Tracing the impacts of public dialogue projects supported by Sciencewise:

Recruiting participants for health research

March 2016

Recruiting participants for health research

Key facts

Date
August 2014 – June 2015 (9 months)

Costs
- Total cost of project: £132,250
- Sciencewise funding: £66,650

Commissioned by
Health Research Authority (HRA)

Delivery
OPM

Evaluation
3KQ

Sciencewise Dialogue and Engagement Specialist (DES)
Suzannah Lansdell

Introduction

The Health Research Authority (HRA) aims to protect and promote the interests of patients and the public in health and social care research, and to streamline the regulation of research. It is responsible for the governance of health and social care research involving the public, and is committed to involving patients and the public in its work.

In 2014, the HRA began to review the principles underlying health research in the UK including the methods for identifying and recruiting participants for health research, through the revision of the Research Governance Framework (last amended in 2008). At the same time, forthcoming changes to the EU Clinical Trials Regulation were expected to allow for greater proportionality to distinguish between high-risk and low-risk research. The HRA saw the potential to make changes that could make it easier for patients to learn about relevant health research and increase the number of participants involved in health research.

This public dialogue was designed to inform the HRA as it developed a UK-wide Health Governance Framework to replace the separate policy documents in England, Wales, Scotland and Northern Ireland. The single new policy framework will be designed to support good practice across the UK and will apply to research that is within the legislative and policy responsibility of any of the four UK Health Departments.

The dialogue considered some key issues within the overall framework, which provides high level guidance for research ethics committees, health researchers, funders and sponsors of health research. It also considered aspects of the supporting operational guidance particularly relating to recruitment, data and consent.

The dialogue project in summary

The public dialogue focused on three main areas:

- How patient data might be used in order to invite people to join research studies and who participants think should be allowed to access patient records in order to check eligibility
- 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.

The dialogue project involved the following main activities:

- **A rapid evidence review** was undertaken and a number of stakeholders were interviewed (e.g. to explain relevant issues from their professional perspective and provide balance), to inform the design of the dialogue.
- **An Oversight Group** was established with seven external stakeholders from the health research and governance fields across the public, private, academic and voluntary sectors. The Group was chaired by Simon Denegri from INVOLVE and included representatives from the Confidentiality Advisory Group (which advises the HRA and the Secretary of State for Health on applications to access patient information), the Academy of Medical Sciences, the Royal College of General Practitioners, GlaxoSmithKline, the National Institute for Health and Social Care Research in Wales, medConfidential and Ben Goldacre (scientist and journalist). The Group also included two patients, plus two HRA staff members and Sciencewise.

The Group met for the first time in October 2014. It worked closely with the project throughout, supported the design and delivery of the dialogue and the materials used, including aiming to ensure the process provided a balance of perspectives to the public participants. The Group also reviewed the final dialogue report.

- **Workshops** with public participants were held in November and December 2014 in four locations: Liverpool, Nottingham, London and Cardiff. In each location there was one 3-hour evening workshop, followed by a reconvened 3-hour evening workshop two weeks later. The same participants attended both workshops in each location, allowing them to develop a good understanding of the relevant issues so that they could provide informed feedback. A total of 108 public participants attended the workshops, recruited to ensure that as many different voices were included as possible. 24 specialists and nine patient experts also attended (around six at each workshop), to join the discussion tables and answer questions from participants. 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 the second workshop.

- **An interactive website** was set up for the project, which attracted 569 unique users, plus 51 responses to a survey and two posts onto a forum page.

- **An internet scan** was initiated through which a continuous search was made on the internet for key terms - e.g. simplified consent. This was intended to enable an understanding of how widely conversations about the issues in the dialogue were spreading.

- **Analysis and reporting**. The dialogue results were analysed thematically by location, to identify common themes. A final report was produced and published (following discussions with the Oversight Group), as well as a documentary video which included interviews with participants at the London workshop. The first draft of the report was produced in January 2015; an agreed report was completed in March 2015. This report was then held for publication until after the General Election, and published in June 2015[1]. An independent evaluation was completed and published in February 2016[2].

The main findings from the dialogue were:

- The majority of participants were open to the idea of research nurses having access to patient notes with the proviso that patients were informed and have the option to opt-out.

- 'Consent to approach' lists were acceptable to the majority but there were concerns: approaches in waiting rooms should preferably be by NHS staff; approaches by leaflet needed a 6 – 8 week response date to allow patients sufficient time.

- The majority of participants supported the use of simplified consent in pragmatic trials of existing licensed products. The opt-in model raised fewer concerns than the deemed consent model. Most also agreed with a simplified patient information sheet which did not repeat the information contained on medicine pack inserts.

- Issues raised by participants around extending access to personal data in medical records included: ensuring patients were made aware, by using more pro-active methods than posters, of changes to who could access their data; eliminating the potential for scope-creep when allowing more people access to records or introducing zero consent; and ensuring personal data would not be passed on for commercial use by insurance companies. Some participants felt that they would prefer researchers who were funded by private pharmaceutical companies not to have increased access, but others conceded that this might not be possible. The type of person who would be accessing patient data was an important consideration for some participants (senior researchers and clinical professionals preferred; access to be limited to NHS staff from the same institution).

Dissemination of dialogue results

- The project report and evaluation report were published on the HRA and Sciencewise websites, with a range of activities to increase awareness of the project and its results (tweets etc).

- The independent evaluation identified other potential opportunities for dissemination. Several Oversight Group members talked about how the dialogue results would both contribute to discussions among peers and within and between organisations, but also how they 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. 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*".

[1] http://www.sciencewise-erc.org.uk/cms/assets/Uploads/HRA-IRPHR-Dialogue-Report-Final-June-24-3.pdf
[2] http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Public-dialogue-on-recruiting-participants-for-health-research-final-evaluation-report.pdf

Impacts on policy

- **July 2015**. The HRA issued a response report summarising all the feedback they had considered on the draft guidance on 'Seeking Informed Consent for Simple and Efficient Trials in the NHS', including the feedback from the public dialogue workshops, and summarised the resulting HRA plans. The results of the public dialogue, and resulting HRA plans, were specifically covered in the response report in relation to the use of information sheets, simplified consent processes, the deemed consent / opt out approach on randomised cluster trials at GP surgeries, and whether verbal consent should be sought and documented in medical notes to access the patient's medical data for the purpose of research. Future guidance was planned on proportionate consent and the use of short information sheets, which were also covered in the dialogue project.

- **October 2015**. The HRA drafted guidance on two specific issues based on the input of the public and patient participants at the public dialogue workshops:

  - The first set of guidance focuses on proportionate consent for simple pragmatic clinical trials. The HRA planned to put out their revised guidance on proportionate consent in research to public consultation and to finalise and launch the guidance in 2016.

    Prior to the formal consultation process, the HRA held a major event in December 2015 in Oxford in order to raise the profile of this issue among key stakeholders. The HRA presented the dialogue results at this event, which was also attended by speakers who all contributed to the dialogue.

  - The second set of guidance focuses on how people are identified and recruited to take part in health research, which has implications in terms of access to patient records and shared data. The HRA has been developing draft guidance but this was delayed pending the completion of the wider Government review by Dame Fiona Caldicott, which started in July 2015. This wider review is looking at consent on access to data and data sharing. The HRA guidance was to be completed following the publication of the report of that wider review. The public dialogue report was submitted by the HRA as evidence to the Dame Fiona Caldicott review of data sharing.

- **Also October 2015**. The HRA issued a response report summarising all the feedback they had considered on the '*Draft UK policy framework for health and social care research*' (the new Research Governance Framework). During 2015, the framework was revised, drawing on the dialogue results alongside a wide range of other research and consultation results.

- **December 2015**. A revised version of the policy framework – '*UK Policy Framework for Health and Social Care Research*' was issued for public consultation between 18th December 2015 and 24th March 2016[3]. The new framework sets out high level principles of good practice in the management and conduct of health and social care research in the UK, as well as the responsibilities that underpin high-quality ethical research. The new framework aims "*to help make the UK an even better place to do research*". It is expected that the new framework will be completed and published in summer 2016.

- **As of February 2016**. The HRA has been asked to advise the UK Clinical Trials Gateway initiative at the National Institute for Health Research (NIHR), drawing on the dialogue results. The Gateway initiative provides an access point for people to express interest in taking part in a clinical trial so that researchers can offer opportunities for taking part in trials. The HRA is advising on future development:

  "*Part two of the dialogue was really helpful to influence that work as we have a broader idea of what the public are happy with and what reassurances they need in place to make them feel safe." (HRA 2016)*

  The Clinical Trials Gateway is also seen as potentially generating financial savings in research recruitment:

  "*If the Clinical Trials Gateway works, that would be a very cost effective way of recruiting people in to trials on a national basis, because it would feed the trials that are funded by NIHR, which are NHS funded clinical trials." (HRA 2016)*

  The HRA considers that further impacts are likely:

  "The nitty gritty policies that the dialogue will have the biggest impact on are not out there yet - the guidance on proportionate consent and the guidance on identification and recruitment of participants. It will be a while before they are both out there and they've both got to go through public consultation and then be launched. There is quite a long lead up time to some of that. So we haven't seen the full impact of that and there will be more to say in the longer term. To be able to say that we've done the public dialogue will make it much easier when we launch the policies properly. I think we will get greater buy in because we can demonstrate that we've considered that aspect of the work."(HRA 2016)

[3] http://www.hra.nhs.uk/about-the-hra/consultations-calls/uk-policy-framework-health-social-care-research-consultation-active/

Impacts on HRA as an organisation

The dialogue has been an important element in the way the HRA approaches its policy making, building on their earlier experience of dialogue – a public dialogue in 2013 (also with Sciencewise support) on the streamlining and simplifying of the research approval process. The need to explore how the public viewed the use of their own data emerged from that earlier dialogue and, combined with a need to review guidance, led to the HRA commissioning this second dialogue.

The independent evaluation report on the dialogue (page 34) identified the views of the Oversight Group for the project on the value of the dialogue approach. One member said they were:

> *"…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" (Oversight Group member 2015)*

The evaluation report also quotes the independent Chair of the Oversight Group as recognising the importance of dialogue within the way the HRA works (evaluation report page 34):

> *".. 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." (Chair, Oversight Group 2015)*

The Chief Executive Officer of the HRA said (evaluation report page 34):

> *"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." (Chief Executive Officer of the HRA 2015)*

The independent evaluation found that the HRA had explicitly said 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." (evaluation report page 34)*

The importance of public engagement is reflected in the focus of the HRA annual review for 2014/15, which chose as the first highlight of the year "*Listening to patients and the public"*. The report goes on to describe *"our work with patients and the public to lead on the new UK wide policy framework to replace the Research Governance Framework and … on proportionate consent in large pragmatic trials*". This is a direct reference to this public dialogue project. The report features three of the participants in the public dialogues on the front cover, and includes descriptions of the dialogue from those three participants over three pages within the report. The emphasis in the annual review reflects the value of the dialogue project for the HRA:

> *"It has been good for us on a number of levels. It has had, clearly, direct value in terms of being able to inform the various policies that we've got going. So there are a number of different policies and guidance documents that it's impacting on directly…. But over and above that it is seen to be a good thing and at an organisation level I think we are quite proud of it, as you saw in the Year in Review document. It's thought that it adds value to our credibility as an organisation. It adds to our authority and makes us appear to be a listening organisation and, at a very high level, it is good for our image as well." (HRA 2016)*

The HRA continues to develop its interest in approaches to public engagement, including co-facilitating a Citizens Jury[4] early in 2016 with the Director of the Jefferson Center[5]. The initiative was funded by University of Manchester to discuss issues with citizens on data sharing, particularly linking primary care records with secondary care records.

The HRA has increasingly committed to further public dialogue and engagement:

> *"It's now seen as an integral part of what we do, particularly in terms of developing policy. The public are seen as a stakeholder alongside everybody else. There is now a general acceptance that we should be talking to the general public in terms of checking their understanding and what they see as risky and how they want things to be arranged to make them feel safe, so I think it is definitely seen as a more acceptable route in terms of policy development." (HRA 2016)*

> *"The advantages of public dialogue are key for us. Our main mission is to protect patients and the public and to promote research to them so we shouldn't really be developing policy that makes people feel at risk. Unless we actually talk to the public we are only second guessing what it is we think they want. We have a long history of only talking to expert patients, very knowledgeable patients who pop up at all the same things, who have been paid to understand research and comment on research proposals. They are not typical members of the public. For*

[4] http://www.herc.ac.uk/get-involved/citizens-jury/
[5] http://jefferson-center.org/what-we-do/citizen-juries/

us it is important that we separate out the patient groups that are very high profile and have a specific viewpoint versus the general public who come to this topic in quite a naïve way but reflect a greater proportion of the general population. There are enormous advantages in using public dialogue in policy development. It also means when we get to formal consultation or launching the policy proper that we don't get highly negative feedback, we are not surprised at that point as we have done all this work in the development stage. Some of it is about identifying unintended consequences of the policy as well. When you are working with it so closely you can't always see what those unintended consequences might be…. I guess the disadvantages are that you can't do it cheaply and it does take a lot of time." (HRA 2016)

The HRA plans to undertake further public dialogue in the near future, and are building it into their organisational structure:

"We definitely plan to use it again. We are now budgeting to do some collaborative work in public dialogue, again in data sharing because that is a big area. Another area we would like to collaborate in is around the use of tissue in research and when that tissue becomes data, which it ultimately does. That's our plan for the coming year. We are building it in to our structure and part of that is about accepting that we will be doing dialogue on an ongoing basis to feed in to policy. Our Chief Executive is very keen that we build in public opinion at an early stage of the process, rather than waiting until we do a consultation to find out that people don't like it." (HRA 2016)

Impacts on others

24 different specialists were involved in the workshops with the public (plus nine expert patients). Their role was to be involved in table discussions, provide factual information, respond to questions and discuss issues with other participants. 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 had an interest in simplified consent, consent to approach models and information governance issues.

The independent evaluation report quotes one specialist who 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*." The evaluation also provides evidence that other specialists commented in feedback forms 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*." Others said (page 35 evaluation report):

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

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

The evaluation report also quoted members of the Oversight Group who confirmed that the dialogue results would be used and would influence their own work and organisations. For example (evaluation report pages 36 – 37):

"In Wales, we'll use it (the report) to build on, especially around approaches to consent."

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

On 22 July 2015, Simon Denegri, the Chair of the Oversight Group, posted a blog[6] following the publication of the HRA dialogue report. He stressed the important role of the dialogue in simplifying the ways in which people get involved in health research. He said:

"I am very pleased that the exercise provides us with some evidence that the public have an appetite for seeing research nurses take on a bigger role in recruiting people to take part in research ... I think we are seeing a slow march towards a simplified consent model and, hopefully one day, dynamic or personalised consent."

The HRA themselves see the credibility of public dialogue growing, although believe there are still sceptics:

"Its credibility has gone up but I don't think it is 100%. We have had some issues with other policy makers that we are working closely with who don't understand why we do it or see it as a bit of a token gesture. That is probably a minority now but there is a bit more work to do." (HRA 2016)

Diane Warburton
Sciencewise Evaluation Manager
12 March 2016

[6] http://simondenegri.com/2015/07/22/blog-consent-consent-consent-new-public-dialogue-report-from-hra_latest/