the findings from the dialogue workshops. The online forum was well designed, easy to navigate and actively moderated site. The numbers of views and comments (2570 views and 900 comments) indicate very high levels of take up (51 survey responses and two public posts in a previous HRA dialogue project[45]) and can be considered excellently delivered.

5.13 Lessons

Stakeholder engagement

One stakeholder was not clearly informed about last minute changes to the process for a workshop. This oversight did not become apparent until the initial dialogue report was written, and it had a small, but significant impact on their acceptance of the findings for that particular section of the report.

Workshops

- Make them fun and interactive by using a variety of processes (eg hands on critique of forms, improv theatre, vox pop reflections, presentations, small group discussions, plenary sessions, Video talking heads, pairs discussions, homework).
- Use specialists to participate in the workshops and have conversations with the public.

Online community

- The content needs to be relevant and connected to the workshop content.
- The website needs to be easy to navigate, actively moderated, and publicise new activity, as this brings people in.
- Be clear about the purpose of the online community and how it will add value.
- With the experience of several projects with on-line elements, BEIS and Sciencewise should consider what the benefits to encouraging on-line elements to dialogue projects are; as in this case they provided a good user experience, but added little to the conclusions.

The achievement of the indicators used to assess **Delivery** are **well met**[46], as opposed to *very well met*, as the communication between the delivery contractor and a key stakeholder failed at a critical moment.

[44] follow up interview January 2018

[45] http://webarchive.nationalarchives.gov.uk/20170712122315/http://www.sciencewise-erc.org.uk/cms/assets/Publications/Sciencewise-HRA-dialogue-impacts-March2016.pdf

[46] Definition of assessments - Appendix 4

6. Impact

This chapter looks at how the findings from the dialogue will be disseminated; whether the objectives were met; how credible stakeholders found the project and the projects impacts on guidance and knowledge.

6.1 Dissemination

Indicators

- Evidence of how, where and when the dialogue results were disseminated to those best placed to act on and learn from them
- Evidence of wider dissemination of dialogue results to other interested parties
- Evidence that decision makers trusted the process and products of the dialogue sufficiently to be willing to disseminate the results to their networks

At the time of writing, the evaluator can only report on the intended plans for dissemination. Both the HRA and HTA said, in post dialogue interviews, that they would disseminate the report and their response to it, including to their stakeholders via websites, newsletters (eg the HTA has 7,000 subscribers to its newsletter), stakeholders websites, with reports to their respective Boards, to NHS Involve and to the Association of Medical Research Charities. The HRA also said, resources permitting, that they would invite dialogue participants back for an event on how the results had been used in the future.

Other OG members said that they would post information about the dialogue on their internal websites, disseminate the findings to their research community contacts, hold information sessions with their Boards for consideration, and share the report and its findings with relevant patient fora.

Conclusion

Whilst the evaluator cannot determine how the results have been disseminated, there are clear intentions from both the lead organisations and other stakeholders to use and disseminate the results of the dialogue.

6.2 Achieved purpose

Indicators

- Evidence that the dialogue achieved its original purpose and agreed objectives; evidence of reasons for any changes in objectives

The objectives of the dialogue were -

1. To undertake a dialogue with the public and patients to discuss and explore the issues(aspirations and concerns) around sharing and storing patient data linked to tissue donated for research purposes.
2. To listen and understand public views towards how such issues can be covered in the broad consent process to maintain public trust.
3. To explore public views on the use of electronic dynamic consent for linking patient data on an ongoing basis to donated tissue.
4. To use the results of the dialogue to inform the HRA/HTA's new guidance on sharing donor data in relation to tissue for research.

Interviews with seven OG members, and the HRA and HTA CEOs, for the Baseline Assessment, suggested that all are clear that new HTA/HRA guidance will be produced to inform researchers of consent and the link between tissue and data, as well as how the outputs will impact their own (where they have them) Codes of Practice, and guidance to research ethics and approval committees.

The intention to inform guidance and practice was evident from the final OG meeting on 19.1.18, and from interviews with the HRA Lead and HTA Lead in late January; the latter saying that once the report was in shape and been analysed, it would help "*researchers in consent form design*", and the work of Access Committees among other uses. The HRA Lead was clear that after considering the findings with the HTA, they would embark on a review of guidance for researchers and promote the findings and conclusions of dialogue in a number of fora, including NHS Involve and the Association of Medical Research Charities.

Conclusion

The dialogue objectives of providing a space for the public to consider and share views on the consent process and the link between tissue and data were both achieved after considerable input from the HRA, HTA and OG members. The intention to use the results to inform new guidance is also clear and plans are in place.

6.3 Credibility

Indicators

- Evidence that decision makers trusted the process and products of the dialogue sufficiently to be willing to use the results in decision making
- Results clearly linked to the purposes of the project, and the initiative or policy to which the results were directed

In interviews with the HRA and HTA Leads after the final OG on 19.1.18, both organisations were confident that the results of the dialogue were robust enough to inform their future guidance in this area. The results are clearly aligned to the need for public views on broad, hybrid and dynamic consent. The HRA Lead was clear about how using Sciencewise good practice in designing the project, and having a diverse and supportive OG was instrumental in providing a quality product, as was having a high quality delivery agent in Ipsos MORI.

Other OG members commented on the dialogue, saying that it reinforced their own good practice or gave them additional information to share with people at the point of consent, and the 5 tests[47] that emerged for good consenting process would prove useful in the future.

Conclusion

Both the lead organisations were confident in the results of the process and that they would be used for their original intention - to inform guidance for researchers and others in this field.

6.4 Impacts on guidance/policy

Indicators

- Evidence of how, when, where and by whom the dialogue results had been used in achieving any specific changes to policy decisions or priorities

No specific changes have yet been made to policy or guidance, but as mentioned previously the HRA and HTA are planning this, and have clear intentions to inform future guidance with the results. Specifically, the OG also noted:

- that the broad consent process would be enhanced with concrete examples of how data might be used and use of visual aids;
- the need to let people know about potential users of data, given sensitivity around commercial use, but also to recognise that this is nuanced and not straightforward to explain;
- that the public experience a difference between consent for use of an individual's own tissue or data relevant to their own health care and consent for personal information to be used in wider data sets.

Other OG members also said that the results would be used "*to inform how we educate the public about our work, as we now have a better handle on what public understand and don't understand*[48]."

A benefit that goes beyond the purpose of the dialogue was expressed by on OG member as follows:

"[I'm] *really pleased to see that the public views sampled here were so positive about the potential of genomics...*[49]"

[47] Relate 1) who can have access. 2) what likelihood your information will be used. 3) what the de-identifying process is. 4) examples of how tissue or data might be used. 5) how the donor will be protected.

[48] OG member at OG meeting 19.1.18

[49] email post OG 19.1.18

In the evaluation questionnaires completed at the end of the workshops, public participants and specialist were asked; "*How much impact do you think these activities will have to future policy or Government activity in this area?"*

Members of the public scored -

	A lot or some impact	Not much impact or no impact	I don't know
Round one	66	5	5
Round two	50	10	5

There was no commentary on the forms to suggest why there was a drop in confidence between round one and two; and the evaluator's other data doesn't reveal anything to illustrate why this might be. But despite this variation, public respondents in both rounds had high levels of confidence that the results would have an impact.

Specialist participants scored -

	Some or a lot of impact
Round one	9/10
Round two	11/11

Conclusion

While the evaluator cannot comment on how the results have impacted policy or guidance, it is clear that there are plans in place, and a need to produce revised guidance, which is the premise of the dialogue itself. Additionally, both public and specialist participants in the dialogue have a high degree of confidence in the results being used to inform guidance for researchers.

6.5 Impacts on participants' knowledge and perspectives on public engagement

Indicators

- Evidence of changes to participants' knowledge and thinking about the topic
- Evidence of change to participants' views on public engagement, and their willingness to engage more in future

This section focuses on the impact on participants' knowledge of the subject or of public engagement, and on shifts in their attitude or behaviour towards consent. It

considers the perspectives of the HRA, HTA and Oversight Group, and of public and specialist participants in the dialogue.

Aside from the results of the dialogue on approaches to consent (characterised in other sections), other learning included a developed sense of what genomics and the Genomics Project are. The potential impact of the General Data Protection Regulations[50] (GDPR)[51] was mentioned as topical issues by OG members at the final OG.

OG members either thought that it had not changed their views on public engagement or that it had affirmed its value and provided an insight into what people think. One OG member said they had learnt about the process of engagement and how useful it can be.

Public participants were asked several questions in the end of the workshop evaluation forms[52] about the impact of the dialogue on:

- their learning;
- their views on consent;
- public involvement; and
- their behaviour with regard to their own attitude to giving consent.

In response to the question "*What did you learn as a result of taking part in these activities?",* public participants said they had learned a lot about:

- biobanks (including how they work, their purpose, their importance for research, how samples are managed, how biobanks are funded);
- the link between data and tissue;
- human tissue and its use in research;
- data (how it is collected and used, how it might be misused);
- a range of consent issues (different types of consent, the need to read the T&Cs);
- (data?) governance;
- genomics (the Genome Project, DNA, why it might be useful to map genomes).

In response to the question "*How has taking part changed your views on consent?"* public participant commented that it had extended their thinking and made them more aware of what they might be consenting to; made them consider consent more thoroughly before consenting; and had made them more likely to consent.

In response to the question "*How has taking part changed your views on public involvement in these sorts of issues?"* public participants' comments were very supportive of public involvement. Comments included -

"It hasn't actually changed my views on involvement"

[50] The GDPR replaces the Data Protection Directive 95/46/EC and was designed to harmonize data privacy laws across Europe, to protect and empower all EU citizens data privacy and to reshape the way organizations across the region approach data privacy.

[51] General Data Protection Regulations

[52] compilations of participant responses are available in the Appendices

"having listened to other public opinions, ideas came up that I hadn't considered"

"made me understand how lay representative can enhance research"

"it should be set out a lot more, so the public can be more involved".

In response to the question "*How likely are you to change something as a result of taking part in these activities?"* - public participants' comments ranged from motivations to donate tissue; to make sure they took notice of the information when being asked for consent; to being more positive about giving consent and being more willing to educate friends and family about the issues.

The comments from public participants indicate that they absorbed the information given to them about the range of issues; reflected on the impact this had on their own orientation towards giving consent and valued being involved in helping the HRA and HTA consider next steps.

Specialist participants at the workshops were asked their views on -

- public engagement;
- whether their views on public involvement had changed; and,
- what they might do differently as a result of taking part.

In answer to the question "*What observations do you have about public engagement as a result of taking part in these activities?",* comments include:

On the opportunity for the public to be involved:

"important because quite often the public doesn't have the opportunity to contribute to clinical research"

"people want their voices and stories to be heard. We need to give them space to air these views"

On the value of public involvement in research:

"valuable in terms of planning for the future, addressing concerns before they become obstacles"

"very valuable part of research - no research would be done if we didn't take public opinion with us"

On the process of engagement used:

"important to have a facilitator to keep conversation flowing and topics on track"

"the HRA and Ipsos MORI put on a great public engagement event. The improvised comedy really brought the issue to life"

In answer to the question, ”*How has taking part changed your views on public involvement in these sorts of issues?”,* the value of engagement is illustrated by these selected comments:

"should be done more - not just patient reps"

"a better understanding of how to get broad views and interested in how interested and aware people are"

"definitely - they identified key aspects related to participation in clinical research"

And, in answer to the question “*What you might change as a result of taking part in these activities?”,* specialist participants said:

"provide information internally about the relevance to our policies and governance of what people think about donated samples and data"

"look at the wording of our consent material - particularly around access committees - ensure more information is on our website"

"more likely to question things before making decisions"

Conclusion

There is clear evidence of both learning about the topic and learning about public engagement from both participants and the Oversight Group.

6.6 Lessons

Again there are no new lessons from this project, but it does reinforce good practice, such as:

Establish a clear pathway for influence on policy or guidelines before the dialogue starts with stakeholders. This will help to frame the dialogue, build participant and stakeholder understanding of what is being discussed, and enable the post dialogue implementation of findings.

Identify all stakeholders who need to know the product of the dialogue, and those might be interested, and consider what needs to be communicated to them and what there continuing information needs might be.

The OG (or its equivalent) and senior management need to be involved and supportive of the process from the outset. From policy buy-in, to support for staff project managing dialogue, to the commitment of resources; a wide stakeholder group will help you produce good materials and processes for the dialogue.

The achievement of the indicators used to assess **Impact** are potentially **very well met**[53], as there is clear intention to apply the results to a review of guidance issued by the HRA, HTA and other stakeholders in the field.

[53] Definition of assessments - Appendix 4

7. Overall Lessons

This chapter lists the key points to consider or reinforce in future dialogue projects. Overall, this project was very well run, so the lessons below are not listed because of an absence of these ideas.

Context

There are no lessons as such to be communicated to the HRA and HTA, but their approach to the dialogue -

- building on previous work,
- ensuring a sound understanding of previous work in the field was shared with OG stakeholders,
- senior management buy-in,
- the support of multiple stakeholders on an OG, and
- an ability to clearly articulate the frame of the work

is an example of good practice to be shared with other dialogue projects.

Scope and Design

There are no lessons specifically, but the evaluator recommends that future projects consider these key aspects -

- creating a variety of experiences at workshops - plenary discussions, presentations, videos, group and pairs discussions, Q&A sessions, using case studies and real examples. As these are all critical in keeping people's attention and building understanding of an issue.
- providing plenty of time for the influence of stakeholders on material and process design to be realised. And aligned to this, the lead organisation to create summaries and guidance to stakeholders about the input needed from them.
- specialist involvement in workshops can enhance understanding and bring real examples to workshops. A well briefed specialist will also further illuminate the understanding of the topic in conversations, both formal and informal, with public participants.
- in the design process, proposed activities and materials should be referred back to the objectives and the purpose of the dialogue to ensure the direction of travel is apt.

Delivery

Stakeholder engagement

- One stakeholder was not clearly informed about last minute changes to the process for a workshop. This oversight did not become apparent until the initial dialogue report was written, and it had a small, but significant impact on their acceptance of the findings for that particular section of the report. The

lesson being, check with the potentially affected stakeholder what the ramification of your process amendment might be.

Workshops

- Make them fun and interactive by using a variety of processes (eg hands on critique of forms, improv theatre, vox pop reflections, presentations, small group discussions, plenary sessions, Video talking heads, pairs discussions, homework).
- Use specialists to participate in the workshops and have conversations with the public.

Online community

- The content needs to be relevant and connected to the workshop content.
- The website needs to be easy to navigate, actively moderated, and publicise new activity, as this brings people in.
- Be clear about the purpose of the online community and how it will add value.
- With the experience of several projects with on-line elements, BEIS and Sciencewise should consider what the benefits to encouraging on-line elements to dialogue projects are; as in this case they provided a good user experience, but added little to the conclusions.

Impact

- Establish a clear pathway for influence on policy or guidelines before the dialogue starts with stakeholders. This will help to frame the dialogue, build participant and stakeholder understanding of what is being discussed, and enable the post dialogue implementation of findings.

- Identify all stakeholders who need to know the product of the dialogue, and those might be interested, and consider what needs to be communicated to them and what there continuing information needs might be.

- The OG (or its equivalent) and senior management need to be involved and supportive of the process from the outset. From policy buy-in, to support for staff project managing dialogue, to the commitment of resources; a wide stakeholder group will help you produce good materials and processes for the dialogue.

Appendices

Public feedback on Round 1 of workshops combined across three locations

Public feedback on Round 2 of workshops combined across three locations

Specialist feedback on Round 1 of workshops combined across three locations

Specialist feedback on Round 2 of workshops combined across three locations

Baseline Assessment

Evaluation Activities

Oversight Group - terms of reference

Definition of assessments

HRA/HTA Consent dialogue - evaluation

PUBLIC feedback - Round 1 combined scores and commentary

London (26.9.17), Sheffield (28.9.17), Birmingham (10.10.17) - 78 returns

Note - not every question answered by each respondent. Evaluator comments are mostly descriptive or reflective and not comprehensive at this moment.

Context and scope

1.	*To what extent did you understand the purpose of the workshop?*	I did not understand it at all **0**	I did not understand it very much **3**	I understood it quite well **47**	I understood it completely **27**

Evaluator comment - According to a handful of participants I spoke to in breaks, the recruiter gave a broad outline of the purpose, and participants were taken through several slides at the beginning of the workshop; and reminders of the purpose at the end of workshop 1.

2a.	*To what extent did the workshop cover the topics you were expecting?*	I wasn't sure what to expect **17**	Not at all as expected **5**	Partly as expected **18**	Mostly as expected **32**	Completely as expected **6**

2b. What else (if anything) were you expecting to cover?

Specific ideas of topics
The threats behind using this system linking human tissue to its data
New techniques for medical research etc
Medical products
I thought it included a person chipping as personal identification
How does/can tissue be used for crime prevention?

Curiosity/open minded
Curious to understand what was already in place
Had no prior expectations
No - I came in open minded
Came with an open mind
I attended this workshop with a open mind, but think I have learned completely a lot from this one session.

As expected, no detail
Covered what I expected
I expected to cover less than what we actually covered

Not sure
I wasn't sure what to expect, so various views were interesting
I didn't know what to expect
Wasn't sure what was being covered until I attended
Wasn't really sure what to expect
I did not know much of what to expect

Nothing
Nothing else
Nothing
N/A
Don't know

End of workshop comment
It opened my eyes abit more regarding tissue. And needing funding by researchers regarding biolab.
Wasn't expecting interesting discussions

Evaluator comment - just one commentator identified the key question of tissue and data linkage. Half of all respondents

said it was mostly or completely what they expected; London and Birmingham had the highest numbers reporting "wasn't sure what to expect" or "not at all as expected". One Birmingham participant said she thought it would be about taking part in medical research and was preparing herself to leave the workshop! But...to generalise from the particular would be to miss the bigger picture - just under a quarter weren't sure what to expect, and nearly three-quarters reported it being partly/mostly or completely what they expected.

Delivery

3a.	H*ow satisfied were you with the level of involvement you had throughout this workshop?*	Not at all satisfied	Not very satisfied **1**	Fairly satisfied **21**	Very satisfied **55**

3b. How else you would have liked to have been involved?

Satisfaction
Totally satisfied
I was very vocal I thought
I was very involved
I was very satisfied with how I was involved through this workshop
Can't think of any, all aspect were covered

Process suggestions
Asked more questions. Hopefully will be able to ask more at next sessions.
More quizzes about it
Time to contribute my opinion - tried to talk on several occasions, but other people were giving their opinion
Maybe an experiment/examples

Process reflections
Educational sections outweighed opinion findings sections, but this is probably necessary for the subject matter.
Happy with the facilitator, encouraged everyone's views
I felt there was a good balance between presentations and interactive activities

N/A
None
N/A x4

Evaluator comment - just one person unsatisfied. My observations confirm that all participants were asked both generally (anyone else want to say?) or specifically (X - what do you think?) to contribute in sessions throughout the workshop.

4a.	*How well were you able to contribute your views during this workshop?*	Not at all well	Not very well **1**	Fairly well **27**	Very well **48**

4b. What would have helped you to contribute your views better?

Improvements
Time pressure was a factor, but event was well structured
Maybe be asked a few more direct questions
More leadership from facilitator
Perhaps smaller discussion groups
Ask everyone individually or take turns
More time
More direct questions

Knowledge
Maybe more knowledge
To have known more before session began
Having better understand from the get go
It's difficult to have a real understanding of the process needed and involved
Some information beforehand on the subject of the research

Satisfaction
I think sufficient time was given
Nothing - I was happy with my level of participation

Nothing
Nothing x5
Nothing really
N/A x3

Evaluator comment - just one person being unsatisfied with their ability to contribute their views during the workshop. This may be due to a lack of knowledge or time, as indicated from some of the commentary.

Impacts

5. What did you learn (if anything) as a result of taking part in these activities?

Biobanks - general
What biobanks are for and the future of biobanks; What a biobank is and there purpose; The procedure of biobanks; Mainly how it's collected and the purpose of the Biobanks; Biobanks and HTA – what they are, what they do; What a biobanks is and what it does

About biobanks x2; More about biobanks; About how biobanks work; How biobanks work; How biobanks work; What a biobank means and what it does; I learn a lot about bio; Learnt about biobanks; I've learnt a bit about how biolabs run; About biobanks - wasn't aware before tonight; All about biobanks etc; That biobanks existed; I learnt a lot about biobanks; Biocentres – a new revelation

How important biobanks are; The importance of the biobanks for future research; About biobanks and the work they do and its importance; Biobanks, their importance and how long they have been around

Biobanks and samples
About sample taking and how much goes into it and everything involved in the running of biobanks
What happens to your sample once taken
How biobanks are funded and tissue process
There's a lot of good that can be done by participating and giving tissue

Biobanks - data and tissue link
What biobank is and importance of linking to data
More about research links between data and tissue
Data and tissue is vital in the cure for anything
Understood about the existence of biobanks. What currently happens re: data and material and future challenges for biobanks
Data and tissue donations and procedures
How consent and data is used
Data levels held and required. Use of tissue – what is defined as tissue
What the process are behind tissue research

Several issues
About biobanks, tissue samples, data protection, confidentiality, consent
Everything about biomedicine
Everything I came knowing nothing and I am now quote educated in the subject and would be happy to give my tissue for research
Quite a lot about data, private companies, bio labs
Regulations around consent; the different organisations involved; research funding
A lot around medical research and the considerations and challenges faced

Tissue
More about human tissue
A lot about what happens to the tissue
The processes behind donating tissue and the approach to confidentiality
The tissue donation process and its uses
What happens to our tissue samples
About the human tissue act
About what tissues are and the Human Tissue Act

More about body tissue

Data
How data is collected and stored - complications for tissue sampling
That data will be misused either way, people will always misuse their level of power
That privacy was a concern for most people

Research
Must think about the future more in terms of human research
The need for a better understanding from the public to the organ research

Consent
To take some of the consent I give - read T&Cs more carefully
I learnt a lot about consent and tissue research
I learnt about how consent is needed and reasons why people may or may not want to give consent
I learned that I have probably donated tissue and signed for it without really understanding what I was doing. I now understand how my tissue and data will be used.
Learnt a lot about medical research and access, which I was unaware of before. Never really thought about exactly what you are consenting to before when signing NHS forms
The negative outcomes than can happen once you consent to giving tissue/blood

General
More about the topic
It was very informative, I learned that each person had lots of different views.
Good to listen to other people's views and opinions.
A lot
Lots! Everything - had no previous knowledge
I hadn't thought about it, so found it all interesting
The topics were very informative
I was educated in something I previously had no knowledge of
Quite a bit
Most people think roundabout the same issues
By and large people were like minded

Far too much red tape to go through

Evaluator comment - unsurprisingly a large number of comments on how people have learnt about biobanks and their function. Perhaps surprisingly, far fewer comments about the links between data and tissue.

6. How has taking part changed your views on consent?

More likely to/will now
More likely to consent
Now will consent to tissue being used by biobank
I did not have any views before I came, but I would now give my consent.
I've never known about these, but with info I've seen and heard, I would take part

No change
Would have given consent before, so am convinced.
It hasn't, consent all the way for me.
It has not changed my views. I would still consent on giving my sample
Have always been open to it
Not really, I would of always consent
Still happy to consent, but want safeguards in place to ensure it is used for greater good
Reinforced that I have no issues consenting

It alerted me to various factors, but not changed my view
Not changed my views on consent, but has given me a lot to think about

It hasn't I have very strong views
No change, I always thought it was/is important
It hasn't x3
None; No; Not at all; Not changed ; Not much; Not a lot; Nothing has changed

It hasn't, but I am reassured by the fact that a committee has to approve the use of your tissue and data
It hasn't, but has made me aware of things to consider
I'm laid back anyway, so still laid back
Not changed my views on what I would like to happen

Changed my view
Yes, I think so
I now think consent is vital
I will always read before I sign a document
It has made me go from not wanting to donate to being more open minded
Now more aware of the information required
A bit more
Yes
I am happy to give consent knowing more about medical research
It changed my views positively
I would be more likely to give consent
Made me more comfortable providing consent
Considerably, however there is still an issue of trust
It's opened my eyes more to giving consent
Makes me think before hastily ticking the consent form

Open to different perspectives on consent
Now I have a greater understanding would consider giving consent

Its food for thought, need to think about it, but it was positive
Made me rethink my initial view and understanding of the issue.
Made me realise the importance.
I will now think more carefully about donating tissue
Yes have changed my views
Cancel my agreement
A lot

Uncertainty
I am still unsure
Maybe
Suppose, was open to it anyway
Too early
Yet to confirm my exact view

General
Much more care is needed, but consent is important for developments in health research
Open discussions with others

Because it will be anon
Knowing once I have given my consent I am non-identifiable
So far so good I learnt about what happens to tissue
Ok if data is properly protected and used
Gives me more security of how my data is kept, as well as how much of the data is released

People have more concerns around consent than I would have expected
Allowed to take others views on board and some issues that I didn't consider
Increased considerations about implications, trust, mgt of data, check/balances, safeguards and importance
That it is a key point! That its needed or medical research...without it, could be useless.

I did not have a view beforehand
Interesting for future

Evaluator comment - a spread of responses, perhaps reinforcing the general approach of being non-partisan about the outcome of the workshops.

7. How has taking part changed your views on public involvement in these sorts of issues, if at all?

General
Realised the importance

Awareness
Should be more to help companies understand

Involve the public!
The public must always be consulted so we are to get a balanced view.
I think public involvement is extremely important
The public should be more involved if it's going to a good cause
Necessary part of developing the use of data to have understanding of public
Confirmed importance of public involvement
At least they listen to us!
No, I think it is very important for public to be aware for this
We need to be more involved in research and to be given more information
It needs more public involvement about these issues
It needs to be increased and more awareness needed
I agree public involvement is crucial
It's good to seek public views and question processes to keep checks and balances
Highlighted importance of these events
I think it was very important that people understand how their tissue and data might be used
Think biobank and research needs more publicity on the benefits of research
Education is needed to general public
I think there needs to be more info for people to consent
People don't know all the info. If they were better informed I think more people would donate.
Good to know people are asked their opinions and views.

Yes - changed
A lot; Quite a lot; Heightened; Changed my view in a good way
Yes; Yes it has changed; Given me so much to think about

Personal impact
I totally understand that the public are a very mixed bag
It was interesting to hear other opinions
I'm more widely informed now - and can see some people's worry over being 'identified' could hamper progress in research
Aware of different views
Surprised at the level of concern around consent
Broader perspective; Being given more info
I feel I have a much clearer understanding
It's made things clearer on body tissue
More interested in finding out more
I need more time to consider
I will research myself more and decide whether involvement is required
Would like to get involved more

No - not changed
Not much; Not really; Views still the same; No; Same as before; Not at all x2; Not so far; Not a lot; Nothing has changed; n/a; Hasn't

Miscellany
I think biobanks are restricted by out of date legislation
Consensus is not always good to achieve success in biobank supplies

Evaluator comment - a fairly strong response, from those who commented, that public involvement is a good thing; and a smaller current of comments on how involvement has been interesting and informative.

8a.	*How likely are you to change something you do as a result of taking part in these activities?*	Not at all likely **9**	Not very likely **24**	Fairly likely **31**	Very likely **11**

8b. Please explain what you will do differently (if anything):

Donate sample/take part

Donate
Consider donations
Maybe donate more; Likely to donate

Giving more blood; Give more blood
I might give blood!

Have a tissue sample taken
If asked, will gladly donate samples
I would have a bio
I would be open to give samples to biobanks
I will definitely donate tissue, give consent!
I will be giving consent to having samples taken
Apply to contribute to research
I would like to donate my tissue for research
Take part

Consent
Research more about what I am consenting to
Read consent forms more carefully and perhaps question how data will be used in future
Read the consent form thoroughly
The explanations given would mean giving consent would be easier
I will be more open to give consent
Consent to use of data if used properly
Give consent where possible
Give more consideration when donating

Research
Look into the issue more - research issue and take more time in making a definite decision.
I already ensure I research organisations etc
I know more about the research
To do more personal research; Research more on topic in question
Because to be more informed gives you a better understanding of what occurs
More you know about certain subject, better equipped you are to act appropriately
I will take a look at information available via the net
Have more questions

Spread the word
Find out how I can help spread the word; Tell people about biobanks

Data
I am more receptable to the idea of giving my personal data

No change
Won't do anything differently
Nothing x3

Evaluator comment - the question is asked, not because there is an assumption that people will change their behaviour, but to understand that if they do change; what that change is. Just over half of the respondents say that they are likely to do something different and of those that commented, that they will donate, research and think through consent more thoroughly.

9.	*How much impact do you think these activities will have to future policy or Government activity in this area?*	No impact	Not much impact **5**	Some impact **32**	A lot of impact **34**	I don't know **5**

Evaluator comment - a high degree of confidence that these workshops will have some impact on policy. Although 10/76 either said it wouldn't have much impact or they didn't know; suggesting a mix of cynicism (reflected in one comment under Q10) or that the message that the outputs from the workshop process would be feeding into consent guidelines for researchers wasn't received clearly.

10. Do you have any other comments about this workshop?

Impact on practice
The Government don't listen very well to anything.
I think it will impact the Government as they will have a better view of what the public think
If implemented, research enhances

Information and learning
I enjoyed listening and learning.
Very interesting and informative
Has definitely opened my eyes
Very interesting and positive to learn other views from diverse backgrounds
Very good information
It was beneficial and informative
It was very informative
Still quite vague so looking forward to more information
Very informative, enjoyable and thought provoking
I found the workshop very beneficial and it has changed some of my opinions
Very informative
I think it very good and keep people informed
Very enjoyable, well led

I have learned a lot about data and consent issues

Enjoyed it
Very well conducted
Excellent
Very well run despite technical issues
Well organised, very friendly people running it, welcoming
Well organised, friendly people, very informative
Friendly staff, most helpful
Interesting, well ran!
Great time look forward to the next
Looking forward to the next one.
I enjoyed it

Process issues
Room had no air - too hot
The specialist should have a greater impact on the presentations
I like that the group is split allowing more integration
I would have liked more involvement in group activities
More direct

No
No x8
n/a
Evaluator comment - a high degree of enjoyment and appreciation of the process and team.

HRA/HTA Consent dialogue - evaluation

PUBLIC feedback - round 2

London (7.10.17), Sheffield (14.10.17), Birmingham (21.10.17)

66 participants returned forms.
Note - not all questions were answered.

Context and scope

1.	*To what extent did you understand the purpose of the workshop?*	I did not understand it at all **1**	I did not understand it very much **1**	I understood it quite well **33**	I understood it completely **31**

Evaluator comment - from Round one, a slight shift towards more understanding of the purpose. 64 out of 66 is a very good indication of the fact that the purpose was understood.

2a.	*To what extent did the workshop cover the topics you were expecting?*	I wasn't sure what to expect **9**	Not at all as expected **2**	Partly as expected **9**	Mostly as expected **24**	Completely as expected **21**

2b. What else (if anything) were you expecting to cover?

Covered more
Covered more than expected
It covered more than expected and opened my eyes to a more globalistic approach from donor to providing to additional sectors etc
More than what I thought was covered

Specific issues
Maybe more detail of how tissue is used.
More on the pros and cons of linking data to tissue samples
Commercial element
Being asked to provide a sample

Different to what expected
Thought it would take a similar approach to last session and talk in detail about what should be in and out of information/consent - more high level approach this session.

Made clear
The preamble was fairly vague, but it was made clear very early in the first session

Didn't know
As I wasn't sure what to expect it was a surprise it was about biobanks. I thought it was about health.
I didn't know what to expect
I don't know what I expected. I've never heard of biobanks before.

All covered
I can't think of anything else it needed to cover
All issues covered extensively
N/a x4; Nothing else; Nothing; don't know; not much more

Evaluator comment - big reduction in those not knowing what to expect. Like round 1, just one commentator referring to the data and tissue link.

Delivery

3a.	*How satisfied were you with the level of involvement you had throughout this workshop?*	Not at all satisfied **1**	Not very satisfied **1**	Fairly satisfied **14**	Very satisfied **50**

3b. How else you would have liked to have been involved?

Satisfied
Happy with amount of involvement
I was happy with my level of involvement
No other way, I was always involved.
Involved enough
I think the whole group was very involved
Did my best
It was OK for me
I was able to contribute very well

Process comment
Very interactive, good use of handouts, videos, comedy guys. Kept us from not becoming disengaged.
Groups easy to work with an non-judgemental

Unsatisfied
Not really possible as certain people liked to talk

n/a x5; nothing; not much more

Evaluator comment - very similar scores to round 1.

4a.	*How well were you able to contribute your views during this workshop?*	Not at all well	Not very well	Fairly well **18**	Very well **47**

4b. What would have helped you to contribute your views better?

Satisfied
Happy with contribution
Loved it
Nothing - I'm quite vocal anyway, he ha ha.

Managing people
Some people are good at sharing opinions. Others could have been asked more frequently to enable a more even spread of opinion.
n/a - I felt everyone had equal opportunity to contribute
Give everyone turns (asking)
Facilitator did well to make sure everyone contributed.
I didn't always know what to say different.

Process comments
Maybe smaller tables (groups) but overall felt good discussing
Maybe answered more questions on paper.
Nothing, the researchers were helpful with sharing an understanding.

Pre-workshop info
More prior knowledge of subject beforehand

Materials
All the leaflets were of great help

not much more; Nothing; N/A

Evaluator comment - all scoring 'fairly well' or 'very well'. In percentage terms 'Very well' improving from 63% to 72% from round 1 to round 2.

Impacts

5. What did you learn (if anything) as a result of taking part in these activities?

General
How far this area goes and how many implications there potentially are for something I may view as being quite small and unimportant
I learnt alot about how everything works.
That no matter what agencies are involved the purpose is to improve medical problems
The whole subject

Biobanks - general
More about what happen with your information with regards to biobanks
The amount of research that goes into biobank and what would happen if research stopped
That biobanks are hugely important in advancement of medical research. It is imperative that data is managed properly.
What a biobank is and does!!
The existence of biobanks! The process involved in gathering, storing and using human tissue.
More about biobanks and what is involved.
What biobanks are for, positives, negatives.
About biobanking
Biobanks
How biobanks work

Biobanks, genomes, consent
I learnt a lot about biobanks, genomes and a lot of info on consent and levels of consent
I came knowing nothing regarding biobanks, tissue samples ect. I now understand the importance of the research and the outcome.
About biobanks, geometrics, consent and wider issues.
I learned a lot about how tissue and genome data is collected, stored and used other people's views on it and the possible risks involved.
I now have knowledge of genomics and biobanks that I didn't have before.
More awareness about genomics and biobanks
Biobank/geo
The nature and process behind storing and monitoring tissue samples.
Learned about biobanks and consent process for tissue donation.
Tissue donation and kind of consent needed.
Lots about HTA and HRA and what is a BioBank, and loads around issues with consent

Data
About data sharing
Security, transparency and data protection.

Structures
Learnt about committees and regulators to protect data.
More about company eg medicom, Gentic, MITC
I learnt alot about the Medicom and Genomic Company

Personal action
I learnt that I would take part in biobanks, whereas I wouldn't have before
That I would in future donate tissue, that I want to educate people to do the same.

Genomics
I've learnt about genomics, the process of what and how information is stored
The opportunities of the DNA - what could be done with them
About genomes and how genetics can be used for relatives of someone suffering a disease.
Learnt about the Genome Project.
Genomics - I didn't have a clue about this.
Genomes - very interesting.
Geo/DNA
More about genomes
Genomes x2
Learnt about the Genome project. I did not know anything about it.
About genomics
Learn about genomics and cells
I had a greater insight into genome application
Gained more information about the genome project.

Consent
More around the law, structure of policy and the scale that goes into consent forms
I learnt a lots about consent forms
The importance of consent, who/what companies can get your data for financial profit
The intricacies around giving informed consent
The levels of confidentiality
Consent forms and process
The pros and cons of consenting and giving your tissue sample

Research
How important research is
The importance of being involved in research. The need for people to contribute to sustain biobanks.
I had no knowledge of this topic beforehand and so this has educated me about medical research.

Donation and tissue
I learnt a lot about what donating tissue can help with medically
Learnt how important tissue samples were to future cures
The complicated nature of tissue and data donation and the range of reasons why people are for or against

Evaluator comment - good to see commentators referring to the range of information that was shared with them; and how consent, biobanks and research are linked.

6. How has taking part changed your views on consent?

Extended my thinking
There is a lot more to think about than just Yes or No
It has opened my eyes
Make me aware
It has made me more aware
Yes more information is always good for making an informal decision
Will be consent in future, but after being well informed
Gave me a better insight into what giving consent entailed
It has given me more confidence and less paranoia about the subject
Not changed, but enhanced my awareness
Has given me a broader view/knowledge
It gives me a broader vision of what are done with gnomes and my rights.
I've become more knowledgeable about where tissues etc go
It shows all the considerations needed.
Its made me realise things need to be outlined to understand.

Specific learning
Learning how your information is used/stored etc
A need for more public information

Research
Made me realise the importance of research for future generations

Consider what I'm consenting to
It's really made me think of reading consent terms and understanding before you sign
Hasn't just made me think more. Ensure I'm happy with wording etc and ask questions
It is very important to understand what you are consenting to and not be flippant when signing
Being given information on what actual takes place
The info I received made it easier to understand and consent
I will read and fully understand consent forms before signing rather than skimming. I would have always participated in medical research however, I am now more aware in this area.

Changed my mind
It's changed my mind about signing consent forms
I would consent now without much hesitation as taking part has greatly improved my understanding
More comfortable than first session.
Massively, I really feel I want to help, if and when the time comes.

I would definitely consent.

Yes x4
I have gone from being against consenting to wanting to take part
In a positive way
Extremely, Quite a lot,

Methods of consent taking
Currently consent is outdated/not in plain English. Needs different methods apps/internet

No change
Unchanged
I would still give my consent, but think it is important to be asked.
Not changed.
No still happy to consent, if not more happy knowing the committee is there to protect data.
No - I would consent.
Not - just don't sell the NHS off.
My views remain the same to giving consent
No, I would have been happy to give consent both after and before this event
It has not. If asked I would have and still would.
No. I would give my consent to all parts.
Hasn't
Not really
Not at all, No x2, No change, Not

Not too much.

Uncertain
Not sure
I was for it, but now unsure

Evaluator comment - the range of commentary indicates that participants have considered their position, absorbed information and made a decision (mainly) about their view on consent.

7. How has taking part changed your views on public involvement in these sorts of issues, if at all?

Unchanged/a little
Unchanged
It hasn't actual changed my views on involvement, cause if interested will state my views.
It hasn't, None, No x2
N/a = read the small print, N/a
Not too much, A little

Personal reflection
I like debating, always have, so not greatly
Having listened to other public opinions, ideas came up that I hadn't considered
I have realised that some people are more paranoid than others in regards to divulging information about themselves
Reassuring to hear different views and opinions
I was surprised by other people's concerns about consent.

Public influence
Made me understand how lay representative can enhance research
It is vital that public are involved so that they can affect change

Import
It's as important as organ donation
The public needs to be made aware of biobanks.
Different perspectives give better understanding.
That public involvement is necessary. Everyone has different views.
People aren't aware enough.
The public need more information on this issue
It should be set out there a lot more, so the public can be more involved, as I think a lot of people want to take part, but are not aware of such thing
Would like to do more

Should be more
Very pro increasing public/patient participation and involvement. Impact and decision making at all levels.
No, I think public should be involved
It's good our views are listened to
I know public involvement contributed
Needs to have a lot more involvement and awareness from the public.
The public needs to be more informed and more involved as the research could benefit younger generations ie our children's siblings ect.
More involvement of public the better
the public needs to be made more aware of how health research happens and where things come from
It is a good thing.
I think it is really important and valuable.
Very good to have involvement.
Very important.
I think it is really important. The vast majority of people want to help, but really like to be educated about these issues.
Raising awareness is more likely to make people want to contribute.
It think it's good to engage the public on these issues as it affects them and encourages them to take part.

Evaluator comment - little change from round 1, commentators think, broadly, that it's important to engage the public.

8a.	*How likely are you to change something you do as a result of taking part in these activities?*	Not at all likely **8**	Not very likely **20**	Fairly likely **21**	Very likely **15**

8b. Please explain what you will do differently (if anything):

Donate
Consider tissue donation
Getting in touch with my doctor about donation
Likely to find research to participate in and register as a blood donor.
Get involved in research.
Would consent to this now.

No change
Not do anything differently
I already would have consented, but now I am even more convinced its the right thing to do. Always read the small print though.
I already consent to having samples taken
I will still be very happy to giving a sample
I would have always consented, but I'm just now more aware.

Gather information
Ensure that I research the organisation fully to make sure I'm happy
I would take more notice of info
I would read information given more in depth and not make rash decisions when giving consent
More research
Read it all
Try to find out what research programme
I would research more.

Personal
Be more positive
I would be more willing because of information received
Will be more open on data sharing
Give things a chance.
Eat healthier
Profit companies put me off.

Engage
Get involved if asked
Be more willing to be involved in any studies

Share my findings/understanding of the subject.
I would educate friends and family members.
Make people aware of genomics.

Evaluator comment - again fairly similar scores and comments to those made in round 1.

9.	*How much impact do you think these activities will have to future policy or Government activity in this area?*	No impact **3**	Not much impact **7**	Some impact **21**	A lot of impact **29**	I don't know **5**

Evaluator comment - a shift, in percentage terms, from round 1 to 2 (6% to 17%) towards the idea that there will be 'no impact' or 'not much impact'. But it is not evident from the collected comments why this might be.

10. Do you have any other comments about this workshop?

Informative and enjoyable
Very informative
Excellent, very informative
Extremely informative and interesting
Very informative, well organised and nice people
Very informative and enjoyable
Thoroughly enjoyed
Well conducted and informative
Very interesting, well delivered
I thought today was great and has really opened my eyes and made me think about the process in greater detail.
I really enjoyed the whole experience.
Enjoyed learning and hopefully making a difference, even if this is small.
Really informative, enjoyed the session
Very informative
Very informative and enjoyable
More practical and clearer understanding
Enjoyable
Interesting

Well run
The workshop was organised very efficiently
Very well run and information provided was relevant and current
Very well ran, a relaxed open platform to express your views
Very informative, well led and organised. I appreciated the contribution of all the experts.
Very good interaction with friendly staff

Experts
It was really interesting to hear the experts views.
The experts were really helpful.

Outcomes
I hope your discussions are useful and used!
Very informative should be made public in terms of sharing information.
The government will change soon.

Process
A bit too long
Very important, but day 2 was very repetitive.
I think we should have watched the video on the first day
It was nice to learn, meet new people and I really enjoyed the comedy.
Good to involve general public. Communication views and opinion.
Facilitator was very distracted at times and didn't seem to direct group
Could be a little less constrained

Website wasn't very easy to follow

HRA/HTA Consent dialogue - evaluation

SPECIALIST feedback - Round 1 combined scores and commentary

London (26.9.17), Sheffield (28.9.17), Birmingham (10.10.17) - 10 returns

Note - not every question answered by each respondent. Evaluator comments are mostly descriptive or reflective and not comprehensive at this moment.

Context and scope

1.	*To what extent did you understand the purpose of the workshop?*	I did not understand it at all	I did not understand it very much	I understood it quite well **1**	I understood it completely **9**

2a.	*To what extent did the workshop cover the topics you were expecting?*	I wasn't sure what to expect	Not at all as expected	Partly as expected	Mostly as expected **6**	Completely as expected **4**

2b. What else (if anything) were you expecting to cover?

- Potentially more concrete examples of the linkage between tissue and data
- Risks and benefits
- Use of tissue in animal experiments
- Have not yet explored genomic data to any extent

Delivery

3a.	*How satisfied were you with the level of involvement the public participants had throughout this workshop?*	Not at all satisfied	Not very satisfied	Fairly satisfied	Very satisfied **10**

3b. How else would you (and/or the public) have liked to have been involved in the workshop?

- More discussion time perhaps
- Perhaps the 'experts' could help design the questions

4a.	*How well do you think the public were able to contribute their views during this workshop?*	Not at all well	Not very well	Fairly well **2**	Very well **8**

4b. What would have helped them to contribute their views better?

- Tighter focus at the start - we wandered off topic quite a lot which limited useful discussion time
- Maybe pick on quiet participants
- Anonymous e-polling during the Qs
- Happy with what was provided

Impacts

5. What observations do you have about public engagement as a result of taking part in these activities?

- People want their voices and stories to be heard. We need to give them the space to air these views.
- It is important to know how to keep steering things to the key points.
- Interested in learning.
- Valuable exercise
- I was very impressed by how insightful the participants were.
- It's important to advertise what biobanks are
- Very valuable part of research - no research would be done if we didn't take public opinion with us
- I thought it was excellent

6. What were the key parts of the workshop that helped the public develop their views on consent?

- Early bit - might be good to show examples of consent forms?
- Didn't really go into detail about consent very much - more about risks and safeguards.
- The presentations, but also discussion with other participants and their experiences.
- The scenarios
- Informative videos by experts. Very understandable presentations on identifiable data and safeguards.
- Data - potential uses and spread
- Interaction
- The videos and group discussion

7. How has taking part changed your views on public involvement in these sorts of issues, if at all?

- Should be done more - not just patient reps.
- Reiterated the value of hearing a range of views.
- A better understanding of how to get broad views and interested in how interested and aware people are.
- No - strong believer in PPE
- Open eyes to other opinion

- May participate again
- Acceptance of biobanks and data use was more prevalent and less critical than expected

8a.	*How likely are you to change something you do as a result of taking part in these activities?*	Not at all likely **2**	Not very likely **4**	Fairly likely **4**	Very likely

8b. Please explain what you will do differently (if anything):

- Be more sure of what people really think about issues related to my job and share with colleagues.

9.	*How much impact do you think these activities will have to future policy or Government activity in this area?*	No impact	Not much impact **1**	Some impact **6**	A lot of impact **3**	I don't know

10. Do you have any other comments about this workshop?

- Might need to refocus initial intro so we can get to the core issues more quickly
- Opting out post consent! Need to be referenced?
- Very reassuring!
- Well run workshop - genuine commitment to involving all participants

Evaluator comment - positive feedback with some useful process suggestions and affirmations of public involvement.

HRA/HTA Consent dialogue - evaluation

SPECIALIST feedback - Round 2 combined scores and commentary

London (07.10.17), Sheffield (14.10.17), Birmingham (21.10.17) - 11 returns

Context and scope

1.	*To what extent did you understand the purpose of the workshop?*	I did not understand it at all	I did not understand it very much **1**	I understood it quite well **1**	I understood it completely **9**

2a.	*To what extent did the workshop cover the topics you were expecting?*	I wasn't sure what to expect **1**	Not at all as expected	Partly as expected	Mostly as expected **6**	Completely as expected **4**

2b. What else (if anything) were you expecting to cover?

- More on consent in terms of data and linking
- Sometimes the facilitator didn't focus as much as I thought they would on the data linkage issue.
- Did not look at the consequences of dynamic consent to the research sector. Participants would need to update contact details etc
- I wasn't sure what to expect. it was probably more related to participation in general rather than 'Tissue' - good!

Evaluator comment - the extra expert completing an evaluation form indicates that they did not really know what they were coming to.

Delivery

3a.	*How satisfied were you with the level of involvement the public participants had throughout this workshop?*	Not at all satisfied	Not very satisfied	Fairly satisfied **2**	Very satisfied **9**

3b. How else would you (and/or the public) have liked to have been involved in the workshop?

- Smaller groups with more specialists
- Great conversations that everyone joined in
- Chance to answer some concerns after discussion - hard to achieve though!
- Perhaps a few 'straw polls' of questions

4a.	*How well do you think the public were able to contribute their views during this workshop?*	Not at all well	Not very well	Fairly well **1**	Very well **10**

4b. What would have helped them to contribute their views better?

- More material to be used
- It was interesting to see how quickly people were developing their knowledge on tissue donation for research

Impacts

5. What observations do you have about public engagement, as a result of taking part in these activities?

- Important because quite often the public doesn't have the opportunity to contribute to clinical research
- Really useful in understanding the reality of what is assumed people will think
- Require more education about consent and activities in the public area
- Valuable in terms of planning for the future, addressing concerns before they became obstacles
- Very important. Views very clear and a lot of consensus - generally I think we worry too much?
- Very necessary

- Important to have a facilitator to keep conversation flowing and topics on track.
- Knowledge changes opinions
- The HRA and Ipsos MORI put on a great public engagement event. The improvised comedy really brought the issue to life.

6. What were the key parts of the workshop that helped the public develop their views on consent?

- The implications on engaging in health research, such as data protection, participation in commercial research, insurance etc
- Videos and examples
- Examples were required a lot of the time to aid understanding of concepts and questions asked.
- Excellent facilitation
- Information
- Presentations and videos. Genomics England.
- Discussion among selves and input from experts to maintain interest.
- Round table discussions, listening to different viewpoints from generalisation/personal experience
- Seeing forms; explanations; videos
- Varied video topics followed by roundtable discussions
- Understand how biobanks work

7. How has taking part changed your views on public involvement in these sorts of issues, if at all?

- Definitely - they identified key aspects related to participation in clinical research
- Engage the public more
- Fine balance sharing the right information and getting relevant views and keeping on track
- People were not aware of issues however were generally interested.
- Very positive
- PI is essentially imagining yourself as a participant.
- No change
- Always been a fan
- Not really - it has shown that I'm thinking in the right directions - now all I need is the money to do some of it!

8a.	*How likely are you to change something you do as a result of taking part in these activities?*	Not at all likely **1**	Not very likely **2**	Fairly likely **6**	Very likely **2**

8b. Please explain what you will do differently (if anything):

- There is too much information to take in. the activities should have been split into at least three sessions.
- Provide information internally about the relevance to our policies and governance of what people think about donated samples and data
- We have dipped our toes in engaging public and will continue with this in some earnest
- Look at wording of our consent material - particularly around access committees - ensure more info is on our website
- More likely to question things before making decisions
- But it gives me the evidence to argue for the resources?
- Not anything I can change, but learned a lot about public awareness, concerns and understanding.
- Increased knowledge leads to different actions.
- Academic

Evaluator comment - more comments here than in round 1 about impact of the workshops on people's work.

9.	*How much impact do you think these activities will have to future policy or Government activity in this area?*	No impact	Not much impact	Some impact **7**	A lot of impact **4**	I don't know

10. Do you have any other comments about this workshop?

- It's definitely helped raising people's awareness of the significance of clinical research in the UK
- Would have been better with more biobank experts present
- Very well handled, think most people will have left feeling positive
- Might have been good to get them to design a consent form?

- The HTA and HRA would be well advised to repeat this periodically
- I was surprised no one mentioned participant expenses. Is this assumed? Or not important?

Baseline Assessment

HRA/HTA Consent to link tissue with data - public dialogue

August 2017

Introduction

This assessment uses the product of seven interviews with members of the Oversight Group (OG) and the Health Research Authority's CEO. An interview with the Human Tissue Authority CEO is taking place after this report is published, but will form part of the evaluator's analysis at the end of the project. The assessment is also informed by attendance at an OG meeting, Project Management Meetings and a review of the email traffic between the contractor, Ipsos MORI and the OG.

It is a reflection of the aspirations of those interviewed. Questions were framed with reference to the Sciencewise Quality Framework[54]. The evaluator will consider these responses in their final analysis.

And readers should note that responses are not weighted - this is a reflection of the plurality of views from the OG members interviewed - and the evaluator's interpretation of what they should pay attention to in the final analysis.

Governance

Role of the OG and its members

The Terms of Reference (ToR)[55] for the OG says that it will comment on the questions being asked of the public; the materials to be used in the workshops; how to communicate issues and consideration of the findings of the workshops. In addition the OG will act impartially, support the HRA and HTA in this process and provide an ambassadorial function.

Oversight Group members understood this to mean that they would consider and feed into materials and ensure that the dialogue process was asking the right questions. And that this might mean a review after the first workshop. A couple of OG members thought that they were being asked for more input than they expected, but did not resent this.

They also thought that they were on the OG to provide specialist knowledge - in law, data protection, privacy, research ethics, practitioner experience, regulatory experience, being managers of researchers, or the funder of researchers - so that the OG would get broad input from this variety of sources and enable a balanced dialogue.

[54] http://www.sciencewise-erc.org.uk/cms/quality-in-public-dialogue-a-framework-for-assessing-the-quality-of-public-dialogue

[55] Oversight Group Terms of Reference - HRA - 25.5.17

A smaller Project Management Group (comprising HRA/HTA and Ipsos MORI) was set up to sign off materials.

Role in consideration of findings
OG members were clear about their role in the joint consideration of findings, but also saw the need to mold them for their own uses (eg MRC, UK CRC, Genomics England guidance to researchers or ethics committees). They also saw a role in making the findings useable for researchers and understandable by the public.

OG members saw a role in assessing the credibility of the dialogue process used, but have faith in Ipsos MORI's track record.

Decisions about recommendations for guidance
The OG were clear on the HRA/HTA role in producing guidance as a result of the dialogue, but as above, saw a role for themselves in informing the HRA and HTA about what is useful and how it is conveyed or used.

Initial observations
There is a common understanding of the role of the OG; disparate organisational responsibilities and the need to collaborate in producing meaningful, understandable and useful guidance.

Key themes to consider in the final evaluation report
- Satisfaction with involvement in the final process design and materials.
- Broad enough input across interests and specialisms.
- Satisfaction with input into conclusions from dialogue that feed into guidance (HRA/HTA or organisation specific).

Scope, design and delivery

Scope of the dialogue
The following[56] purpose and objectives of the dialogue is taken from the HRA/HTA Business Case to Sciencewise -

To engage the public and patients in a dialogue to gain a greater understanding of public/patients views on the consent required for sharing patient data alongside tissue for research, to inform the development of a new joint HRA/ HTA guidance on data derived from tissue and consent for sharing patient data with tissue for research which maintains public trust.
. This would include:
- *considering what elements should be included in the broad consent process*

[56] from HRA/HTA Business Case to Sciencewise 2017

- *what needs to be in place (accompanying information, assurances etc.) in order to make those donating tissue and sharing their data feel comfortable with that decision.*
- *exploring electronic dynamic consent for linking patient data to tissue on an ongoing basis.*

Objective 1 - To undertake a dialogue with the public and patients to discuss and explore the issues (aspirations and concerns) around sharing and storing patient data linked to tissue donated for research purposes.
Objective 2 - To listen and understand public views towards how such issues can be covered in the broad consent process to maintain public trust.
Objective 3 - To explore public views on the use of electronic dynamic consent for linking patient data on an ongoing basis to donated tissue.

All the interviewees understood how these objectives would be useful for researchers; both in understanding the public's views on consent and data usage, but also in having clearer guidance for tissue and data use (when linked) and informing their own Codes of Practice, guidance or frames of reference.

Design and delivery of dialogue
OG members were keen to see -

- a broad representation of the public in the workshops. They were confident about the sampling approach and had a good understanding of qualitative approaches.
- how patient views would be considered. Although there was also an appreciation that patient views might be a separate strand of influence alongside feedback from researchers and organisations.
- practitioners sharing their work with the public in the dialogue sessions
- how the public were educated in consent processes and research (eg how consent is sought, different uses, the law); how data is used, both now and into future, and on both a mass and individual scale.
- whether the public expressed a community or solidarity aspect on the use of data.
- how people responded to different methods of educating and engagement methods being used including discussion, presentation, and types of group work
- how the public were informed about the security of data; its regulatory framework; governance; who has access; how access to data works; and how data is kept safe.
- how perspectives on seeking consent face to face or on-line were addressed; and how the risks and benefits of each approach were considered.
- why there might be a difference in opinion between consent to use tissue and consent to use data; how might concerns about data vary with concerns about tissue use?
- tracking of public opinion across dialogue; how it changed and what affected this?
- how the on-line element works

Outputs of dialogue

OG members wanted to understand the difference between patient views and public; as they already know a lot about patient views. The dialogue was relatively novel for many OG members organisations.

The dialogue would also provide ideas for communicating issues of consent to public, because they will have seen what works and doesn't.

The public responses to consenting to link tissue and data were key outputs for the OG, but also more generally approaches to consent taking and what the public are specifically worried about.

One OG member said they wanted to understand -

- do the public understand how much data could be accessed, how extensive this is - and what constraints they'd like?
- issues around re-identification?
- perspectives on different uses and users - eg are the public happy for NHS use, but not commercial use?
- do the public understand genetic data and its implications?
- do the public want to see re-consent in future (eg dynamic consent) - to be contacted project by project - and also that researchers will pick up new data as you continue to use health services?
- what makes a clear and understandable consent process?
- how do you know when you've really given informed consent? especially given that new techniques will arise and people won't know what these are at the point of consent

Initial observations

A good understanding of the dialogue process and their role in informing it.

OG want to see -

- a comprehensive walk through consent processes, types of research and the different frames in which consent might be sought.
- whether public thinking shifts, as a result of being informed in a dialogue process
- what parameters the public come up with for the development of consent guidance

Key themes to consider in the final evaluation report

- How OG, HRA and HTA use this data in parallel to other inputs (from researchers, organisations, patients etc); the weight given to the public perspectives in comparison and the OG's confidence in the outputs.
- The workshop processes enabling participants to understand and be able to discuss issues from an informed perspective.
- The clarity of reporting and alignment with expectations.

Impact

Guidance and codes of practice
All are clear that new HTA/HRA guidance will be produced to inform researchers of consent and the link between tissue and data. The OG are interested in their role in the balance between public, professional and other inputs to guidance; as well as how the outputs will impact their own (where they have them) Codes of Practice, guidance to research ethics and approval committees.

Of particular interest is the impact any new HRA/HTA guidance has on the understanding of the term "access to medical records" by both public and research gatekeepers.

There was a word of caution - the dialogue may result in a confirmation by the public that the existing system is what they want; or they may seek further restrictions. In this scenario the impacts will be different.

Other policy
The main other impacts that interviewees saw was the impact on how their respective organisations engage the public; one, in particular, saying it was good timing for the dialogue, as there are a lot of other issues coming up around public health and the disclosure and use of data on large scales; as this is key to wider understanding of the health of the nation.

One interviewee also mentioned a possible impact on their grants programme; as the outcome of the dialogue might prompt further research on consent approaches.

Other impacts
Several people mentioned that the outcome of the dialogue might affect their training programmes for researchers, committees and others.

Initial observations
- Commitment to using the product of the dialogue to inform further guidance for researchers on consent around the linking of tissue to data.
- Consideration of impacts on organisational practice outside the HRA/HTA - both in terms of specific guidance and training.

Key themes to consider in the final evaluation report
- Intentions or concrete plans for new HRA/HTA guidance.
- Other organisation's plans to act on the product of the dialogue.
- Impacts on public engagement practice or plans.

Learning

Personal learning
Several people expressed a personal interest in how the process of dialogue works in action; either because they practiced as a facilitator or because their organisation was considering the use of public engagement.

Organisational learning
Interviewees reported that the learning they gathered about the workshop process would impact on their public engagement approaches and senior management buy-in. They were also keen to see how the online component worked and what made it work/not work. And the dialogue would inform communications with the wider public, by illustrating what works and doesn't in getting the concepts across.

Dissemination
The dialogue reports and HRA/HTA guidance is intended (by the HRA/HAT) to be disseminated -

- through research forums
- HRA & HTA websites
- by speaking at different events
- through press and specialist journals
- at the Annual Conference of NHS Involve
- through learning and development programmes.

Other OG members reported that the reports and guidance would inform their own local Codes of Practice, guidance to researchers and advice to ethics and approval committees.

Other
One interviewee raised a concern that there would be an under-representation of certain groups in the dialogue and that further work might need to be done to address who these people were and what their needs might be.

Initial observations
The HRA has already used both Sciencewise funded and other funded public engagements and is clear about its continuing learning needs around the use of dialogue and useful means of disseminating findings and learning from public engagement. For other organisations there is a range of novelty about the dialogue approach, which they hope to learn from.

Key themes for the final evaluation
Check the dissemination routes.
Describe learning from a range of perspectives and its possible and probable impact on practice of both consent taking and public engagement.

Carl Reynolds
Evaluator, 3KQ

August 2017

Evaluation activities

1. Baseline interviews – June and July 2017

We will undertake a round of telephone interviews with 8 to 10 of the Oversight Group members. The purpose of the interviews is to explore the perspectives, expectations and assumptions of a mix of project stakeholders with respect to objectives of the engagement, challenges, and credibility. The interviews will feed into the baseline report and will enable the evaluators to revisit these initial expectations and assumptions towards the end of the project. The interviews will be semi-structured to allow for comparison, but also to enable a conversation between the evaluator and the interviewee, which should enable other underlying issues to emerge.

2. Baseline assessment report – July 2017

This will be a succinct internal report (2-4 sides), summarising in brief the findings to date. Salient findings are therefore shared as they emerge so that value can be added to the delivery of the project as it unfolds, rather than waiting until the end when it is often too late. The baseline report draws together the results of the baseline interviews and the evaluator's observations of email correspondence and other documents circulated.

3. Writing and agreeing an evaluation plan – July 2017

The evaluation plan sets out the proposed way forward for the evaluation, after the Baseline interviews and assessment of the initial documents have established the scope of the project and its objectives. It was agreed by the HRA Project Manager (following input from Sciencewise) in July 2017. It is the map to guide 3KQ's work.

4. Initial evaluation activities – June to September 2017

The evaluator will begin activities by observing and (where appropriate) feeding into Project Management Group meetings, as well as document review where relevant. We also propose providing some more formalised formative feedback on the workshop and on-line developments as these progress throughout June and July.

5. Ongoing / flexible evaluation activities – September and October 2017

Set elements of the activity we plan to evaluate are:

- Workshops and online community set up.
- Delivery of face to face dialogue events. Areas covered by the evaluation will include clarity of objectives, sampling and recruitment (specific to each event), incentivisation, stimulus materials, facilitation plan and delivery, participation and interaction, role of specialists, recording, reporting and analysis of public views, and consideration of outputs / impacts.
- Delivery of online community. Areas covered by the evaluation will include clarity of objectives (and their achievement), methodology, response format, sampling and representativeness, analysis and reporting, consideration of the outputs / impacts, and the integration of online dialogue outputs with the wider process.

- Overall dialogue activity, including level and quality of engagement, maintenance of engagement, range of topics, methods, achievement of workshop objectives and impacts on the participants and project.

6. Interim evaluation report – end October 2017

We will produce an internal interim report that summarises a review of the design and delivery of the dialogue based on evidence so far. This is a high-level report that sets out an overall assessment of delivery together with a handful of key learning points, evidenced by observation, participant questionnaires and content owner questionnaires –and interviews.

7. Impact interviews – end December 2017/January 2018

Telephone interviews will be used to explore and understand stakeholders' perceptions of how the dialogue is likely to make a difference to their thinking, learning, actions or decision-making – covering aspects of impact, context, scope and governance. As a comparator we will speak to the same people we interviewed for the baseline assessment to test the extent to which the project met expectations and assumptions.

Interviews will be semi-structured and conducted on a confidential basis, to encourage people to speak freely. Although the content of the interviews will influence the evaluation conclusions and may be reported with quotes where appropriate, they will not be attributed without permission. This will be explained at the start of the interview. Notes made by the evaluators will not be published or passed on.

8. Analysis and final reporting, including impact assessment – February 2018

The data set emerging from the various evaluation elements is a mix of quantitative and qualitative data. It will allow conclusions to be explored, confirmed or amended, and backed up with sound evidence. All detailed analysis reports from individual events will be available to allow disaggregation, and summaries are provided in the first instance.

Ongoing activities

Observation/contribution to Oversight Group meetings and project management calls. We will join Project Management Group calls as an observer and, again, to input where appropriate. And attend at least one Oversight Group meeting.

Observation of a selection of dialogue workshops. We will monitor the process of producing the stimulus materials and developing the plan for each workshop. We initially plan to observe four face to face workshop events so we can see how the workshops are framed, introduced, run, and reacted to. Attendance at the events also allows us as evaluators to conduct brief informal interviews to complement the formal exit questionnaires and enable us to comment on the process used.

Questionnaires for workshop participants. We will use written questionnaires to collect quantitative and qualitative data from workshop participants (both public, patient experts and specialists) after each significant engagement activity. In particular, the questionnaire would be focussed on perceptions of the quality of delivery and perceptions of Impact. Participants are asked to respond to a statement using a simple five point Likert scale (Strongly Disagree to Strongly Agree). This allows rapid completion of the forms with minimal confusion. It also allows the extraction of a variety of useful quantitative metrics. Each question is followed by a "comments" prompt to also enable a qualitative response.

Content owner review questionnaires. We will provide a short questionnaire to be completed by the 'content owner' – the HRA project manager. The questionnaire will explore the content owner's views on the process and outputs, as well as their early views on impacts and usefulness, or what they plan to do with the outputs.

Formative reports on activities. We will provide formative feedback during the development stages of the project, and after each significant engagement activity, making recommendations for adaptations (if necessary), key learning points about the process used and its effectiveness. This includes after each workshop we observe, and for the online community. We will provide a summary of feedback from any participant questionnaires relating to these kinds of activities.

Document review (including online activity). There are various documents that we will review during the project design and delivery, including: the Terms of Reference of the Oversight Group, stimulus materials and workshop plan for the dialogue sessions, press statements, correspondence with stakeholders, and more broadly the email traffic on the project. We will review reports that cover how information emerging from the dialogue is captured, analysed, reported and used to influence policy and research decisions. We will also review any online and social media activities undertaken as part of the dialogue process.

Liaison with key parties. The first point of contact for the evaluation team will be the HRA Project Manager, Amanda Hunn. All evaluation-related emails will also be copied to the Evaluation Manager at Sciencewise. Key relationships are as follows:

- Project manager: regular telephone and email liaison, project management meetings.
- IPSOS/Mori: liaison regarding project delivery and formative evaluation.
- Sciencewise (Dialogue and Engagement Specialist and Evaluation Manager): ongoing liaison and advice as needed.
- Project Management Group/Oversight Group: attending meetings as observers or to input where appropriate; interviews with members (and other stakeholders as appropriate); occasional specific input.

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Oversight Group - terms of reference

The OG specified its role as being to comment on:

- *Key questions to be addressed*
- *Background/stimulus materials (ensuring it is comprehensive, balanced and neutral and accessible to a lay audience)*
- *Communications strategy*
- *Outputs from the dialogue exercises including written reports.*

The Oversight Group also advised on:

Impartiality

- *Ensuring that the dialogue process is balanced and perceived as such by the outside world.*
- *Supporting the overall process and ensuring that the right questions have been asked at the right time and that the right people are in the room.*

Support for HRA/HTA on the process

- *Helping to develop the criteria on which the success of the project is going to be judged. Oversight group members are often members of key organisations who will use the outputs of a dialogue, so help from them on what success "looks like" is useful.*
- *Acting as a sounding board for potential activities or decisions about the process or content.*
- *Giving advice when things get challenging for the project manager – dealing with uncertainties, providing independence where needed, advice on finding and contacting the right people quickly.*

Ambassador role

- *Providing informed input to, and feedback from, the dialogue – at set up stage, throughout the dialogue and with dissemination of findings and impact of outcomes.*
- *Members are key players, so when it comes to dissemination of the results of a dialogue they often own or can influence policy change in relevant institutions.*
- *Providing a credible independent voice for the process, if needed – quotations explaining the integrity of the process can be provided to media; in the case of controversy, media interviews could even be arranged."*

Definition of assessments

Very well met	Met to the greatest degree that could be expected. No improvements are identified that could realistically have been implemented.
Well met	Met, with only one or a few relatively small improvements identified, but without any substantive impact on the output of the dialogue.
Fairly well met	Met, but with a series of improvements identified that could have substantially improved the process and/or impact of the dialogue.
Not very well met	Falls short of expectations in a substantive and significant way.
Not met	Effectively not met at all.