Case Study

HRA patient and public engagement

A public dialogue seeking the views of patients and the public to underpin HRA strategy and policy

Vital statistics

Commissioning body:
Health Research Authority

Duration of process:
7 months: January 2013 – July 2013

Total public participants involved:
60 at four reconvened public dialogue workshops, 1,295 in the general public omnibus survey and 68 participants at eight patient workshops

Total experts involved in events:
17 clinical researchers at the public dialogue events

Cost of project: £151,500 total cost including public dialogue, patient dialogue and omnibus survey, Sciencewise funding = £84,000

The Health Research Authority (HRA) is an NHS organisation established on 1 December 2011 as a Special Health Authority. The purpose of the 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, and improvements in the nation's health.

The HRA has responsibility for protecting patients from unethical research, while enabling them to benefit from participating in research. It has been tasked with streamlining and simplifying the research approval process and removing duplication from the current system for research review and approval. In the course of reviewing these processes, the HRA was keen to take the opportunity to listen to the public and patients on the benefits and risks of clinical trials and other health research, and to take account of their views in developing new approaches. Talking with patients was not new to the HRA, but talking to the general public face to face was quite new and different.

The resulting public dialogue was a relatively small-scale project that has had significant impacts on the governance and regulation of health research, and on the future strategy of the HRA.

Policy maker view

"Feeding into the transparency agenda has been the biggest achievement ... complete consensus of patients and public who expect findings of clinical trials to be published and fed back to participants."

HRA.

Influence on policy and policy makers

Janet Wisely, Chief Executive of the HRA, and Simon Denegri, Chair of the dialogue project Oversight Group, gave evidence at the House of Commons Select Committee on Science and Technology inquiry on clinical trials in July 2013. They provided written and oral evidence drawing directly on the dialogue findings.

The Select Committee's report (September 2013) refers directly to the findings of the dialogue. It draws particular attention to the finding on public suspicions of the pharmaceutical industry and the sense that making a profit was incompatible with developing products of benefit to patients. The HRA response to the Select Committee's report (October 2013) also refers to the dialogue and its findings, and explains that the dialogue has informed the HRA's transparency strategy. The Government's response to the Select Committee's report (November 2013) specifically referred to the need to address the issue of public suspicions of the pharmaceutical industry, and the work to make patient information sheets more user friendly.

The project was pivotal to the strategic direction of the HRA as it is a relatively new organisation seeking to establish a precedent of transparency and openness.

Background

Health research covers a vast span of clinical science and academic disciplines, funded by both private and public sectors. Clinical trials form an important element of this work, which can be therapeutic in patient studies or non-therapeutic, such as Phase 1 trials in healthy volunteers. This can range from testing new pharmaceuticals in clinical trials; large-scale biometric studies; through to the piloting of the most advanced genetic therapies.

The HRA has been tasked with streamlining and simplifying research approvals processes, while protecting and promoting the interests of patients and the public in health research, so increasing confidence and participation in health research, and improvements in the nation's health. The Select Committee inquiry on clinical trials noted that the clinical trials market is worth £29 billion per year and that the UK's share of the market had dropped since 2000 – the UK did have the third largest share of global trials but, by 2006, it had dropped to ninth place.

In reviewing research approvals processes, the HRA commissioned a series of public dialogue events and a general public omnibus survey so that some findings emerging from the public dialogue workshops could be tested with the wider population. In addition, the HRA themselves conducted a series of dialogue events with patients recruited through existing patient and public involvement (PPI) networks. This was to enable a comparison to be made between these active service user network members and the general public. The types of research referred to in the dialogue sessions covered a range of conditions or therapy areas such as cancer, diabetes, cardiovascular and mental health.

The project also fed directly into the wider debate launched by the HRA on the transparency of research through publication of research findings. The HRA published its views in its paper 'Transparent Research' (May 2013), which refers directly to the dialogue project findings.

> *"The HRA's paper 'Transparent Research' is evidence of a welcome ambition to improve research registration, publication, data access and participant information. I endorse the HRA's approach and urge researchers, research participants and the public in general to support the HRA's proposals."*
>
> **Professor Iain Chalmers,**
> Coordinator of the James Lind Initiative.

The findings of the dialogue triggered the HRA to develop guidance for researchers on 'Information for patients at the end of a study' and informed the development of the 'HRA Strategy for public involvement' – both these initiatives were consulted on in late 2013/early 2014. Dialogue findings are also informing revisions to the standard template for patient information sheets that are used by most health researchers.

The results are also being fed into the wider Research Governance Framework, which is being revised in 2014 by the HRA for research across the UK and, in the longer term, into revision of the Governance Arrangements for Research Ethics Committees.

From stakeholder interviews, the project evaluators concluded that, as a result of the project, the HRA has emerged as a role model in patient and public engagement. The project has helped the HRA establish its credibility as a new organisation, resulted in those in the health research field buying into the organisation and built strong new partnerships.

> *"The project has been massively informative and helpful in allowing the HRA to take patient and public engagement forward. It's also enriched all our understandings of communicating with public and patient groups, especially in raising an awareness of research."*
>
> **HRA.**

The HRA has developed a new public involvement strategy and a communications strategy to guide its own work, drawing on the dialogue findings.

The HRA learnt that "talking to the public is not a tick box but adds value to what they are doing ... it has enhanced our reputation as an organisation and we want to do more of it as a consequence."

> *"We feel we have done a really thorough job in developing our strategy for public involvement, and got a much better strategy as a result of it."*
> **HRA.**

Key messages from the public

The dialogue found that public participants had very little knowledge about health research, how clinical trials worked and the role of regulators. The public's decisions about taking part in trials were most likely to be based on the costs and benefits to them as individuals, with societal benefits being less important. They were keen to eliminate or minimise safety risks, and ensure that the best care and information is available to those participating, both during and after trials. Patient participants were less concerned about risk and safety, and more concerned about non-compliance and poorly managed studies.

Most participants were positive about the role of public and patient engagement by the HRA as part of its strategic decision-making. The broad view was that, as health research is of significant importance to individuals and society at large, there was an ethical imperative to involve the public in this work.

Many participants believed the proposed streamlining of the research approvals process could tackle many of the problems with the current system. Most were enthusiastic about the HRA co-ordinating the process and believed this would improve efficiency without affecting patient safety. Some were more sceptical about how this would work in practice.

Participants talked most about transparency when discussing what happens at the end of a study and the publication of research results. Some believed it was an ethical duty of researchers to publish all research and the duty of the HRA or research ethics committees to ensure that happens. There was a general call to bridge the public's knowledge gap through improved information and accessibility.

The HRA and NHS staff were very highly regarded by participants and trusted to protect public health and wellbeing above other considerations. In contrast, pharmaceutical companies were seen as having vested interests in the conduct of research and were not trusted to behave ethically. Patient participants were less critical than the public of the pharmaceutical industry.

The main feedback on patient information sheets was that individuals have different reading preferences. Therefore, researchers should make available information sheets with a varying level of detail. Some participants also noted a need for information to be made available for the lifetime of the project. Patient participants proposed a new heading in patient information sheets on patient and public involvement to encourage the early consideration of the issue by researchers.

The dialogue activities

Specific objectives

The dialogue focused on the benefits and risks of clinical trials and research involving patients. It examined the ethical issues that might arise, and the procedures required to approve health research and protect the patients and the public.

The key objectives for the elements of the public dialogue were to:

- Understand public views on the perceived risks for individuals agreeing to participate in research (different types of research and different individuals) and to what extent the public feel protected by the current systems in place to approve health research.
- Explore the extent to which the public and others trust the views of their doctor in advising if they should participate in research. Who else would they trust in giving such advice and what needs to be in place to gain or maintain that trust?
- Explore what needs to be in place to gain or maintain the public's trust.
- Explore to what extent the trust held by the public varies according to the type of researcher/research organisation (that is, pharmaceutical, charitable, academia versus NHS).
- The HRA is tasked to protect and promote the interests of patients and the public in health research. Given the current awareness in the public of research ethics committees what needs to be in place to ensure that they can fulfil their role?
- Understand the patient perspective as to how the HRA should engage with the public in the future, including the extent to which the HRA should engage directly with the public and what should be influenced by such engagement?
- Understand what the dialogue and research tells the HRA about the common and different views that emerge from different types of public. For example, how does the general public perspective differ from that of patients?

Public dialogue

A total of 60 participants, who were recruited to reflect the demographic diversity of people living in England, attended the initial series of four, 3-hour long evening workshops. One week later, 56 of those returned for the second set of reconvened workshops. Workshops were held in Bristol, London, Manchester and Newcastle. The events were facilitated by two professional facilitators with additional input from the HRA. A minimum of two clinical researchers attended each reconvened workshop session to answer questions, raise issues and generate further dialogue among participants. Participants were asked to complete a task after the first workshop. This was used to encourage participants to consider and discuss the issues raised in the first workshop and to act as a warm-up for the second workshop.

The primary purpose of the first set of workshops was to inform participants about health research in the UK, and focused mainly on clinical research trials to illustrate ethical and research governance issues. Hypothetical case studies were used to prompt thinking about different research projects. The second set of workshops focused on informed dialogue about the research approvals process, starting with the current system and then discussing the HRA's plans for streamlining the process.

Patient dialogue:

Eight patient workshops were held across England, seven with patients and one with clinical trial healthy volunteers. Each session lasted for three hours. Researchers were present at five of the eight workshops. The patients were recruited via the National Institute for Health Research (NIHR) Research Networks, major health charities and industry. Some had been patient representatives, some participants in research studies and some had reviewed research proposals as part of patient and public involvement.

Omnibus survey:

As part of a wider weekly omnibus survey, Ipsos MORI conducted a face-to-face survey with 1,295 participants, which involved 11 questions.

Dissemination of project findings:

A detailed report was produced on the public dialogue activities. The HRA then published a report that drew on all the strands of work to produce overall conclusions. The reports were fully disseminated to HRA staff around the UK, and promoted to various other audiences through presentations and articles.

What worked especially well (focusing on the public dialogue workshops)

Structuring the dialogue around separate patient and public strands worked very well to identify the contrast between patient and public experiences and responses, and where there was consensus. The project generated a cogent set of results, which faithfully articulated the views and attitudes expressed by participants. The results provided the HRA with unique insight and valuable intelligence in respect of public and patient perspectives on, and recommendations for, the research approval and governance process.

> *"As a process, it was open and transparent and people were really striving to get something that was meaningful at the end of the day. I thought it was really fabulous."*
>
> **Oversight group member.**

The project generated higher-than-average trust among public participants in the likely influence of the project in mobilising change compared with other dialogue projects. 55% of these participants believed that the dialogue project would have an influence on the HRA decision-making on the issue, 35% were uncertain and 11% thought the project would have no influence. The seniority and status of the specialists attending the second set of workshops (senior academics and health researchers) may have influenced participants' belief in the importance and, thus, likely influence of the findings. Having researchers in the room worked very well in supporting the deliberative process because: " They make it real for the public in a way a third party can't do." (HRA)

The motivation to do the dialogue was partly that the HRA was a new organisation with a mission to protect patients and the public, and had not actually asked them before. The HRA wanted to test what was comfortable for these constituencies and what was at risk in terms of proposals for the future. In the event, this was achieved, and the project was seen by stakeholders as providing: "an important barometer of 'where the public are' and the kind of communication role/strategy the HRA should adopt." (HRA)

The most valuable aspect was finding out what the public thought: "It was refreshing to hear from the general public that don't have a vested interest or come from a particular health experience" and "Finding out what patients and the public think rather than just talking to researchers." (HRA)

What worked less well

There were no experts at the first round of public events, leaving the provision of information and answering of questions to the facilitators. They presented information on the nature of clinical research and the structure of research governance frameworks, but were unable to answer detailed follow-up questions. In the confusion of roles between facilitation and provision of information, participants sometimes lost confidence and became frustrated. There was a lack of consistency in the facilitators used at different events and so they they were unable to build up expertise about the project and less able to deal with questions from the participants.

Equally, too many experts overbalanced some other discussions. In three of the four second sets of workshops, there were three experts present – often two sitting at a single table of seven or eight public participants – resulting, on occasions, in public participants sitting back and listening to a debate between the experts, unmediated by the facilitator. In a few cases, the experts directed the discussion by asking the participants questions to focus the discussion.

Public participants raised a number of issues and how they could be addressed. These included timing – more time for events and avoiding finishing too late in the evening, better facilitation, clearer roles for experts in terms of how they support participants' discussions and a better mix of participants.

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Reports

Full project and evaluation reports available from Sciencewise on **www.sciencewise-erc.org.uk/cms/hra-patient-and-public-views/**