sciencewise
EXPERT RESOURCE CENTRE

BIS Department for Business Innovation & Skills

Case Study

Identifying and recruiting participants for health research

A public dialogue to inform the development of the Health Research Authority's (HRA) policy framework and guidance

Vital statistics

Commissioning body:
Health Research Authority (HRA)

Duration of process:
August 2014 – July 2015 (12 months)

Total public participants involved:
108

Total stakeholders involved:
On-line engagement attracted 569 unique users, 51 responses to a survey and two posts on a forum page

Total experts involved in events:
In total, 24 experts and 9 patient experts

Cost of project:
£132,250 total
Sciencewise contribution = £66,650

The NHS constitution outlines the rights 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.

The 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 started to review the principles underlying health and social care 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 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 people taking part.

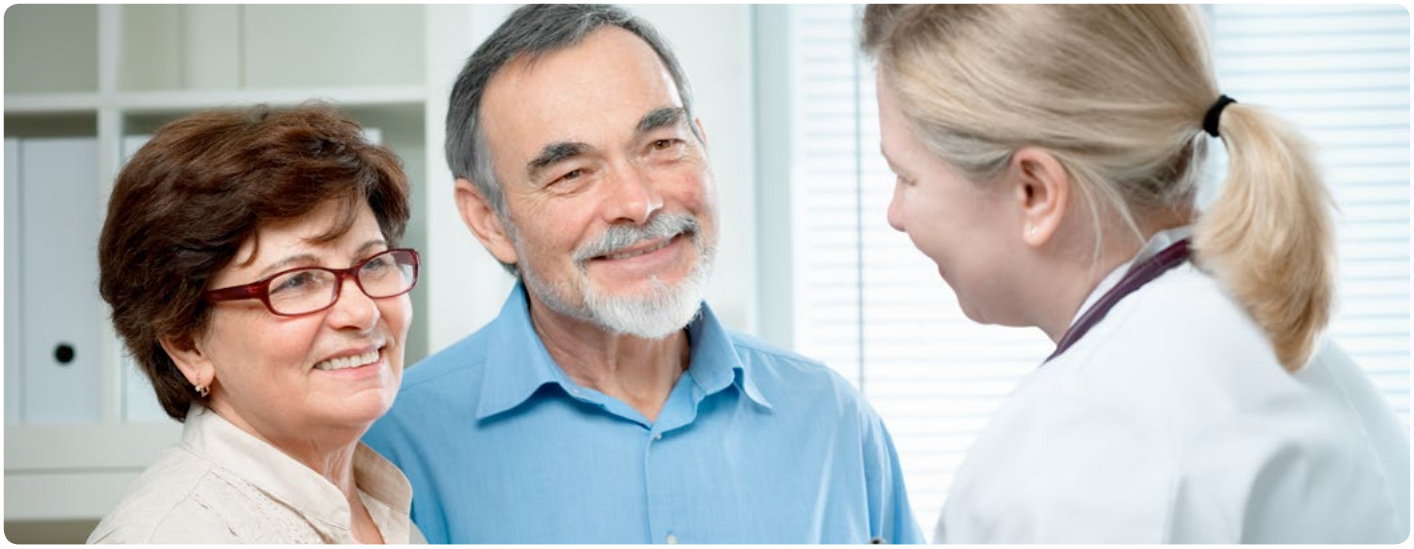
The HRA wished to explore:

- *Who the public think should have access to their data so that people can be informed if they might be eligible to take part in a study*
- *Different models of consent to approach*
- *Simplified consent processes in trials of existing licensed products.*

Policy maker view

"[The dialogue] 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."

HRA



Background

Prior to the project starting, the HRA began the process of producing a new policy framework to replace the Research Governance Framework (RGF) in England which was last amended in 2008. The HRA took responsibility for the research policy in England when it became a non-departmental public body (NDPB) as part of the Care Bill in 2014.

There is a different RGF in each of the devolved administrations and the intention was that the HRA would develop a UK-wide framework to replace the individual ones. Each country committed to adopt the new policy and withdraw the equivalent policy documents. The HRA included patient/public opinion when it was developing those elements of the policy that were of direct relevance to them.

Although the existing Clinical Trials Regulations allowed proportionality, this had not been widely applied. The new EU Clinical Trials Regulation, which will come into force in 2016, will build further scope for proportionality. The HRA thought it was important to have public views on the wider application and the practical application of the new EU Clinical Trials Regulation in the UK. The draft RGF was sent out for formal consultation across the UK in 2014, which was at the same time that the dialogue project took place.

The HRA intended to develop the notion of proportionality by producing guidance on proportionate consent for simple and efficient trials of licensed drugs and commonly used treatments. There are many licensed treatments where there is still uncertainty about the effectiveness of different drugs within the same class (e.g. statins). Given the lower risk associated with this type of study, the guidance would suggest a simplified consent process is acceptable.

In addition to the new RGF, the HRA is also developing new guidance to inform researchers how best to identify and approach potential study participants. The HRA felt that it is imperative that patients/public are able to inform the development of this guidance.

This public dialogue was designed to inform the HRA during its development of the UK-wide RGF. The single new RGF is 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; and aspects of the supporting operational guidance – particularly relating to recruitment, data and consent.

Influence on policy and policy makers

- In July 2015, the HRA issued a response report summarising all the feedback it 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. The draft guidance was open for comment in 2014 at the same time as the dialogue workshops were held. The 2015 response report included the HRA's responses to the feedback it received and the subsequent plans it developed. The results of the public dialogue and resulting HRA plans are specifically covered in the report in relation to:
  - The use of information sheets
  - Simplified consent processes
  - Deemed consent/opt-out approach on randomised cluster trials at GP surgeries
  - 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 the use of short information sheets, which were also covered in the dialogue project.

- In October 2015, the HRA commenced development of 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 in research including that in pragmatic clinical trials. The

HRA plans to put out its 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 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 a wider Government review of consent on access to data led by Dame Fiona Caldicott. Therefore, the guidance will be completed following the publication of the report of that wider review.

- The results of this public dialogue project were submitted as evidence to the review on data sharing led by Dame Fiona Caldicott.
- In October 2015, the HRA issued a response report summarising all the feedback it had considered on the 'Draft UK policy framework for health and social care research' (the Research Governance Framework (RGF)). During 2015, the RGF was revised using the dialogue results, and a wide range of other research and consultation results.
- A revised version of the RGF was issued for public consultation between 18 December 2015 and 24 March 2016. The new RGF sets out high-level principles of good practice in the management and conduct of health and social care research in the UK, and the responsibilities that underpin high-quality ethical research. The new RGF aims 'to help make the UK an even better place to do research' and it is expected that it will be published by autumn 2016.
- More generally, this dialogue project has been an important element of the way the HRA approaches its policy-making. The importance of public engagement is reflected in the HRA annual review for 2014/15, which had as the first highlight of the year 'Listening to patients and the public'. The annual review 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.

Key messages from the participants

The public dialogue focused on three main areas:

- How patients' data might be used to invite people to join research studies and who the participants think should be allowed to access patients' records 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 overall key results from the workshops were:

1. The majority of participants did not believe that research nurses had access to patients' notes in hospitals or GP surgeries.
2. Following discussions, the majority of participants were open to the idea of research nurses having access to patients' notes, with the proviso that patients are informed and have the ability to opt-out. For research-active general practices, posters in the waiting room were not seen as being sufficient to ensure all members of the surgery were actively informed about changes to who has access to patients' records.

> *"You've got to ask the question if it's going to be good for the patients, and if the answer is yes then it must be a good thing."*
>
> **Liverpool workshop participant**

3. While the majority of the participants accepted the use of 'consent to approach' lists in principle, there were concerns about both of the models reviewed. For approaches in the waiting room, participants wanted sensitive, common-sense approaches by someone who could be identified as being attached to the hospital. There was a preference for this being a member of NHS staff. For approaches by leaflet, the participants were concerned that many people would not read the leaflet or realise they had consented by default to be on the 'consent to approach' list. A three-week response date was not deemed to be sufficient to allow people the time to receive the letter and respond, with six to eight weeks being recommended as suitable.
4. The majority of participants supported the use of simplified consent. There were fewer concerns raised about the impact on patient-GP relationships for the opt-in model than there were for the deemed-consent model. Most participants agreed with using a simplified patient information sheet that did not repeat the information contained on medicine pack inserts. Most people agreed with the use of zero consent in the mattress example.

> *"As someone who has signed these forms, it is intimidating. I think the simplified forms proposed would be less intimidating. I think I would have preferred to have them."*
>
> **Expert patient Liverpool**

5. Common themes arising from the discussions at the workshops included raising public awareness of the role of NHS patients in health research; ensuring patients were made aware of changes to who can access their data by more pro-active methods than using posters; 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 (including by insurance companies).

The dialogue activities

The main objectives of the dialogue 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.

The dialogue project involved the following activities:

- Establishing an Oversight Group (OG). This involved seven external stakeholders from the health research and governance fields across the public, private, academic and voluntary sectors – including representation from a privacy group to provide challenge. The OG also included two patients, two HRA staff members, and a Sciencewise Dialogue and Engagement Specialist. The OG supported the design and delivery of the dialogue project, and of the materials used, including aiming to ensure the process provided a balance of perspectives to the public participants. The OG also reviewed the final dialogue report
- To inform the design of the dialogue project, 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)
- Workshops with public participants were held in Liverpool, Nottingham, London and Cardiff. In each location, there was one 3-hour evening workshop, followed in two weeks by a reconvened 3-hour evening workshop. The same participants attended both workshops in each location. This allowed them to develop a good understanding of the relevant issues so that they could provide informed feedback. The 108 public participants who attended the workshops were recruited to ensure that as many different voices were included as possible. In total, 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 feed back their thoughts on it at the beginning of the second workshop.
- Developing an interactive website for the project which attracted 569 unique users, 51 responses to a survey and two posts on a forum page.
- Undertaking an Internet scan through which a continuous search was made on 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.
- The dialogue results were analysed by location to identify common themes. An analysis meeting was held between OPM (the dialogue project delivery contractor), the HRA and Sciencewise to identify overall results and main messages. A final report was produced and published (following discussions with the OG), and a documentary video featuring interviews with participants at the London workshop was produced.

What worked especially well

The dialogue was timely, met all its objectives and was expected to inform the relevant strands of HRA policy and guidance covering access to data, approaches for consent and simplified consent.

The OG had a strong governance and review role, enabling the HRA to work with a range of stakeholders to help shape the dialogue and contribute to the content of the materials. This approach made good use of the range of organisations and individuals on the OG.

Recruiting participants worked well. The range of participants involved was very diverse in terms of socio-economics, age, gender and ethnicity.

Workshop design and delivery. The range of clear information provided was critical to helping participants get a grasp of the subjects they were discussing. OPM worked with the HRA, with commentary from the OG, to design a process that flowed from one topic to the next. Rather than a 'first workshop educate, second workshop deliberate' model, participants were given the opportunity at each workshop to understand issues and reflect on them. 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. Specialist input was also valued by the public. A video were also commissioned as stimulus material for the workshops.

What worked less well

Time was very tight for the research and production of materials, and the design of the workshops. This put a lot of pressure on the team. Given more time and budget, an engagement with the wider field of stakeholders might have produced a larger range of perspectives on the issues being discussed. Ideally, the OG would have been established earlier and there would have been more opportunities for the members to meet. They would also have had more time to consider materials, 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.

The digital strand of the engagement was intended to enable wider participation and enable a comparison with the public dialogue workshop findings. However, due to budgetary limits, not all activities planned to promote this aspect were implemented and lower than anticipated response rates were achieved. In addition, the Internet scan was not as thorough as it might have been. Consequently, it did not yield any useful information.

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Reports

Full project and evaluation reports available from Sciencewise on **www.sciencewise-erc.org.uk/cms/hra-health-research-policy-public-dialogue-health-research-recruitment-data-use-and-consent/**