Public Dialogue on Recruiting Participants for Health Research, HRA

Final Evaluation Report

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Executive Summary

This report sets out the findings of the evaluation of the Health Research Authority's (HRA) *Recruiting Participants for Health Research* dialogue conducted in September to December 2014, with financial and knowledge support from Sciencewise[1]. The dialogue was delivered by Office for Public Management (OPM) Group and evaluated by 3KQ.

Context and Aims

The Health Research Authority (HRA) in conjunction with Sciencewise commissioned OPM to design and deliver a public dialogue on identifying and recruiting participants for health research. It was designed to engage members of the public and patients in order to inform the HRA in the development of a new policy to replace the existing Research Governance Framework and associated guidance. It explored the issues raised in identifying and recruiting participants for health research, including access to patient records, consent to approach lists, and simplified consent.

The dialogue built on a previous HRA public dialogue in 2013 which focused on public views on the HRA's remit to streamline and simply the research approval process and transparency.

The broad objective of the dialogue was to engage the public in order to inform the HRA in developing its future policy framework and guidance. Documents within this framework provide guidance for research ethics committees and health researchers when identifying and recruiting participants for health research. In particular the dialogue findings were intended to inform the HRA as it develops a new policy to replace the existing Research Governance Framework and associated operational guidance in 2015.

Activities and Content of Dialogue

The dialogue had four objectives -

- To inform the development of the HRA's new UK wide policy to replace the existing Research Governance Framework and its associated operational guidance.
- To provide opportunities for members of the public and patients to discuss and explore their aspirations and concerns about the governance of health research in relation to recruitment, data and consent, especially:
  - How patient data might be used for identification and recruitment into research including perceived benefits and risks and who participants think should be allowed to access patient records for research
  - Different models for approaching potential research study participants including consenting to being approached directly about research
  - The plan to develop simplified models of consent for simple and efficient clinical trials of already licensed drugs and other interventions in common use.

[1] Sciencewise is a BIS funded programme to improve Government policy making involving science and technology by increasing the effectiveness with which public dialogue is used. They provide co-funding and specialist advice to help Government Departments and Agencies develop and commission public dialogue. See www.sciencewise-erc.org.uk

- To identify areas of public and patient consensus, disagreement and uncertainty raised by these aspects of health research governance.
- To enable the HRA to build on previous experience in public dialogue, to pioneer innovative approaches in public and patient engagement where appropriate, and to develop knowledge and understanding of public dialogue and its potential for future applications.

The project used three different strands of evidence building: eight 3-hour public dialogue workshops - held on weekday evenings, an interactive website and an internet scan[2]. There were eight workshops in total in four locations - Cardiff, Liverpool, London and Nottingham, engaging a total of 108 members of the public, 24 experts and 9 patient experts. Each location had an initial workshop, followed by a further workshop. The participants remained the same in each location, but each workshop dealt with new information.

In workshop one, participants were given background information on - what health research is; the role of the HRA, and; what a clinical trial is. Participants considered - What is in a medical record; who has access to medical records; different types of data (anonymised, pseudonymised and identifiable); how potential participants are identified as eligible to be invited to take part in a health study; what a research nurse is and their role; and access to data in a GP surgery and in a hospital setting in order to identify potential participants in health research.

In between workshops, the public participants were asked to consider a sample patient information sheet and feedback their thoughts on it at the beginning of workshop two.

In workshop two, participants considered - the homework exercise; two consent to approach models; two models of simplified consent; what a patient information sheet should contain for simplified consent; pack leaflets that come with medicines; and a zero consent scenario.

The on-line engagement attracted 569 unique users, 51 responses to a survey and two posts onto a forum page.

An Oversight Group (OG), comprising 10 stakeholders from the health research and governance fields (including two patients), a Sciencewise representative and two people from the HRA, was brought together to support the HRA and OPM (the delivery contractor) to design the dialogue process and the materials used, review the report and its findings.

This Evaluation

A range of data was employed to evaluate the achievement of the dialogue's four objectives; how the Sciencewise Guiding Principles had been observed, and how additional questions in the Invitation to Tender (ITT) had been addressed. This data came from -

- Observations at four of the eight workshops (London x2, Cardiff and Nottingham), and a review of the materials and processes used,
- Observations of two Oversight Group meetings,

[2] An internet scan is a process where a continuous search is made on the internet for key terms - eg simplified consent. This enables an understanding of how widely conversations about the issues in the dialogue are spreading.

- Interviews with nine out of ten Oversight Group members (before and after the workshops), OPM (after the workshops), Sciencewise (before and after the workshops), three HRA officers, including the CEO (two before and three after the workshops), and participants in the workshops (two public, two experts, two expert patients),
- An overview of email traffic (around 250 messages) between HRA, the contractor, the Oversight Group and Sciencewise,
- Documents produced by the HRA and the contractor.

Evaluation findings

The dialogue met all its **objectives**. The dialogue will inform various strands of HRA policy and guidance development covering access to data, approaches for consent and simplified consent. The public, patients and expert participants to the dialogue overwhelmingly agreed that they had the opportunity to discuss and explore their aspirations and concerns. Areas of consensus, uncertainty and agreement were identified, but the distinction between public and patient views was not made. The HRA has learnt more about the use of public dialogue - especially how not to undertake a digital engagement.

The delivery and design of the workshops met their objectives well, but the digital engagement did not; although the HRA and its OG have learnt a lot about how not to do it.

The **Sciencewise Guiding Principles** were all met, but there was some scope for improvements. The dialogue was timely and met with a requirement to review policy guidance, and also followed on from a previous dialogue; although the timing for OG members to review materials was short. The workshop processes and materials were engaging and informative and OPM worked well to elicit a range of views from participants on the subjects being discussed. The range of participants in the room was very diverse in terms of socio-economics, age, gender and ethnicity.

External stakeholders were involved in the OG and contributed to the shaping of the dialogue, reviewed materials and influenced the drafting of the final report. Their role would have been enhanced by more meetings - either physical or virtual.

Participants were **highly satisfied** with the dialogue - public (94%), patients (17/20), specialists (28/32)[3]. All of the OG, bar one (who was not clear how the dialogue results could be used to inform policy), were also largely satisfied with the dialogue.

The **main achievement** of the dialogue is that it will inform policy in these areas -

- The replacement for the Research Governance Guidance. The HRA have now issued a draft version of the replacement policy for the RGF. Although it is a high level document, various elements of it have been influenced by the public dialogue including the commitment to proportionality in low risk studies[4].
- Guidance on Simplified Consent. The HRA is currently drafting guidance on simplified or proportionate consent and the public dialogue findings are feeding directly into that.

[3] Note - scores are a round up of responses across both workshops and all locations. So, although there were 20 different specialist participants, the total of their responses is 32.

[4] *Proportionality* is the concept that the requirements for assessing the ethics and risks of research, before its its allowed to proceed, are in relation to its risks, burden on patients and degree of intrusion.

- Guidance on Recruiting Participants for Health Research. The HRA is also drafting guidance on recruitment of participants into health research and this will build on a number of case studies including those used in the public dialogue work and so will adjust these to build on public feedback. Specifically the guidance will include recommendations for the reassurances sought by the general public in the dialogue.
- Discussions on the role of Research Nurses in accessing patient records and health research.
- Other, as yet unspecified, guidance which is critical to the wider stakeholder research community and/or to protect the interests of the public.

Impacts on public participants include a better knowledge of the subject and how the field of research works. For the HRA and its stakeholders, they reflected in interviews that they will use the findings to advance the discourse on how members of the public respond to issues of data access, being approached to be in research and ways of simplifying consent. The HRA believes the dialogue was valuable - but it's too early to clearly assess how the wider field will respond.

The dialogue's **costs** are broadly in line with other similar exercises, and it has the **benefit** of directly impacting on policy in this year, as indicated above. It has also deepened the HRA's understanding of dialogue and likely to prompt more thinking on the use of digital engagement in the wider field.

Credibility ratings were high across all respondents in interviews and on workshop evaluations. There were one or two remarks from the OG on the value of qualitative methods versus quantitative methods, but in the context of a parallel stakeholder consultation on simplified consent, that shows broadly similar findings, the credibility of the dialogue findings is robust.

Several **lessons** emerge from the dialogue, but two that stand out, because they relate to resourcing and design, are -

- establish an Oversight Group earlier and provide more time for them to consider materials and the shape of the dialogue, and/or consider engaging a wider stakeholder group to test the representativeness and potential bias of materials and processes used in the dialogue, and
- be clear on what you can reasonably expect on digital engagement (including doing some research on what digital engagement has worked and why), allocate an appropriate budget and manage expectations accordingly.

1. Introduction

This report evaluates the HRA public dialogue on Recruiting Participants for Health Research, commissioned by HRA in September 2014, which ran until December 2014, and was reported on in March 2015. The need to observe purdah before the General Election in May 2015, meant that publication of this and the dialogue report were postponed until after the election. The evaluation considers the quality of the public dialogue process and its impacts; and identifies lessons learnt by both participants in the dialogue and those governing the dialogue process, to aid the development of good public dialogue process.

2. Background

The policy context

"To make the UK a great place to do research, where more money invested in research goes into carrying out relevant, good quality research." AMBITION OF THE HRA

The NHS constitution outlines the right of all patients to be informed about research studies they are eligible to take part in. However healthcare professionals may not always know about relevant research opportunities or the associated inclusion and exclusion criteria or may be too busy to discuss research with patients. And additionally there are difficulties recruiting sufficient patients into studies in a timely fashion.

In response to both the findings of an earlier dialogue and feedback from stakeholders in the research field, the HRA used this opportunity to review the principles underlying health research in the UK, including the methods for identifying and recruiting participants for health research. This comes at a time of changes to the EU Clinical Trials Regulation allowing for greater proportionality[5] to distinguish between high-risk and low-risk trials. This context provides the potential to make changes that could make it easier for patients to learn about relevant trials and increase the number of participants involved in health research.

Proposals being considered by the HRA include research nurses having access to patient records 'consent to approach' lists and simplified consent processes.

The public dialogue

The public dialogue was commissioned by the Health Research Authority (HRA) in conjunction with Sciencewise in September 2014 via competitive tender processes. OPM were selected as the dialogue delivery contractor for both the workshops and the digital element of the project; 3KQ were selected as the independent evaluators for the project.

The dialogue project, including the digital engagement, was jointly funded by the HRA (a total of £65.6k made up of £35.6k cash, plus an additional £30k in time and funding videos and the internet scan exercise) and Sciencewise (£66.6K), giving a total project cost of £132.2k plus VAT. In addition Sciencewise provided advice and support (including the involvement of a Dialogue and

[5] The HRA uses the term 'proportionality' to express a need to make regulatory burdens proportionate to the risks and resources involved in health research.

Engagement Specialist - DES) to the value of £15k. These costs include the governance, delivery and evaluation of the project.

The broad objective of the dialogue was to engage the public in order to inform the HRA in developing its future policy framework, and in particular for identifying and recruiting participants for health research. Documents within this framework provide guidance for research ethics committees, health researchers and others across the research community including funders and sponsors of research. In particular the dialogue findings were intended to inform the HRA as it develops a new policy to replace the existing Research Governance Framework and associated operational guidance in 2015.

The specific objectives of the dialogue identified by the HRA[6] were:

- To inform the development of the HRA's new UK wide policy to replace the existing Research Governance Framework and its associated operational guidance.
- To provide opportunities for members of the public and patients to discuss and explore their aspirations and concerns about the governance of health research in relation to recruitment, data and consent, especially:
  - How patient data might be used for research including perceived benefits and risks and who participants think should be allowed to access patient records for research
  - Different models for approaching potential research study participants including consenting to being approached directly about research
  - The plan to develop simplified models of consent for simple and efficient clinical trials of already licensed drugs and other interventions in common use.
- To identify areas of public and patient consensus, disagreement and uncertainty raised by these aspects of health research governance.
- To enable the HRA to build on previous experience in public dialogue, to pioneer innovative approaches in public and patient engagement where appropriate, and to develop knowledge and understanding of public dialogue and its potential for future applications.

OPM designed and delivered four reconvened public workshops in England and Wales throughout November 2014. This form of engagement was chosen because it allowed the public to learn about current and potential research recruitment and consent processes, actively informed and engaged participants in discussion and debate, and provided the chance to ask questions and discuss with specialists and patients in the room. In addition OPM developed a website - with an interactive forum and a survey - and maintained a specific Twitter presence for the dialogue. Full details of the dialogue project activities follow in section 4.

[6] In the Invitation to Tender - August 2014

3. Evaluation - aims, objectives and methodology

Aims and objectives of the evaluation

The **aims** of the evaluation were -

- to provide an independent assessment of the impacts and quality of the dialogue project to demonstrate the extent of the project's success, credibility and effectiveness against its objectives, covering both the outcomes of the dialogue as a whole and the design, delivery and governance of the dialogue activities (including an assessment of impacts on policy and decisions, organisational learning and change, and on those involved)
- to contribute to increasing the wider effectiveness and use of public dialogue

The **objectives** for the evaluation were -

- to gather and present objective and robust evidence of the nature and quality of the impacts, achievements and activities of the project in order to come to conclusions
- to identify lessons from the project to support capacity building across Government and the wider development of good practice in public dialogue

The evaluation approach and research

An Evaluation Plan[7] was produced by 3KQ, in collaboration with the Sciencewise Evaluation Manager and the HRA at the beginning of the project. The following methods were used to **gather evidence** and **assess** the impacts, achievements and activities of the project -

- Review of documents, emails[8], process design, materials, website (rphr.org.uk) and other communications to get an understanding of the interactions between the Oversight Group and between the contractor, OPM, and others.
- A review of the contractor's final draft report on the dialogue.
- A Baseline Assessment[9] formed after interviewing nine of the Oversight Group, the Sciencewise Dialogue and Engagement Specialist (DES) and the HRA Chief Executive.
- Observation of four workshops - two in Round 1 and two in Round 2. Observing London and Nottingham in Round 1 and London and Cardiff in Round 2. This included observations of the form of interactions between the facilitation team and participants (eg how much was a conversation or discussion; and how much was responding to a series of questions); observing the role of the experts and patients; how material was deployed and used; and how the process was applied.
- Observation of two Oversight Group meetings - one considering the process and materials to be used in the dialogue before the workshops began, and the other considering a draft of the OPM dialogue report after the workshops had concluded.

[7] Appendix 2

[8] As of 24 February 2015, there were 248 emails read or sent by the evaluator.

[9] Appendix 1

- Analysis of workshop evaluation forms from all eight workshops.
- Post workshop interviews with eight of the Oversight Group, the HRA Chief Executive, OPM, the Sciencewise DES, two public participants, two expert participants and two patient participants.

This evaluation **evidence** is derived from -

- qualitative data from participants in the workshops or those with oversight (the OG, HRA, Sciencewise), using interview notes, ad hoc conversations, notes of OG meetings, and comments on workshop evaluation forms;
- assessment of the quality of activities and impacts based on analysis of evaluation data from observation and interviews; and
- analysis of the quantitative figures from the scores on the workshop evaluation forms.

The **measures** used to assess evidence against were -

- Sciencewise seven key evaluation questions on Objectives, Good Practice, Benefits, Value and Satisfaction, Governance, Impact, Costs and Benefits, Lessons for the Future. These were spelt out in the ITT and Sciencewise guidance note SWP07[10];
- Sciencewise Guiding Principles[11]: Context, Scope, Delivery, Impact, Evaluation. These overlap to some degree with the seven questions above.
- Other ITT requests to measure the influence of 'expert' patients on the dialogue and how feasible it was to distinguish between the public and experienced patients in the dialogue process; and
- Other measures emerging from the Baseline Assessment on how participants understood and reflected on issues raised in the dialogue, and the time available; the quality and range of materials; how experts and patients influenced the dialogue; time to explore generalities and assumptions; how emergent ideas would be captured. Many of these are contained within the Sciencewise questions.

One overarching **observation** is that what the public participants think of as 'good' or 'excellent' does not always align with the evaluator's own observations or the views of some expert and patient participants in the dialogue.

[10] Sciencewise (2014). *SWP07 Evaluating Sciencewise public dialogue projects*. http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Publications/SWP07-Evaluating-projects-27March14-FINAL.pdf
[11] Sciencewise (2013). *The Government's approach to public dialogue on science and technology*. http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Publications/Sciencewise-Guiding-PrinciplesEF12-Nov-13.pdf

4. The dialogue workshops

This section describes and assesses the **design and delivery of the public dialogue workshops** and covers -

4.1 Recruitment and Sampling

4.2 Specialist and patient input to the workshops

4.3 Design and Delivery of the Workshops

4.4 Resourcing of the workshops

4.5 Recording and analysis of discussions

4.6 Post workshop reporting

4.7 Distinction between public and patient views

4.8 What worked well and less well

4.9 Lessons for the future

The analysis evaluates against these measures -

- Sciencewise Guiding Principle 3 - Delivery;
- ITT requests to measure - the influence of 'expert' patients on the dialogue and how feasible it was to distinguish between the public and experienced patients in the dialogue process; and
- Baseline Assessment inquiries on - how participants understood and reflected on issues raised in the dialogue, and the time available; the quality and range of materials; how experts and patients influenced the dialogue ; time to explore generalities and assumptions; how emergent ideas would be captured.

The Baseline Assessment inquiries overlap with many of the elements within the Sciencewise Guiding Principles.

4.1 Recruitment and sampling

The recruitment of public participants was undertaken by OPM's partner recruitment company using face to face street recruitment in line with a strict quota, in four cities - Cardiff, Liverpool, London and Nottingham. The quota was developed and agreed with input from the Oversight Group, based on recruiting 28 participants per location to ensure at least 25 participants attended each workshop. One concern of the Oversight Group was the low number of older people proposed in the original quota - OPM responded to this request and ended up with 25 out of the just over 100 public members being 65 or over - 6 of these being over 75. Primarily, the quota was purposive and aimed to hear as many different voices as possible within the sample. However, OPM also aimed to ensure the views of those groups known to hold the greatest concerns about health research were heard, namely people from lower socio-economic groups and ethnic minorities. Therefore, OPM matched the quota for ethnicity to the census data for the locations of the workshops. The table shows the characteristics of participants at the workshops.

Age group	No.	Ethnicity	No.	SEG	No.	Gender	No.
18-24	18	Asian	15	AB	31	Female	58
25-34	19	Black	17	C1	26	Male	52
35-44	16	Mixed Race	4	C2	26		
45-54	17	White	72	DE	27		
55-64	15	Other	3				
65-74	19						
75+	6						

The public participants were provided with incentives for attending each three hour workshop (£40 for the first workshop and £60 for the second), which encouraged a very high turnout rate, with at least 26 public participants attending every workshop.

The range of ethnicities, socio-economic group, ages and gender is very good and demonstrates a thoroughness in getting the right mixture of people into the workshops.

4.2 Specialist input to the workshops

In **advance of the workshops** the OG and the HRA were involved in the production of materials and the design of the workshops. Initial ideas were developed at the Inception Meeting (12/9/14) and taken to the OG meeting (7/10/14) for further discussion. OG members were also taken aside to be filmed for one of the stimulus videos during the meeting. The OG meeting agreed a process to review and sign off materials, using email exchanges and telephone conferences, in advance of the first workshop in Liverpool on 3rd November 2014. Given that OPM had just under four weeks to research, prepare drafts, circulate for comments, revise, re-circulate, get signed off and produce materials, they did an impressive job (given the materials file runs to over 40 pages). But as the Sciencewise DES and some OG members commented, it put a "*lot of pressure on the team*", and that there needed to be some thought given to "*materials development and how to make the process easier*", "*we were asked for very quick responses and I think we needed to have one or two more meetings - we didn't own the project*".

The OG had both a governance role and a review role - enabling the HRA to work with a range of stakeholders to help shape and review the dialogue, but also to contribute to content and review materials. Given the range of organisations represented on the OG (including NGOs, Government,

research community, ethical specialists, engagement specialists) this was a good approach. Given more time and budget, an engagement with the wider field *might* have produced a larger range of perspectives on the issues being discussed. But a subsequent internet search by the evaluator and the internet scan undertaken by OPM at the end of the project did not indicate any other internal or external voices either strongly pro or anti the issues in the dialogue. As one of the OG, who represents an organisation very critical of data protection practice, said, "*the dialogue hasn't produced any surprises and is in line with what's expected and known*".

A**t the workshops t**here were three types of input: 1, the **HRA representative** was present at all the workshops and presented information and concepts; 2, video was used to convey the thoughts of **stakeholders from the Oversight Group**; and 3, **specialists in the field and patients** participated in the workshops.

In **workshop one**, the HRA representative -

- introduced the role of the HRA and the broad purpose of the dialogue,
- presented and took questions on medical records and what is in them,
- presented and took questions on who can access GP and hospital records; and the different forms of data,
- presented and took questions on what health research is, and more specifically what a clinical trial is,
- presented what a research nurse is and their role in research (including in research active GP practices) , and
- observed and contributed to table discussions, where clarification was needed

In **workshop two**, the HRA representative -

- presented and took questions on different models on concept to approach
- explained that there is a lack of evidence about the effectiveness of existing licensed drugs
- presented and took questions on the concept of zero consent
- observed and contributed to table discussions, where clarification was needed

Video was used -

- in workshop one, to explain issues around access to medical records and the difficulties in recruiting participants into studies, and
- in workshop two, to explain the issues surrounding simplified consent.

Both videos used specialists from the Oversight Group to present ideas and concepts.

Other **specialists**[12] or patients were invited as participants to be involved in table discussions and did not present information in front of the whole group, but did contribute facts and occasionally opinions to table conversations and the odd plenary session.

The recruitment of specialists and patients was undertaken by HRA for the three workshops in England, and Alex Newberry, National Institute of Health and Social Care Research, in Wales. The specialists included a range of leading researchers from primary care, hospital and academic settings, three research nurses, two from the National Institute of Health and Social Care Research and one specialist linked to the Health and Social Care Information Centre; all of who had an interest in simplified consent, consent to approach models and information governance issues. The nine patients were recruited from patient bodies and provided insight into participation in health research. An average of six specialists and patients attended each workshop.

There was a better representation of specialists and patients at the Cardiff workshops - with a minimum of four specialists and four patients at each workshop. In contrast the first London workshop had two patients present. Overall 20 specialists attended first round workshops and 13 second round; with 8 patients attending round one workshops and 13 in round two. An additional HRA officer attended three workshops.

When possible, specialists and patients were briefed in advance to encourage them to participate in discussions without arguing for a particular perspective. In the four workshops observed for the evaluation, the **specialists** provided factual information when asked by the facilitator; responded to questions and discussed issues with other participants, and mostly remained neutral and descriptive. Two exceptions were a specialist at a London workshop who didn't understand their role and began a critique of the HRA and its models (the HRA representative intervened to clarify the specialist role) and a patient in Liverpool who suddenly made very critical comments to the whole room about pharmaceutical funded research, which had a very negative impact on subsequent views in workshop 1[13]. The **patients** observed ranged in their behaviour from keeping to descriptions of how they experienced the NHS and their treatment, to being more assertive about the rights and wrongs of the NHS, but in all cases they were receptive to the facilitators bringing them back to task. As one patient observed, "*I really enjoyed the interaction and was interested in the change in participants confidence from the first meeting to the second*[14]."

4.3 Design and delivery of the workshops

The workshops[15] were designed to enable participants to be informed about and then consider their reactions to a range of ideas and proposals. Although the workshops were reconvened with the same public participants, they discussed distinct material[16] at each workshop. There was not a specific link between workshop one and workshop two; although contextual information like - what is in a medical record, how research is carried out and concerns about consent and privacy, carried from one workshop to the other, and helped to inform discussions.

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[12] See Appendix 3

[13] Reported subsequently by the HRA representative

[14] Patient, Liverpool

[15] Detailed process plans can be seen in Appendix 4

[16] OPM report on the dialogue - Identifying and recruiting participants for health research - Workshop materials annex 2

Both rounds of workshops were arranged with four tables with seven or eight public participants sat with one or two specialists, one or two patients and a facilitator. Interspersed with the table discussions were presentations to the whole group and plenary discussions.

In **workshop one** -

- Participants were introduced to the *objectives for the dialogue* by the HRA officer, and the *objectives for the workshop* by the OPM lead facilitator.
- Participants were asked in table discussions, by the facilitator, some baseline questions to establish their knowledge of *'what is in a medical record'* and then had a discussion about how they knew this. The HRA officer then gave a presentation outlining *what is in a medical record*, followed by a discussion of who participants thought had *access to their medical records*.
- A presentation by the HRA and short mime by OPM, then introduced participants to *different types of data, health research and clinical trials*. An additional presentation from the HRA followed, with a stimulus video introducing the discussion topic on *access to patient records*. Throughout these information giving sessions, participants had the opportunity to ask any questions about what they had heard so far, drawing upon the expertise in the room.
- The table discussion on *access to patient records in a hospital setting* was designed to understand participants' opinions towards the topic and what was deemed as acceptable. This was followed by a second discussion topic on *access to patient records in a general practice* setting, introduced by the HRA through a presentation.
- At the end of the first workshop participants were given a *homework exercise* to take away with them. They were asked to read an example of a *long patient information sheet* in preparation for some of the topics covered in workshop 2. As OPM state in their report of the dialogue, *"This gave participants the opportunity to fully engage in the information sheet, something that would have been difficult within a workshop setting due to the length of the document."*
- Evaluation forms were handed out for participants to complete at tables while table facilitators stepped outside.

In **workshop two** -

- Participants were facilitated at tables and discussed whether they had talked about the first workshop with family and/or friends and if they had visited the *website* or read the *homework exercise*. This was designed as a warm-up session, allowing participants to re-engage with the issues discussed at the first workshop held two weeks beforehand.
- A presentation by the HRA introduced participants to *consent to approach* principles followed by an explanation of a *first model where patients are approached in a hospital waiting room and asked if they would be willing to join a register of people who might be interested in being approached about specific trials (known as the consent for consent approach)*. A table discussion followed, asking how acceptable participants found the first model and whether they had any concerns. Next a *second model of consent to approach* was explained to participants by the HRA, in which patients are sent a leaflet in the post, and participants subsequently discussed this at tables.

- After the break, a stimulus video and presentation given by the HRA introduced *simplified consent* and participants had the opportunity to ask questions. This was followed by a discussion at tables of participants' views on the acceptability of the proposals and what reassurances they might need.
- At tables, having been provided with examples of *all the items that might be covered on a patient information sheet for research together with examples of the pack insert leaflet that patients would receive with their medicine*, participants were taken through a checklist, by the table facilitator, covering what may and may not be included on the proposed simplified patient information sheet. This was designed to provide an understanding of participants' opinions on what needs to be included on a simplified information sheet.
- A final table discussion looked at *zero consent* option following on from a brief presentation by the HRA, introducing the proposal.
- As in the first workshop, participants were again provided with an evaluation form and asked to fill this out at tables while facilitators left the room. To finish, the HRA explained what would happen next and thanked participants for their insights and time.

In terms of the dialogue process conveying the objectives of the dialogue to participants, scores for the **awareness and understanding of objectives** were very high; suggesting that they were easily conveyed and retained.

Patients *awareness and understanding of objectives*[17] - Very high scores across two rounds (tend to agree/strongly agree 21 out of 23 responses)

Public *awareness and understanding of objectives* - Very high scores across two rounds (tend to agree/strongly agree 84% of responses)

Specialists *awareness and understanding of objectives* - Very high scores across two rounds (tend to agree/strongly agree 33 out of 33 responses).

On the **design and delivery of the workshops** public feedback[18] scored between 89% and 95% (tend to agree plus strongly agree scores) across all locations and both rounds of workshops[19], on these questions -

- being *adequately informed to be able to discuss the issues - Workshop 1 90%, Workshop 2 92%*,
- being able to *ask questions and get appropriate answers - Workshop 1 92%, Workshop 2 94%*,
- having *enough time to discuss the issues - Workshop 1 89%, Workshop 2 89%*, and
- being *able to contribute and have my say - Workshop 1 95%, Workshop 2 95%.*

These are very high scores and demonstrate how the public appreciated the design and delivery of the workshops. As one public participant said, *"The facilitators ran the sessions very smoothly - the transitions between sessions flowed, they weren't random, there was a natural progression from*

[17] Q1 on Workshop Evaluation sheet - see Appendix 5

[18] Returns per workshop round ranged from 101 to 106 people

[19] From Workshop Evaluation sheet - see appendix 5

one idea to the next. The breaks were spaced right, and although there was some jargon, mostly it was jargon free and clear and understandable."

On the same questions, the specialists and patients[20] had similar scoring[21].

Patients scores (tend to agree and strongly agreed) were -

- being *adequately informed to be able to discuss the issues - 16 out of 20*,
- being able to *ask questions and get appropriate answers - 19 out of 21*,
- having *enough time to discuss the issues - 13 out of 21*, and
- being *able to contribute and have my say - 18 out of 21.*

Specialist scores (tend to agree and strongly agreed) were -

- being *adequately informed to be able to discuss the issues - 26 out of 32*,
- being able to *ask questions and get appropriate answers - 31 out of 32*,
- having *enough time to discuss the issues - 20 out of 33*, and
- being *able to contribute and have my say - 32 out of 33.*

The fall in numbers of both specialists and patients on the evaluation of having *enough time to discuss the issues* is dealt with in section 4.8

The facilitators dealt with the odd moment of confusion well, for example in one workshop there was some confusion at one table about the fact that there was an intermediary stage between *being approached* to potentially be part of research *and being in a research study*; the fact that there was a *consent stage* was not, initially, made clear by the facilitator. Once it became obvious that the participants were struggling, participants were reminded of the sequence.

As several participants said, "*The facilitators were clear and concise*[22]"; and the materials used helped people to work through and understand issues. OPM used a mixture of presentations (both Powerpoint and video), discussions using prompts, and plenary sessions. The process of seeking consent was animated using a mime session which was remarked on as "*…clear and makes it easy to understand and remember the process*[23]".

Across both workshops a succession of materials were used to explain a concept and provide information to enable a discussion. One specialist commented, it was a "*really good format and*

[20] Note - the number of evaluation forms returned from patients and specialists does not tally with the register of named specialists and patients. The explanation is a confusion on the distribution of forms at workshops where the evaluator was not present. The mis-match is minor and does not materially affect the findings.

[21] Specialist and Patient scoring is provided as numbers, rather than percentages; as percentages are not a relevant measure with such low numbers.

[22] Public, Liverpool

[23] Public, Cardiff

resources - stimulated discussion very effectively[24]"; and a patient said that the process used "*simple examples with defined outcomes*[25]".

Although a large volume of materials was used (the printed version of materials for both workshops is 43 pages long) the facilitators managed several extended conversations between public participants, experts and patients - especially on Consent to Approach Lists - as opposed to a just a series of questions and answers. On it's website (sciencewise-erc.org.uk - What is public dialogue?) Sciencewise gives a definition of dialogue as -

"Public dialogue allows a diverse mix of public participants with a range of views and values to:

- *learn from written information and experts*
- *listen to each other, and share and develop their views*
- *reach carefully considered conclusions*
- *communicate those conclusions directly to inform Government's decision making."*

During each phase of the workshops, the facilitators checked people's understanding of the information and concepts being shared with them; clarified agreements or divergent thoughts; and provided time for people to discuss issues and adapt their thinking.

4.4 Resourcing

There were four facilitators (a lead facilitator - who also facilitated at a table - plus three other table facilitators) at each workshop - with the same four present at round 1&2 for each location. Each round of workshops had the same lead facilitator (OPM used two lead facilitators) and the HRA representative attended all the workshops and presented most of the key concepts that the HRA wanted to explore with the participants. The OPM lead facilitator also introduced concepts and ideas to be discussed.

Participants were split into four tables for the duration of the workshop; comprising 6 to 7 members of the public, 1-2 specialists and 1 or 2 patients (if available) at each. Each participant had access to water, pens and paper. There was a range of materials available for each exercise, OPM used video, mime, cards, presentations, questions and discussions to enable the consideration and discussion of the ideas and models presented to the participants. The HRA drafted most of the resources.

The lead facilitator, along with the HRA representative, took responsibility for introducing the process, topics and information. Table facilitators were responsible for facilitating and recording the discussions in line with the detailed process plan, encouraging all participants to join in the dialogue.

4.5 Recording and analysis of discussion

The discussions were noted (on worksheets) by each table facilitator, who also used an audio recording device to enable subsequent checking of the accuracy of their notes. The facilitators also summarised discussions to check input, and used reflecting and clarifying to check understanding. At both workshops, one facilitator used a laptop to record notes, but there was no feedback on

[24] Specialist, Liverpool

[25] Patient, Liverpool

whether this was an issue on participant forms or in ad-hoc evaluation conversations with participants.

The workshop also used some plenary sessions to capture key points, but did not employ any systematic way to record agreements with whole group. At tables, the closest approach to identifying agreement or collective views was to ask "*So do you agree?*", but there was no explicit effort made to check whether everyone did. The assumption in practice appeared to be that if no one spoke up to disagree, the group agreed.

Additionally, participants at the London workshop were interviewed and filmed by Elliot Manches, Close-up Research, for a documentary video. This was shown to the OG on 19th January 2015, as part of the evidence for how the public had understood the issues and experienced the dialogue workshops.

4.6 Post workshop reporting

After the workshops finished the records were analysed thematically by location, with four location reports of key findings being created. These key findings identified common themes, key differences and necessary reassurances raised by the participants in relation to each of the three topic areas covered: access to health records, consent to approach lists and simplified consent. In early December the HRA, Sciencewise and the OPM project team had an analysis session, working through the findings from the four locations to identify overall findings and main messages.

A second wave of analysis returned to the detailed notes to identify additional issues before the development of this final report. The report was commented on by HRA, Sciencewise and the Oversight Group prior to final drafting.

The final draft report was presented to an Oversight Group meeting on 19th January 2015, and following discussions the OG decided to allocate until the end of January for further comments on the report. On 25th February 2015 a conference call was held between the HRA, Sciencewise, OG members and OPM to agree a way forward, after OPM had received a track changed document with 244 suggested amendments or comments and a supplementary document of other suggested changes, in the previous week. The report was then finalised for publication and held until after the 2015 General Election.

4.7 Distinction between public and patient views

The HRA's second objective - *to provide opportunities for the public **and** patients to discuss and explore their aspirations and concerns* - was reinforced at the project Inception Meeting on 12 September 2014, and a direction to understand the distinction between the public's thoughts and the experts patients' thoughts in the dialogue was made. The OPM report (April 2015) refers mainly to "participants" and only provides a few explicit patient perspectives. So while both the patients present and the public participants had opportunities to discuss, a comprehensive distinction between the views of the public and the view of patients is not made in the OPM report.

The evaluator did not observe either the lead facilitator (in plenary sessions) or the table facilitators make a distinction between public views and patient views; by, for example, reflecting that 'the public among you seem to be thinking this, but those of you who are patients are disagreeing'.

4.8 What worked well and less well

What worked well - workshop delivery and design

The range of **clear information** provided was critical to helping participants get a grasp of the subjects they were discussing. As one specialist said, "*The people on our table had not researched the background, but clear information was provided during sessions in easy snippets.*[26]" Several members of the public also thought that the information was "*Very good information, very well explained, ""I feel well informed and it was well presented*", "*Very informative and interesting*[27]" and a patient observed that it was "*informative and interesting*[28]".

OPM worked with the HRA, with commentary from the OG, to design **a process which flowed** from one topic to the next. They had adapted their initial plans for the workshops to take into account the HRA's needs to cover distinct, but related proposals. OPM did not adopt a 'first workshop educate, second workshop deliberate' model, instead they gave participants the opportunity at each workshop to both understand issues and reflect on them. As one public participant said, *"The facilitators ran the sessions very smoothly - the transitions between sessions flowed, they weren't random, there was a natural progression from one idea to the next.*[29]*"*

The facilitators and presenters were **clear in their explanation** of materials, tasks and issues for discussion, kept the conversations going and ensured that people were all given the **opportunity to speak**. Observations at four workshops show that not once was there a table where someone did not speak. As two public participants[30] said, it was "v*ery enjoyable*" and I "e*njoyed participating.*"

Specialist participants were also valued by the public: it "*helped having an expert present*" said one member of the public[31] and **specialists** themselves told me in breaks that they enjoyed the workshops and thought it "*Interesting to hear the views of the public and patients*[32]", and that it was "*a highly encouraging event - fair, balanced, informative and non-judgemental*[33]."

Patients conveyed similar messages*, "I came in to cover at short notice, but the information letter and presentations were clear"* and it was *"Informative and interesting.*[34]*"*

In post workshop interviews, OG members who had attended workshops commented *"…what they (the public) were being asked was communicated well and understood…"* and they appreciated *"…watching the facilitators and how they helped people to move understanding along….".*

Participants also appreciated that the **information provided was fair and balanced.**[35] -

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[26] Specialist, Cardiff

[27] Public participant, Nottingham, London and Cardiff

[28] Patient, Cardiff

[29] Public participant, London

[30] Public participant, Nottingham and Liverpool

[31] Public participant, London

[32] Specialist, Nottingham

[33] Specialist, London

[34] Patient, London and Cardiff

94.5% of the public tended to agree or strongly agreed.

17 out of 23 patient responses tended to agree or strongly agreed.

31 out of 33 specialist responses tended to agree or strongly agreed.

There was one specific **exception**. The **video** on simplified consent was considered to be in favour of simplified consent -

"Video is somewhat biased towards increased access to data by researchers" Specialist, Nottingham

"Slightly pro-record sharing, especially the video, but I would expect this" Specialist, Liverpool

"Swayed in favour of the researchers" Public participant, Liverpool

The video itself did raise some issues and concerns, but said these would be dealt with by emphasising safety and confidentiality; and saying that guidance would be in line with 'reasonable expectations'. This could be understood as saying 'you'd be unreasonable not to think this was reasonable!'. The main proposer of simplified consent in the video used phrases such as the current process being "extremely long", "way in excess of what is needed", with "long, intimidating" forms, which caused people to be "left in the dark" . What was absent from the video was a counter view saying why the current system is in place and what it protects.

This was echoed by two patients who thought commented on the simplified consent discussions -

"I think there was an understandable bias towards change" Patient, Cardiff

"It feels like a manipulative process" Patient, Cardiff.

In **summary**, the design, materials, flow of the workshops, opportunities to contribute and the value in having specialists and patients present was appreciated and worked well. The involvement of the OG and HRA in the design of both the workshop process and the materials used was very good, considering the time and financial constraints of the project.

What worked less well - **workshop design and delivery**

Having ***enough time for discussions***, while scoring very highly with the public (89% tended to agree or strongly agreed in round 1 and 90% in round 2), prompted a few more comments than other points on the evaluation forms. A couple of public participants commented -

"Sometimes we had too many ideas and not enough time" Public participant, London

"Bit rushed when getting into debate" Public participant, Liverpool

On the other hand, another public participant said,

"Three hours is a long time to concentrate on important issues" Public participant, London.

Experts and OG members (who had attended workshops) said,

[35] Q2 on Workshop Evaluation sheet - see appendix 5

"Discussion would get going and facilitator would leave table to do presentation = a little disjointed" Specialist, Cardiff

"It was mostly question and answer, but then there were a lot of people around the tables and not a lot of time." Oversight Group member

"Tricky balance - maybe needed more time" Specialist, Cardiff

"Not enough if you want discussion on each model. There is only enough time to scratch the surface" Specialist, London

"…it's not a flaw in the process, it's more about the time available to enable people to properly grasp a subject" Oversight Group member.

"I'm not certain that there was the right balance between discussion and deliberation. Some of the facilitators seemed to have a list of questions that they went through quite quickly, and while there was some discussion among the groups, I think there could have been more." OG member

The evaluator observed that the time available to discuss issues was at times compact, and the discussions, at times, were more akin to a question and response session, with little inter-participant discussion. This varied according to topic, and the **consent to approach** discussions in the first half of workshop 2 had far more exchanges between participants than any other session. One OG member who attended workshops also observed that they felt there was enough time for discussions, but the table facilitators were not always prompt in bringing the discussions back to the topic at hand.

One or two specialist and patient participants commented on the **volume of materials** used in the workshops -

"Sometimes information was presented in a confusing way" Specialist, Liverpool

"In some instances, more clarification was needed for some of the participants to avoid discussing the wrong issues" Patient, Cardiff

Two of the OG members and a HRA officer (in addition to the HRA officer presenting materials) attended workshops. The two OG members commented on the amount of materials people had to understand:

"Participants were given a lot of new concepts in one go - so there was a lot to take in. I'm an expert in this area, and I found it difficult to absorb it all." OG member

"…in the overall limits of the format there were a lot of ideas to get across…I don't think we needed to look at or consider what should be on patient information sheets in such detail." OG member

Inevitably, given the complexities of the subjects being discussed, participants needed to be not only brought up to speed, but also to work on realistic examples. Given that over 94% of public participants thought they had a *better understanding of the issues*; and over 89% thought they were *adequately informed to be able to discuss the issues*[36], the comments from specialists and others should be seen as commenting on the volume of materials, but not their accessibility or how they were used.

[36] See Appendix 5 - Scores from combined evaluations on Q3,4,5

On a minor point, in workshop 1, evaluation observation indicated that public participants had some trouble in distinguishing between the discussions on access to records in GP surgeries and in the hospital system. This **confusion** was not immediately picked up by the table facilitator, and reinforces what one specialist said, *"I think many of the public participants tended to relate everything to their GP surgery and were not able to relate as well to hospital system. Not sure we got our points across" Specialist, London*

In **summary**, what worked less well tended to be identified by a minority of the specialist participants - the public responded very well to the materials shared with them and reported that they had the time to discuss and consider the issues in the dialogue.

Conclusion

Overall, the design and delivery of the public dialogue workshops was **well met.**

4.9 Lessons for the future

Any lessons for the future should be seen as tweaks, rather than substantive changes. Given the feedback from specialists and the evaluator's observations, these are -

- check materials for any perceived bias, or their potential to be seen as biased,
- extend the time for an Oversight Group and/or stakeholders to consider and review materials and workshop design,
- ensure the facilitators understand the subject matter to a deeper level, to enable the discussion to be kept on track and avoid conceptual misunderstandings among participants,
- ensure a distinction is made between the input of different types of participant - in this case patients and the public,
- consider a wider stakeholder engagement in the conceptualisation of the materials and positions presented to workshop participants.

5. Digital engagement

This section describes and assesses the **digital engagement aspect of the public dialogue.**

"I don't think we're there yet" Oversight Group member

Sciencewise encourage projects to look at digital engagement and encouraged the HRA to put it in the project bid. It was seen as being experimental and not too clearly shaped in terms of its objectives. The digital engagement was tendered separately, but the contractor bid for this piece of work and the dialogue in the same package. The budget for the digital element was £10K; £1K of which, according to OPM, was to be spent on advertising to attract users to the website, but because of other budgetary impacts contributed to the cost of food, staff and extra rooms at venues. The website (rphr.org.uk) was illustrated with many pictures and had twelve clickable links on its home page. These included an *About* link which describes the public dialogue and the role of the initiators (HRA), contractors (OPM) and the co-funders (Sciencewise). Once clicked through to the *About* page, there was no link back to the *Home* page; readers had to click on another heading, for example *Background.* From the *Background* page, there were links on to the *Issues* page, which explained the issues being considered in more detail before providing a link to the *Discussion Board*.

The front end of the website and the *Issues* page set out the three issues of the dialogue - Access to Patient Data, Consent to Approach Lists and Simplified Consent, but the *Discussion Board*'s headings were Consent to Approach Lists, Simplified Consent and Join the Debate. The Access to Patient Data had no provision made for it, and the Join the Debate strand could be seen to absorb all of the strands.

At the end of February 2015, there were three topics on the Discussion Board. *Simplified consent* had one response - "*Maybe consent could be give (sic) by text message"*. The second strand, *Join the Debate*, initiated by OPM with the words, "*Join the discussion to let HRA know your views about ways of recruiting participants for health research*", also had one response. In neither of these strands had OPM responded to the posts, by for example asking how the text message might be verified as being from a potential research subject. The third strand on *Consent to Approach Lists* had one post. As of 18th January 2015, there were 579 unique visitors to the website and 51 of these completed the survey. Of these 51, confidentiality and the ability to opt out were key in considering who has access to patient records. This is in line with the findings of the public dialogue, but 51 responses from 579 visitors to the site is not a huge return in terms of volume.

The overwhelming view from the OG in post workshop interviews can be characterised by these quotes -

"I don't think we got anything from it…the public and patients didn't engage with it." Oversight Group member

"I think we've learned how not to do it. The thing we need to think about is how to use digital for dialogue - how to enable a two way process, not just a survey." Oversight Group member

"Not sure how you could increase interest…but at the moment it indicates that it wasn't worth the money spent." Oversight Group member

"I think we did it partly because it's trendy and sexy to do so. It was a bolt on. I think we need to consider 'why'…to do it properly." OG member

"I think the HRA needs to understand how to do digital engagement more clearly - how it should be hosted, facilitated, what resources are needed, how to market and publicise it." HRA officer

The Oversight Group meeting on 19th January 2015 also criticised the digital engagement as being of little use. In subsequent interviews, two OG members suggested that the money may have been better spent by having an Omnibus survey on say, simplified consent, to draw some quantitative comparisons with what people thought in the dialogue.

OPM highlighted that the OG has between them around 500,000 tweet followers, and expected more traffic to be driven to the website as a result of this, but their analysis of traffic to the website shows just 142 people looking at the site via Twitter links.

Evaluation assessment indicates that not having a *Home page* link or a link to a suggested way to navigate the website did not make the experience of moving around the website an easy one. It was also suggested, by the OG, that the links to videos were a long way in, and they could have been hosted on the Home page.

The lack of contractor response to the people who had posted; and the difficulties in navigating the site suggest that the operation and structure of the digital engagement was also some way from being optimal.

Internet Scan

The HRA funded an additional piece of work called an internet scan. This is designed to scan the internet for key terms relating to the dialogue and see what conversations, comments or chatter is happening on the theme of recruiting participants for health research. The scan did not produce any findings suggesting that the issues in the dialogue were being discussed on the internet. The HRA[37] said that there was "*relevant material on the medConfidential website, but this did not appear*" and questioned whether the relevant search terms had been used for the scan.

Conclusion

The digital strand of the engagement was supposed to enable wider participation and enable a comparison with the public dialogue workshop findings. It did not do so. This aspect of the project is **not met**.

[37] Comments on the evaluation report - June 2015

Lessons for the future

- When working with digital engagement specialists in advance of tendering a contract, be clear to ask them what is possible and reasonable given the budget, timescale and resonance of the issue - to avoid disappointment later.
- Consider more what digital engagement is seeking to achieve, as some of its outcomes seem to be diametrically opposed to those of public dialogue. For example, it is easy to set up and run an online survey, but it is not possible within the confines of the survey to explain concepts in sufficient depth. Similarly the recruitment for the public dialogue workshops is understood to be representative, whereas those taking part in digital engagement tend to be self-selected and may have much stronger predefined views. So, even with a much larger response, it is not certain how to combine the online responses with those given in the public dialogue events. Some more clarity on the scope of public dialogue would be appreciated.
- Retain a marketing budget.
- Retain ongoing digital support on the Oversight Group or as part of the Sciencewise support. For example, the Sciencewise specialist in digital engagement could provide ongoing support for the digital engagement elements of a project by sitting as a member of the OG.
- Target a wide range of relevant stakeholders by email to make them aware of the website - it is low cost.
- Design the website so that it is easier to navigate, and has pages on its forum that align with the issues being discussed.
- Manage forum discussions.
- Manage the comments made on the website to control spamming.
- Provide a Home page link and consider a ‘How to use this website’ section.
- Specify what the internet scan will include and agree search terms and the duration of the search with the client.

6. Management and governance

This section addresses how successful the **governance** of the project has been, including the role of stakeholders, oversight groups, the commissioning body and Sciencewise.

Active and effective project lead. The HRA had a dedicated officer who acted as Project Manager from the conceptualisation of the dialogue through to its conclusion. They provided the day-to-day contact for the contractor and evaluator; convened the Oversight Group; initiated, wrote and contributed to presentations and materials at the workshops; recruited specialists and patients for the workshops; attended and presented at workshops; resolved logistical issues, such as catering at venues; and kept the HRA informed of progress. This role was essential to both the successful running of the dialogue and its supportive activities, and also enabled the HRA to have a deep appreciation of the findings from the dialogue and be 'hands on'.

Other engaged staff from the HRA. An officer responsible for developing guidance on simplified consent attended three workshops and sat as an observer on the OG. A Patient Involvement Coordinator observed one of the workshops, and the HRA CEO was interviewed before and after the dialogue workshops.

Effective Oversight Group. The HRA established an Oversight Group (OG) to oversee the dialogue process and ensure it provided a balance of perspectives to the public. Members of the group had the opportunity to provide expertise and share their experience of the issues being covered. A meeting was held on 7th October to discuss the proposed methodology of the dialogue. OG members also proof-read the dialogue materials and website text (making sure materials were fair, accessible and covered a collection of different views) between then and the beginning of the public dialogue workshops on 3rd November 2014. And the OG met after the dialogue workshops to consider the findings and the presentation of the report.

The group was made up of a range of experts with different areas of knowledge and experience. It was chaired by Simon Denegri from INVOLVE.

The following people also sat on the OG -

- Mark Taylor, external member of Confidentiality Advisory Group[38] hosted by the HRA
- Rachel Quinn, Academy of Medical Sciences
- Prof Roger Jones, Royal College of General Practitioners
- Adrienne Clarke, GlaxoSmithKline
- Ben Goldacre, member of the research community
- Alex Newberry, National Institute for Health and Social Care Research, Wales
- Sam Smith, medConfidential
- Suzannah Lansdell, Sciencewise

[38] CAG provides independent expert advice to the HRA (for research applications) and the Secretary of State for Health (for non-research applications) on whether applications to access patient information without consent should or should not be approved.

- Amanda Hunn, HRA
- Clive Collett, HRA (as an observer)
- and two Expert Patients, who remain anonymous.

The main comments from the OG about their role are -

"It would have been good to have more OG meetings…but overall I think we played a useful role as a check/balance/consultative voice for the HRA."

"I'm quite happy with how it worked"

"The OG did what it could in the time constraints. I think we should have had more questions about the digital approach, particularly about whether it was needed."

"The OG doesn't seem to have a role in advising on it (how the dialogue informs policy) and perhaps it should have been in the ToR. Even just a quick consultative role would be useful, but ultimately it is the HRA's decision on how the dialogue will inform policy."

"I don't think we had enough time to consider materials. I'm impressed that OPM turned it around, but they should have had longer."

Sciencewise support role. The Dialogue and Engagement Specialist from Sciencewise provided support and assistance throughout the project (attending OG meetings, contractor/client meetings, answering emails etc), and this was appreciated by the HRA Project lead. They were also active in a conciliatory role between for the contractor and HRA on matters of process design, workshop materials and report structures, although the HRA sometimes felt they were "on the contractor's side". The HRA lead also thought, on reflection, that it would have enhanced the project to have the Sciencewise Digital Specialist on the OG for the duration of the project, but she did acknowledge good support from them in the construction of the tender documents.

Other stakeholders. Due to both budget and time constraints the Oversight Group also provided a wider stakeholder perspective. There was not a separate stakeholder engagement to, for example, consider materials to be used in the workshops and on-line.

Conclusion

Overall the governance of the project was **well met**. The OG provided a wide range of perspectives, were active in the consultation on workshop design, provided insightful comments on reports and worked well with the HRA.

Lessons for the future

- Consider wider stakeholder engagement to assess the range of materials to be used in the dialogue and whether they reflect the range of views, facts and opinions on the subjects at hand
- Gather the OG together earlier and have more meetings to consider materials and the process used in the dialogue
- Consider the practicality of extending the Terms of Reference for an OG to include a consideration of dialogue results and their thoughts on what should and should not influence policy

7. Context

This section addresses whether **the conditions and circumstances leading to the dialogue process were conducive to the best outcomes.** Evaluation assessment is made against Sciencewise Guiding Principle 1 - Context.

Purpose. The project objectives were clear and stayed consistent throughout the project. In addition objectives for each workshop were produced and the OG was clear about it's role.

Timing. The need for the dialogue arose out of a need to review guidance, and as a result of a emerging ideas from a HRA dialogue in 2013 on the public's understanding of how their data was and could be used by health researchers. There were also wider drivers from the research community to address the simplification of the consent process, access to data and ways to approach people for consent to be in research. The results of the dialogue will feed directly into the revision of several pieces of HRA guidance to be produced in 2015; on the replacement to the Research Governance Framework, Guidance on Simplified Consent and Guidance on Recruiting Participants for Health Research.

Buy-in from policy makers. The HRA is the lead body for producing guidance and policy on health research and will use the dialogue findings to review policy and guidance. It will also use the dialogue findings in discussions with NIHR and others on the role of research nurses. One aspect of the dialogue - simplified consent - is also of interest to Ministers and currently the National Information Board is looking how we can make the procedures for setting up and running pragmatic trials in primary care more effective.

Conclusion

The dialogue was timely, had considerable buy-in from policy makers and the criterion was **very well met**.

8. Impacts and outcomes

8.1 Dialogue objectives

This section address how and to what extent the **dialogue objectives** were achieved and were they the right ones. Evaluation assessment is made against the Sciencewise evaluation guidance note SWP07 and the Sciencewise Guiding Principles.

Objective 1 - To inform the development of the HRA's new UK wide policy to replace the existing Research Governance Framework and its associated operational guidance.

It is clear that the HRA, Oversight Group, and the public participants, feel that the dialogue will be used to inform the HRA's review of policy and associated guidance for England. Although there is a small minority of the Oversight Group who are not sure that the product of the dialogue gives clear enough messages from the public, they did not disagree that the HRA will use it to inform the development of policy and guidance. 93% of the public participants, 15 out of 21 responses (across both workshops) for patients, and 28 out of 31 specialists' responses (across both workshops) agree or strongly agree that they *feel confident events will be used to inform HRA's review of policy*[39]. These are very high figures and illustrate a high degree of confidence in the HRA.

The HRA stated, in pre and post dialogue workshop interviews[40] that the dialogue results would influence -

- The replacement for the Research Governance Policy Framework
- Guidance on Simplified Consent
- Guidance on Recruiting Participants for Health Research
- Discussions on the role of Research Nurses in accessing patient records

The Guidance on Simplified Consent has also been consulted on with a range of stakeholders, and the HRA reiterated that the results of this dialogue would be analysed alongside the responses to the stakeholder consultation, when drafting the revised guidance.

The topic of of Research Nurses and their access to patients notes will include guidance in its guidance on Recruiting Participants for Health Research, but the HRA will also have discussions with the NIHR on the role of research nurses; as the public did not understand that they had a role in research and were uncomfortable with the concept that research nurses could have access to patient data, without making the public aware. As the dialogue contractor reported, the public initially reported - *"…an almost unanimous response that they would not be allowed access. Some groups thought that they would have access, 'but only with consent'*[41]." After discussions, the public could see that there might be a need for them to do so, and so placed conditions on this - that the public should be made aware of this activity and they should be able to opt out of their notes being used in this way.

[39] Q10 on Workshop Evaluation sheet - see appendix 5

[40] Interviews with the lead HRA officer, HRA CEO and another HRA officer

[41] Findings - Who has access to your patient record? and Appendix 4 - Summary of Views on Access to Patient Records

On access to data, this will be covered in the the forthcoming Guidance on Recruiting Participants for Health Research. The HRA believe that there will also be *"additional guidance, but developed over a longer time frame; and this will be influenced by forthcoming EU regulations on data protection.*[42]**"**

Members of the Oversight Group had a range of responses to the dialogue findings. Mostly they were positive -

"…the dialogue hasn't produced any surprises…" Oversight Group member

"I think the HRA will take into account the range of opinions and views on the proposals…they can take comfort, as it's predominantly positive" Oversight Group member

"On simplified consent the [dialogue] report is helpful and will contribute to refining the policy." Oversight Group member

"For the simplified consent documents…the public dialogue findings will provide a comparator, but at the moment it looks as though they are broadly complementary." OG member

There were a few comments that were less certain -

"It raises some principles, but it also raises as many questions as answers." Oversight Group member

"In some areas it gives confidence about moving forward, in other areas we need further work to explore issues" Oversight Group member

"…difficult to see how the dialogue will inform a clear set of guidelines." Oversight Group member

Conclusion

The objective was that the dialogue would *"inform the development of the HRA's new UK wide policy to replace the existing Research Governance Framework and its associated operational guidance"*. It is clear that the HRA has in motion processes to use the dialogue findings to influence and inform policy. Initial drafts of both the new policy framework for health and social care research and new guidance on the identification and recruitment of potential participants have been completed since the findings of the dialogue were made available and have incorporated relevant aspects of the findings. It is also timely - the policy framework needed to be reviewed; and it is a condition of Sciencewise funding that a dialogue will influence policy. The objective is **very well met**.

Objective 2 - To provide opportunities for members of the public and patients to discuss and explore their aspirations and concerns about the governance of health research in relation to recruitment, data and consent, especially:

- **How patient data might be used for the identification of potential participants in research including perceived benefits and risks and who participants think should be allowed to access patient records for research**

[42] HRA officer

- **Different models for approaching potential research study participants including consenting to being approached directly about research**
- **The plan to develop simplified models of consent for simple and efficient clinical trials of already licensed drugs and other interventions in common use. - yes, but some caveat on time available - participant quotes, OG quotes, observations**

The evaluation of the workshops and the digital engagement is in sections 4&5, but in summary public feedback[43] scored between 89% and 95% (tend to agree plus strongly agree scores) across all locations and both rounds of workshops[44], on these questions -

- being *adequately informed to be able to discuss the issues - Workshop 1 90%, Workshop 2 92%*,
- being able to *ask questions and get appropriate answers - Workshop 1 92%, Workshop 2 94%*,
- having *enough time to discuss the issues - Workshop 1 89%, Workshop 2 89%*, and
- being *able to contribute and have my say - Workshop 1 95%, Workshop 2 95%.*

These are very high scores and demonstrate how much the public appreciated the design and delivery of the workshops. As one public participant said, *"The facilitators ran the sessions very smoothly - the transitions between sessions flowed, they weren't random, there was a natural progression from one idea to the next. The breaks were spaced right, and although there was some jargon, mostly it was jargon free and clear and understandable."*

On the same questions, the specialists and patients[45] had similar scoring[46].

Patients scores (tend to agree and strongly agreed) were -

- being *adequately informed to be able to discuss the issues - 16 out of 20*,
- being able to *ask questions and get appropriate answers - 19 out of 21*,
- having *enough time to discuss the issues - 13 out of 21*, and
- being *able to contribute and have my say - 18 out of 21.*

Specialist scores (tend to agree and strongly agreed) were -

- being *adequately informed to be able to discuss the issues - 26 out of 32*,
- being able to *ask questions and get appropriate answers - 31 out of 32*,
- having *enough time to discuss the issues - 20 out of 33*, and
- being *able to contribute and have my say - 32 out of 33.*

[43] Returns per workshop round ranged from 101 to 106 people

[44] From Workshop Evaluation sheet - see appendix 5

[45] Note - the number of evaluation forms returned from patients and specialists does not tally with the register of named specialists and patients. The explanation is a confusion on the distribution of forms at workshops where the evaluator was not present. The mis-match is minor and does not materially affect the findings.

[46] Specialist and Patient scoring is provided as numbers, rather than percentages; as percentages are not a relevant measure with such low numbers.

Conclusion

The objective does not ask for a precise quantification of the *opportunities* afforded to *discuss and explore*, but it is clear that the public experienced plenty of opportunities to do so, although patients less so. In terms of being the right objective - a dialogue by definition needs to provide opportunities to discuss and explore issues; some of the themes emerged from a previous dialogue and there was a need to address these themes as part of a guidance review. This objective has been **well met**.

Objective 3 - To identify areas of public and patient consensus, disagreement and uncertainty raised by these aspects of health research governance.

The evaluation of the workshops and the digital engagement is in sections 4&5. In summary, the dialogue was successful in identifying areas of broad consensus, disagreement and uncertainty; but it was not designed to identify the specific differences between public and patient views. This is partly due to the differing numbers of patients attending each event, and the fact that the contractor did not consider ways to collect and analyse their input separately.

The Oversight Group was clear in its feedback on the contractor's report, that it highlighted some principles, some clarity on some issues and uncertainties on others. As one OG member put it, "*I think we need a bit more precision in the report, what was the amount of consensus?*" And another commented - *"I think there's also a difficulty in differentiating between what the public said and what patients said; I'm not sure the facilitators made the distinction in their group work."*

In pre and post workshop interviews with OG members the key issue was understanding the plurality and pattern of the public and patients thoughts, and while it is hard to distinguish between public and patient views, there are clear messages (albeit with caveats) on the issues that were discussed.

Conclusion

This objective has been **met**. It would have been well met, or very well met, if the OPM report made more of a distinction between public and patient views. Most views in the OPM report are referenced as "participants".

Objective 4 - To enable the HRA to build on previous experience in public dialogue, to pioneer innovative approaches in public and patient engagement where appropriate, and to develop knowledge and understanding of public dialogue and its potential for future applications.

Build on previous experience

The HRA conducted a public dialogue in 2013 on the streamlining and simplifying of the research approval process. The need to explore how the public view the use of their data emerged from this dialogue and, combined with a need to review guidance, the HRA commissioned this dialogue.

As one OG member put it about the current dialogue - "*…impressed by both the look of it and the quality of the process used. It's clear it (dialogue) can work well, even on a not very engaging subject. So it's a considerable success"*. Suggesting that the HRA has built on its previous experience and maintained a quality approach to dialogue.

Pioneer innovative approaches in public and patient engagement

While the dialogue used a plurality of approaches in the workshops, none of them were innovative; as they have all been used in other workshops or dialogues. In the context of the HRA and it's peers however, the use of dialogue is pioneering. As the Chair of the OG commented - "*.. the HRA is streets ahead of the other regulators on the use of public dialogue - they involve people in decision making, have a cohesive strategy to do so and should be applauded for it.*" And the HRA's CEO said, "*Much of the engagement in this field is more 'tick box' and we want to enhance patient and public involvement. We have a culture of finding different ways to engage with people - not just patients who have first-hand experience, but also the general public who might in the future."*

The HRA also explored the use of digital engagement in public dialogue; and while it did not work as desired, there are lessons to be learnt about specifying its purpose, its design and the outputs needed from digital engagement.

Develop knowledge and understanding of public dialogue and its potential for future applications

Several learning points have emerged from this dialogue - from the small scale (more time to consider materials) to the larger scale (the need to develop a better understanding of how to deploy digital engagement) and the HRA CEO has made it clear that they will continue to use dialogues with the public and patients to 'test' their appetite for reforms, innovations and changes to policy and guidance. HRA funding has been agreed for future public dialogue on data sharing for secondary research purposes and on the role of the Confidential Advisory Group (CAG) which gives approval on behalf of the Secretary of State for identifiable data to be shared without consent in circumstances where consent cannot be sought. This exercise will be funded in total by the HRA.

"…it was good to do and it has generated valuable debate…I think there needs to be a more educative phase before the dialogue, so the issues are more in the public domain" Oversight Group member

"Some things to think about in terms of how people are recruited, how long workshops are and the types of people who show up." Oversight Group member

Conclusion

This objective is **well met**. Subsequent discussions between the HRA, Sciencewise and other agents doing public and patient engagement will embed some of the lessons and produce thoughts for future dialogues. This is also an appropriate objective as it contributes to the development of both the HRA's practice and the wider field.

Lessons for the future

- Continue to explore other ways of public engagement and dialogue.

8.2 Influence

This section addresses what **influence** on public participants, policy makers other than the HRA[47] and other stakeholders, the dialogue has and will have.

Specific influence on knowledge

The post workshop video produced by OPM demonstrates that public and patient participants developed an understanding of the issues being discussed - *"The workshops raised issues that I was not aware of - consent, privacy, access to information[48]"* and for one public participant, being a participant has changed the way they relate to their care professionals - "*By chance I needed some NHS care in the run up to these workshops; so it as very interesting for me to learn about what goes on behind the scenes. It was good to know how information is used and the ethical issues surrounding it. Now I know these things I can ask more pointed questions in the future and not just take things for granted.*"

Other members of the public[49] said, in workshop 1, that they, "*learnt what the current process is and how things could be done differently*", "*who has access to my files*" and that they gained "*new insight into how info is shared in GP practices and hospitals*". In workshop 2, members of the public said that they had learnt about "*what statins were and their differences*", "*about the process of trials*" and the "*different consent procedures*". One person said that it was "*all really useful info*".

Influence on specialists

One specialist said that the results of the dialogue would validate their work, as the models used in the dialogue were based in their practice; and they hoped that this would then draw other research practitioners to them; to seek use of their approach and materials.

Other specialists commented[50] that they had learnt about the "*public's viewpoints and knowledge of access to their records*" and "*how people new to the subject thought about these questions*", but also that they observed that dialogue "*stimulated discussion very effectively*."

"Thank you - this will help inform our local practices too" Specialist, London

"The breadth of strong feeling, with a suggestion that younger individuals are more willing to share full access" Specialist, London

"Feel more able to understand public concerns about record access" Specialist, Liverpool

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[47] For the impacts on the HRA - how the dialogue informs policy development, dissemination of results and impacts on their use of dialogue see section 8.2

[48] Public, London in post workshop video

[49] Q12 on workshop Evaluation sheet - see Appendix 5

[50] Q12 on Workshop Evaluation sheet - see Appendix 5

Outside of the dialogue workshops, one OG member remarked how they will *"quote from the (dialogue) report in our work…" Oversight Group member*

Dissemination

This section covers how the dialogue results will be **disseminated** and the use of results beyond informing HRA policy.

Note - The findings here relate to early internal dissemination and future intentions for dissemination of the results.

"I'll flag it up in our Task Group.." Oversight Group member

"I'll disseminate it to colleagues in the National Cancer Research Consumer Liaison Group…" Oversight Group member

"On simplified consent we'll feed back to Ministers" HRA officer

Several OG members talked about how the dialogue results would both contribute to discussions among peers and within and between organisations, but also how it could form the core of articles on dialogue in, for example, the British Medical Journal, the Journal of Health Research and Policy, and the British Journal of General Practice. Especially as, as one Oversight Group member put it, *"the findings will be of interest to GPs, especially on the prospects for simplified consent and approaches to consent"*.

More generally, the HRA believe that the results of this dialogue will contribute to the general debate about access to patient data across the health field.

Conclusion

It is too early to understand the depth and range of this dialogue's influence, but it is part of an ongoing discourse about consent, the ability to opt-in or opt-out of your data being accessed and how people are approached to be in research. It is clear that it has not only affected the stakeholders in the field, but also the public and patient participants who took part.

There is a clear intention to share the findings among peers and by working for publication of related articles. However, until the report is published, this cannot be verified.

8.3 Other changes

There are a few other potential impacts as a result of the process on the development of **policy** decisions and approaches to future policy making - "*In Wales, we'll use it (the report) to build on, especially around approaches to consent*[51]." And another OG member thought -

[51] Oversight Group member

“It could affect thoughts around the care.data work - especially views on opt in/opt out perspectives”.

The dialogue raised a number of issues which were not directly relevant to the dialogue objectives, but were felt to be useful to **explore** later -

“…the dialogue didn’t really explore the concept of research itself as a good thing…” Oversight Group member

“I also think that finding out that people don’t read the information provided with medicines, suggests a possible study into how people could more effectively get the information.” Oversight Group member

The OG meeting on 19th January 2015 also thought that it would have been good to have the time to understand what people understood the NHS to be (both conceptually and literally); and the need to consider the role of non-NHS researchers, for example sociologists or academic researchers.

9. Costs and benefits

This section looks at the **costs and benefits** of the dialogue.

As the policy changes have not yet been reflected in published guidance etc, the benefits of the dialogue can only be considered in terms of immediate reflections and aspirations, and will also need to be measured over a longer time frame and include -

- how dialogue practice develops specifically in the HRA, as a result of the accumulated reflections and lessons from this and an earlier dialogue in 2013, and
- specific, as opposed to likely, impacts on HRA policy making, guidance and regulations.

Participants - both expert, patient and public related both enjoying the process and learning from it. Additionally they appreciated the thought and consideration put into the design and delivery of the process by OPM, HRA and others.

For the wider community using or advocating public dialogue, a consideration of whether the same results could be got more cost-effectively on-line, using other methods, for example opinion polls or on-line engagement, could be considered. In this dialogue the benefit of dialogue itself does not seem to be in question, but one OG member did remark - *"I'm reflecting on whether these forms of exercise are past their sell by date. I think the field needs to be refreshed. People will say the drawbacks of the exercise are that only 100 people were involved, or 'it doesn't reflect what I see and hear around the country'."* The latter point being unintentionally ironic given it refers to the dismissal of a qualitative approach by an anecdotal approach.

There is larger consideration - the comfort taken in quantitative numbers - but this reflects the diversity of the research field; as another OG member put it - *"I think it comes down to the qualitative versus quantitative argument - different people from different research disciplines will have contrasting ways of interpreting the results of the dialogue."*

The costs of the dialogue were -

Sciencewise grant	£66,650
HRA (and other) cash	£35,650
HRA (and other) in kind	£29,950
Total	**£132,250**

In addition, Sciencewise mentoring and other support was provided, costing £15,075.

The design, governance, workshops, materials and products of the dialogue all met their objectives - mostly well or very well - with the exception of the digital engagement. This did not meet its objectives and produced no benefits, other than a need to consider why it didn't work.

Conclusion

While more money could have been spent on this dialogue - to engage the wider stakeholder field, to run an Omnibus survey, to construct a more effective digital engagement - the objectives of the dialogue have been **very well met** within the resources allowed. But it should be noted that the contractor reports that they believe the budget to be 20% less than was needed; as they spent significantly more days on the project than they budgeted for.

10. Credibility

The HRA needs to find the dialogue process and products credible, as it will use the findings to inform policy and guidance development. By the same token, the OG and the wider stakeholder field needs to find the results credible - in how they are applied to policy and guidance development.

The HRA CEO says, for example "*…it will fundamentally affect the draft guidance on 'access to notes'…*" and "*Simplified consent will only move forward with researchers using the support garnered from the dialogue*".

All, **bar one**, of the OG group related how they thought the dialogue would inform policy and guidance - the one exception saying that "*There's an issue of sample size - how representative will the group be seen as? And the digital aspect can't really be used, so I'm not sure the dialogue can be used to clearly inform policy.*"

In comparison, the HRA reported that a consultation exercise that ran in parallel to this on the simplified consent issue, attracted 103 responses from individuals and organisations. The dialogue engaged 108 members of the public, 20 experts and 13 patient experts; as well as ten stakeholders from diverse perspectives on the OG.

Participant feedback to the question on the post workshop evaluation form - *I feel confident that these events will be used to inform the HRAs review of research policy*[52] - scores 93% and 94% in each round of workshop for the public; specialists score this 16/18 and 12/13 in each round; and patients score it 7/8 and 8/13 in each round - demonstrating a high level of credibility from the dialogue's participants.

Conclusion

The participants, HRA and all, bar one, of the OG believe the dialogue will be useful and effective in informing HRA policy. Additionally, the dialogic elements of the project and its governance are all consistent with good practice in the field, as set out by the Sciencewise Guiding Principles. It's credibility is **well met**.

[52] Q10 - see Appendix 5

11. Lessons

This section comprises of the lessons from each previous section.

Design and delivery

- Check materials for any perceived bias, or their potential to be seen as biased.
- Extend the time for an Oversight Group and/or stakeholders to consider and review materials and workshop design.
- Ensure the facilitators understand the subject matter to a deeper level, to enable the discussion to be kept on track and avoid conceptual misunderstandings among participants.
- Ensure a distinction is made between the input of different types of participant - in this case patients and the public.
- Consider a longer and wider stakeholder engagement - for example with patient advocate groups, other privacy campaigners - in the conceptualisation of the materials and positions presented to workshop participants.

Digital engagement

- Work with digital engagement specialists in advance of tendering a contract to be clear on what is possible and reasonable given the budget, timescale and resonance of the issue.
- Consider the need for a digital engagement specialist on your Oversight Group, potentially provided by Sciencewise.
- Design the website so that it is easier to navigate, and has pages on its forum that align with the issues being discussed.
- Manage forum discussions.
- Manage the comments made on the website to control spamming.
- Provide a Home page link and consider a ‘How to use this website’ section.

Management and governance

- Consider a longer stakeholder engagement to enable a deeper assessment of the range of materials to be used in the dialogue and whether they reflect the range of views, facts and opinions on the subjects at hand.
- Gather the OG together earlier and have more meetings to consider materials and the process used in the dialogue.
- Extend the Terms of Reference for an OG to include a consideration of dialogue findings and their thoughts on what should and shouldn’t influence policy.

12. Conclusions

The dialogue met all its **objectives**. The dialogue will inform various strands of HRA policy and guidance development covering access to data, approaches for consent and simplified consent. Specifically -

- The replacement for the Research Governance Policy Framework
- Guidance on Simplified Consent
- Guidance on Recruiting Participants for Health Research
- Discussions on the role of research nurses in accessing patient records

The public, patients and specialist participants to the dialogue overwhelmingly agreed that they had the opportunity to discuss and explore their aspirations and concerns. Areas of consensus, uncertainty and agreement were identified, but the distinction between public and patient views was not made. The HRA has learnt more about the use of public dialogue - especially how not to undertake a digital engagement.

The **delivery and design of the workshops** met their objectives well, but the digital engagement did not; although the HRA and its OG have learnt a lot about how not to do it.

The **Sciencewise Guiding Principles** were all met, but there was some scope for improvements. The dialogue was timely and met with a requirement to review policy guidance, and also followed on from a previous dialogue; although the timing for OG members to review materials was short. The workshop processes and materials were engaging and informative and OPM worked well to elicit a range of views from participants on the subjects being discussed. The range of participants in the room was very diverse in terms of socio-economics, age, gender and ethnicity.

External stakeholders were involved in the OG and contributed to the shaping of the dialogue, reviewed materials and influenced the drafting of the final report. Their role would have been enhanced by more meetings - either physical or virtual.

Participants were **highly satisfied**[53] with the dialogue - public (94%), patients (17/20), specialists (28/32). All of the OG, bar one (who was not clear how the dialogue results could be used to inform policy) were also largely satisfied with the dialogue.

The **main achievement** of the dialogue is that it will inform policy that will be of interest to the wider stakeholder research community and protect the interests of the public.

Other **impacts** include a better knowledge of the subject and how the field of research works amongst public participants. For the HRA and its stakeholders, the findings will also be used to inform discussions on how members of the public respond to issues of data access, being approached to be in research and ways of simplifying consent. The HRA believes the dialogue was valuable - but it's too early to clearly assess how the wider field will respond.

The dialogue's **costs** are broadly in line with other similar exercises, and it has the **benefit** of directly impacting on policy in this year -

- The replacement for the Research Governance Policy Framework

[53] Q13 on the evaluation form - Appendix 5

- Guidance on Simplified Consent
- Guidance on Recruiting Participants for Health Research
- Discussions on the role of Research Nurses in accessing patient records.

It has also deepened the HRA's understanding of dialogue and is likely to prompt more thinking on the use of digital engagement in the wider field.

Credibility ratings were high across all respondents in interviews and on workshop evaluations. There were one or two remarks on whether an additional quantitative survey would have been useful to compare to the qualitative dialogue workshops. This is an approach other dialogues have taken.

At the same time as this dialogue, there was a parallel stakeholder consultation conducted by the HRA on simplified consent, that shows broadly similar findings to the public dialogue - again offering some credibility to the dialogue findings..

Several **lessons** (see previous section 14) emerge from the dialogue, but two that stand out are -

- establish an Oversight Group earlier and provide more time for them to consider materials and the shape of the dialogue, and/or consider engaging a wider stakeholder group to test the representativeness and potential bias of materials and processes used in the dialogue, and
- be clear on what you can reasonably expect from digital engagement (including doing some research on what digital engagement has worked previously and why) and manage expectations accordingly.

The evaluators appreciate the time, reflections, documents, correspondence and thoughts that were shared with them in the compilation of this report. Thank you to all who worked with us.

Appendix 1 - Baseline Assessment

Baseline Assessment
Recruiting participants for health research - a HRA Public Dialogue
November 2014

Introduction
This assessment uses the product of eleven interviews with the Oversight Group (OG), Sciencewise Advisor and HRA Chief Executive, and is further informed by -

- an overview of the myriad of email exchanges between the contractor, OPM, and HRA in the design of materials, website and process for the dialogue
- an overview of documents produced by HRA
- the evaluator's notes from observation at an OG meeting and participation in the Inception Meeting

to produce an initial assessment of the thinking and aspirations of the Oversight Group, HRA and Sciencewise for this dialogue. It's principal frame of reference is the objectives for the dialogue, but the subsidiary questions and Sciencewise principles that will characterise the achievement of these objectives in more depth, have also been considered.

Informing future policy
The website for the dialogue states that "the purpose of the Health Research Authority (HRA) is to protect and promote the interests of patients and the public in health research in order to support both their confidence and participation in health research…"[54] and the first of four objectives of the dialogue is to "inform the development of the HRA's new UK wide health research governance framework and its associated guidance"[55]. Oversight Group members were asked how they understood the dialogue would influence policy development.

A range of perspectives emerged from the interviews covering the **process** of influence; what people hoped to see reflected in the **content** of the review; and views on the **principles** in operation.

Process - Everyone was clear that the HRA Board makes the final decision on the new "research governance framework and its associated guidance"; with some interviewees sharing an understanding of the role of HRA officers and the role of other partner organisations, like the Department of Health or Information Commissioners Office on use and access to data issues. Other interviewees also reflected on the role of the OG in ensuring that the product of the dialogue was considered in the HRA's process of review.

Interviewees also talked about how policy might be affected in areas other than those covered by the dialogue, for example by suggesting general principles for consent and data use applicable in other areas of research; influencing interviewee's own organisational perspectives on consent; or characterising principles which may then be used to advance an argument in common law.

For many of the interviewees the use of a public dialogue approach was novel, but those who had experienced previous dialogues spoke about how they had shaped policy in other areas and how the general field of public and patient engagement had matured and developed over the last couple of decades.

Content - Several interviewees raised the specific issue of understanding what the public and patients would find acceptable in terms of being approached to be part of a research project and

[54] www.rphr.org
[55] from Invitation to Tender

the ways in which people would be informed about, and then asked to give (or decline) consent for their data to be used or included in research. Related to this was an aspiration to understand how views change during the dialogue and how they have changed more widely over time.

As well as seeing several models of consent being shared within the dialogue, a consideration of how participants in research will be kept informed about their participation and the results of research was also flagged.

Principles - A number of interviewees raised issues which can be characterised as principles that either the dialogue or the HRA should consider-

- The **transparency** of the the process used in the dialogue (eg will the report on the dialogue be in the public domain?) and that it will be clear to an outside observer how the findings of the dialogue are used by the HRA;
- The role of the OG in ensuring the dialogue findings are fed into the HRA review (**governance** and **scrutiny**);
- The HRA demonstrating that its stated belief that its work is better informed by what the public say is evident (**walking the talk**);
- That the needs of researchers and public safety are also considered (**plurality**).

Initial evaluator observations

The work assessing whether the product of the dialogue does inform policy will follow after the public dialogue events and the digital engagement is closed. However, it is clear that the OG understands the HRA's responsibility to use the findings of the dialogue in its shaping of future research governance guidelines. And that the HRA is committed to, and sees the value in, using public dialogue to inform policy development.

It is also clear that whether consciously or not, the OG's general thinking on dialogue and its role in supporting the project aligns with Sciencewise good practice principles.

Members of the OG also have expectations of how the dialogue might inform their own or other organisations' approaches to the issues and the use of dialogue. Follow up questions in early 2015 will assess whether these expectations might be realised.

Shape of the dialogue

The second dialogue objective focusses on providing "…opportunities for members of the public and patients to discuss and explore their aspirations and concerns about the governance of health research in relation to recruitment, data and consent…". In relation to the public dialogue itself, interviewees talked about -

- their perspectives on the dialogue process - for example, were there a range of activities to build understanding and allow learning and discussion?;
- the quality and usefulness of materials used - did these reflect the plurality of views on the subject? Did they help to both build understanding and promote dialogue?;
- production of materials - stakeholders should be involved in this;
- involvement of experts and patients - how do they influence thinking? How are they 'managed' in the workshops?;
- time for building understanding - dialogue requires some reflection time, what are people expected to do between events?;
- time for discussion and deliberation - is there enough time to really have a discussion on the issues and engage with experts?;
- the capture of emergent ideas - surprising things may emerge, how will they be captured, explored, interpreted and reported?;
- the impact of the dialogue process on the public and patients, but also the thinking of experts and other stakeholders - how will changes in thinking be tracked?

- how the public were influenced by patient or other expert views - how does the process avoid introducing a bias towards one view or another?;
- whether assumptions and generalities were explored - is there time to discuss and talk about where people get their understanding from?;
- the composition of the public and how this might be defended against criticism - are the selection criteria right? Will there be enough much older people?
- will people come back to the reconvened workshop?

With regard to the digital engagement, interviewees were mainly interested in how the people engaging with it compared to the general population; the numbers who got engaged; whether any further depth of insight was gained through providing a digital platform; and an interest in how it works in practice.

Initial evaluator observations
The discussions at the inception meeting, Oversight Group and in email exchanges between OPM, Sciencewise, the OG and HRA, make it clear that much thought has gone into the workshop design; the role of patients and stakeholders; and the production of stimulus materials. With workshops starting next week, the reception by the public, patients and stakeholder participants in the workshop to the processes designed and materials produced will be measurable - and enable an assessment against the Scope and Delivery aspects of the evaluation among others.

Product of the dialogue
The third objective of the public dialogue is “To identify areas of public and patient consensus, disagreement and uncertainty raised by these aspects of health research governance”. All of the interviewees expressed a view that reaching a consensus wasn’t necessarily important - what was critical was an appreciation and exploration of the public and patients’ thinking underlying their perspectives on the issues being discussed. And whether this exploration highlighted any general principles which would be useful for the HRA.

Interviewees also suggested that this would -
- indicate areas that needed more explanation;
- help to characterise questions for the following consultation;
- in sharing the variation of views demonstrate that the HRA were open to a plurality of opinion;
- help to assess accountability, by making clear which views had or hadn’t influenced policy and why;
- understand the diversity of opinion and through exploration, understand what informed it

Initial evaluator observations
These thoughts and reflections demonstrate that the OG is not interested in finding the ‘right’ answer, but has a genuine interest in the findings of the dialogue and the process by which those findings where arrived at. It reinforces the desire to see time and space in the dialogue for issues to be discussed and explored meaningfully.

Learning from the dialogue process
The fourth objective of the dialogue is “To enable the HRA to build on previous experience in public dialogue, to pioneer innovative approaches in public and patient engagement where appropriate, and to develop knowledge and understanding of public dialogue and its potential for future applications”. In addition, the dialogue process and its usefulness will have a wider resonance among the Sciencewise community and among the partner organisations involved in this dialogue.

The main aspects of desired learning to emerge from the interviews were that many interviewees have not directly experienced a dialogue process; so were keen, in a general sense, to understand how a dialogue process worked and how it is different to other forms of public engagement.

What difference the digital platform brings to the findings and the process was of explicit interest to members of the OG; as were its mechanics and how it managed to embrace dialogic elements, rather than just be a information portal and a survey platform.

How the stimulus material is received, and its potential for further use was cited by several interviewees; and what questions or information elicit more responses than others.

Can the public and patients be seen separately? How is this done and what is the effect of it? Does the randomly selected member of the public vary in their view from the patient representative?

There was also an interest in how this process might compare to that being used in other arenas eg the ongoing consultation on care.data.

Initial evaluator observations

These are not unexpected and will be reflected in the evaluation of, among other things -

- how the project is delivered in the workshops;
- how the HRA considers the process, the elements of it and its future usefulness;
- how the OG responds to outputs;
- other 'noise' from interested parties;
- and whether the dialogue process becomes more understandable and explicable to those OG members who have little or no experience of it.

Next steps

My next tasks as an evaluator are to observe four of the eight dialogue events, analyse evaluation forms (for the public, patients and experts) from all eight events, conduct and analyse ad-hoc interviews with participants at the dialogues and review all of this in the context of the the process design and material production activities, objectives of the dialogue and the wider Sciencewise and OG questions from the ITT[56].

Subsequently I'll be talking to the OG and a few other stakeholders about the dialogue findings and how they are, and will, affecting policy development and their personal and organisational learning about the use of dialogue processes.

Carl Reynolds
Independent Evaluator, 3KQ

November 2014

[56] see the Evaluation Plan for details

Appendix 2 - Experts present at the workshops

- Anita Hanson, Senior Research Nurse in Pharmacology
- Charlene Roe, Manager of Oncology Research Team
- Claire Shovlin, Cardiovascular researcher
- Dr Lamiece Hassan, Governance Research Officer
- Dr Malcolm Oswald, Independent IT Professional and advisor to HSCIC
- Emma Thomas-Jones, Primary Care Research, Cardiff University
- Graham Wylie, CEO Medical Research Network
- Hugh Davies, HRA Ethics lead and paediatric researcher
- Jane Darmanin, Velindre Cancer Centre Clinical Trials Unit
- Jenny Preston, Consumer Liaison Manager, NIHR
- Keith Wilson, LHCH Patient Research Ambassador
- Kelly Gleason, Research Nurse
- Libby Batt, Research Nurse, Velindre NHS Trust
- Lisa Hurt, Public Health Research, Cardiff University
- Lorraine Burgess, Clinical Research Unit Manager, Liverpool and Broadgreen University Hospital
- Micaela Gal, School of Primary Care Research, Cardiff University
- Nina Gobat, School of Primary Care Research, Cardiff University
- Prof Tjeerd Van Staa, University of Manchester
- Professor Brendon Delaney, Kings College, London
- Rhian Hughes, NIHR CRN
- Rhodri Huws, Department of Health and Social Care Research, Welsh Government
- Sir Ian Chalmers, Health Services research, co-founder of Cochrane and coordinatator of the James Lind Initiative
- Tim Sprosen, University of Oxford
- Urmi Bapat, Clinical Researcher and ethics committee member

There were also nine patient experts who remain anonymous.

Appendix 3 - Workshop Participant Evaluations

WORKSHOP 1 - combined scores and commentary

1	I am aware of and understand the **objectives** for this whole dialogue process	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	2	4		20	80	94%
	Patient	1			4	3	7/8
	Expert				2	18	20/20
	Comments **Public** - Objectives outlined at the beginning; Interesting; Very well informed; The facilitators were clear and concise; To help with the process of medical; Well informed; Very well presented. **Patient** - I came in to cover at short notice, but the information letter and presentations were clear; Would have liked more info before. **Expert** - I work for the HRA, so yes; Clearly explained during session; It all leads to the commercial selling of patient data.						
2	The **information** presented throughout the workshop seemed fair and balanced	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1		5	38	62	94%
	Patient	1			5	2	7/8
	Expert		1	1	3	15	18/20
	Comments **Public** - Very good; Some 'anti-research' comments/questions were met with disdain by one particular 'professional' ; Took everyone's comments into account; Interesting; Swayed towards the favour of researchers; Well informed; They was good and honest. **Patient** - But not all research saves lives. This was emotive message; I think there was an understandable bias towards change. **Expert** - Video is somewhat biased towards increased access to data by researchers.						
3	I feel that I now have a better understanding from this workshop of the **issues** involved in how I might be approached to be a participant in research.	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	2	2	32	70	93%
	Patient			3	2	3	5/8
	Expert		1	1	6	11	17/19

	Comments **Public** - Well informed; I got to see both sides - the good and the bad of getting involved; Experts were communicating the message clearly; Very informative and interesting; But I don't want to take part in research. **Patient** - Good knowledge available; I feel I already understood this, but have some further insight gained. **Expert** - Think many of the public participants tended to relate everything to their GP and surgery and were not able to relate as well to hospital system. Not sure we we able to get the points across in the time; Lots of confusion between different stages of research process and what level people should opt in; Yes, although it is not a simple area; The miming session was clear and makes it easy to understand and remember process.						
4	I feel that I now have a better understanding from this workshop of the **issues** involved in how patient data is and might be used to identify and recruit participants for research.	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	3		3	27	70	94%
	Patient			3	1	4	5/8
	Expert		2		10	8	18/20
	Comments **Public** - Good; Much required info and talk; Extremely satisfied with process. **Experts** - Difficult in a short deliberative process; On my table limitations on disclosure no matter who looked at data, not clear.						
5	I felt that I was adequately **informed** today to be able to discuss the issues	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agreew
	Public	2	2	6	32	62	90%
	Patient	1		1	3	2	5/7
	Expert		2	2	8	8	16/20
	Comments **Public** - Good info; Definitely. **Patients** - Perhaps use simpler/clearer terminology/concepts?; You are getting people to give opinion without full facts; Did not adequately allow for lack that some people may have low literacy levels (evaluation forms and use of post it notes and written objectives). **Experts** - The people on our table had not researched background, but clear information provided during sessions in easy snippets; Quite rushed at times, lots of information to take on board.						
6	I could ask **questions** easily and get appropriate **answers**	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agreen't Know
	Public	1	3	4	32	65	92%
	Patient				4	4	8/8
	Expert			1	5	14	19/20

	Comments **Public** - Helped having expert available; Every question I asked had an appropriate answer; Lots of talking over each other at tables; Some questions were not answered; Very organised. **Experts** - Asking Qs very easy - though only a selection arrived in plenary; Yes, good idea to have experts, but could have checked the nature of their expertise first and made sure tables more balanced.						
7	I had enough **time** to discuss the issues	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	2	4	6	43	51	89%
	Patient		1	2	4	1	5/8
	Expert	1	5	1	10	3	13/20
	Comments **Public** - Sometimes we had too many ideas and not enough time; Plenty. **Experts** - Within tables yes, plenary no (only selection addressed); Rushed at times; Discussion would get going and facilitator would leave table to do presentation = a little disjointed.						
8	I was able to **contribute** my views and have my say	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	3	1	32	69	95%
	Patient	1	1	1	4	1	5/8
	Expert			1	10	9	19/20
	Comments **Public** - More than some. **Patients** - The man next to the facilitator was a bit quiet; Some people made no contribution and others dominated the discussions. **Experts** - As always some more vocal than others; Some 'group think' - might have captured individual views more; Sometimes more participants vocal than others .						
9	I understand how the **results** of the workshop will be used and how we will hear what happens next	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	2	1	5	37	57	92%
	Patient		1	3	3	1	4/8
	Expert		2	1	10	7	17/20
10	I feel **confident** that these events will be used to inform the HRAs review of research policy	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	2		4	35	59	93%
	Patient			1	4	3	7/8

	Expert			1	7	9	16/17
11	No single view was allowed to **dominate** unfairly in the events	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	3	3	34	59	93%
	Patient	1	1		3	3	6/8
	Expert		2		4	13	17/19
	Comments **Public** - Very across the board discussions. **Patients** - Unequal contributions from group. **Experts** - Once a strong opinion expressed, rest of the table tended to follow.						
12	I feel that I have **learnt** something new from being involved	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	1	6	20	73	92%
	Patient		1		4	3	7/8
	Expert		1		6	10	16/17
	Comments **Experts** - Interesting to hear the views of the public and patients; Thank you - this will help inform our local practices too; Feel more able to understand public concerns about record access.						
13	Overall I am **satisfied** with these **events**	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	2	2	27	69	95%
	Patient		1		6	1	7/8
	Expert		1	1	5	12	17/19
	Comments: e.g. what did you learn new? **Public** - Learnt what the current process is and how things could be done differently; Who can have access to my files; New insight into many areas of how info is shared in GP and hospital and who has access to this info; How info is accessed; Who has access to notes; Ethics; Research nurse (concern) and their role; Has information within doctor's are available to most people. **Experts** - How people new to the subject thought about these questions; The breadth of strong feeling, with suggestion that younger (less pathology?) individuals more willing to share full access; Public's viewpoints and knowledge of access of their records; Good format and well run .						
14	I am more likely to get involved in these kinds of events in the future as a result of taking part in this one	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public		1	1	24	74	98%
	Patient			2	2	3	5/7

	Expert		1	2	6	10	16/19
	Comments: Very, very helpful; Very enjoyable (P); I have enjoyed it (P), I have learnt something new, so wouldn't mind taking part Would like to be involved in organising events (PAT); I would have been interested anyway! (EXP), Work for the HRA - so probably!; Time! (EXP),						

Note - The Patient and Expert evaluation forms are worded slightly differently. The main difference is that they ask how they think the public received information. Not all questions are answered - which accost for discrepancies in totals for experts and patients between questions.

Other comments

Public - Great facilitators!; 3 hours is a long time to concentrate on important issues; 3 hours is somewhat too long.

Patients - Very well presented.

Experts - This was a highly encouraging event - fair, balanced, informative, non-judgemental; I think it would have been better if there was a broader representation of research nurses as experts; Well structured event. Always difficult to get people really reflecting on the issues though; It would have been better to have every table with a facilitator who was not the main speaker.

1	I am aware of and understand the **objectives** for this whole dialogue process	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public		2	4	30	66	94%
	Patient			1	2	10	12/13
	Expert				2	11	13/13
	Comments **Public** - Very good information; Good; Very well explained; Very well presented by all; Very informative; Beneficial for the future research; Very well explained. **Patient** - It feels like a manipulative process; A lot better debate than last time. **Expert** - Not totally clear how the assessments of the models will be used.						
2	The **information** presented throughout the workshop seemed fair and balanced	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	2	4	38	58	93%
	Patient		2	1	5	5	10/13
	Expert				10	3	13/13
	Comments **Public** - Explanation given before and during discussions; Well balanced; Good; Very informative; Some of the terminology went over my head. **Patient** - Simple example with defined outcome; Leading to a pre-arranged end; **Expert** - There were several complex concepts (eg why the statin trial is not testing a 'new' drug) that were difficult to explain or understand; It seemed that the HRA did want the models to be accepted - they were not just thought experiments .						
3	I feel that I now have a better understanding from this workshop of the **issues** involved in the various ways I might be approached for my **consent** to be a participant in research.	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	1	3	35	63	95%
	Patient		1		8	4	12/13
	Expert		1		7	5	12/13
	Comments **Public** - Amazing content; Interesting. **Patient** - Opinion management; **Expert** - The info presented is still quite sketchy. I can't say they are better educated in any meaningful way; Patients are clear that they like to know whats happening to them; I personally felt it might have confused them a bit more.						

4	I feel that I now have a better understanding from this workshop of the **issues** involved in the **information** people need before consenting to be a participant in research.	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	2	1	3	39	57	94%
	Patient			1	8	4	12/13
	Expert			3	5	5	10/13
	Comments **Public** - Some complicated issues, but OK; Less worrying about being approached;						
5	I felt that I was adequately **informed** today to be able to discuss the issues	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agreew
	Public	1	4	3	35	60	92%
	Patient		1	1	5	6	11/13
	Expert			2	7	3	10/12
	Comments **Public** - Very informative; Better knowledge came from patients; Excellent discussions. **Experts** - Some negative issues of GPs taking part in research might perhaps have been highlighted if not naturally brought up eg GP spends less time talking about your condition as enrolling you in research. GPs may get paid;						
6	I could ask **questions** easily and get appropriate **answers**	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agreen't Know
	Public	1	3	2	29	68	94%
	Patient			2	4	7	11/13
	Expert				3	9	12/12
	Comments **Public** - Some people in group were overpowering **Experts** - Seemed to work well						
7	I had enough **time** to discuss the issues	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	2	2	7	39	54	89%
	Patient		2	2	4	4	8/12
	Expert		2	4	3	4	7/13

	Comments **Public** - Bit rushed when getting in debates. **Patients** - In some instances, more clarification was needed for some of the participants avoid discussing the wrong issues. **Experts** - A lot to cover in a short time. Felt maybe tired towards end of long session; Tricky balance - maybe needed more time; Not if you want enough discussion on each model. There is only time to scratch the surface of each.						
8	I was able to **contribute** my views and have my say	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	2	1	2	28	70	95%
	Patient				5	8	13/13
	Expert				5	8	13/13
	Comments **Public** - 100% **Patients** - Not always relevant. Need to call people back to point at issue.						
9	I understand how the **results** of the workshop will be used and how we will hear what happens next	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	3	3	9	35	50	85%
	Patient		1	1	5	4	9/11
	Expert		1	1	4	7	11/13
	Comments **Public** - This is to come post 9pm; Excellent presentation, enjoyable; Excellent discussions **Patients** - I think this will be outlined before we leave; **Experts** - Not explained clearly - do participants see the results of workshop and get chance to comment - ensure they think their issues were included. Were explained after form filled in and put in envelope;						
10	I feel **confident** that these events will be used to inform the HRAs review of research policy	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	1	3	37	60	95%
	Patient		1	3	3	5	8/12
	Expert			1	3	9	12/13
	Comments **Public** - Very pleased **Patients** - If they are it will be pre-planned **Experts** - But is it enough to get clear impression of public opinion across UK - minority groups etc; Who knows? Fingers crossed!						

11	No single view was allowed to **dominate** unfairly in the events	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	1	2	3	30	67	94%
	Patient			2	4	7	11/13
	Expert				5	8	13/13
	Comments **Public** - True **Experts** - Very well facilitated						
12	I feel that I have **learnt** something new from being involved	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	3		3	17	80	94%
	Patient		1	2	4	6	10/13
	Expert			1	4	8	12/13
	Comments **Public -** From people's experiences; I have definitely learnt something new; Many facts (interesting) **Experts** - Views of public and patients; A new format of involving the public. New models of consent; Lay views are always interesting						
13	Overall I am **satisfied** with these **events**	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	3	1	2	29	69	94%
	Patient		1	1	3	7	10/12
	Expert			2	4	7	11/13
	Comments: e.g. what did you learn new? **Public** - A lot; A lot of new words; What statin meant and differences of each case study; Bit too long; The workshops raised issues that I had not been aware of (consent, privacy, access to information); Quite a lot about national health; About process of trial; Different consent procedures; About the many types of consent; Who has access to my records - research process etc; Hospitals; All really useful info **Patients** - I think that more needs to be done to address literacy issues and some people didn't understand some of the questions we were being asked; **Experts** - How variable public engagement with research is and how trusting the public is; Depends on the level of conclusions you are yet to draw; Really good format and resources - stimulated discussion very effectively						
14	I am more likely to get involved in these kinds of events in the future as a result of taking part in this one	Strongly Disagree	Tend to Disagree	Neither	Tend to Agree	Strongly Agree	**Total** - tend to agree/strongly agree
	Public	3		2	18	80	95%

	Patient			3	3	6	9/12
	Expert			1	2	10	12/13
	Comments **Public** - Happy to attend more studies; Again, excellent!; Very good; It was very informative and positive; Very interesting subjects; Very interesting; Interesting **Patients** - I would like to see what impact the event makes before deciding; Both informative and interesting **Experts** - HRA staff - so probably						

WORKSHOP 2 - combined scores and commentary

Note - The Patient and Expert evaluation forms are worded slightly differently. The main difference is that they ask how they think the public received information. Not all questions are answered - which accounts for discrepancies in totals for experts and patients between questions.

Other comments

Public - What a waste of life; Excellent - learnt a lot!; The process needs to be more transparent and clear; Enjoyed the discussions very much

Patients - I would like to know more how a level of confidence is reached on what public opinion is. Privatisation of the NHS would completely change views on this issue; Note to one of the presenters - doctors can also be she, not just he.

Experts - My favourite quote: “NHS: we do research. If you don’t like it - join BUPA!”; Attendee’s own experience with the health service informed their own views; I believe we heard that consent is not always necessary and that we should use data to progress medicine even without consent - but concerns over data linkage dominate as a concern

Commentary on the responses

Public responses

There were between 101 and 107 responses for all the questions. Across both rounds of workshops the public responses score consistently very highly. All questions score over 80% for *tend to agree or strongly agree.*

90% + - questions 1,2,3,4,6,8,10,11,12,13,14

80% + questions 5,7,9.

Question 5 scored 89% on workshop one and 92% on workshop two - and reflects a slight disagreement or neutrality on the issue of being **adequately informed**.

Question 7 scored 89% on workshop one and 90% on workshop two with just two locations showing a slight disagreement with the statement that there was **enough time to discuss the issues**.

Question 9 scored 89% on workshop one, but dropped to 83% for workshop two - reflecting a a neutrality of disagreement with the statement that **people understood how the results of the workshop would be used and that people would hear what would happen next**.

These scores are very high and show that the vast majority of the public (94% across both rounds of workshops) tended to agree or strongly agreed that they were **satisfied** with these events.

Some outliers
Q1/workshop 1 - 4 of the 26 Cardiff participants strongly or tending to disagree with the statement that they were aware of and understood the objectives for the whole dialogue process. This shifted to just one disagreement in round 2.

Evaluator comment - I observed two round one workshops and two round two workshops - the facilitators repeated the objectives more often in workshop two than workshop one. But considered in the context of 95% of respondents agreeing that they were aware of and understood the objectives of the dialogue, this figure may reflect one of the Cardiff patient participant's comments that there was a literacy issue with some of the public participants.

Q14/workshop 2 - 3 of the 26 Cardiff participants strongly disagreed that they are more likely to get involved in these kinds of events in the future. One of these stating - "What a waste of life".

Evaluator comment - despite being paid an incentive, it is perhaps inevitable that a small minority of participants will find the subject matter a little dry.

Patient responses

The patient participants varied between workshops, so the scores are not made by the same people. In round one there were a total of 8 responses from patient participants (ranging from 1 in Liverpool and London) to 4 in Cardiff. And in round two there were 13 patient participant responses (ranging from 1 in London to 5 in Cardiff).

I have not considered percentages as the numbers are too low. Overall the *tend to agree* and *strongly agree* scores improve between round one and two (with the exception of Q10 - confidence in the workshops informing the HRAs review of research policy).

Q3&4/workshop 1 - show 3 out of 8 respondents expressing *neither* on the statement that participants now have a better understanding of the issues. The number not agreeing drops dramatically for workshop 2 to 1 out of 13.

Q6/both workshops - all respondents in both workshops *tend to agree* or *strongly agree* that people could ask questions easily and get appropriate answers.

Q7/both workshops - 3/8 in workshop one and 4/13 in workshop two said *neither* or *disagreed* with the statement that there was enough time to discuss issues.

Evaluator comment - constraints on the time and the notion that the dialogue was about the principles of consent and access, rather than the specifics of a range of different scenarios, may have influenced this scoring.

Q8/both workshops - 3/8 said *neither*, *tend to disagree* or *strongly disagree* in workshop one to the statement that people were able to contribute and have their say; in workshop two all 13 respondents agreed with this statement.

Evaluator comment - this may reflect the fact that people become more comfortable with the format and shift. But it is worth noting that public responses to this question were 95% agreeing for both rounds.

Expert responses

The expert/specialist responses varied from 20 in workshop one to 13 in workshop two. And, again, there was variation in the people who attended - only a small minority attended both workshops.

Scores are consistently high across all the questions (with the odd dissenter), with the exception of Q7 which shows 7/20 in workshop one scoring *neither, tend to disagree or strongly disagree* on the statement that people had enough time to discuss the issues and 6/13 in workshop two. Critical comments included - “rushed at times”, “with tables yes, plenary no”, “a lot to cover in a short time”, “tricky balance”, “only time to scratch the surface”.

Evaluator comment - constraints on time and the fact that the experts will have a far deeper and broader understanding of the issues no doubt contributed to this.

Appendix 4 - Calibration and Definitions 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 substantively 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.