Ipsos MORI

Health Research Authority

Patient and Public Engagement Project: Patient and Public Dialogue Workshops

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1. Executive Summary

Purpose and Methodology

The Health Research Authority (HRA) has an ambitious programme of work to streamline and simplify the research approval process. The approval system covers all types of health research that involves patients across England including clinical trials. It is important for the HRA to understand what the implications of these proposed changes are for patients and the public and to understand the degree to which they feel protected or made at risk by the system for approving health research. The findings from this public dialogue activity are crucial in enabling the HRA to make informed decisions on the strategy for the management of health research in the UK.

Ipsos MORI was commissioned to carry out public dialogue as part of a wider engagement exercise with HRA stakeholders, which also includes internal stakeholders, health researchers and delivery partners, and patients (via PPI networks). Dialogue with patient groups was facilitated by the HRA. The dialogue was co funded by the Sciencewise Expert Resource Centre (Sciencewise-ERC)[1]. Public dialogue was held in four locations, with each group of participants attending two evening workshops. In total 60 members of the public attended the first workshop, and 56 the second. Eight patient workshops were held including 68 participants in addition to researchers.

Perceptions of Health Research

The patients who attended the workshops were particularly well-informed about health research and most had either been a participant in a research study or taken part in Patient and Public Involvement in the research process. Some had undertaken training in research and so their perceptions of health research were broadly accurate.

The general public, on the other hand, had little idea of what health research involved and only a hazy idea of what a clinical trial was. Their views were mostly informed by the media. Whilst the public realised that health research was necessary to bring new treatments to market, they did not perceive the potential therapeutic benefits of participating in such research.

Unless they had a reason to have insight, for example, a few participants had close relatives who were currently taking, or had taken part in a clinical trial, their level of understanding was poor and they frequently struggled with the rationale behind the use of placebo and blinding ('Blinding' refers to the situation where neither the doctor nor the patient knows who has been given the new experimental treatment and who has been given a placebo to avoid bias). Members of the public were surprised that adults who were unwell and children took part in clinical trials and thought they were the preserve of healthy adults.

Many patients in the workshops had a clear view as to how treatments came through development, what was in the pipeline and what had been launched recently elsewhere within their area of interest. In the main they also had a clear understanding of how the pharmaceutical industry worked with the NHS to develop and test new products and the subsequent benefits, not just to themselves but also for others.

In contrast the general public were deeply suspicious of the pharmaceutical sector and many held a view that making a profit was incompatible with developing new treatments of benefit to patients. Pharmaceutical trials were thought to develop in isolation to the NHS and the links between different organisations was not recognised.

[1] The UK's national centre for public dialogue in policy making involving science and technology issues

Consent
It was difficult for the public to come to clear conclusions as to who is in the best position to take consent to enter a health study in a hypothetical situation which they had difficulty relating to. As predominantly healthy people, their main contact with the NHS was usually with their GPs and so this coloured their perceptions. Their view was also influenced by the nature of their relationship with their GP. Those who favoured the GP to take consent tended to have positive and long standing relationship with them, whereas those who disagreed with this view were often not able to consistently see the same GP.

Many of the patients attending the workshops had long term conditions and so came under the care of a hospital consultant; this in turn influenced their view as to who would be best person to take consent. Although patients were aware that a familiar doctor might have an undue influence on a patient who might want to please the doctor in return, the overall view seemed to be that it was better to have someone who knew the patient and was familiar with their condition. Having said this, the person taking consent was expected to be very knowledgeable about the individual study and in a position to handle any questions. It was recognised that some patients might be in an especially vulnerable position for example, mental health patients who have been sectioned and in this scenario the doctor delivering care could take advantage of a patient's willingness to please the doctor.

Who could advise people thinking of joining a clinical trial?
Patients expected anyone in a position to advise them to be an expert in the subject matter of the trial. For that reason, they did not believe that their GP, in many cases, would be able to offer them good advice. There was consensus that they would like a neutral person to offer advice but they were unable to identify anyone who could fill that position. Patients increasingly made use of the internet to find information about studies they had been invited to join.

Many patients would also seek advice from family and friends although Phase 1 patients sometimes deliberately avoided telling friends and family in case they tried to talk them out of it.

This was a difficult question for the public but they too liked the idea of a neutral person who could give advice about whether to join a study as well as providing advice and support throughout the duration of a study.

Proposals to streamline the research approval process
All groups were shown a diagram of the current research approval process and a diagram showing how it might look in the future. The HRA is currently piloting two aspects:

- An early assessment process to identify any problems
- Local R&D decision to happen sequentially after HRA assessment including ethical review HRA co-ordination of the whole process.

Both the public and patients were surprised by the problems caused by the current system and shocked by the complexity. There was some concern that introducing an early assessment process combined with running the local R&D approval sequentially might lengthen the overall process but once they had been told that the local R&D approval would be time limited, most people both patients and public were, in the main, supportive of the approach.
Whilst both patients and public were keen to see bureaucracy and duplication removed from the system, there were concerns that there had to be a way for any valid problems identified by local R&D to be fed back to the Research Ethics Committee.

Both patients and the public were generally supportive of the coordination provided by the HRA as long as they were able to provide sufficient resources to manage the process. There was concern that an inadequately resourced process might produce even longer timelines.

Annual reporting
Not surprisingly members of the public had little idea about how research is reported and the different mechanisms in place to report and monitor research. They tended to conflate discussion about annual reporting to the research ethics committee with the wider dissemination of the study findings. In general

members of the public supported the proposed changes to simplify the system for reporting to research ethics committees on the basis that it would reduce the burden placed on researchers. Patients were also generally supportive of the procedures provided it tightened up the focus on the final stages of the study.

Researcher Passport

Initially participants in the public workshops were concerned that the researcher passport concept was elitist and might place a hurdle in the way of new researchers. The initiative, which builds on current work, is to avoid multiple approval on the suitability of researchers to enable them to do research at different NHS Trusts. After further discussion most public groups were supportive of the concept of the researcher passport provided that it was regularly reviewed and would not act as a barrier to less experienced researchers. Patients spent less time debating the issue and with the exception of one group, the majority thought that the concept of the researcher passport was a good idea and were supportive of the HRA taking a role in centralising this function. Patients assumed that the passport would be reviewed every 3-5 years assuming that an interim review could be triggered by poor behaviour or a change of employment status.

Patient and public involvement

Discussion of this topic was largely confined to the patient workshops; participants in the public workshops were not asked to discuss the concept of patient and public involvement.

Patient and public involvement was regarded as a crucial element of producing robust research by all the patient groups. Patients said that knowing that patient and public involvement had taken place would increase their trust and confidence in a study and make them more likely to take part. They wanted research ethics committees to tackle researchers about this topic but acknowledged that by this time it might be too late to successfully incorporate involvement. They hoped that early assessment by an Ethics Officer might be a way of picking up on the absence of patient and public involvement at an earlier stage. Participants in a number of patient groups suggested that 'patient and public involvement should be a heading in the patient information sheet template as part of HRA guidance and suggested that this might prompt researchers to consider the issue at an earlier stage.

Publication/ dissemination of research results in the public domain

Patients and public were clear that research results should be published. Publication was seen as promoting both transparency and accountability and would improve relationships between patients/public and the research community.

Both groups tended to focus mainly on making research findings available to the study participants. The general public groups tended to conflate the publication of findings to the wider world and to study participants. Both groups were equally keen that study participants should have feedback specific to themselves i.e. they should be informed as to what arm of the study they have been in on completion of the study. Patients were very aware that even if the results were published in a peer reviewed journal that the public in many cases would not be able to access the paper. They were therefore very keen that the study findings are published in a place which is accessible by the general public and using a language which the public can understand. A number of groups suggested that it should be possible to have 'lay' research summaries with the top line study results published on a central website such as the HRA's.

Almost all groups were supportive of the HRA taking a role in encouraging publication, although there was some concern as to the level of influence that the HRA could bring to bear. Some patient groups suggested that if a company refused to publish the results of a trial, this should mean that NRES would withhold ethical review for any new studies from the same organisation. Similarly some members of the public suggested that research ethics committees should insist that all research is published.

Patients recognised that it would not be appropriate to target all researchers and all types of research and were supportive of the HRA targeting their actions to certain types of studies and research organisations.

Providing information to participants at the end of a study
Patients and public both agreed that information should be fed back to individual participants on completion of a research study, for example, whether the patient was in the intervention or control arm. Patient groups considered this in more detail and concluded that this sort of information should not be sent to patients automatically but should be made accessible if the patient wanted to know.

Whilst patients initially thought that newsletters might be a good way of circulating the general findings of research, they concluded after debate that it was preferable for study participants to be able to choose to access this information rather than be given it *carte blanche*. It was suggested that this information could be made available via the internet.

Role of the HRA in communicating information to the public about clinical trials and health research issues
Both patients and the public called for the HRA to communicate more openly about health research, the role of the research ethics committee and the role of the HRA. They strongly believe an open and transparent agenda would increase confidence in health research.

Benefits and risks in health research
Most members of the public in the workshops acknowledged that society benefits from most, if not all, health research. In this sense, most agreed that health research should be supported and encouraged. Without any serious health conditions to take into consideration, the public focused more on the risks of taking part in research than the benefits.

Although they initially described clinical trials as 'scary', the public weighed up participation in trials as not very risky when thinking about society as a whole, because they believed that society benefits from most, if not all, health research.

For some groups in society, medical research is perceived to be more risky, however. The most vulnerable groups are perceived to need protection; especially where a trial could be seen as a 'last chance' for effective treatment for the terminally ill, or where a currently effective therapy is withdrawn in favour of a 'less tested' one.

Patients were very clear about the benefits of research; both in terms of the generation of new treatments but also in the role that patients can play as a 'participant'. Patients did not regard research as inherently risky, their greatest concerns were focused on areas of non-compliance or poorly managed studies.

What needs to be in place for patients/public to have trust in research and the research approval process?

The public level of trust in research varied according to the funder. Research funded by the NHS is seen as the most trustworthy whilst research funded by the pharmaceutical industry is seen as the least trustworthy. Members of the public in the workshops implied that making a profit from the drug development is incompatible with benefiting patients. The public currently does not understand the interconnected relationships between those funding research and those undertaking research.

Both the patients and the public asked for greater **transparency** in health research including the publication of research findings. Patients went further and noted that publication in academic journals did not necessarily allow wider public access. They suggested publication of lay summaries of research findings in an accessible manner, possibly on open website.

Similarly both patients and public expected there to be **regulation** of the research approval process and they had confidence in the role of the **Research Ethics Committee** to review health research. Both groups expected the HRA back up its requirements of researchers and research organisations with powers of enforcement.

Patient groups explained that their confidence in research was increased by knowing that Research Ethics Committees had a lay component. The general public were less impressed by this aspect. Similarly patients noted that their confidence in individual studies is greatly increased by knowing that there has been some **patient and public involvement**. Patients had confidence in research that was deemed to be scientifically robust. Confidentiality of patient records was regarded as a given.

In general patients including Phase 1 participants wanted to know that the research they took part in was led and conducted by competent and trained researchers. Phase 1 participants were reassured by knowing that the research had been reviewed by a Research Ethics Committee and that the units conducting the research had been accredited.

How should the HRA engage with patients and public in the future?

A large majority of the public were positive about the idea of the HRA continuing to work with and engage with both patients and the public to inform its on-going strategy and policy. To some extent this conflicts with their dismissive attitude towards the inclusion of lay members on research ethics committees. The majority of patients on the other hand feel that future engagement should be restricted to patients and carers only. All groups were supportive of a panel model of engagement.

2. Introduction

2.1 Background

The Health Research Authority (HRA) is a NHS organisation established on 01 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 is working closely with other bodies, including the MHRA and NIHR, to develop a unified approval process policy for health research involving the public and to promote proportionate standards for compliance and inspection within a consistent national system of research governance. This aims to ensure that research involving members of the public is ethically reviewed and approved, that they are provided with the information they need to help them decide whether they wish to take part, and that their opportunity to do so is maximised by simplifying the processes by which high quality research is assessed.

In developing this policy approach, the HRA is committed to making it easier to do good quality research in the NHS, and this will require a fundamental assessment of how we review and manage research in the NHS. This pubic dialogue will therefore not only inform how the new HRA operates, but will also lead to updates in the current DH policies such as the Research Governance Framework and the Governance Arrangements for Research Ethics Committees (GAfREC), which, as proposed in the Care Bill 2013 will be the HRA's responsibility pending its status changing from Special Health Authority to Non-Departmental Public Body. It is essential this policy work is grounded in the views of patients and the public.

The HRA has set out an ambitious programme of work to improve the environment for health research in the UK. The findings from this proposed public dialogue activity will be crucial in enabling the HRA and DH to make informed decisions on the strategy for the HRA and policy for the management of health research in the UK.

The Health and Social Care Act 2012 gives the HRA the responsibility for the policies outlined in the table below, and these will be informed and updated based on this dialogue work.

Policy	**Policy Area**	**How and when the policy will be informed**
Research Governance Framework for Health and Social Care	This document sets out the broad principles, requirements and standards of good research governance.	The Research Governance Framework was last amended in September 2008. The HRA will take responsibility for the RGF in late 2014 and is considering now issues that will underpin the principles on which the revision is based. The HRA will prepare new drafting for the RGF ahead of the formal transfer of responsibility and this means there is opportunity now to influence this policy.
Governance Arrangements for Research Ethics Committees (GAfREC)	This document is the policy of the UK Health Departments describing what is expected from the research ethics committees that review research proposals relating to areas of the UK Health Department's responsibility. It also explains when review by these committees is required.	GAfREC was last revised in February 2012, however there is a window of opportunity now to influence the piloting of new systems of ethical review and the update of GAfREC as proposed in late 2014 / early 2015 when the RGF is revised

2.2 Engagement in the HRA

The HRA has an engagement strategy, and convened a working group to advise on the patient and public involvement element of this engagement strategy.

The HRA working group on Patient and Public Involvement has identified the need for the HRA to map out the current landscape of patient and public involvement in research in the NHS. This is a separate piece of work that it being taken forward by the HRA. There are several patient networks through which the HRA could seek the views of NHS service users. But the HRA must ensure that it also seeks views from the broader public to inform the development of its patient and public involvement strategy, and ultimately to inform our approach and policy for the management of research in the UK. Thus additional dialogue is required with the 'non-patient' to help understand the public attitudes to health research across the widest range of health research sectors.

2.3 Objectives

The public dialogue focused on the benefits and risks of health research involving patients. It examined perceptions of health research the ethical issues that might arise and the procedures required to approve health research, recruitment of patients, consent and views on proposals to streamline and simplify the research approval process including:

- Restricting R&D decisions to local issues only with a time limit
- Early assessment
- Annual reporting
- Publishing research findings.

The elements of the public dialogue covered by the Sciencewise-ERC grant were:

- What are the perceived risks for individuals agreeing to participate in research? (Differentiating between different types of research)

- To what extent do the public and others trust the views of their doctor in advising if they should participate in research?

- To what degree do the public and others trust charities (e.g. Cancer Research UK) to protect their interests in research?

- To what degree do the public and others trust the pharmaceutical industry to protect their interests in research?

- Awareness of the HRA role: the HRA has a National Research Ethics Service and all health research studies must have approval from a HRA research ethics committee. To what extent can research ethics committees protect patient and public interests if the public are largely unaware of their role?

- The HRA is tasked to protect and promote the interests of patients and the public in health research, what should the HRA's engagement with the public look like? To what extent should the HRA engage directly with the public and what should be influenced by such engagement? How should the public influence the role of the HRA?

- To what extent do different views emerge from different types of public? For example general public versus patients?

2.4 Sciencewise

This project was supported and part-funded by Sciencewise-ERC. The Sciencewise Expert Resource Centre (Sciencewise-ERC) is funded by the Department for Business, Innovation and Skills (BIS). Sciencewise-ERC aims to improve policy making involving science and technology across Government by increasing the effectiveness with which public dialogue is used, and encouraging its wider use where appropriate to ensure public views are considered as part of the evidence base. It provides a wide range of information, advice, guidance and support services aimed at policy makers and all the different stakeholders involved in science and technology policy making, including the public. The Sciencewise-ERC also provides co-funding to Government departments and agencies to develop and commission public dialogue activities.

The results of in-depth deliberative public dialogue exercises designed to help policy makers to take account of the public's views, concerns, hopes and expectations in the development of better policy on science and technology issues can be found on their website. Visit www.sciencewise-erc.org.uk for more information and guidance.

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3. Methodology

There are two distinct elements to the work covered by this report:

1. Ipsos MORI conducted workshops with the general public. The public sections included in this report are drawn from the report written by MORI entitled 'Public Dialogue Workshops', written for the HRA in June 2013.
2. The HRA carried a further eight workshops; six with patient groups, one a mixed group of patients and public (Children and Young People) and one with participants of Phase 1 clinical trials. Henceforth these workshops are reported under the heading of patients. Phase 1 participants are only specifically referred to if they had something different to say.

In addition the HRA commissioned MORI to conduct a large scale face to face interview survey of the general public. The findings of this survey will also be reported on the HRA website.

3.1 Public dialogue events

Public dialogue workshops were held in four locations (London, Bristol, Manchester and Newcastle) with each group of participants attending two 3-hour evening workshops (from 6:30pm to 9:30pm). Each re-convened session was held one week after the first session. Public dialogue is a process of engagement that brings together members of the public, policy makers and in this case, researchers:

- to discuss in depth, and where possible reach conclusions about,
- the social, ethical and practical issues raised by up-coming policies.
- to make more robust decisions reflecting (rather than at odds with) public values.

3.2 Public dialogue - recruitment & sample

Sixteen adults aged 18+ were approached in the street and recruited in advance for each location and as a minimum had to agree to attend both workshop sessions.

In addition, people were excluded from participation if they were NHS employees, or working in another health or clinical capacity, particularly clinical research in NHS, pharmaceutical companies or universities. They should also not have taken part in qualitative research in the past nine months.

Quotas were placed on gender, age, social grade and ethnicity to ensure a broad range of participants were recruited. Potential participants were also asked about their self-reported health and a series of questions to discern their general attitude and knowledge about science, clinical trials and health research ethics. Soft quotas for age and gender were applied to these questions, with a view to ensuring a good mix of attitudes and knowledge within each workshop.

Public dialogue - event structure

A total of 60 participants attended the initial workshops (Workshop #1) and 56 the second (Workshop #2). In each session, participants were split into two groups, averaging 7-8 people per table and ensuring a good mix across demographic characteristics.

The events were facilitated by MORI researchers. In addition, two Ipsos MORI note takers were present at each event to record the dialogue as it happened.

The HRA client lead also attended several of the sessions, and provided additional input throughout the sessions. Health researchers were also invited to attend the Workshop #2 sessions to answer questions, raise issues and generate further dialogue among participants and at least two attended per session. Other observers were present at other sessions, including the Sciencewise lead, evaluators from Cardiff University and HRA project Steering Group members.

The table below provides an overview of attendance at each session.

Location	Workshop 1					Workshop 2				
	Date	Attendees	Client	Researcher	Observers	Date	Attendees	Client	Researcher	Observers
Bristol	05/03/13	16	1	0	2	12/03/13	15	0	2	1
Newcastle	06/03/13	13	1	0	1	13/03/13	12	0	3	1
London	19/03/13	15	1	0	3	26/03/13	14	1	3	4
Manchester	20/03/13	16	1	0	1	27/03/13	15	1	3	1

The two sessions were structured along the basic premise of:

- First workshop: to inform and educate participants about health research in the UK. This used clinical research trials as a primary example of health research to illustrate many of the ethical and research governance issues that need to be addressed when evaluating health research proposals. In this workshop, participants were largely engaged in thinking about the issues presented from the perspective of being a 'potential research participant'.

- Second workshop: to engage participants and researchers in an informed dialogue about the research approvals process. The initial focus was on the current approvals system, shifting to a discussion about the HRA's proposals for streamlining the approvals process by taking a more central role in co-ordination of research governance, and enhancing specific aspects of the process. In this workshop, participants were encouraged to think about the issues from a broader 'citizen' perspective and thus to consider the wider societal implications for health research and the strategic role of the HRA.

The workshop materials and discussion guides for both sessions are included in the appendices.

3.3 Role of health researchers at the public workshop sessions

In line with the principles of public dialogue set out by Sciencewise-ERC and others, health researchers were invited to the second workshop in each location, to enrich the dialogue and discuss the research approval process. The HRA located and invited relevant health researchers. They were briefed in advance (in writing from Ipsos MORI and on the day): to engage participants in discussion; to offer their own experiences of working in research as examples; and to ask questions of participants to open up the discussion. While they were asked to talk freely, they were also asked explicitly not to present themselves as the ultimate experts and not to correct participants even where their perceptions might not be correct. This was so that we could explore perceptions and where they came from, rather than closing down conversations early. We asked the researchers to take care that their expertise was presented in an un-intimidating way, and to use lay person's language, so that participants were able to follow the discussion. The facilitators also assisted in moderating the role of researchers and their discussions on each table.

Some of the researchers invited to attend had roles in the development of the HRA's new guidelines, as well as long experience in research. Some were **very clearly supportive of the HRA's proposals and as such effectively promoted these to their group, in other instances researchers suggested changes to the current system that went beyond those proposed**. Some participants were more forthcoming with their contributions and questions than others. **The researcher contributors will inevitably have influenced the form and content of what was discussed in their own group.**
This meant that, as is normal for public dialogue, each workshop had a slightly different focus and covered off different themes and questions in different ways. **Across the workshops as a whole,**

however, the key issues were all covered, and in analysis we were able to compare responses on a thematic level to understand public perceptions (see data collection and analysis sections, immediately below). In analysis, we also bore in mind the interaction of researchers and participants when drawing conclusions or evaluating the balance of opinion based on the weight of discussion.

3.4 Data collection at the public dialogue sessions

As mentioned above, note takers were present at each event to make detailed anonymised notes of everything heard and any notable observations throughout the session – including during plenary and the refreshment break. Sessions were also digitally recorded in their entirety, to further support analysis and quality assurance. Flipcharts were used to capture participant feedback for some exercises and facilitators took charge of noting summaries of the table's views on these flip charts. They were also then used in-session to support both facilitators and participants. They were checked during the sessions and used to refer back to earlier thoughts and observations as the discussions progressed. A core team of facilitators attended the events, in most cases attending several locations, and each facilitator made their own field notes of reflections after the event. All of these sources of data have been utilised in the drafting of this report.

3.5 Analysis of the public workshops

Once the series of workshops were concluded, the Ipsos MORI workshop facilitators and the HRA client lead held an analysis session to explore the emerging themes when set against the research objectives and specific research questions we set out to address.

As a result of this session, the team arrived at a shared understanding of the range and depth of the data, and to agree a structure for this report that ensured coverage of all perspectives. With this structure as a basis, members of the team then conducted further detailed analysis of the workshop notes, flip charts and audio recordings.

3.6 Patient/ Phase 1 participant dialogue events

Eight workshops were conducted in March and April 2013 across England; seven with patients and one with Phase 1 clinical trial healthy volunteers. The patients were recruited via NIHR Research Networks and so were particularly well informed. Many of the patients acted as patient representatives, some had been participants in research studies and others reviewed research proposals as part of patient and public involvement. Some patients had been trained in research methods in order to take part in patient and public involvement; a couple of patients even formally recruited other patients to take part in clinical trials. The Phase 1 participants were recruited directly from companies conducting Phase1 studies. The table below illustrates the basic demographics of each group.

Group	Location	Gender	Total No
Mental Health	Birmingham	M 2 F 6	8
Parkinson's	London	M 7 F 2	9
Diabetes	London	M 5 F 4	9
COPD	London	M 6 F 3	9
Cancer	Sheffield	M 1 F 3	4
Stroke Survivors	Newcastle	M 7 F 1	8
Children & YP	Liverpool	M 4 F 13	17
Phase 1	London	M 2 F 2	4

The patient workshops unlike the public workshops were not reconvened. Patient workshops took place just once for each group and were just three hours long. A decision was made not to reconvene the patient groups as they were starting from a more informed base. Patients were already familiar with health research and clinical trials. In some cases they had an awareness of the function of the Research Ethics Committees which meant that more time could be devoted to the HRA's proposals to streamline the research approval process and other initiatives. Researchers were present at five out of eight patient/participant workshops. There were a small number of carers also present in the patient groups.

The facilitator took notes at all patient workshops. This was supplemented with material written by the participants themselves and in workshop a transcript of the meeting.

3.7 Context at the time of fieldwork

Before and during the period of the fieldwork, commercial TV showed advertisements at primetime for Cancer Research UK. In addition a major film was released in the middle of the fieldwork for a film called 'Side Effects'. Neither item was explicitly mentioned by the public or patients during the workshops although it is possible that the media could have influenced public perceptions.

3.8 Report structure

Below are the detailed findings derived from both the public and the patient workshops. Each section contains a topline summary followed by the results for the public dialogue workshops followed by the findings of the patient groups.

4. Perceptions of health research

The patients and public had very different perceptions of health research and clinical trials. This is in part, due to the fact that the patients recruited to the workshops were largely very experienced and knowledgeable about their condition. Many had either been a research participant or were involved in reviewing research or working with researchers. The public, in contrast only had a hazy understanding of health research and clinical trials, in particular.

4.1 General perceptions about health research

Public

The general public's perception of health research and clinical research in particular is vague and not well-informed. A common perception of a clinical trial seemed to essentially take the form of a Phase 1 scenario whereby healthy people are injected with experimental drugs and held in 'quarantine'.

The initial perception of health research with patients was that it only took place with healthy people. Workshop facilitators informed the participants about health research and in many groups there was shock and surprise that people who were not well might take part in a clinical trial. The public were also shocked that children might be take part in a clinical trial. A considerable amount of reassurance was required to satisfy the public that this was the only way of developing treatments for these groups.

The media represent a significant influence on the public perceptions of health research, although there is widespread recognition that newspapers and the wider media often exaggerate.

'I'm very concerned about the poor quality of health and science reporting in the news which prevents people from understanding clinical trials. Attention grabbing headlines with lack of evidence to back up could put people off from taking part'

(Newcastle #2)

The public currently does not understand the interconnected relationships between those funding research and those undertaking research. In other words, there is currently no substantive recognition that regardless of whether research is funded by the NHS or a pharmaceutical company, or a health charity, most of the research is conducted within the NHS and carried out by NHS staff.

NHS and NHS staff are very highly regarded and trusted to protect public health and well-being above other considerations. Overwhelmingly, participants want to take the advice of their doctor in deciding whether to participate and trust him or her to protect their interests. This trust extends to a wider NHS care team.

In contrast, pharmaceutical companies are very much seen as having vested interests in the conduct of research, and as a consequence cannot be trusted to behave ethically. Making a profit is often seen to be mutually exclusive to the aim of benefiting patients or advancing long-term healthcare.

'I was worried that if it is funded by a company, that would have an influence on the research'
(Manchester #1)

'Pharmaceutical companies just need to protect their own interests'. (Bristol #1)

Few participants are aware of the role of charities in health research, even when prompted for their views on these. It is worth saying, however, that charities are not *dis*trusted, unlike the pharmaceutical industry, however some members of the public doubted their competence to lead/conduct research.

Patients

The patients invited to participate in this project were in the main very well informed and knowledgeable about research and some had been participants in research including Phase 1 studies and several contributed to patient involvement in research, including reviewing research proposals. Consequently

in stark contrast to the general public, they were very familiar with health research and clinical trials in particular. Needless to say the patient groups included in these workshops had a very positive attitude towards research. For example, the mental health group suggested that participating in research was beneficial because it helped them *'find a voice'.*

Whilst awareness of health research and clinical trials was very high amongst the patient groups, it was pointed out that this had come about over time:

'When I was first diagnosed I didn't even think about trials or research – Diabetes is not like cancer where everyone is expected to go into a trial'. (Diabetes Group)

Despite their positive attitude to research, they were aware that research applications varied in quality and required both scientific and ethical assessment to weed out poor studies. They were also aware that some studies might be carried out unnecessarily.

Patients were able to appreciate the integration of organisations across research studies, so, for example, they understood that the pharmaceutical industry funded research that took place in the NHS and was led by NHS researchers. So whilst there was at times scepticism shown towards the pharmaceutical industry, they understood the importance of the pharmaceutical industry in bringing drugs and other treatments to market for the benefit of patients. Indeed the patients attending these workshops were very well informed about the pipeline and talked knowledgeably about new treatments in development and also about treatment which had been licensed in other countries.

4.2 Perceptions of placebo and blinding

Many of the patients who attended the workshops had been trained in research methods or had reviewed research and so they were, in the main, au fait with the concepts of placebos and blinding ('Blinding' refers to the situation where neither the doctor nor the patient knows who has been given the new experimental treatment and who has been given a placebo to avoid bias). In contrast, there was some concern about the use of placebos and blinding in clinical trials in the public workshops and several respondents struggled with the rationale behind the use of placebos and blinding:

'My son had Crohn's disease and was really sick not long ago… Lots of treatments, recently a treatment he wasn't responding well [to]..[he was offered] a clinical trial, they said it might be a placebo, so it might not be real...He was running out of treatments…I didn't want to waste time 'cos he's so sick if its only placebo. I said I'm happy to put him on it as long as it's not [placebo]…It's more to test placebo than to test the drug – testing two different things'. (London #2)

'interesting when the doctor doesn't know, I thought they always did know…It made me curious to think what kind of trial my son would have been offered. If I had more information at the time maybe I would have made a different choice. I didn't even know what a placebo meant' (London #2)

'is there much of a difference with drugs and placebos? If not, they should use placebo, as drugs muck you up a bit' (London #2)

5. Recruitment of patients into health research

The public had little understanding of how their records can be accessed or who might have access to them. There was a common assumption by the general public that more people in the NHS had access to their records, than in reality. Most participants in the public workshops were comfortable about a range of NHS professionals having access to their records, principally because of high levels of public trust in these professions. The patients in the workshops were keen to access clinical trials and so a majority of patients were happy for suitably qualified researchers to have access to their records to search for suitable patients to be invited to join research studies. The patients had a greater understanding of how research databases could be used for this purpose and talked about the use of anonymised databases but also the concept of 'consent for consent' databases where patients give consent to be approached.

5.1 Who should be able to search patient records to identify suitable patients?

Public

The general public were asked to consider who they think should be able trawl patient records to find patients for a trial. Participants were asked to consider various professionals who could access patient data such as;

- a patients' GP;
- members of their care team; and
- a research nurse or research team.

It was clear from the discussions that the issue of how patient records can be accessed and who might have access to them did not initially have a great deal of saliency amongst workshop participants. There were a number of reasons for this confusion. Firstly, participants had limited prior knowledge and understanding of these issues, perhaps because many had good health and had had limited interactions with health care professionals. Secondly, participants assumed that health services are more joined-up than they are, with some suggesting that any healthcare professionals could easily access patient records. Following this assumption some participants thought a wide variety of healthcare professionals were *already* accessing their records.

'Anybody can get hold of your medical information. Everything about you is on computers'

(Newcastle #1)

Finally, participants were often unaware that the healthcare team already looking after them might also be conducting the research.

Once the subject was explained in more detail, most participants were happy with the option to allow members of the research team, as well as other groups, to trawl patient data. The key reason for this was that participants trusted healthcare professionals working within the NHS and felt they could all be trusted to prioritise the interests of the patients.

'Everybody in the hospital is concerned about my wellbeing and getting well: doctors, nurses and [pharmaceuticals]'

Newcastle #1

Participants were also reassured by the fact that patients always have the option of choosing whether or not they would like to take part in any research.

'I'd be happy [about people looking through my records] as long as I had the right to decline'

Newcastle #1

Finally, some participants felt that the ability of researchers and care teams to share information would ensure that patients' care was more joined-up throughout the course of a trial.

Those participants who disagreed with the proposal did so because they were uncomfortable about their records being seen by anybody but their GP. In particular, there were concerned about too many people being able to access the more personal or embarrassing information that might be on patients' records (such as their sexual health). They believed that a patient's GP should only allow other professionals (such as members of the research team) to access their records if it was in the interests of the patients. Participants' concerns around this issue may relate to a mistaken belief that health professionals would be looking at named rather than anonymised records as part of their trawl of patients' records.

'Unless your GP has recommended you, then I believe all this information should be held confidentially' Bristol #1

A small number of participants were uncomfortable about the impersonality of trawling through patients' records. One participant was concerned that such a process would not involve *"looking at patients as individuals".*

Participants were also concerned that a cursory investigation of patients' records might not be sufficient to ensure that trial participants are healthy enough to take part. Participants were particularly concerned about trial participants' mental health and wellbeing, with some suggesting that more nervous or vulnerable patients could be more easily manipulated into agreeing to take part in a trial that they do not feel comfortable with. This view is likely to be based on the fact that many participants' image of a typical trial was one that is high-risk (with the potential for a significant break-through), and only involving healthy patients (Phase 1). Many participants were surprised to be told that trials can involve unhealthy patients, and may involve testing relatively small amendments to accepted practice as well as more high-risk studies.

Some participants were concerned about pharmaceutical companies accessing records: it was explained that this does not currently happen and there are no plans for this to happen.

Patients

Patients were in the main keen to find out about relevant research and studies which they might be able to take part in. There was some concern that to an extent this was a postcode lottery and that if care was provided by a district general hospital outside a big conurbation, patients might not get invited to join studies in the same way that those attending large teaching hospitals. Even patients with cancer noted that they are not given the same opportunities to participate in trials despite the fact that there is a drive to include all cancer patients in a trials and that they are treated by a multi-disciplinary team who have a role to consider possible studies. With this in mind, there was a feeling that patients had to some extent be proactive in finding out about possible clinical trials for themselves rather than passively wait for the studies to come to them.

Several of the groups suggested that researchers were able to recruit all the patients they needed via patient support groups such as Stroke Clubs the Stroke Association etc. They acknowledged however that not all patients joined such groups and that those in such groups might be different due to self-selection. The Chronic Obstructive Pulmonary Disease (COPD) group also noted that where researchers need to recruit patients with rare condition they might need to try other ways to find suitable patients.

Generally speaking patient groups were keen for researchers to have access to their patient information:

'I would feel comfortable with a suitable accredited individual who could look at my data in an anonymised dataset without obvious identifiers'. (Cancer group)

'I would not be offended if researchers looked at my notes – I would feel privileged'. (Diabetes Group)

'I would not feel angry – 5% of people might be angry' (Diabetes Group)

'There is no problem in anyone having access to my clinical details'. (COPD Group)

'There needs to be a change in culture from the top down'. (Diabetes Group)

Several groups suggested that researchers could make greater use of the media to recruit patients, including social media such as Facebook and Twitter. Indeed the Phase 1 participants noted that companies are already seeking to recruit participants for Phase 1 studies through Facebook.

5.2 Should potential study participants have a mechanism for signalling a wish to participate?

Public

Many members of the public, particularly in the Newcastle workshop, were keen to ensure that patients should have the opportunity to take part in trials that could potentially help them by allowing them to have access to new drugs and treatments. They believed that this could be managed by making GPs responsible for informing participants' about any trials that they might be able to take part in.

'Maybe the doctor should be responsible to make patients' aware of clinical trials as part of their remit' (Newcastle #1)

Others, particularly in Bristol, suggested that it would not be difficult for anyone (who was online) to find out about trials which were going on and so the onus could remain on individuals for finding out. Some participants had been asked to research trials in the gap between workshops 1 and 2 and reported back that they had not found it difficult to find some trials in their area. However, they had not searched for trials in particularly specific areas of medicine.

Some felt that there was already a process in place for matching potential participants with trials, but were hazy about who organised it or the details.

'You get letters through the door if you have a specific illness from different companies offering you to test this or that'. (Newcastle #1)

Some participants felt that the GP should certainly remain in the loop, because if they were to find out about trials from elsewhere they had little faith that their interests would be protected.

'If I was sick maybe Alzheimer's or something like that I wouldn't like to hear someone just walk in my room and say hi there there's a new drug blah blah blah. I would like to hear it from a doctor' (London #1)

One risk of placing the onus on GPs to recommend trials is that GPs may not have the time and resources available to manage this additional role.

Only one group was asked to comment on the topic of identifying suitable patients for inclusion in studies. This topic was subsequently removed from the public dialogue after the first workshop as it was taking a disproportionate amount of time. Consequentially the HRA may cover this topic in future engagement with the general public.

Patients

Some patients were happy for researchers to see their identifiable patient records but after some debate all patient groups were supportive of the concept of anonymised databases which could be accessed by researchers.

However it was noted that whilst the first approach to the patient still had to be made by the GP, some GPs might not bother to contact their patients. Indeed many patients felt that there was an excessive concern over the privacy of data. One patient said:

'Confidentiality is a total myth – there are limits to our confidentiality and we should admit this'.
(Mental Health Group)

'We need to understand the limits to our privacy'. (Mental Health Group)

Patient groups debated different ways that they could be approached to take part in research and some concluded that they did not always wish to rely on the GP to approach them. It was suggested in some groups that people should be able to opt out of being approached directly by researchers but that the default position could be that researchers should be able to approach them after searching an anonymised database. It was suggested that the technology existed which would allow researchers to trawl anonymised databases and which would allow individual patients to be contacted without revealing identifiers to researchers or requiring the GP to get involved.

Some groups debated the 'consent for consent' approach whereby individuals give prior consent to being contacted directly by researchers. Researchers and patients in the Diabetes Group spoke positively about the DARTS (Diabetes Audit and Research in Tayside) an electronic research database in Scotland designed to link both primary care and secondary care records to create a diabetes register. A researcher in the Diabetes group drew everyone's attention to the DeNRoN project which is attempting to meet the Prime Minister's challenge to increase the number of people with dementia participating in clinical research from 4% to 10% by developing a Recruitment and Feasibility Tool (RAFT) which allows patients and their carers to register their interest in being contacted about research. This 'consent for consent' approach was supported by the group.

6. Consent

Members of the public had mixed views in the workshops as to who should consent patients to take part in health research. GPs were identified for this role, as they were seen to be impartial and able to offer 'trusted' advice. Others preferred to be able to talk with specialist research teams. Patients in the workshops were mostly under the care of hospital consultants and so in the main had a preference for consent to be sought by a hospital consultant specialising in the condition under question or a specialist nurse. Relationships with GPs were more mixed, with some patients having little regard for the GP's ability to understand the issues.

Both patients and public discussed the possibility of having access to an independent specialist to seek consent and/or give advice. Both groups liked the idea of having a neutral person with specialist knowledge to be able to offer advice about whether or not to take part in a clinical trial. Some members of the public would like to see such a person on hand to give advice throughout the duration of a study.

Patients were supportive of a two stage approach with a short easy to read patient information sheet in the first instance, followed by a longer more in-depth patient information sheet if the patient is interested. The public did not have strong views on this issue.
Patients would like to see the patient information sheet include a section on 'patient and public involvement' and would like re-assurance that the end of the study is adequately covered by the patient information sheet. For example, patient would like to see sections on:

- Will the study findings be published?
- How will the study findings be shared with participants?
- Will study participants be told what arm of the study they were in?
- Can they continue on the treatment beyond the end of the study?
- How will side effects be monitored in the long term?

6.1 Who should consent patients?

The public had mixed views on who should give advice to people who were interested in taking part in research. The general public are more likely to refer to GPs rather than hospital specialists as this reflects their contact with the NHS. However several people were concerned that GPs could be paid by pharmaceutical companies to promote their research. In addition, concerns were expressed about GPs' lack of specialist knowledge, though for some this would be counter-balanced by knowledge of the individual's patient history.

Patients were more likely to suggest that consent should be taken by the research team given their specialist knowledge. Whether this was a research nurse or other member of the team was not considered to be important. Having access to an independent specialist was suggested by some as a way to overcome the drawbacks of seeking consent via GP or a researcher involved in the trial.

Public

The public had mixed views on who should consent patients to take part in health research. Some argued that GPs should take on this role, while others felt it should be managed by the research team. Those participants who favoured consent via GPs often had very positive and long-standing relationship with their GP. In contrast, some of the patients who disagreed with this view explained that they did not have a regular doctor but were assigned a different doctor every time they visited their local practice.

The principle reason for arguing that GPs should consent patients was the assumption that GPs are independent and impartial (assuming that are not involved in the research themselves) and less likely than members of the research team to try to persuade patients to take a particular decision.

'Doctors are more likely to give you impartial advice about the trial as they won't benefit from the trial'

(Bristol #1)

While many members of the public shared this view, one was concerned that GPs might be paid by pharmaceutical companies to promote their research, while others were concerned that GPs may have particular opinions about their patients taking part in health research that could make them more biased when giving advice.

Participants suggested that the fact that most people trust their GP meant that the GP would be well-placed to introduce the research to them, and reassure them that the research was legitimate and managed and funded by a reputable organisation[2].

'I would like my GP to be the first person and the last person I see personally. Not just some random person with a briefcase'

(London #1)

While GPs might not have specialist knowledge of the specific research area being investigated, many participants felt that their understanding of patients' own health history and background would be advantageous as they would be able to consider the patient's specific needs and background when advising them about the research.

Some members of the public suggested the research team should manage consent believing that they would have the expertise needed to provide participants with all the information required to make a decision. These participants suggested that GPs might not necessarily know enough about the trial to do this. Whether this was a research nurse or other member of the team was not considered to be important, so long as they were knowledgeable about the trial.

'You would need somebody who is actively involved in the trial so I know I'm getting all the information I need" - opposing the previous point about asking questions'

(Bristol #1)

Patients

Patients were asked who they thought would be the best person to take consent from them in order to take part in a research study. Each group debated whether it was better to have a person that they knew them because they delivered clinical care to them or whether it was preferable to have consent taken by a neutral person:

'A neutral person could help overcome the power differential between a health professional and patients who want to ''help'' people they know'. (Mental Health group)

After much discussion most patient groups struggled to identify an appropriate neutral person.

Patients generally had trust in the doctor that provided the bulk of their care. In some cases this was a GP and for others it was a hospital consultant. Where care was normally provided by the GP, patients were divided as to whether this was the best person to ask for their consent. Not all patients had a good relationship with their GP and some could not make an appointment to see a specific GP. Those patients under the care of a hospital consultant had little time for GPs.

Patients were more likely to suggest that consent should be taken by the research team given their specialist knowledge. Whether this was a research nurse or other member of the team was not

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[2] It is worth noting that this discussion took place before the approvals system was explained to participants.

considered to be important. Most patients in the workshops were under the care of a hospital consultant and tended to have high levels of trust in this relationship. Consequently they trusted the hospital consultant to take their consent:

'As a newly diagnosed stroke patient, your life is in their hands, you trust them of course'. (Stroke Survivors Group)

Patients acknowledged that there were times when being asked by the doctor that is responsible for your clinical care could have an undue influence. It was noted that patients with mental health problems could be particularly vulnerable. For instance, one patient explained that she was sectioned at the time that her consultant psychiatrist asked her to consent to take part in a clinical trial and she felt with hindsight that she had been under pressure to agree. Most people felt that it was useful to have a person who knew about you and your condition although a minority of patients were happy for a stranger to consent them if they knew more about the study.

The participants in the Children's and Young People Group preferred to have consent taken by someone that knows them. They felt this would make them feel more comfortable, would enable them to listen more closely and to also ask questions. They did not believe that having a familiar person seeking their consent would put undue pressure on them. They could see the advantages of having a neutral person but overall thought that a stranger might make them feel uncomfortable and might be a 'little intimidating'.

It was explained in the session that the first approach to a patient would normally be by someone in their clinical care team and that this might mean that research nurses might be excluded from this process. Some patients, most notably the COPD patients, felt that this restriction was unnecessary:

'This is a long winded way of going about things' (COPD Group)

There was view that staff devoted to clinical care should devote their time to that task and not divert their attention to taking consent.

6.2 Who to turn to for advice if considering joining a study

Public

The general public agreed that in addition to the patient information sheets they would expect to have a face-to-face conversation with a professional with sufficient knowledge to answer any questions about the research.
Some would also like to be able to talk to patients who have been through similar research programmes.
In addition to pre-consent advice and information, some participants emphasised the need for patients to also have access to such support throughout the lifetime of the project.

The public had mixed views on who should give advice to people who were interested in taking part in research. GPs were again identified for this role, as they are seen as impartial and able to offer 'trusted' independent advice. The general public are more likely to refer to GPs rather than hospital specialists as this reflects their contact with the NHS. However several people were concerned that GPs could be paid by pharmaceutical companies to promote their research. In addition, concerns were expressed about GP's lack of specialist knowledge though for some this would be counter-balanced by knowledge of the individual's patient history.

One participant suggested a GP should refer patients to independent specialist professionals who would understand the specific research area whilst not being actively involved in that particular research project. Participants in Manchester suggested that an independent specialist should be available to fulfil this role. The advantage of these suggestions is that they could potentially ensure that research participants are able to talk to somebody who is has the knowledge to provide detailed information whilst still being independent from the research study.

'You could ask a doctor if they know someone in the field for impartial advice' (Bristol #1)

'An independent government advice service would be less inclined to have an interest in the research' (Manchester #1)

Patients

Patients were keen on the idea of having someone to turn to for advice and to discuss whether they should join a study or not. Many would turn to their GP as their first port call, whilst other felt they this was not always an option depending on the relationship that an individual has with their GP:

'That's OK if you have confidence in your GP and you have a good relationship with your GP' (Diabetes Group)

There was also concern that staff responsible for delivering clinical care particularly in primary care may not have the expertise to explain a study to a patient. For example:

'They are not well-informed; they are difficult to get to see and would only give you 7 minutes'. (COPD Group)

Many patients suggested that they would ideally want to discuss the trial with an expert who understood the study but was independent of the research team. Patients were unsure as to where they could find this type of advice and did not believe that their GP could provide the necessary level of expertise.

'An independent doctor would have to be fully briefed and well versed in that particular study'. (Diabetes Group)

Having access to an independent specialist was suggested by some as a way to overcome the drawbacks of seeking consent via GP or a researcher involved in the trial. However it was acknowledged that finding somebody 'neutral' was a 'tough call' and there were reservations that almost anybody they could seek advice from would have a 'vested interest' and would in all probability be pro-research and could not therefore be neutral. Realistically this meant that most patients if in the care of a hospital consultant would discuss the study with their consultant or a nurse practitioner within the same team.

Several groups thought that they would like to be able to talk to a patient representative or service user body for advice but acknowledged that they would also not be neutral. Some patients and Phase 1 participants said they would like to be able to talk to patients already in the study.

Many patients across all groups turned to the internet to find information about the study they had been asked to join and increasingly could find information about either the trial or at least about the drugs or interventions being used. Even participants in Phase 1 studies carried out thorough internet searches to find out what they could about the previous use of a chemical and its possible side effects, including side effects in animals.

Patients were likely to discuss their options with friends and family, especially carers who might have to bear a disproportionate burden if they decided to take part in research. Interestingly the Phase 1 participants were divided over this point with some people discussing the possible study with their spouse and seeking their approval before signing up whereas another participant said she avoided mentioning to her friends and family that she was planning to take part in a study as she knew that they would try to dissuade her.

Some groups of patients also had to deal with capacity issues, namely the Mental Health group, the Parkinson's Group and the Stroke Survivors Group. Judging capacity was considered to be a fraught issue:

Do you assume that people have capacity or do you make them jump through hoops to demonstrate capacity'

(Researcher in Mental Health Group)

The stroke patients noted that initially after a stroke up to a third of patients suffer from aphasia. Aphasia is particularly difficult in relation to consent as it not only impacts upon communication including speaking, reading and writing; it also impacts on cognition by affecting the understanding of language. It also means that patients with aphasia are more likely to be excluded from studies.
Many stroke patients also have neurological fatigue; this can be a variable condition even on the same day so the lack of capacity is not consistent over time and vary within the same day.

6.3 Patient Information Sheets (PIS)

Public

The general public were asked to look at typical patient information sheets that patients would see if they were asked to take part in a trial. Some participants in each group were given a longer version of the information sheet while others were given the shorter version so that each break-out group could compare the advantages and disadvantages of each. It is worth noting that there was not sufficient time to allow participants to read the information sheets in detail. Instead, participants were asked to skim read the sheets and comment on their 'top of mind' thoughts about the sheet.

'Assuming everything is OK I would not read the terms and conditions like on ITunes. I'd accept it all. There should be a summary "we don't think you're going to die'

(Bristol #1)

'I've actually done a study for a science park. I preferred the longer version to a shorter version. I prefer more info than less. I don't think I would have done it if I got the shorter version '

(Manchester #1)

The public did agree that the information sheets would need to be supplemented by a face-to-face conversation with a professional who could answer any questions that patients had about the research. Some suggested that the sheets could include or be supplemented by a document where GPs or other professionals could write up their answers to any questions that patients had raised in their conversations about the research. This would help the patients to remember and reflect on the answers they had been given in any previous conversations.

Some members of the public also explained that they would like to talk to patients who have been through similar research programmes. This would help them to understand more about what the trial is likely to be like in practice, and to consider whether they have any other questions that they would like to ask in advance of the trial.

'It's more personal to have a discussion, the paper is more impersonal' (Manchester #1)

Most participants agreed that the information sheets were well designed and answered most or all of the questions that they might ask if they were taking part in a trial. They also explained that they thought that the information sheets were fair and did not appear to be hiding any information – although some would have liked to have seen more information before making a decision.

'It's quite fair about some of the things that could go wrong' (Bristol #1)

Some younger participants felt that the sheets could be formatted in a clearer way with a greater use of colour and pictures. There was also some demand for information to be available in different formats such as a DVD. The disadvantage with this is that additional formats would cost money.

Some participants explained that would not agree to take part in any research unless they had been provided with full details of the research including summaries of previous research similar research

projects to help them consider the risks and develop their understanding of the importance of the research.

'If you had a real problem, you'd want to read everything even if it [seems] irrelevant' (Bristol #1)

What information did participants want to see?

The general public suggested a number of things they would like to be told about before agreeing to take part in a research study. In particular they suggested that they would like to know about any potential risks and side effects. Other issues included:

- practical details such as the timings and any expenses payments or incentives;
- methodological details such as whether a placebo is being used, and the chances of receiving a placebo treatment;
- whether a helpline or any other support would be available to patients;
- what is happening after the trial, and the length of time it might take for any new intervention to be used in the NHS
- how the results are likely to be used; and
- whether the results are likely to be published.

Patients

Patients talked generally about what they expect to find in a patient information sheet and discussed the best approach to take when taking informed consent including the recommended two stage process whereby potential participants are initially shown a summary information sheet and if they are interested, they are given a much longer more detailed patient information sheet. The vast majority of patients were supportive of this approach providing that it did not unnecessarily prolong the time period that consent takes or require more journeys to be undertaken. One comment made in support of this two stage process:

'Nobody ever reads the terms and conditions of a contract; why would you read the long version of an information sheet?'

(Mental Health Group)

A couple of patients suggested the use of videos as a way to explain studies and this went down well with others in the group.

Some patients considered that the research approval process was overly focused on the start of studies rather than what happens at the end. Patients and some members of the public were concerned about what happened to patients at the end of studies and felt that more information could be given up front in the patient information sheet about what happens at the end of study in terms of:

- will the study findings be published
- will the study participants be able to continue to access the treatment when the study ends
- will study participants be able to find out what arm of the study they were in
- what long term monitoring will be put in place to identify side effects.

Some patient groups, in particular, the Children's and Young People Group were keen to see a heading in the patient information sheet which covered patient and public involvement in the study. They felt that this would improve patient confidence in the study and aid recruitment. They also felt that having such a heading in the patient information sheet guidance would act as an early prompt to researchers to consider the issue.

7. The Role of Research Ethics Committees

Research Ethics Committees were generally highly regarded by both patients and public alike and inspired confidence. Views on 'lay' membership of the committees was mixed; with patients seeing a 'lay' membership as reinforcing the independence of Research Ethics Committees. The public, on the other hand, was more sceptical about the inclusion of 'lay' members.

Every group was shown information on:

- What an ethics is and what they do
- How the membership of a Research Ethics Committee is made up
- What types of decisions can be made and the percentage distribution of decisions made.

Public

The general public were not aware of the existence of Research Ethics Committees but did have an expectation that regulation would be in place and expected that this regulation would be efficient. The current system was generally regarded as providing appropriate safeguarding of patients and there was some surprise about the degree to which patient safety is embedded in the system. The work of Research Ethics Committees was praised however there was some surprise amongst the public that Research Ethics Committee membership included lay members. Members of the public did not instinctively see the benefits of lay membership and thought the committee should be made up entirely of 'experts'.

Patients

Patients were very surprised at the high volume of provisional decisions made by Research Ethics Committees. Nevertheless they were reassured that Research Ethics Committees made 'conservative' decisions and did not rush to give entirely favourable opinions. Patients generally had confidence in Research Ethics Committees. Phase 1 participants also had a high regard for Research Ethics Committees and said that knowing that a study has been approved by a Research Ethics Committee implied that it was 'safe' and made them more likely to consider taking part in it.

Although patients were pleased to know that ethics committees are obliged to include 'lay' membership, they are sceptical of the impact that a generic 'lay' view can make given that only a limited number of conditions could be covered by any one ethics committee. Some groups suggested that ethics committees should be able to seek the advice of informed service user groups in relation to particular studies.

8. Proposals to streamline the research approval process

The majority of the members of the public in the workshops believed that the proposed streamlining of the research approval process had the potential to tackle many of the problems identified in the current system and most were enthusiastic about the HRA co-ordinating the process and believed this would improve efficiency without affecting patient safety. A minority were sceptical about the proposals and were concerned that the early assessment, in particular, might add delay to the overall timescale. Patients were also broadly supportive of the proposals to streamline the current system. They believed that removing duplication and bureaucracy could bring clinical trials on stream earlier and so enable new treatments to be used more widely sooner.

The HRA has proposed to streamline the approvals system with the aim of making it more effective. Three elements were discussed in the workshops;

- an early assessment process to identify any problems in researchers applications;
- the HRA coordination of the process (including local site decision) with ethical approval and governance assessment happening together with local decision taking place sequentially rather than simultaneously; and
- a potential time-limit placed on local sites and the development of shared systems for gaining decision from site .

The proposed streamlined system for approvals was discussed after the participants had had the opportunity to discuss the current system and think about the benefits and drawbacks of the way that it works in practice.

8.1 Views on current and new systems of approval

Public

Members of the public had very different starting points as a result of their own prior interest in, experiences with, and understanding of health research. While some took very little time to understand and discuss the merits and shortcoming of the current system and proposed changes, others struggled to fully understand these.

There were a range of views represented in each of the four workshops. Members of the public in London tended to be the most sceptical about the proposed amendments, while participants in Manchester and Newcastle were amongst the most positive. Bristol lay somewhere in-between.
In general, participants from all four areas believed that the current system safeguards patients and some explained that they were surprised by the extent to which the safety of patients is embedded in the current system. Participants were particularly positive about the work Research Ethics Committees do although there was some discussion around the involvement of lay members.

In contrast to this, most felt that the current delays and duplications inherent in the current system were unacceptable, with many believing that the current system is likely to be discouraging research. Some participants, particularly those in London, felt that the delays currently occurring may have some benefits as a slower process may allow for further scrutiny because they thought that a longer period to reach a decision implied a longer and therefore in-depth review. Researchers disagreed with this view and suggested that in their experience delays in the current system happen as a result of bureaucratic and administrative problems rather than as a result of some local sites considering proposals more carefully than others.

This view was (to some extent) supported by some researchers who suggested that the local approval process could improve the quality of their proposals. One researcher explained that she would like the channels of communication between sites and researchers to remain open while the approval process

was taking place so that the expertise that exists in some local sites could be used to improve the quality of research proposals.

'Some local sites are very good … the research managers in some of the hospitals provide good advice'

(Researcher)

Some researchers and participants suggested that the fact that R&D approval is managed at a local level could be an advantage as the R&D managers involved may have specific knowledge about local circumstances that might not be available at a national level.

'It's still good to have local level input… things are different at a local level'

(Manchester #2)

In contrast, other participants were surprised that R&D approval was given at a local level and concerned that this could result in some sites having stricter criteria than others. Some of the more sceptical participants were particularly concerned that research could begin in one site when another had not given their approval as officers in the latter site could notice something that needs to be investigated.

Problems with the current system

While members of the public generally felt that patients were safeguarded by the current system they were concerns about the bureaucratic and administrative difficulties researchers could have in seeking site approval.

'Sometimes it can take 5 years and sometimes it can take 5 months. It is a very haphazard process at the moment and very frustrating' (Researcher)

'Every time we went to look at something in more detail we had to go back to the main committee and down to local level' (Researcher)

The public were often surprised about these problems and most were concerned that these may adversely affect patients (as potential new treatments may be delayed) researchers (as new research might be costly, slow and difficult to manage) and the British economy (as researchers might decide to conduct their studies elsewhere). In addition, some participants suggested that more junior researchers (in particular) may struggle to conduct research as a result of the complexity of the research governance process.

'It's delaying potential lifesaving medications' (London #1)

'I feel relatively assured but the delay in the development of the drug concerns me'

(Newcastle #1)

Participants were also concerned about the risk that the current system can result in researchers having to repeat administrative tasks by providing the same information in different formats due to the varied demands of sites across the country. Many were generally surprised that a single system was not already in place that would avoid the risk of this problem occurring, and some explained that they were disappointed when researchers' described the diversity that can exist between Trusts operating in the NHS.

Participants suggested a number of potential solutions for this problem including structural changes (such as the use of time-limits), an increased standardisation of the information that researchers have to submit to local sites, and representatives from local sites attending Research Ethics Committee meetings so that the ethics and governance arrangement could be managed together. Researchers suggested the latter suggestion would be impractical, while the former suggestions have been included as part of the proposed new approvals system.

Efficiency, effectiveness and speed of approvals

Some participants, particularly those who were most sceptical about health research, suggested that the length of time needed to approve some research projects could be seen as a positive aspect of the current system, as it could help to ensure that the research proposals are thoroughly scrutinised and that no short-cuts are taken. This view was based on participants' initial assumption that the additional time taken in some sites was a result of the site's own higher levels of scrutiny, rather than the result of administrative or bureaucratic delays.

> *There could be good reasons for slowing things down, what about Thalidomide?*
>
> (London #2)

The researchers disagreed with this view and provided participants with a range of examples highlighting the bureaucratic problems they had experienced including being asked for inappropriate safeguards, or finding that hospitals did not have sufficient resources to provide approval in a timely fashion.

'It gets buried under a pile of paper and there is no regulation to get it signed'

(Researcher)

Support for the proposed system

Most members of the public in Bristol, Newcastle and Manchester and some in London demonstrated some support for the streamlined system. These participants suggested that it has the potential to tackle many of the problems identified with the current system such as the delays and financials costs that can occur when seeking local site approval.

In particular, participants suggested that the new system could;

- be faster and easier to navigate;
- be less costly;
- allow for a greater differentiation between the roles of the Research Ethics Committees and Local Approval; and
- increase accountability.

They suggested that these changes would improve the approvals system and encourage more research to be conducted. Participants who supported the changes to the system believed that patient safeguarding would not be affected by the changes.

Scepticism around the proposed system

While no participants stated that the proposed system would be <u>worse</u> than the current one, a minority were sceptical about the proposal suggesting that it might not work well in practice or that it does not address some of the concerns participants had about the current arrangements.

In particular, more sceptical participants suggested that;

- a lack of sufficient resources in the HRA or at local sites could produce delays and bottlenecks;
- cultural change will be needed if local sites are to change the way in which they work;
- infrastructure problems (such as different IT systems) might make it difficult for sites to co-ordinate and streamline their approval systems;
- the proposed new system does not reflect their own priorities around increasing transparency and reporting research; and
- that the new system could lead to short-cuts being taken if there was insufficient time to consider proposals.

Participants in London were amongst the most likely to be sceptical about the proposal and many had mixed or negative overall views. Those who were most sceptical about the proposed system often considered the risks to individual patients as being more important than the potential wider benefits that

the research could bring to society. To some extent members of the general public in London were led in their view by the opinions expressed by a health researcher attending the group. The latter expressed strong negative views about early assessment and this tended to influence the group she was sitting in.

The following sections consider participants' views of specific aspects of the proposed system.

HRA coordination

The proposal includes an increased role for the HRA who could coordinate responses from local sites and any other approvals that might be needed. It was proposed that the ethical approval and local site approval would take place sequentially rather than simultaneously.

Many participants agreed that the ethical and local site reviews should take place in sequence rather than at the same time as this could reduce the risk of time-delays occurring if there were disagreements between the two bodies. Some suggested that this change could slow down the process for more straight-forward proposals although this was not considered a significant issue.

Participants were generally more enthusiastic about the HRA co-ordinating the process of gaining local site approval believing that this could speed-up local site approval; particularly in the case of larger and more complex studies using a number of sites.

'*[I like the] co-ordination of HRA over local sites [so they are] time-regulated and managed by the HRA'*
(London #2)

Some participants suggested that the HRA would encourage local sites to share best-practice and integrate their local site approval systems, consequently reducing waste and the duplication of effort.

The public also suggested that this element of the process would help increase the differentiation between the roles of the Research Ethics Committees and local sites as ethics committees would be able to insist that the sites only look at governance issues rather than ethical issues.

'It's a lot clearer to local sites approval that they are not involved in the ethics at a local level which is good'

(Manchester #2)

It was argued that this change could in turn increase accountability as there will be more clarity over the Research Ethics Committee's and local sites' responsibilities.

'It gives patients a clear body to go to in terms of ethics, there aren't local variations'
(Manchester #2)

Those participants who were more sceptical of the proposed changes suggested that the HRA would need to have the resources in place to manage this additional role. If this did not happen a bottle-neck could occur with the HRA struggling to approve proposals on time.

'I'm negative because of the [risk of] bottle-necks' (London #2)

Some believed that the proposals would not go far enough, and the continued existence of a local site approval process would mean that the problems with the current system would still remain as long as local site approval was sought.

'The end problem is still the local site problem' (London #2)

A time-limit on local sites

The facilitators explained that a time-limit could be imposed on local sites to ensure that they check proposals on time. Many participants were in favour of this approach as long as local sites had the resources they needed to manage these additional demands. Some of the participants who approved the time-limit in principle were concerned that in practice it might take some time for local sites to be able to manage these new demands.

'The paper model is perfect but there might be stuff to iron out' Bristol #2

The implementation of the new system

Members of the public had some suggestions around the implementation of the new system

Some of the more sceptical participants suggested that the proposed system should be trialled in some areas so that any teething problems could be rectified before the system is fully introduced.

Some believed that the proposed system should require researchers to publish all their results. The participants believed in not tackling this problem the proposed system did not respond to their greatest concern about the current system.

Some participants felt that the new system could go further in ensuring the local site agreement is not an impediment to research taking place. This would involve more centralised decision making. This view was made by those who were concerned about the differences that occur between different NHS trusts.

Patients

Researchers in attendance at workshops were invited to give illustrations of the problems they had encountered in seeking research approval. For example, researchers specialising in the area of children and young people gave some examples of their experience of seeking R&D approval:

For one questionnaire based study that did not require the researcher to visit the site, the following problems arose:

- One local Trust asked for the researcher to be vaccinated against measles
- Another asked the researcher to have a chest x-ray
- Another asked for a CRB (Criminal Records Bureau) check even though the same researcher had only just had a new CRB check conducted two months previously but the Trust would not accept this.

Researchers in the diabetes group also gave dramatic examples of delays suffered waiting for R&D approval. In one case the researcher cited a delay of a year in waiting for one Trust to give R&D approval. In another instance a researcher gave an example of a Trust requiring double the level of insurance. Overall the new process was regard by the diabetes patients as both professional and efficient and the patients felt they would have more confidence in the new process.

As with members of the general public, patients were very surprised at the problems experienced with the existing research approval process. The Children and Young People group were supportive of a new streamlined system to reduce duplication in the system. They considered the new system to be quicker, more efficient, and good. They felt that the new system would be faster and so would be more attractive to researchers. Overall it was felt that as long as the quality of the research is not affected, speeding up the approval process *'can only be a good thing'.* Other comments included:

'We feel pretty safe doing a clinical trial because there are so many levels they have to go through'. (Children and Young People)

'I think it is better for the local sites to only look at the aspects that concern them'.

(Children and Young People)

'Good because more research can be done more quickly'. (Children and Young People)

Other patient groups were equally supportive of the proposed changes:

'Think it makes sense – would like to see more research happening and happening faster'.
(COPD patients)

'We have confidence that the ethics committee can make an adequate assessment'.
(Mental Health Group)

'If the HRA can secure local trust approval within the timescale, then it is a preferable way of doing things'.
(COPD patients)

Some patients pointed out that there was an opportunity to centralise decisions about issues such as data quality and security that should have national standards instead of being considered locally:

'This is an opportunity to standardise things and improve quality'. (Cancer Group)

'I'm all for centralisation'. (Cancer Group)

It would make better use of the ethics committee time'. (Cancer Group)

8.2 Early ethics assessment

The HRA proposal suggests that a trained Ethics Officer should consider each research application before it is shown to the Research Ethics Committee for full review.

Public

The general public had mixed views about this proposal. Those supporting early assessment suggested that it could take pressure away from the Research Ethics Committees by reducing the time they spend considering poorly written research proposals where elementary mistakes have been made. They suggested that this would also allow committee members to use their time more effectively as all the proposals they look at would be of a good standard. Some researchers supported this view arguing that the early assessment could potentially reduce the time spent managing the small proportion of submissions (6%) that get an unfavourable response.

Other researchers did not support an early assessment process as (from their experience) there was no need for this additional step to be implemented as most researchers submit high quality proposals. When it was suggested that students and less experienced researchers might not always manage this, researchers suggested that in their experience university supervisors would not allow poorly designed proposals to be taken to Research Ethics Committees. It is worth noting that the researchers attending the workshops were relatively senior and experienced at their job.

Researchers' views and experiences of the early assessment had a significant impact on the views of some participants who were more sceptical about this recommended change than the others. Some participants were concerned that the early assessment placed a significant amount of pressure on the person who had the role of managing the early assessment.

'It would [put] a lot of pressure to put on one person' (London #2)

Some participants were concerned that the person managing this job may not have the training or ability to manage the variety of different research proposals that are regularly presented to committees, or the time to look at each proposal in detail. For this reason, some felt the proposal could lead to

bottle-necks. In addition, some participants suggested that the involvement that there would be a bigger risk of bias if a single person is looking at a proposal at the early stage of the approvals process rather than a full committee.

'I don't want just one person there saying what is fair and what is not' (Bristol #2)

Both of these concerns could be said to relate to a perception that the person giving the assessment would be making value judgements about the proposal rather than simply providing more practical recommendations for improving the paperwork and forms being sent to the committee. The precise role and remit of the person making the early assessment has a significant impact on participants' views.

Patients

Overall patients were supportive of the concept of the early assessment providing that piloting was able to demonstrate that it would not impact on the timeline of ethical review. Most groups thought the early assessment would help to produce better quality applications and improve the overall timelines. The cancer patient group, in particular, welcomed the role of the Ethics Officer, though there was some concern about the technical level of expertise that this role would require.

'Early assessment can work if there are professional trained people that know what to look for'.
(Cancer Group).

The young people like the 'early assessment element' - they thought that this was an opportunity to send out early guidance such as the Patient Information Sheet guidance if it would be helpful at this point. However there was concern that Trusts could be forced to undertake research against their will.

9. Annual reporting

There was broad support from both patients and public to streamline the annual reporting system as long as transparency and accountability were retained.

At the present time researchers have to send annual reports to the Research Ethics Committees and the local sites where they are working. These reports are not always read and provide limited information. They also place an administrative burden on researchers. The HRA proposals include;

- a simple annual assurance system;
- reporting through a single online portal or email; and
- a greater emphasis on the final report.

The proposals were presented by the facilitators. The researchers provided information on how these changes would work in practice.

Public

It is worth noting that the general public had little understanding of how research is reported and the different mechanisms that are in place to report and monitor research. This meant that some participants may have had different assumptions around what the reports look like and how they are written.

In the main the general public supported this proposal on the basis that it would reduce the administrative burden that researchers, sites and the Research Ethics Committee will have to face without reducing the transparency of the research.

The public suggested that a combined Research Ethic Committee and local site report was a "common sense" solution that would be quicker to read, write and disseminate. Some suggested that patients might find this report more helpful if it was made publically available.

Some participants suggested that introducing more flexibility around the timings of the report might be sensible. It was suggested that the frequency of the report could change depending on the research taking place. This view was suggested by researchers who stated there was no particular need for reports to always be annual when other time periods might be appropriate;

'It shouldn't [necessarily] be every year, just every period' (Bristol #2)

Some participants felt the reports should all be public. Others suggested they should not necessarily be public if this placed an additional burden on the research team, and if there was a risk that the public could be confused by the report.

'By making it public… [and] opening it up to public scrutiny it might slow the process even more' (Manchester #2)

Participants agreed that the emphasis should be on the final report as this was the most important of the reports to be published and the most likely to be read. The timings of the workshop did not allow a great deal of explanation around the different forms of publication that could potentially take place. This meant that participants had limited understanding around what would be published and the format and details likely to be published using different media.

Patients

The subject of annual reporting was not covered in all patient groups and was omitted in some cases to allow time to cover other priority topics. Patients in general thought that there was scope to improve the current system and tighten the process up to ensure that reports made to the Research Ethics Committee were reviewed. They were concerned at the lack of attention paid to existing annual reports

and wanted reassurance that sufficient attention would be paid to the reports generated by the new system.

'Sounds reasonable'. (Stroke survivors' group)

Patients also wanted to know how the current annual reporting to Research Ethics Committees allowed researchers to report side effects experienced after the trial had completed.

10. Researcher Passport

Facilitators introduced the concept of the 'researcher passport' system which is currently implemented by local Trusts. The initiative, which builds on current work, seeks to avoid multiple approval of the suitability of researchers to enable them to do research at different NHS Trusts with a focus on competence to undertake research rather than the practical issues of checking identification, CRB status and occupational health. There would be ways of updating accreditation over time. Facilitators asked the participants to discuss whether the HRA should have a role in centralising this function to ensure that it operated consistently as there was evidence that different Trusts operated the system inconsistently. Workshop participants also discussed the notion of the researcher passport indicating some sort of quality measure of the researcher based on track record and publications.

Members of the public initially struggled with the researcher passport concept and were concerned that it might lead to elitism amongst researchers. Once they had been re-assured by researchers that this was not the case, they were generally supportive of centralising the researcher passport function within the HRA. Patients liked the idea of the researcher passport but were sceptical of the HRA having the resources to undertake such a large function. Patients also wanted reassurance that the process would not result in a bigger bureaucratic hurdle for researchers.

Public

Some members of the general public were initially concerned that researcher passports could be 'elitist' as they could make it difficult for less experienced researchers to manage projects. Researchers disagreed with this view suggesting that the passport would increase the efficiency of research proposals but would not be considered something that would be used to establish how experienced or good a researcher is. A Researcher explained that researchers working on larger projects would have less experience so might not have a passport but would still have a good reputation.

> *I see it as something that facilitates rather than to boast about, you wouldn't put it on your CV*
>
> (Bristol #2)

After some consideration, researchers and participants supported the idea of a passport on the assumption that it was regularly renewed, so that poorly performing researchers could lose their passports, and would not act as a barrier to less experienced researchers managing projects. They believed that the passport could save time and a duplication of effort when research proposals are going through the approvals system.

> *It would be good as long as it's continually reviewed*
>
> (Manchester #2)

The public had few ideas about how the passports would work in practice but one Researcher suggested that the passports should include some space to enclose continual professional development indicators that could be considered overtime, and the group agreed that this seemed sensible.

Patients

The majority of patients thought that the concept of the researcher passport was a good idea and were supportive of the HRA taking a role in centralising this function. One group made an analogy with the revalidation process carried out by the GMC.

Views on how often the researcher passport should be renewed varied from once every 3 years up to every 10 years but most groups thought between 3 and 5 years was the optimum. Regardless of the duration between routine reviews, patients wanted reassurance that in the interim, that reports of poor behaviour or a change of employer contract would trigger a review. One group were very keen that it should contain a photograph of the researcher.

Just one group was not supportive of the researcher passport concept – the Parkinson's patient group. They felt that the HRA needed to be careful to not place a further burden on researchers and advised the HRA to proceed with caution.

Phase 1 workshop participants pointed that even experienced researchers with an excellent track record could take on too many studies at once and place an excessive burden on the staff actually conducting the study which could put patients at risk. They felt that the Researcher Passport would not address this concern and required reassurance that this particular risk would be addressed elsewhere in the process.

11. Patient and public involvement

Patient and public involvement was not specifically addressed in the public workshops, although it was discussed at length in the patient workshops. Patients considered that patient and public involvement increased confidence amongst potential study participants and led to a more robust study design. They strongly supported the HRA in taking a stronger line with researchers and sponsors to encourage patient and public involvement but recognised that it really needed to be undertaken at a very early stage in the study development and that by the time a study reaches a Research Ethics Committee it may be too late. They also recognised that that insistence on patient and public involvement had to be proportionate and wanted a targeted approach focusing on clinical trials.

Public

Members of the general public were not specifically asked about patient and public involvement on the basis that it might not be particularly meaningful to them. However they came close to the topic when discussing the lay membership of Research Ethics Committees. They were initially very sceptical of the concept of lay membership of Research Ethics Committees and could not see how a lay person could contribute to the working of the group. There was a general view that the entire membership should be given over entirely to 'experts'.

After some debate, some of the public recognised the contribution which lay members could make to the Research Ethics Committee but they were keen to see the 'professionalization' of the Research Ethics Committee and in a number of groups the participants said spontaneously that they thought the lay members of Research Ethics Committees should be paid.

The concept of deferment to health professionals was strong across all groups and this may have some bearing on the public's preference for 'experts'.

Patients

The Children and Young People Group were very concerned that the HRA should play a role in encouraging patient involvement in research:

'Ethics committees should strongly advise that there should be patient involvement'.

There was a clear view that patient involvement was beneficial to all:

'I think that having patients involved in the initial stages of a research project is important in the success of the trial'. (Children and Young People)

'Patients feel empowered by research'. (Cancer group)

'Patient involvement is like motherhood and apple pie – it cannot be challenged'. (Mental Health group)

'It is the most crucial thing'. (Parkinson's Group)

Patient involvement was considered useful in a range of activities including:

- *'even having the patients comment on the ideas of the research could be beneficial for the study'* (Children and Young People)

- Reviewing patient information sheets – ensuring easy to read and understandable information

- Sense checking questionnaires – reducing ambiguous questions.

In demanding that researchers undertake patient involvement, the young people thought that there was more that the HRA could do to explain what it means. In asking researchers what activities they have

undertaken in relation to patient involvement, there was a sense that the HRA could be more demanding in seeking an answer to this question. It was suggested that the completion of this open question should be mandatory. The young people noted that it was important that patient involvement activities are made interesting.

At least two groups wanted patient and public involvement to be made obligatory with an opt-out box where researchers could explain why it was not appropriate for their study. Other groups pointed out the importance of ensuring that the requirement for patient and public involvement is proportionate and does not place an unnecessary burden on researchers. Several groups highlighted the need to target patient and public involvement in the area of pharmaceutical trials. The diabetes group was concerned that patient and public involvement was often active in the early stages of a study but tended to die out before the study completed when there were other aspects that patients could contribute to.

Patient groups suggested that it would be helpful to include Patient and Public Involvement as a heading in its own right in the Patient Information Sheet template as part of the guidance for researchers. This would have the added advantage of encouraging researchers to think about the issue at an early stage and would inspire confidence in patients that their needs had been considered in the development of the research.

12. Publication/dissemination of research results in the public domain

Publication of research findings is seen as a key issue by patients and the public alike. Some argued for the principle of publishing all research, believing it to be the ethical duty of researchers to do so and the duty of the HRA and Research Ethics Committees to ensure that research is published. There was general support for the HRA to have the responsibility for [and enforcement powers] to ensure appropriate publication of research findings.

Patient groups realised that just because a study is published does not make it accessible to the general public and would like to see research findings published on an accessible website in a format they can understand.

It was felt that publication of research findings would improve transparency and accountability, encourage higher research standards and improve relationships between patients/public and researchers.

Public

The public were asked to discuss whether all research should be published and how this should be encouraged or facilitated by the HRA. Facilitators and researchers explained how publication has traditionally been managed in peer-reviewed journals, and how it can now been shared more easily online.

The general public conflated giving the results of studies to the study participants versus releasing findings to the general public and other researchers and tended to mix up these concepts in discussion. For many members of the public, research publication is seen as the key issue. Some argued for the principle of publishing all research believing it to be the ethical duty of researchers to publish their results, and the duty of the HRA or the Research Ethics Committees to ensure that research is published.

'Research should all be published: because that would be the right ethical thing to do'

(London #2)

'Could you say that not publishing results is a violation of ethics because the whole process is making sure you protect people? If you have drug Y and it's not published that it failed for some reason and then you test it again and it harms people again'

(Newcastle #2)

'Shouldn't it be an ethical responsibility by the ethical association (RECs) to disseminate and share that information?'

(Newcastle #2)

One of the key arguments for publication was that it would improve transparency and accountability in research. Participants suggested that asking researchers to publish their results would encourage higher research standards as more people would be able to consider the work that they had done.

'Publication would make them have a better standard. If they published they would have someone to answer to '

(London #2)

Patients and researchers also felt that the publication of research would improve the relationships between patients and the public on one side and researchers on the other. One Researcher suggested that patients and the public should have access to all NHS research as in most cases they will have funded at least some elements of the research process through general taxation.

'it help the relationship between patients and the public'

(Researcher)

While many acknowledged that few members of the public would read published reports, most felt they should be published so they can be read if needed. In particular, some participants felt they would like to look up the available health research on a topic if they had been asked to take part in a trial.

'If somebody in your family was unwell you would want all the details'

(London #2)

For this reason, participants and researchers in some groups suggested that a two reports should be published for each piece of research; one that could be understood by the lay person, and a more technical report for professionals.

'[you need] one that is geared to the average person, and … the next level up'

(London #2)

Researchers had mixed views about this; some were concerned about the administrative burden this would place on researchers, while others argued that it was already considered good practice to send an easy to understand summary of the report to any patients who have been involved in any trial.

Members of the public supporting the publication of all research suggested that with more research being published there would be less of a risk of research studies being unnecessarily repeated. This was a particular concern to those participants who were most worried about the risk that research might have on patients.

'It would stop duplication down the line' (Manchester #2)

'If you are only publishing the positive results you are not giving the bigger picture'

(Manchester #2)

Some participants (particularly in London) believed that research publication would significantly improve their trust in health research and the approval system in a way that other proposals would not. When asked to discuss the proposed changes to the approval process participants argued that the new system would have limited impact (from their perspective) if the new system did not include a demand that all research is published so it can be read by the public.

'The issue of publication is more important' (London #2)

Other participants were less passionate about this issue. These participants felt that most research should be published in principle but were more likely to agree that some research should not be published if there was a good reason for this. One example where some felt publication should not be necessary is if the act of publication would be too bureaucratic compared to the potential benefit of publication. Participants felt that for small studies and some student studies there might be little public benefit associated with publication and the researchers may find that publication could take time.

'It would slow things down if researchers had to publish everything' London #2

In contrast, researchers suggested that they would encourage their students to seek publication whenever possible as it would help them in their career.

Some researchers were concerned that the publication of some research could mislead the public who may misunderstand the findings. They were concerned that patients and the public could misunderstand the research and this could lead to poor decision making. The scare stories that were published about the MMR vaccine were cited as an example of this.

'There are nuances in the way you display facts. You can put up results that show a tiny difference and make it look massive'

(Researcher)

Some participants agreed with this view while others suggested this reason was not sufficient to stop publication.

It should be all published because information is knowledge; if you are educated you can make an informed decision'

(Manchester #2)

Despite this reservation most participants were in favour of publication and believed that a government body such as the HRA should have a role to ensure that is happens.

Patients

All patient groups were supportive of the concept of publishing findings of studies and felt that the HRA could and should do more to encourage publication of findings. One group (Parkinson's group) expressed more caution than the others as they felt that unless the HRA were able to follow up non-compliance with some leverage that there was no point venturing in to this area and there was a risk of placing an extra layer of bureaucracy:

'need to be cautious – if you push too hard, you might push them away'. (Parkinson's Group)

Most patient groups were familiar with online academic journals and portals such as Medline but many of them also expressed concern that most academic publications had restricted access so although researchers might be able to access journals, the general public were generally excluded. One patient said:

'Service users can't access academic journals anyway; they want the information published in a place they can access' (Mental health service users)

All groups suggested that they wanted access to published findings however some groups went on to suggest that they would be happy to see lay summaries. It was suggested that 'lay summaries' could be made available in a different ways, including on the HRA website. Patients also appreciated the importance of 'negative findings' and noted the need not to re-invent the wheel, otherwise *'researchers may run around in circles'* (Diabetes Group). There was a general sense that more could be done to make findings available on the internet and researchers should adhere to *'an open society principle'* (Parkinson's Group). Similar comments included:

'Publishing results in the public arena is a moral obligation'. (Cancer patients group)

'There needs to be a culture of open access'. (Cancer patients group)

Patients were aware that these changes would not be easy to implement and might require substantial culture change. In some groups, patients suggested that Research Ethics Committees should insist that all research is published.

In a minority of groups there was an awareness that some studies might be undertaken unnecessarily because previous finding had not been shared. There was concern that without a systematic review, there was an over reliance by both the ethics committee and the funder on the researchers themselves to demonstrate what research had already been undertaken and to justify the need for the study.
Patients were surprised to know that GSK had agreed to publish research findings and felt that more could be done to promote this.

Phase 1 participants expressed an interest in accessing the long term findings for the studies they had been involved in. They were not so much interested in the findings of the study they had participated in, but were keen to know if the study had taken part in had progressed to further stages and if the drug had finally been licensed.

13. Providing information to participants at the end of the study

Patient groups differentiated between providing general information to participants at the end of study and providing patient specific information to individual patients at the end of a study such as informing patients what arm of the study they had been in. Patients talked about the HRA needing to *'tighten up the end of projects'.*

There was a strong feeling in most patient groups that the findings of individual research studies should be made available to participants after the study is completed. They recognised that not all participants would welcome knowing the results and so they suggested that participants should be given access to a website where they can access the study findings rather than study findings being sent out *carte blanche.* They acknowledged that there may be good reasons for not feeding back study findings at an individual level, for example, in genetic diagnostic studies where no treatment is available.
There was a suggestion that with some studies with particularly sensitive findings that it might be necessary to provide counselling to participants.

It was also recommended that in the event of the death of a participant shortly after the completion of a study that findings should also be made available to partners or carers.

In terms of providing information to individual participants, it was felt that most participants would want to know what arm of the study they had been in.

Several patient groups expressed concern that much of the existing focus was the start-up of the study and felt that there was not enough emphasis on what happens at the end of a study. The Parkinson's group felt that in some studies there might be a need for psychological support and even counselling at the end of a study. They noted that at the beginning of a study patients might not be able to accurately predict how they would feel at the end of the study and even if they had been given information about what would happen at the end of a study in the patient information leaflet that this might not be taken in at the time. They suggested that participant information leaflets should also be made available at the end of studies to support people with coping on completion of a study and explaining what will happen to them, what information they might receive about the study findings and how, if they can continue on the study treatment, and any further monitoring which take place.

14. Trust and risk in research and the research approval process

14.1 Public views on trust

Ipsos MORI has previously found very high levels of trust in doctors and other health professionals in the NHS, more ambivalence about charities and academics (perhaps as a function of little understanding of their role in research) and overt scepticism and even fear of pharmaceutical companies. Although opinion poll data does not specifically identify pharmaceutical companies, private companies are undoubtedly viewed less positively than public services.

One of the key issues for the HRA in addressing public understanding and trust in health research is that the public currently does not understand the interconnected relationships between those funding research and those undertaking research. In other words, there is currently no substantive recognition that regardless of whether research is funded by the NHS or a pharmaceutical company, or a health charity, most of the research is done within the NHS by NHS staff.

'If it's run by a pharmaceutical company and not your doctors, I wouldn't really want that'

(London #1)

'If there's a pharmaceutical company involved… it's like corruption'

(Manchester #2)

'There's a difference between your doctor offering you a drug and a pharmaceutical company – they are trying to test the drug more than the doctor, who's trying to get you better.'

(London #1)

However, a small minority of participants did understand this relationship.

'When you test new drugs and methods to make people better, I think that pharmaceuticals and doctors work hand in hand'

(Manchester #1)

Furthermore, participants' views on many of the detailed aspects of health research, particularly relating to informed consent and whether or not they would wish to be associated with a particular research study, but also access to personal data and publication of results, were very much shaped by the [perceived] involvement of different organisations; primarily NHS and pharma, but also charities and academia.

'The average person has a lot more trust in the NHS than pharmaceutical companies [All participants in this group note their agreement]. ... The pharmaceutical companies are in business to make money. The NHS is just plodding along'

(Bristol #1)

Views on the NHS and its staff

Positive views on the NHS as a national institution and at the local level are well documented, so it is no surprise that participants spoke highly of the NHS throughout the discussions.

'It's an institution. No one has an NHS like ours. Greatest social achievement of the modern world'

(Bristol #1)

GPs were particularly well trusted, but the public also trust their wider care teams at hospitals.

Many participants expressed the belief that above all the NHS exists to protect public health and wellbeing, and that it is inherently protected from financial and commercial interests. Therefore, most people believed that doing a clinical trial under the auspices of the NHS would mean that the patient's interests would be automatically protected.

'Hospitals have so many regulations. They wouldn't put the public in danger to get a few quid'

(Newcastle #2)

However, there was seen to be some overlap between the NHS and pharmaceutical companies and a feeling that pharma has too close links with GPs. Consequently, despite generally positive views of GPs' approach to patient welfare, for some participants GPs are not seen as untainted by financial motives.

'It's a confusing situation. Is he [GP] in it for money? Can you still trust him?'

(Manchester #1)

'A lot of these doctors are getting under-the counter incentives to prescribe particular drugs. E.g. pharmaceutical companies were giving out holidays to Las Vegas!'

(Bristol #1)

'Most GPs have pens and penknives from the pharmas'

(Newcastle #1)

This gives rise to a reflection that the recent shift in Government policy to local commissioning of health services through Clinical Commissioning Groups (CCGs) has the potential to exacerbate the perception of too close-ties between GPs and pharmaceutical companies and therefore to undermine GPs' 'trustworthiness' in respect of patient access to clinical research trials and treatment options.
Overall, many members of the public expressed the view that the NHS should be 'run as one organisation' and protected from any financial considerations which, they feel, could potentially clash with the best interests of patients. So, all of their views on trust in any healthcare regulation system are mediated by this wider belief.

'I just feel disappointed that I can't regard the NHS as unified.'

(Bristol #2)

Trust in patient confidentiality

There were mixed views about the level of trust members of the public had concerning patient confidentiality in the NHS, particularly as it relates to identification of patients via their records for possible participation in health research.

'Patient confidentiality is very strict in the NHS. I'm confident that my treatment is kept confidential'

(Newcastle #1)

Similarly, several participants reflected on local GPs' or the NHS care teams' knowledge in relation to potential new drugs [sic] that may be trialled. Some felt that they might not be best placed to provide appropriate advice and information to patients.

'How much do NHS teams know about new drugs? That would be a problem as they won't necessarily be up-to-date, so that might not help'

(Newcastle #1)

'I would see my GP for general advice - about the general process of a clinical trial – but would need a specialist to find out about specific information'

(Newcastle #1)

Views on the pharmaceutical industry

In contrast to the NHS, pharmaceutical companies are seen by the public as having vested interests in the conduct of research, and as a consequence are not trusted to behave ethically. Indeed, making a profit is often seen to be mutually exclusive to the aim of benefiting patients or advancing long-term healthcare. This view was not just expressed by participants, but underlined by at least one of the Researchers.

'Medical trials shouldn't just be for making money, but for the future health of people'

(London #1)

'What is happening is that the pharmaceutical companies will [do a lot of research abroad], because it's all about the money'

(Researcher)

Even if charities or the NHS were to be involved, the fact that a commercial company might be providing the actual [drug] therapy to be tested was seen as not in the interests of participants.

'I don't think that they're making the drugs themselves. There's like a company that's providing the pills for them or making them. So whoever is involved they will be incentivised by the pharmaceutical companies to make the drugs'.

(London #1)

Members of the public noted a range of unethical practices they believed would be a consequence of participating in a 'pharma-led' research study as opposed to an 'NHS-led' one, such as cheating the system:

'Could a drug company try and spot something [referring to loophole or weakness in the approvals process] to push something through an easy way?
[A Researcher then agreed with this perception] 'Yes ... it's worrying'

(Manchester #2)

or biasing research findings to hide 'bad' data :

'I was worried that if it is funded by a company, that would have an influence on the research'

(Manchester #1)

'Pharmaceutical companies just need to protect their own interests.'

(Bristol #2)

Some participants did become more conciliatory towards pharmaceutical companies as the discussion progressed and participants became more knowledgeable about the ways that pharma and NHS can work together. However, this remained a minority view.

'It doesn't matter who is funding the research if you're dealing with the NHS day-to-day. It depends on the reputation of the company. If it's good, it doesn't matter'

(London #1)

That said, people do not necessarily consider efficiency to be a crucial consideration. In their final summations, participants drew a distinction between the supposed efficient new process, and the current process, questioning the loss of local input and rigour as a consequence of 'streamlining'. This again reflects what we know about public trust in organisations more generally; that irrespective of perceived inefficiencies, people tend to trust public bodies more because of their public focus and greater perceived accountability, whereas the more efficient private sector is seen as less publicly accountable but instead governed by the needs of shareholders.

Views on large medical charities

In contrast to well formed, (though often inaccurate) views on the NHS and pharmaceutical companies, few participants understood or commented on the role of large health and medical charities in health research.

'Charities supporting trials have no need to know any details ... about the participants of the trial, even in selection'

(Newcastle #1)

'I didn't even know charities did research. What research would they do?'

(Bristol #1)

14.2 Patients views on trust

Patients were asked what would engender a sense of trust in research and the research approval process. The following reflects the key concepts as identified by patients:

1. **Transparency** – this relates to both the publication of findings and the information given to potential participants and actual participants. For example *'having full information about what is going to happen to you.'* Patients supported targeted pressure by the HRA to encourage publication of studies. In some groups it was suggested that if a company refused to publish the results of a trial, this should mean that the Research Ethics Committee would withhold ethical review for any new studies from the same organisation. Patients also wanted better communication with the public about what health research is and roles played by Research Ethics Committees and the HRA.

2. **Regulation** – Patients were keen to know how the HRA was going to enforce the various aspects which were debated in the workshops such as publication and time limits etc. The power to enforce certain aspects was seen as crucial to implementing future progress and maintaining public confidence.

3. **Patient and public involvement** – This was only recognised as an issue by patients. The patients understood the benefits of patient and public involvement and were concerned that any involvement should not be a token gesture and should be carried out with the appropriate target group.

4. **Knowing that it has been reviewed by an ethics committee** – patients as well as the public had faith in the role of the Research Ethics Committee. Even Phase 1 patients said that knowing that study had been reviewed by a Research Ethics Committee signified 'safety' to them; it implied that the Ethics Committee safeguarded the study.

5. **Lay membership of the Research Ethics Committee** – Patients wanted reassurance that the 'lay' members of ethics committees really are 'lay'. This is in direct contrast to the general public who don't really understand the contribution which lay members can make versus expert members.

6. **Fair science -** Knowing that is a study is scientifically robust and therefore a fair comparison of treatments is important, especially to the participants of the Children and Young People's Group.

7. **Having someone that can explain the study to you/answer your questions/having the risks explained to you**:

   'If people could answer my questions I would feel safe'.

8. **Anonymity/confidentiality** – patients were concerned about privacy in their personal data, especially general practice records which could reveal data of a sensitive nature.

9. **Having competent, professional researchers** – Patients talked about having health researchers that could inspire confidence in them and who knew what they were doing. Encompassed within this concept was the idea that researchers should behave in a professional manner at all times and that studies should be adequately resourced in terms of staff. This implies a duty on the HRA in terms of ensuring the training of researchers and the implementation of the researcher passport.

10. **Accreditation of Phase 1 units** – This was perceived very positively by Phase 1 participants. Accreditation implied that the unit was adhering to certain standards and so increased their confidence in the unit.

14.3 Public views on the benefits of health research

Most participants acknowledged that society benefits from most, if not all, health research. In this sense, most agreed that health research should be supported and encouraged. The benefits of research were perceived at a very general level:

"you test new drugs and methods to make people better" Manchester#1

"it's a benefit to people with incurable diseases to be in a trial, and a benefit to the rest of society"

However the public were also concerned about the vulnerability of people who were ill taking part in a clinical trial. When weighing up the risks to them personally, participants focused on the costs and the benefits to themselves. Without a serious health condition, the focus of the public tended to be on the risks of the research rather than the benefits.

Participants had mixed views around the personal risks that they might face in participating in research trials. Most believed they would make choices based on their perceptions of the potential costs and benefits of the trial to them as individuals, with the potential societal benefits being less important. The onus here was on eliminating/minimising safety risks and ensuring the best care is available to those participating.

> *If you're ill you want to get better and you'll try whatever it is to get better. You trust your doctor to tell you the information if you're fit and healthy … you wouldn't risk your health unless there is a reward*
>
> Bristol #1

Participants who were most concerned about placebos also tended to be amongst the most sceptical about the benefits and risks of health research. Those who understood and supported the use of placebos often felt reassured by the fact that patients participating in a trial would often continue to receive the current treatment in addition to any placebo treatment.

14.4 Patient views on the benefits of health research

Since they were mostly very well informed, the patient groups were very clear about the benefits which derived from health research and from clinical trials in particular. They were less clear about the benefits of non-applied research and consequently were sceptical about the benefits of blue sky research until researchers pointed out some of the outcomes of this type of research.

Patients had a clear understanding of how new drugs and other treatments were developed prior to licensing. They were aware of what drugs were in pipeline and what drugs had become available in other countries.as well as in the UK. They also supported speeding up the process of development new treatments and bringing them into clinical use more quickly.

In addition to the obvious benefits of generating new treatments for themselves and others in a similar position, patients also talked about the role that participating in research had given them. One patient talked about participating in research as 'giving them a voice'. To some extent this merged with their roles in patient and public involvement which they saw as an extension of their role as a patient.

Even though Phase 1 participants were clearly motivated by the financial inducements, they were also very interested in how the drugs they had been involved in testing had progressed over time:

"I know the good effects that trials can have on the quality of life". Phase 1 group

Phase 1 participants also considered the thorough medical screening on joining a study as a direct benefit to themselves.

14.5 Public perceptions of risk

Perception of risk is a challenging area to debate and recent behavioural theory reveals that individuals are often bad at calculating and discussing personal risk as it pertains to themselves and others.

In these workshops, public views on the risks of participating in trials were somewhat contradictory and often changed over the course of discussion. Public dialogue participants were challenged throughout to offer their personal view of ethical considerations and expectations of the approvals process, and at other times to take the position of informed citizen and consider the benefits for society. Often, these different perceptions of risk contradicted one another.

Many people could see the value of health research at the societal level, and felt it was broadly not risky, irrespective of the potential risks to the research subjects.

'Whether negative or positive, the result is good in the end as the whole point is to know what happens... Even if it ends in the death of a patient, it might benefit people going forward'

(Newcastle #1)

However, some groups were seen as particularly vulnerable, especially the elderly, those with serious or critical conditions, or children who were ill. For these groups trials were seen as more risky.

'There does seem to be a crisis now in older people just swallowing pills willy nilly which is making their condition even worse if they're not monitored. I am a bit suspicious about who is to gain from all these pills being given to old vulnerable people in the community'

(London #1)

There was some contradiction here, as many believed that very ill people should do trials ("it's a benefit to people with incurable diseases to be in a trial, and a benefit to the rest of society") but, being very ill, they might be more vulnerable and take a decision against their best interests ("It's unacceptable to offer people trials at the moment when they are most desperate for help with their illnesses").

When weighing up the risks to them personally, however, participants focused on the costs and the benefits to themselves. Most imagined that they would be well placed to weigh up these costs and benefits. They could perceive undertaking a trial in a life threatening situation but otherwise clinical trials were perceived as inherently 'risky'. Patients talked about trials being 'scary'.

'Unless it's a life-or-death situation I wouldn't want to take part. I really believe in it. It's great if somebody else does it, if it's for medical advancement, but I wouldn't do it'

(Manchester #1)

'I wouldn't do a trial unless I was going to die, then I might.'

(London #1)

'If you're talking about a life threatening illness, I would take any opportunity. Everything else is irrelevant. If someone gets offered a trial, I think they'd be very lucky. They'd be foolish not to take it.'

(Bristol #1)

The public considered the following areas of personal risk, about which they felt they needed to be informed in order to judge the riskiness of a trial.

- Taking up time – how long with the trial last?
- Payment – how much will I get, and will this compensate me if there are any side effects?
- Opportunity cost – what other effective therapies are available for my condition?

  Asthma is relatively well controlled unless you're chronic. To enter into a trial may not be beneficial and actually make your particular illness deteriorate

  (London #1)
- Expertise and experience of the trial team
- Performance of the therapy or drug in previous trials – how many previous trials have there been, and what are the sample sizes?

  'I'd ask is this the first trial you've done?'

  (Newcastle #1)

- Risk of being left out on a limb without being treated for any side effects or mistakes – whose care am I under? What aftercare is there?
- Risk of benefiting from a therapy, then the therapy is withdrawn after the trial – risk of being in a worse position than before.

When considering different types of trials, those trials which involved adding something new to an existing course of treatment were <u>not seen as risky</u>. Surgical trials could be perceived as risky but this was largely because the mechanisms behind these trials were not well understood.

> *'Hang on, surgical trials? The surgeon would have to just pretend to operate. Well I've had a replacement hip – are you saying that maybe I didn't have one after all and it was just a placebo hip?'*
>
> (Bristol #2)

Research involving qualitative discussions were seen as potentially upsetting to participants if they were focused on sensitive topic matter (in response to a case study about a bereavement counselling trial) but not <u>risky</u> in the same way as drug trials. Broadly, the more physically invasive the trial and the more lasting the side-effects or consequences of failure could be, <u>the more risky it was perceived to be</u>.

As noted above, while some criteria are universal when considering personal risk it is also important to note that different people, and different sections of society, will base their judgements of risk on different criteria. Consequently, a secondary challenge for the HRA is to understand, respond and reassure different constituencies within its key audiences.

14.6 The role of regulation in perceptions of trust and risk

Trust is closely linked to perceived **accountability**. When discussing health research in general and before introducing the HRA, there was no spontaneous knowledge of the HRA's role as regulator for trials. However, some participants did assume that regulation must exist.

'Surely there's a government briefing on safety of trials, there must be a set standard'

(London #1)

'I would assume there would be safeguards'

(Newcastle #1)

Others still needed reassurance and were surprised by the extent of safeguarding currently in place.

'Are the doctors involved fully qualified and of good calibre? Not struck off doctors!!'

(London #1)

Later, when discussing the new proposals around regulation, both patients and the public were keen to understand how the HRA would implement and enforce elements of the new system. Particular examples include:

- enforcing governance decisions in the time frame
- enforcing publication of research findings
- imposing sanctions on those not compliant with requirements for publishing
- monitoring and revoking the proposed researcher passport
- deciding whether or not to progress an application overall, or to demand further revision.

The HRA making itself accountable for this and holding other bodies to account was a key driver of trust in the whole system.

Accountability is also significant in terms of reassuring research participants about their well-being during and following a trial. It seems that while people accept there may be consequences to participating in a trial, be it negative side effects or psychological impacts, they need to know there would be adequate redress and support post-trial if they needed it.

'HRA has got a role and a responsibility to the participant'

(Bristol #2)

'It's important that they are told that there will be aftercare whether you're on the placebo or the trial drug'

(London #1)

14.7 Patients' perceptions of risk

Patients and Phase 1 participants were asked if there were any particular aspects that would make them feel at risk or uncomfortable about a research study. They identified a number of issues which they felt would make them feel unsafe. In some cases they were speaking from past experience.

Lack of patient involvement

Not surprisingly patients in the workshops ranked patient and public involvement highly and the absence of it in a study would ring warning bells. The absence of patient and public involvement was seen as a clear sign that the study did not have their interests at heart.

Pressure to consent

Several patient groups identified that being put under pressure to consent would make them feel uncomfortable. This applied equally to Phase 1 participants as well as the Children and Young People Group.

Inability of research teams to adequately deal with questions asked of them

Patients expect the study team to have an expert knowledge of the protocol and to be able to confidently handle any questions put by participants or potential participants, both during the consent process but also during the study itself.

A study requiring repeated input from a Research Ethics Committee

Patients suggested that any study that required repeated input from an ethics committee to get the science and ethics right would make most patients feel that the researchers do not know what they are doing. Workshop participants wondered how many iterations might be required and/or allowed to get a study right.

Side Effects which remained undetected or unreported

Patients were concerned about studies with side effects that had been overlooked or side effects that might not appear until long after the study had completed. Reassurance as to how long term side effects might be detected and reported is required.

Poor management within the research team/ a disorganised study
Study participants noted that conflict between members of the research team might signify problems and might lead to people making mistakes.

Over-burdened/under resourced research teams
Phase 1 participants were concerned that it might be possible for clinical research leads with a good track record in research to take on too many studies with the result that their teams might struggle to conduct studies safely on a day to day basis. A system to oversee and approve the number of studies being undertaken by any one unit would allay their fear; the researcher passport system focusing as it does on individuals was deemed suitable to deal with this concern.

15. How should the HRA engage with patients and the public in the future?

The large majority of members of the public in the workshops were positive about the idea of public and patient engagement by the HRA to inform it's future strategy. By comparison, patient groups expressed the view largely that only patients and carers should be consulted and that it would not be appropriate to include members of the public in future discussions.

The concept of a 'panel' was hazy for some but overall was seen as a useful model for the HRA to adopt giving it the flexibility to include appropriate individuals as and when required.

There was also a general call from both patients and the public to communicate more widely about health research and clinical trials.

Public

A large majority of general public were positive about the idea of public and patient engagement by the HRA as part of its strategic decision-making. As health research is of significant importance and potential benefit to individuals and society at large, the broad view is that there is something of an ethical imperative to involve the public in this work.

'They should use the public because it affects the public so therefore the public should be used'
(Newcastle #2)

'Yes because we are paying for it …and we're the guinea pig' (Bristol #2)

Additionally, people recognised there is currently a gap between public knowledge about health research – and trials specifically – which affects the extent to which people are perhaps willing to participate in research.

'You always get people saying 'we're left in the dark and we never knew' so it's good to get people involved'
(Manchester #2)

'It's useful to publicise… to inform … talk to people directly…in a language they understand … and communicate it's not all about side effects'
(Manchester #2)

'You get better ideas about communicating it to the general public and socialising people of the street'
(Newcastle #2)

It was also felt that greater engagement of the public and patients by the HRA would help to inform and communicate the work done around clinical trials, and would thus increase general transparency and trust in the system.

'It's actually showing there is a system. The more people who get educated about it the better'
(Newcastle #2)

'It would make me trust it more'
(Bristol #2)

'It builds trust in the system and the NHS. And it would make people feel that the NHS is working for the public'
(Manchester #2)

Public, patients or research participants?
Views from the general public were mixed concerning where the HRA's emphasis should be in terms of who it engages with – the public, patients or people who have been involved in health research. While generally the view was that a cross section of society should be engaged, there was also mention of the importance and greater relevance of people with experience of trials.

'All walks of society' (Bristol #2)

'They could get the opinion of the man in the street'
(Newcastle #2)

'I think that patients who have been through a research trial could also offer useful insights, they could identity weaknesses in the system better … I feel as though I wouldn't be able to comment'
(Manchester #2)

'Patients who've been in research studies would bring a different dynamic'
(London #2)

'Wouldn't you want someone with experience of disease to be on a panel?'
(Manchester #2)

'… especially people who have been in hospital for extended periods'
(Bristol #2)

'I think it's important to have people who are not medically trained… they have tunnel vision. We need to have other people who can think outside the box'
(London #2)

A small minority said that for them, the lay members on Research Ethics Committees were adequate representatives of the public perspective and could continue to provide public opinion by proxy. One or two preferred delegation to experts in this specialised field.

'Normal people will not have so much weight where knowledge is concerned'
(London #2)

Mechanisms for engagement
There was very limited discussion about the mechanisms for engagement people would prefer or support. Even when pressed and given examples such as the proposal for a Panel, members of the public could not sufficiently conceptualise what this might look like.

'Patients are important and maybe different panels for different types of medicine'
(Newcastle #2)

'Panels of people is difficult on a regular basis. But maybe a questionnaire would be better'
(Newcastle #2)

However most were not clear what a panel would actually be like, and asked numerous questions of facilitators concerning what this might constitute in terms of numbers, subject matter, required knowledge, frequency of contact, types of involvement and so on. This suggests that the detail will be important in driving involvement. Few were overtly supportive of participation in deliberative workshops similar to that they had taken part in, though most acknowledged they had enjoyed the process and learned a lot. Some were concerned that even long, reconvened sessions were not enough to give an informed view on a subject.
Furthermore, while participants see engagement as important, they were unsure whether they, or others, would ultimately make the time and effort required to participate if voluntary and unpaid. On this basis, some suggested that expenses should be paid while others suggested a 'jury-style system'.

'With a voluntary system people will always find that they don't have time – they have to do babysitting instead or something'

(Newcastle #2)

There was some debate in Manchester as to whether those involved should get some form of expense payment. While some participants wondered if this may bias views, others thought it would be necessary to get people to attend.

'If you pay someone are you going to get the true views or are they just doing it for the money?'
'… People would have to take a day off for it'
'… Reality of life is that you have to pay people for it'

(Manchester #2)

Patients

Not surprisingly patient groups were entirely supportive of the HRA conducting future engagement to inform future policy. Both the Mental Health Group and the Parkinson's group suggested a round table made up of people with a variety of conditions, carers, medical charities and representatives from the Pharmaceutical industry. However most patients did not have strong views as to what form this engagement should take and were happy to see a mixture of methods employed ensuring that engagement took place across the country and was not confined to London and allowed input from people across the country. There was a common view amongst most patient groups that future engagement with the HRA should be confined to patients and carers and that the general public should not have a role in this. Patients were sceptical that the public had sufficient understanding of the issues to be helpful':

'*Most people don't have a clue'.* (Diabetes Group)

'*They don't know enough'* (Stroke survivors Group)

One patient group after further debate re-considered and thought that it might be useful to engage with the general public as well as patients. The Children and Young Persons' group pointed out the importance of including people of their age in the engagement process.
The Phase 1 group was also keen to see future engagement between the HRA and Phase 1 participants.

15.1 Role of the HRA in communicating information about clinical trials

Across the board there was an unprompted call from patients, the public and the Phase 1 group for the HRA to communicate with the public about what health research is, the role of Research Ethics Committees and clinical trials, in particular. They would like to see the work of the Research Ethics Committees given a higher profile in the public arena. They strongly believe an open and transparent agenda would increase confidence in health research.

Cancer patients group were very clear that the HRA should have a role in raising awareness of clinical trials and also to train general practice in research:

'It is absolutely fundamental that the HRA has a role in raising awareness in research'.

(Cancer patients)

Members of the public also called for the HRA to communicate about health research and clinical trials:

'*This has changed my ideas about clinical studies'* (Manchester #2)

'Need to communicate it's not all about side effects' (Manchester #2)

Patients are particularly keen to see the HRA make greater use of social media to communicate with them including Twitter.

Whilst patient groups think that particular emphasis should be placed on promoting the lay membership of research ethics committees, the public appear intuitively to not trust this concept with a preference for ‘expert’ opinion and professionalism.

16. Conclusions

It is clear from this project that the public is under-informed about health research. However, evidence from the dialogue suggests that when informed about its value and conduct, the public recognises the need to bridge the gap between low levels of knowledge as a way to encourage people to participate as research subjects. Furthermore, enhancing public knowledge about health research is seen as an ethical imperative given its importance to society at large. More information and openness at every level is seen as key. It should be noted that the workshops with patients were focused on mainly very informed patients with experience of research and hence may not representative of more naïve, newly diagnosed patients.

The public were not unduly worried about the security of their medical records within the NHS; they mostly had confidence that that their data would be held securely and took **confidentiality** as a 'given'. However they did not understand the concept of the 'clinical care team' in relation to confidentiality and in many cases assumed that that access to their patient records was widespread across the NHS. Patients understood the concept of the 'clinical care team' but were keen to maximise the opportunity to be invited to participate in health research. Whilst many patients said they would be happy for researchers to look at their identifiable records to find suitable people for studies, most patient groups reached the conclusion that it should be possible for researchers to have access to **anonymised datasets** in order to find participants for research. Some groups took this concept further and discussed the notion of '**consent for consent'** whereby patients could give their consent to be directly approached by researchers.

Members of the public had mixed views in the workshops as to who should **consent** patients to take part in health research. GPs were identified by the public for this role, as they were seen to be impartial and able to offer 'trusted' advice. Others preferred to be able to talk with specialist research teams. Patients in the workshops were mostly under the care of hospital consultants and so in the main had a preference for consent to be sought by a member of the research team with specialist knowledge; be that a hospital consultant specialist or a specialist nurse.

Both patients and public liked the idea of having a neutral person with specialist knowledge to be able to offer advice about whether or not to take part in a clinical trial. Some members of the public would like to see such a person on hand to give advice throughout the duration of a study.

Patients noted although all study participants are given **patient information sheets** at the start of a study, their focus will not always be on what will happen at the **end of study** and they might feel differently at the end than at the beginning. Consequently patients would like to see the provision of information sheets to participants as a research study comes to an end. Ideally this would encompass what information participants can expect to be given at the end of study such as what arm of the study they have been in, whether they will be able to continue with the treatment they received, how side effects might be monitored in the long term and how and where they can access the study findings.

Transparency of research findings is also seen as an important element in building public trust in health research, and thus there is support for the HRA's proposal to champion and improve the way in which research findings are published as well as the way information is fed back to study participants. Transparency is important to both patients and the public alike. Patients understand the need to take a proportionate approach in demanding publication of findings and were supportive of the HRA taking a targeted approach in this respect, with clinical trials and the pharmaceutical industry seen as the highest priorities.

Independence is another important facet of public trust in the system. As such, there is tacit support for the HRA as an independent body to hold researchers and funding organisations to account, so long as it has the regulatory powers, reach and capacity to monitor and sanction where appropriate. There is doubt by some patients that the HRA has the regulatory power to make **enforcement** effective and therefore have reservations about what the HRA can actually achieve.

As part of this agenda, it is important to maintain the **independence** of Research Ethics Committees and the wider approvals process. Patients but not the general public were impressed by the presence of lay members on research ethics committees but they require greater reassurance that some of the lay members are truly 'lay'. The presence of lay membership helps to strengthen the independence of Research Ethics Committees in the eyes of patients. Case studies of lay members could be used to illustrate this point on the HRA website.

Another important aspect of building public **trust** in the research approvals process concerns assurance that the system places patient well-being at its core. The current system is seen as providing many aspects of safeguarding that the public expects, however, there is a desire for greater access to independent and knowledgeable advice for patients throughout the process. This encompasses access to independent advice provided to potential research participants to enable them to come to an informed decision about consent. In the workshops, several similar suggestions were made for research participants to have access to a 'helpline' and/or 'neutral' specialist advice from the pre-consent phase to the post-trial phase through which they could seek independent advice and support, with an emphasis on providing advice during the consent stage.

The HRA could facilitate greater **access** or awareness of trials among public/patient groups to overcome any barriers posed by the current reliance on care teams or patients' GP to make them aware of research trials. Both patients and the public called for the HRA to do more to communicate with the public about health research and clinical trials in particular. Despite the fact that the public assume that regulation is undertaken, communication about the role of Research Ethics Committees would be welcomed.

Ensuring **consistency** of approach across the system is considered by participants to be a primary duty of the HRA, and as such there is broad support for the proposals put forward to streamline the research governance process. There is less support amongst the public for the early assessment phase, with some expecting this to create another potential delay in the approvals process which would counter any benefits. Patients however understood that this element would be piloted and were more supportive. Patients were generally keen to see more research studies and to speed up the timelines to bring treatments to market; as a consequence they could see the logic of the HRA proposals for making changes to the current research approval system. Patients and researchers considered centralisation of research governance and the enhanced research passport system as a significant improvement on the current system.

Patient and public involvement in research was identified by patients in the workshops as crucial for them to have confidence in a clinical trial. As a concept, patient and public involvement is not familiar to the general public and intuitively has no meaning for them; as evidenced by their lack of enthusiasm for 'lay' membership of Research Ethics Committees. Nevertheless patient and public involvement is seen by patients as an essential element in study design to engender patient confidence and trust in research. Patients are very supportive of the HRA in taking forward the patient and public involvement agenda be this via the application form, via early assessment, through the ethics committees themselves, or through general communication and training. Patients acknowledge that this aspect needs to be delivered in a proportionate fashion and does not relate to all types of studies.

When talking specifically about engaging potential participants in research, again communication is seen as vital. In this respect, the basic aspects of communication such as source, tone, style and presentation of patient information sheets can be significant. Given varying needs and expectations among different people, these nuances will be important yet most likely difficult to get right. Testing of patient information sheets with experienced patients alone (which is the normal practice via patient and public involvement) may not be sufficient. Patients taking part in patient and public involvement at a study level are often very well informed about both their condition and research when perhaps a greater level of naivety may be desirable.

Future engagement to inform the HRA's on-going strategy and policy was generally seen as a good thing. Views are mixed however in terms of the extent to which the HRA can and should engage with the public about its strategic agenda, and then how this might be achieved. Patients were adamant that

future engagement should include both patients and carers in the process. There was general support for the development of a 'panel' of people from which individuals can be drawn to advise on different aspects of the HRA's work.

While most participants believe that the current system provides appropriate protection of patients, many are concerned about the duplication of effort, inconsistency of approach and delays that can occur. For this reason, there is support for many of the proposed changes based on the assumption that they would streamline the system without putting patients' safety and wellbeing at risk. The HRA's task to protect and promote the interests of patients and the public in health research is an objective wholly supported by both the public and patients.