Evaluation of the project:

Health Research Authority (HRA)
Public and Patient Engagement (PPE) Project

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Contents

Executive Summary

The Health Research Authority, in conjunction with Sciencewise, initiated a public and patient dialogue process in order to understand views pertaining to intentions to streamline and simplify the research approval process. The HRA was established in December 2011 to protect and promote the interests of patients and the public in health research: facilitating and ameliorating confidence and participation in health research.

In line with this mission, this project was initiated to engage a range of public and patient perspectives in a dialogue to explore expectations around the benefits and risks of clinical trials and research involving patients, the ethical issues that might arise, the procedures required in relation to health research and its role in protecting the individual, and to gain views on how the public should be engaged and influence the HRA in the future. As the HRA's final report stipulates[1],

> 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 (p. 5).

The project involved 4 reconvened workshops, or 8 workshops in total, with 60 public participants across 4 locations in England (Bristol, London, Manchester and Newcastle); 8 workshops with 68 patients and carers, including one workshop with participants of Phase 1 clinical trials; and a survey of 1,295 public respondents. The market research company, Ipsos Mori, was recruited to implement both the public dialogue workshops and public survey. Patient dialogue workshops were undertaken by the HRA.

An evaluation was established as a part of the Sciencewise aim of improving 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. The evaluation was intended to respond to six core questions, namely: did the dialogue met its objectives; did the dialogue meet standards of good practice (Sciencewise principles); were those involved satisfied with the dialogue (value to them); what difference/impact did the dialogue make; what was the balance overall of the costs and benefits of the dialogue; and finally what lessons emerged for the future (what worked well and less well, and more widely)?

Evaluation activities comprised qualitative and quantitative components: workshop observation; exit-poll surveys; stakeholder interviews; and documentary analysis.

The dialogue project has already achieved significant impacts on policy and decision making. The results of the dialogue were presented by the HRA to the House of Commons Select Committee on Science and Technology inquiry on clinical trials in July 2013. The dialogue was also referred to by the Department of Health and the Academy of Medical Sciences in their own evidence to the Committee. The Committee report refers directly to the evidence on the findings of the dialogue, and it has recommended that the HRA take a much stronger role in encouraging transparency through the publication of research findings. The impact of the dialogue results on the HRA work on transparency has perhaps been the project's greatest achievement to date. The HRA has continued to work closely with stakeholders, including the pharmaceutical industry, to take this work forward and develop guidance and regulations on this issue.

[1] Amanda Hunn (2013) *Patient and Public Engagement Project: Patient and Public Dialogue Workshops*, published by Health Research Authority and Ipsos MORI

The dialogue results have also fed into the HRA development of guidance at the end of 2013 for researchers on Information for Patients at the End of a Study, which was consulted on in early 2014. Dialogue findings have also been incorporated into the development of the template for patient information sheets, to encourage researchers to think early about patient and public involvement. Internally, the HRA has drawn on the results of the dialogue in developing its own public involvement strategy. More widely, having seen the results of the dialogue, the National Institute for Health Research is revising its plans for training materials for patients.

Overall, we would suggest that the project has also been a success in generating new learning in the context of co-ordinating and facilitating public dialogue in the context of health-related research and research-based issues. The deliberative aspects of the project seem from the responses of those participating to have been both successful and enjoyable, with many positive impacts such as the dialogue experience stimulating enthusiams among participants for further/future involvement in patient and public engagement (PPE) in health research and other domains, and an overall sentiment that the workshops were successfully co-ordinated. Also evidenced from both public and patient workshops, was a real sense of hope and expectation that the project and its deliberative findings would influence the HRA approach to research approval processes. Where often dialogue participants express a strong degree of ambivalence or doubt towards the overall impact of a dialogue process and the mobilisation of its findings in exercising change or genuinely influencing policy-decisions and decision-making, this project demonstrated that participants were not only invested in its process but optimistic of its capacity as a change agent.

Many of the immediate impacts of the project are also already discernable not least as members of the HRA are already incorporating the findings of the consultation into practical guidance and through an extensive programme of internal and external dissemination. In generating both a corpus of evidence that reveals public and patient attitudes to the research approval process, and in establishing a precedent for public/patient engagement/dialogue work at the HRA (and beyond), we can report that the project has satisfied and exceeded its initial aims and objectives.

Our observations of the public workshops reveal a process that overcame multiple obstacles to produce a cogent set of results, which faithfully articulate the views and attitudes expressed by participants and provide the HRA with unique insight and valuable intelligence in respect of public and patient perspectives on, and recommendations for, the research approval and governance process. Here we consider the project outputs.

The final report of the public workshops, produced by Ipsos Mori, offers a broad synthesis of public views and valuable insight into public citizen's accounts of governance and approval processes in health research. The report details:

- Public perceptions of health research and clinical trials, placebo and blinding
- Public views on recruitment and consent
- Public views on research approvals system and regulation
- Public views on public and patient engagement
- Public views on how to increase trust in the HRA and health research

The final report of the patient workshops, produced by the HRA, offers a synthesis of views and valuable insight into patients' accounts of governance and approval processes in health research. The report details:

- Patients' perceptions of health research
    - General perceptions of health research
    - General perceptions of placebo and blinding
- Patients' views regarding recruitment of patients into health research
    - Patients' views of who should be able to search patient records to identify suitable patients
    - Patients' views of whether potential study participants should have a mechanism for signalling a wish to participate
- Patients' views of consent
    - Who should consent patients
    - Who to turn to for advice if considering joining a study
    - Views on Patient Information Sheets
- Patient views on the role of Research Ethics Committees
- Patient views on proposals to streamline the research approval process: views on current and new system of approval and early ethics assessment
- Patient views on annual reporting
- Patient views on the Research Passport
- Patient views on Patient and Public Involvement
- Patient views on the publication/dissemination of research results in the public domain
- Patient views on providing information to participants at the end of a study
- Patient views on trust and risk in research and the research approval process
- Patient views on the HRA should engage with patients and the public in future

The face-to-face interview survey of 1,295 adults (aged 18+) in England on attitudes towards health research focused on issues of confidence in the research approval/governance process:

- Confidence in being treated with dignity and respect if participating in a health research study in the UK
- Confidence that personal data would be held securely
- Confidence in participating in a health research study (where prior knowledge of it having been reviewed by a Research Ethics Committee)
- Impact of patient and public involvement in relation to confidence in a study
- Confidence in participation in a health research study as dependent on the funding source
- Confidence in research funded by pharmaceutical companies
- Access to patient records to find suitable patients for health research studies

Our exit-poll analysis of the public dialogue workshops revealed that:

- 95% of public participants surveyed stated that the workshop was well run
- 95% of public participants surveyed stated being in some way satisfied with the workshop overall (very satisfied 56%; fairly satisfied 39%)
- 55% of public participants surveyed stated a belief that the dialogue project would have an influence on the HRA's decision-making process

- 90% of public participants surveyed stated that public dialogue exercises were in some way important (54% very important; 35% important) in helping the HRA protect and advance the interests and welfare of patients and the public in health research

Our exit-poll analysis of the patient dialogue workshops revealed that:

- 87% patient participants surveyed stated that the workshop was well run
- 92% of patient participants surveyed stated being in some way satisfied with the workshop overall (63% very satisfied, 29% fairly satisfied)
- 75% of patient participants surveyed stated a belief that the dialogue project would have an influence on the HRA's decision-making process
- 100% of patient participants surveyed surveyed stated that public dialogue exercises were in important in helping the HRA protect and advance the interests and welfare of patients and the public in health research.

Exit-poll analysis also demonstrated that the experience of the project by both public and patient participants had resulted in them being:

- More likely to get involved in events like this in future (46%)
- More likely to engage the HRA in such matters (16%)
- More likely to get involved in other health related issues (18%)
- More likely to get involved in discussions on other issues (20%)

Our observations of both the public and patient workshops revealed a myriad of new learning indispensable to public engagement practice – particularly learning focused on health issues – and deliberative dialogue in the context of patient and public involvement in health research. This learning ought to be recognised as a highly significant outcome and impact of the project, particularly in problematizing the dialogue process; pointing towards solutions in overcoming obstacles to and limitations of dialogue processes; and for its contribution to a corpus of knowledge in apropos of dialogue and engagement processes with both public and patient constituencies. A major achievement of the project in other words, has been its success in establishing new understanding of public and patient cohorts' attitudes, as two distinct constituencies, and dialogue roadmaps specific to each of these in the context of deliberations around governance and approval processes in health research.

The project's contribution to new learning in dialogue and engagement practice focuses on what we have interpreted as prioritisations for effective dialogue design and successful delivery, namely:

- Clear and agreed 'conversational' and 'informational' roles and expectations attributed to facilitators and experts as 'process' and 'content' specialists, respectively.
- Clarity around the roles of facilitators and experts to public/patient dialogue participants and what public/patient participants might reasonably expect from them.
- Facilitators' significant experience in the moderation of experts in dialogue processes is essential, particularly where experts are conspicuously partisan, passionate and forceful in their views and liable to dominate dialogue and enervate the potential for non-expert involvement and leadership in discussion.

- Dialogue moderation should allow for expansive yet not overly tangential, unrelated or fragmented discussion.
- Consistency in assigning the same facilitation personnel is essential in maximising and assuring the fluency of dialogue, especially where dialogue events are reconvened and where informational content is demanding and/or complex.
- Attentiveness to hospitality and hosting is necessary for making participants feel welcome, invited and at ease in the dialogue process. It may be helpful to think of dialogue facilitators as hosts serving public participants as guests, in the analogy of a dinner party.
- Appropriate sequencing of 'informational' and 'conversational' aspects of dialogue. Sequencing of this sort might not necessarily have to be linear, but at least follow some sort of knowledge incrementalism, where participants are provided basic content stimulating and supporting their deliberative discussion.
- An insistence on facilitators' rehearsal and refinement of audio-visual presentations prior to workshops.
- Appropriate and relevant selection of stimulus materials, where possible with the advisement of experts.
- Consideration of and planning for those dialogue participants with physical impairments and/or disabilities.
- A commitment to reflexive practice: recognising the importance of learning by doing and dialogue practitioners/facilitators engaged in critical reflections.
- Ensuring there is time and opportunity within a dialogue session for participants to verify what is reported as having been discussed.
- Maintaining balance and impartiality: circumventing the potential (no matter how remote or un-intentioned) of bias. We would argue for the ideal of a clear separation in the roles of sponsor and facilitator so as to avoid issues of bias. This would help alleviate and/or quash any sense or suspicion among participants that the dialogue was simply a process of 'consensus-making' or 'rubber-stamping' for a decision already made, as opposed to a legitimate exercise in public deliberation. Equally important is avoiding leading lines of questioning; presentation of all sides of an argument and equal representation of these in the selection of experts.
- Finally, careful formulation in question design: avoiding content-specific questions that non-experts might not possibly be able to answer.

Our experience of the project's governance allows us to report clear leadership and effective stewardship from the HRA and effective scaffolding from Sciencewise throughout the process. The project appeared well conceptualised and adopted an appropriate methodology, incorporating and triangulating both qualitative and quantitative approaches to data collection. Our own interface with the sponsors and members of the Oversight Group was positive: open and fluent. Updates were regular in the form of e-mail and we enjoyed regular contact and debriefing with both members of the HRA and Sciencewise. We attended two meetings of the Oversight Group. These were useful events in terms of providing an account of what the project was due to achieve and what it had achieved. These meetings might have been more frequent. Restrictions of time however, dictated otherwise. They nevertheless provided an opportunity for Oversight Group members to offer their own insight and commentary. Furthermore, they were essential for disseminating and feeding-back to prominent and proximal stakeholders – through the Oversight Group's immediate and extended

network. Our interface with the contractors was rather less fluent, though we did manage to build some rapport as the workshops progressed.

The translational fluency of the project and the transition through its various components, public workshops; patient workshops; and survey was relatively consistent, though we did observe more aspects of what we might term *transitional inefficiencies* in the context of the public workshops, where there were specific challenges for instance in terms of the management of time and expertise. Nonetheless, whilst we observed certain issues in terms of process, these were not drastic enough to prevent the project from fulfilling its stated aims and objectives.

The project generated three written outputs: Patient and Public Engagement Project: Patient and Public Dialogue Workshops (HRA report); Public Dialogue Workshops (Ipsos Mori report); and Survey of the General Public: Attitudes Towards Health Research (HRA report based on an Ipsos Mori omnibus survey), the content of which we have already detailed. These reports were uniformly well written, making clear and substantive assessments of the dialogue and survey processes. The quality and comprehensiveness of these reports and the complementarity of their findings with our own observation, provides good indication that the kinds of obstacles and hiccoughs, to be expected of any project, especially a multi-method project of this kind, were neither so drastic nor insurmountable as to prevent the successful translation of aims and objectives into solid outcomes and quality evidence. Furthermore, the translation of the project into multiple impacts, which we report on in a final chapter, again attests to this translational fluency.

Our consultation with a variety of individuals involved, in various capacities, with the project has revealed five major impacts or impact themes. These relate to:

- the impacts of the project on policy and decision making by Parliament, the HRA themselves and more widely
- the project resulting in the increased legitimacy of dialogue based activity and the establishment of PPE as a core activity in the overall context of the HRA's portfolio of work and specifically in the context of health research approval and governance processes
- new learning and competencies resulting from the direct experience of the dialogue process
- the enlarged perspective gained from an inclusive and democratic approach to decision making processes in health-research
- and finally, the emergence of the HRA as a role-model in patient and public engagement.

Reflecting on our observational findings, exit-poll analysis and stakeholder consultations, we would advise that the project has positively impacted on policy and decision making on health research, the individual and institutional perspectives of those involved in the project's implementation and steer, and on the recognised value of public engagement as a catalyst for scientific transparency, accountability and democratic decision-making for regulatory and legislative policy.

1. Introduction, background and context.

The Health Research Authority (HRA) was established on the 1st December 2011 as a Special Health Authority designed to protect and promote the interests of patients and the public in health research: facilitating and ameliorating confidence and participation in health research.

In line with this mission, this project was initiated to engage a range of public and patient perspectives in a dialogue to explore expectations around the benefits and risks of clinical trials and research involving patients, the ethical issues that might arise, the procedures required in relation to health research and its role in protecting the individual, and to gain views on how the public should be engaged and influence the HRA in the future.

The focus of the public dialogue was in addressing the following questions:

1) What are the perceived risks for individuals agreeing to participate in research?
2) To what extent do the public and others trust the views of their doctor in advising if they should participate in research?
3) To what degree do the public and others trust charities (e.g Cancer Research UK) to protect their interests in research?
4) To what degree do the public and others trust the pharmaceutical industry to protect their interests in research?
5) 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?
6) 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?
7) To what extent do different views emerge from different types of public? For example general public versus patients?

The project consisted of three discrete but interlinking exercises designed to elicit the attitudes and opinions of patients and the public, and therefore provide the HRA with greater intelligence of stakeholder views. Exercises comprised of: public dialogue workshops convened in four locations in England, with each group of participants attending two evening workshops (facilitated by the market research company Ipsos Mori); seven workshops with patients and carers and a workshop with participants in Phase 1 clinical trials (facilitated by the HRA itself); and an interview survey of 1,295 members of the general public (also administered by Ipsos Mori) intended to quantify the more qualitative findings of the dialogue 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.

Project Elements

We provide an illustrative guide, which establishes the precise details of each project strand in Figure 1. Figure 2 illustrates the distinction between the first and second sessions of the public

workshops. Figure 3 provides an overview of what was distinctive between the two workshop strands – public and patient – and documents characterisations of participants; the workshop format; and processes of recruitment.

Figure 1: Project Strands

Public Dialogue Events
Held in four locations: London, Bristol, Manchester and Newcastle
Two 3-hour evening workshops (6.30pm-9.30pm)
Each reconvened session conducted one week after the first
60 participants attended first workshop, 56 the second workshop
Participants split into two groups (7-8 per table)
Two note-takers present at each event
HRA representative present at a number of workshops and provided additional verbal input
Health researchers were invited to attend the reconvened sessions to answer questions, raise issues and input to dialogue (with at least 2 attending each reconvened session)
Other observers present: Sciencewise Dialogue Expert/Representative; HRA project steering group members and the evaluator.

Patient Dialogue Events
Conducted in March and April across England in Birmingham, Liverpool, London, Newcastle and Sheffield. Each workshop occurred just once and lasted for 3 hours
Eight workshops: six with patients; one with a mixed group of patients and public (children and young people); one with participants of Phase 1 clinical trials
Six patient workshops involved the following groups respectively: • **Mental Health (Birmingham: 8 participants; 2 male , 6 female)** • **Parkinson's (London: 9 participants; 7 male, 2 female** • **Diabetes (London: 9 participants; 5 male, 4 female)** • **COPD (London: 9 participants; 6 male, 3 female)** • **Cancer (Sheffield: 4 participants; 1 male, 3 female)** • **Stroke survivors (Newcastle: 8 participants; 7 male, 1 females**
• The mixed group workshop (children and young people) occurred in Liverpool and involved 17 participants; 4 male, 13 female)
• The Phase 1 workshop occurred in London and involved 4 participants; 2 male and 2 female
• Patients were recruited via NIHR Research Networks

General Public F2F Survey
• Ipsos Mori undertook a face-to-face survey of the general public: 1,295 interviewed as a part of wider omnibus survey
All respondents were 18+
Survey confined to England

Figure 2: Functions of Public Dialogues 1 and 2

Figure 3: Distinctions between the knowledge and outlook of *patient* and *public* dialogue participants

Patient dialogue workshops	Public dialogue workshops
• Participants were well informed about health research • Many acted as patient representatives • They had either participated in a research study or a PPI component of a research study • Some had undertaken training in research methods as a part of PPI • Some had reviewed research proposals as a part of PPI • Clear understanding of pharmacological development and the relationship between the pharmaceutical industry and the NHS in the development/testing of new products • In some instances an awareness of the function of Research Ethics Committees • Workshops were not reconvened (patients starting from more informed base) •Researchers present at 5 out of 8 workshops •Small number of carers present in patient groups •Recruited through patient networks	• Participants had little idea of health research • Had a hazy idea of a clinical trial • Participants' ideas mostly informed by the media • They demonstrated low levels of understanding • They demonstrated deep suspicion of the pharmaceutical sector • They thought that pharmaceutical trials develop in isolation to the NHS • Workshops were reconvened • Researchers invited to reconvened sessions •On-street recruitment of 16 adults (18yrs +) for each location. • Exclusions: NHS employees; health/clinical workers; pharameutical employees; health employees; those who had participated in qualitative research within previous 9 months • Quotas on gender, age, social grade and ethnicity

As Figure 3 evidences, health researchers were invited by the HRA to the reconvened public workshops for the purpose of enriching dialogue and discussions focused on the research approval process. Researchers were briefed on the day of the workshop (in written note provided by the facilitation team) to participate freely in discussion: invited to contribute with their own experiences and engage other participants with lines of questions, yet were explicitly asked to refrain from self-presenting as definitive experts and correcting the contributions of participants. Researchers were asked to present their expertise in unintimidating ways and through avoiding specialist language.

The HRA's own report of the reconvened public workshops advises that some of the researchers attending these sessions had roles in the development of the HRA's new guidelines and could therefore potentially have biased or unduly influenced the course of dialogue, being 'very clearly supportive of the HRA's proposals' (p.14). The HRA report does however note that the influence of researchers, in terms of the extent of their involvement in the dialogue, varied, and that their participation did not prevent the key issues being covered.

2. Evaluation

Our evaluation of the project focuses primarily on the process, outcomes and impacts of the deliberative engagements, summarised in the original service description, focused on external engagement with patients and public groups. The evaluation was established as a part of Sciencewise protocol and stipulated good practice in public dialogue/engagement for policy purposes, to provide an independent assessment of the project's credibility, effectiveness and success against its objectives, covering both the dialogue processes and their outcomes (including an assessment of impacts on policy and those involved); to contribute to creating excellence in public dialogue to inspire and inform better policy making in science and technology; to gather and present objective and robust evidence of activities, achievements and impacts to support increased understanding of the value of public dialogue; and to identify lessons to support capacity building across Government, and the development of good practice in public dialogue.

The evaluation relies upon several information sources: a) documentary evidence (e.g. details of the project sponsors' criteria may be ascertained from project documents); b) participant questionnaires (given to those attending events); c) evaluator observation of various public events, using an 'observation protocol' to record pertinent issues related to information translation, and d) interviews with relevant parties. Copies of the observation protocol and the participant questionnaire can be found in Annex A and B respectively.

Our approach to evaluating the process and impact of the project was informed by a combination of four methods: a) participant questionnaires; b) observation of events according to an observation protocol; c) interviews with various participants involved in the process; d) documentary analysis. In turn:

- **Participant questionnaires**: we designed a bespoke questionnaire, distributed at public and patient deliberative workshops
- **Observation of events**: we designed an observational protocol which was used to guide the formation of a critical record of the public and patient deliberative workshops; oversight group meetings
- **Interviews with stakeholders**: we undertook interviews with key project stakeholders comprising members of the HRA's project team; members of the project oversight group including the oversight Group Chair and a Sciencewise representative.
- **Documentary analysis**: we consulted with a variety of written materials throughout the multiple stages of our evaluation ranging from stimulus materials incorporated into dialogue events, to the final report.

As the report will reveal, different aspects of our methdology reveal different and not always complementary findings. For instance, whilst the general mood of surveyed participants at both public and patient workshops suggests that the deliberative aspects of the project were by and large successful, our own ethnographic observations point to specific challenges in dialogue design and implementation that were not always successfully surmounted. We would however argue that these aspects of a dialogue process identifiable as weaknesses, shortcomings or the parts that did not go so well, are simultaneously significant and enormously useful as catalysts of learning. Project 'weaknesses' might then also be regarded as some of the more pertinent and ironically positive impacts, in the context of their providing invaluable knowledge; and experiential knowledge at that.

What doesn't work or work so well is often far more useful and richer in a learning sense, than knowing what did work well.

Our approach to evaluation is based upon the criterion of *translation quality*, which is concerned with the efficiency of information/ knowledge gathering, recording, transmission and interpretation between the various stages of the activity, and involving various parties (including the sponsors and stakeholders/participants), and its comprehensiveness and appropriateness. Use of the translation criterion by necessity requires the consideration of the sponsor objectives (in this case, both project objectives and Sciencewise principles of good practice in public dialogue), as these specify the initial information/knowledge targets for the project to achieve.

A key ambition in our approach to evaluation, is that our evaluation findings are regularly communicated in such way that they might contribute to the formative and incremental learning of a dialogue project. In the context of this project, a commitment to evaluation for formative learning was easily achieved where workshops were concentrated into a short-space of time. We should comment here however, that despite the hugely tight and congested scheduling of workshops, and a lack of reasonable time for critical reflection, dialogue facilitation teams, clearly learnt from and committed themselves to a process of formative learning, evidenced in the fine-tuning of workshop materials and sequencing.

We now turn to the objectives for our evaluation work that were specified at the outset. Those objectives were to:

- Provide an independent assessment of the project's credibility, effectiveness and success against its deliverables and objectives, throughout and at the end of the project.
- Contribute to the overall Sciencewise aim of creating excellence in public dialogue to inspire and inform better policy-making in science and technology.
- Contribute to the development of mechanisms throughout the project to aid reflection and learning in relation to the project's own engagement processes.
- Gather and present objective and robust evidence of activities, achievements and impacts to support Sciencewise work in increasing wider understanding and awareness of the value of this work.
- Identify lessons for the project to support Sciencewise work in capacity-building across Government, and the development of future good practice.

Evaluation focused on whether the project had answered a number of 'key questions' that are standard to public dialogue projects funded by Sciencewise. These questions were:

- Has the dialogue met its objectives?
- Has the dialogue met (Sciencewise) standards of good practice?
- Have those involved been satisfied with the dialogue (of value to them)?
- What difference/impact has been made by the dialogue?
- What was the overall balance of costs and benefits for the dialogue?
- What are the lessons for the future? What worked well and less well, and more widely?

The various project outputs and cognate impacts, demonstrate that the project has succeeded in meeting its objectives: in securing a new knowledge and understanding of public and patient perspectives and attitudes on governance and approval processes in health research,

The second key question asks whether the exercise reflected good dialogue practice according to Sciencewise. The Sciencewise principles are (in summary):

- the conditions leading to the dialogue process are conducive to the best outcomes (Context)
- the range of issues and policy opinions covered in the dialogue reflects the participants' interests (Scope)
- the dialogue process itself represents best practice in design and execution (Delivery)
- the outputs of dialogue can deliver the desired outcomes (Impact)
- the process is shown to be robust and contributes to learning (Evaluation)

In terms of 'context', the project has ultimately yielded positive outcomes in terms of substantiating a solid platform for future dialogue and engagement work in the context of health research. The project has also revealed the myriad intricacies of successful engagement with public groups and multiple lessons in terms of taking a dialogue agenda forward, some of which will be discussed in our penultimate discussion of the project's impacts, issues and other insights (Chapter 6.)

Regarding 'scope', the project has proved a brave and worthwhile endeavour in diversifying engagement tactics in health research and through invoking the 'public' as a discrete constituency, distinct from patient populations. In splitting engagement to these two populations the engagement has sought to diversify and pluralise the views of user-groups.

Regarding 'delivery', the dialogue process was managed in two parts: the HRA designed and delivered the patient group workshops and Ipsos MORI designed and delivered the public workshops. Both types of workshops enjoyed similar successes and shortcomings, which should be read in the context of their specific cohort. Both were largely endorsed by participants as successful events.

Regarding 'impact', the project has already achieved signficant results in relation to influencing policy and decision making, as outlined in the final chapter of this report.

And regarding 'evaluation', the sponsors have clearly made efforts to ensure a thorough assessment has taken place by commissioning the independent evaluation of which this is the report.

Regarding the third question, 'satisfaction', the vast majority of public participants provided testimony which suggested they had enjoyed and taken some sense of personal fulfilment from the dialogue process.

Turning to whether the project will make a 'difference' (the fourth question), in addition to the short term impacts of the project on policy and decision making mentioned above, it is likely that further impacts will continue to be apparent over time given the extensive dissemination of project findings

and a sense that the project has established a precedent in PPE for the HRA. These are powerful and convincing indicators of the project's immediate and potential impact.

Regarding costs and benefits (the fifth question), it is always enormously difficult to determine the value of an activity whose impacts are essentially diffuse and are in ways quite abstract – related more to behaviour or culture change than any more tangible or measurable impact. Nevertheless, we might and should infer that the cost and potential benefit gained is entirely justified as an exercise, given the immediate impacts, which have cemented the importance and value of PPE and has set a precedent for PPE in health research contexts.

Regarding 'lessons' (the sixth question), these have been addressed within the executive summary and are further discussed in the later chapter identifying these in detail.

As an exercise in professional capacity building and building good-practice, we believe that all those involved in the dialogue process have in many ways benefitted: in broadening attitudes, ideas, and strategic approaches for PPE – learning what works, what doesn't so well, and what to do in future.

This report concludes our independent review of the HRA dialogue project's credibility, effectiveness and success. The work we conducted has been rigorous and evidence-based and informed by personal attendance by at least one of the evaluation team at examples of each type of event. We should comment that much of the success in completing this evaluation stems from the helpfulness and patience of members of the wider project team in supporting and expediting the evaluation process. The ease with which we were able to undertake evaluation was significantly boosted by the spirit of co-operation and collegiality shown by the HRA project-lead and members of Sciencewise, who as we have come to know are integral to scaffolding the evaluation process, and the wider project community, as well as those among the oversight group who were not only interested in what we were doing as evaluators but receptive and obliging in our requests to draw on their own experiences of the project.

Evaluation Timeline

An evaluation timeline responded to the agreed timeline for project activities.

Evaluation Activity	Date of Activity /Evaluator present: Watermeyer (RW), Bartlett (AB)
Inception meeting	18th January 2013 (RW)
Development of participant questionnaire and evaluation materials for public workshops and consultation meetings	February 2013 (RW)
Attendance at deliberative public and patient workshops	March-April 2013 (AB)
Evaluators/HRA teleconference	Regularly throughout duration of project (RW)
Oversight group final meeting	8th May 2013
Interviewing of key project stakeholders	1st June- 20th June 2013 (RW)
Analysis of project final report	June 2013 (RW)
Delivery of draft evaluation report	1st July 2013 (RW)
Attendance at project 'wash-up' meeting	8th July 2013 (RW)
Delivery of final report	Tbc

Figure 4: Evaluation Timeline

3. *Public* Dialogue Workshops: Exit-poll Analysis

Overview

This chapter considers the exit-poll data gathered through the administering of an exit-poll questionnaire by the evaluation team at six of the eight public dialogue workshops. Exit-poll results, reflect respondents' impressions from workshops conducted at two reconvened sessions in London and Manchester (n=4 workshops) and one each of the workshops in Bristol and Newcastle. Each of these workshops was also attended and observed by the evaluation team, which is reported on in Chapter Four.

At the end of each dialogue workshop, public participants were asked to complete an evaluation questionnaire (see Appendix B), which asked for their honest reflections on the workshop experience. Questions were focused on eliciting from participants their thoughts on: how well organised, structured and facilitated the workshop had been: what they identified as its strengths and weaknesses; what they had gained from the workshop, such as in the way of any new learning; what they would recommend changing in re-running and improving the workshop; and what they considered the impacts of the workshop would be to the sponsor and themselves as prospective/future participants of other public dialogue exercises.

It is important to note that the intensity of the scheduling of the workshops (both public and patient), and their geographical spread (whilst working to a limited evaluation budget), resulted in us being unable to attend each and every session, though clearly we were able to observe and undertake an exit-poll analysis of the greater majority of workshops. Exit-poll surveys were consequently administered only at workshops, we ourselves as the evaluation team, attended. We believe that the administering and collection of questionnaires, other than by ourselves, would have not only potentially undermined the integrity of the survey process but made unreasonable demands of third parties. Overall, however, we have been able to collect and analyse a huge wealth of data which demonstrates comparability and complementarity between workshops; an opportunity for generalizability; an ability to make robust conclusions.

The following analysis introduces each question, and follows with a statistical breakdown and graphical illustration of results, before providing brief commentary on each finding. The chapter concludes with a conclusion synthesising the headline findings drawn from this analysis, which are also presented in the executive summary. We begin first with a summary overview of key findings from the data.

Headline Findings

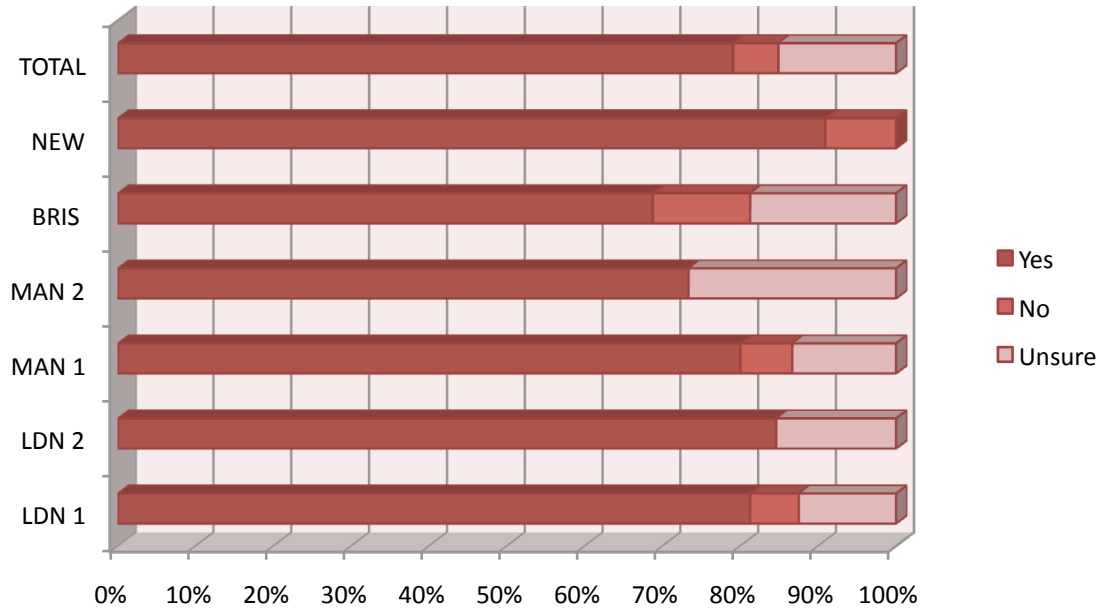
- A majority (70%) of respondents stated that the information provided prior to the workshop was clear.
- A majority (80%) of respondents stated being clear as to why they had been invited to the workshops.
- A majority (93%) of respondents stated that the aims of the workshop, and the whole process of which it had been a part of, had been made clear from the outset of the workshop.
- A majority (78%) of respondents stated that the membership of the public participants involved in the workshop had been appropriate.
- The only types of individual seen to be missing from the event were reported as those with expertise of clinical trials and medical research.
- 64% of respondents stated that they had been provided an opportunity to say ALL they wanted to say. Only 3% stated that they had only been able to say a little of what they wanted to say.
- A majority (82%) of respondents stated there was sufficient time to discuss all that needed to be covered.
- A majority (70%) or respondents stated having learnt a lot of new things.
- A majority (78%) stated that their views had changed to some extent.
- A majority (86%) of respondents stated that summing-up accurately reflected what was discussed at the workshop.
- A majority (95%) of respondents stated that the workshops were well run.
- Respondents stated that some of the best things about the workshops were: the quality of the process; the workshops as an opportunity to speak and be heard; the workshops as an opportunity to be involved in collective discussion; the workshops as a learning experience.
- Few items were provided by respondents as 'worst things about the workshop'. The only persistent criticism related to a lack of time.
- A majority (95%) of respondents stated being satisfied with the workshop.
- 55% of respondents felt that the dialogue project would influence the HRA's approval process. 35% of respondents were unsure.
- Respondents were largely unanimous in declaring that dialogue events are important in helping the HRA protect and advance the interests and welfare of patients and the public in health research.
- Respondents stated that the project experience had increased the potential of their being more likely to get involved in events like this in future; more likely to engage the HRA in such matters; more likely to get involved in other health related issues; and more likely to get involved in discussions on other issues.

Analysis

Question 1: *Was it clear from the information you were sent before the workshop what it would be about?*

N= number of responses to question; % calculated to nearest decimal point

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRIS 2	NEW
Yes	n=13	n=11	n=12	n=11	n=11	n=10
No	n=1	-	n=1	-	n=2	n=1
Unsure	n=2	n=2	n=2	n=4	n=3	-

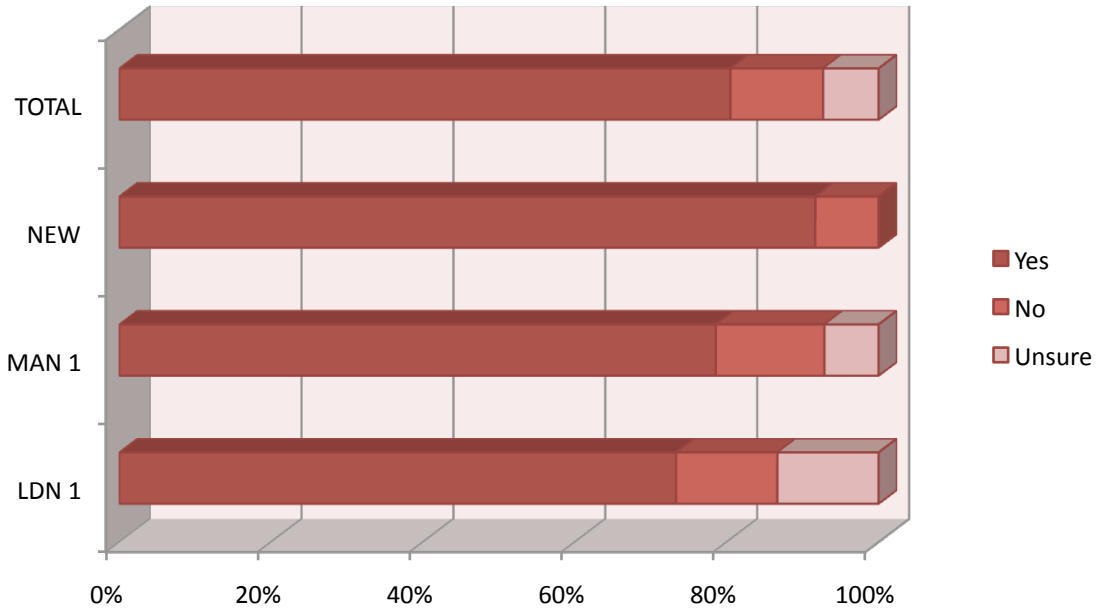


DISCUSSION

The vast majority of respondents (70% or n=68) stated that information provided prior to the workshop made clear what it would be about.

Question 2: *Was it clear to you from the information you were sent prior to the workshop why you were invited?*

Location	LDN 1	MAN 1	NEW
Yes	n=11	n=11	n=10
No	n=2	n=2	n=1
Unsure	n=2	n=1	

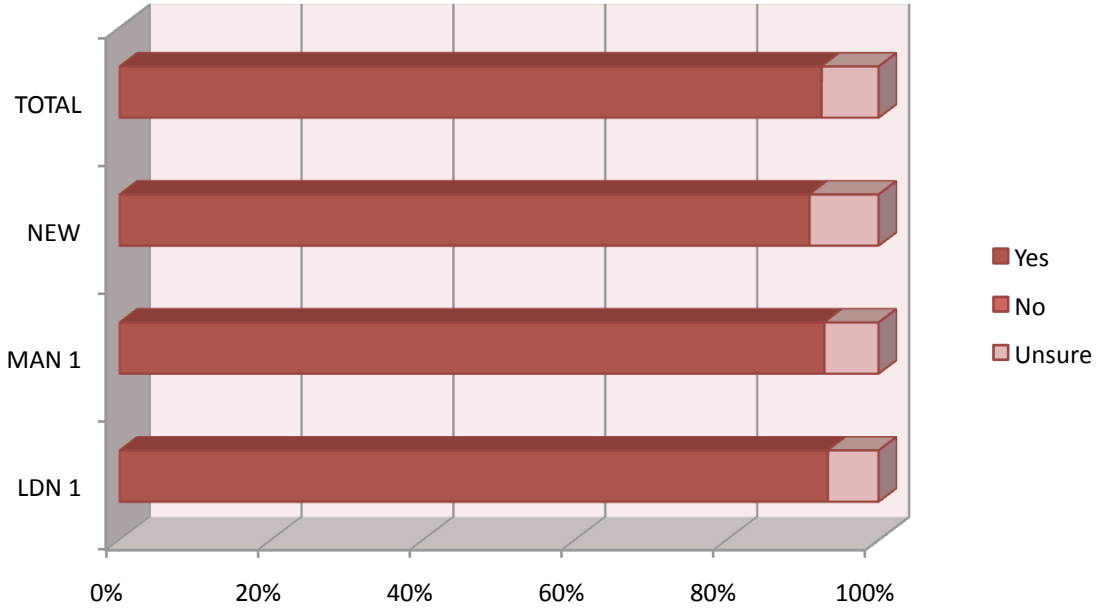


DISCUSSION

Respondents at the first-round of workshops at London, Manchester and Newcastle were by and large (80%) clear as to why they had been invited to the workshop.

Question 3: *Were the aims of the workshop, and the whole process of which the workshop is a part of, clearly explained from the outset?*

Location	LDN 1	MAN 1	NEW
Yes	n=14	n=13	n=10
No	-	-	-
Unsure	n=1	n=1	n=1

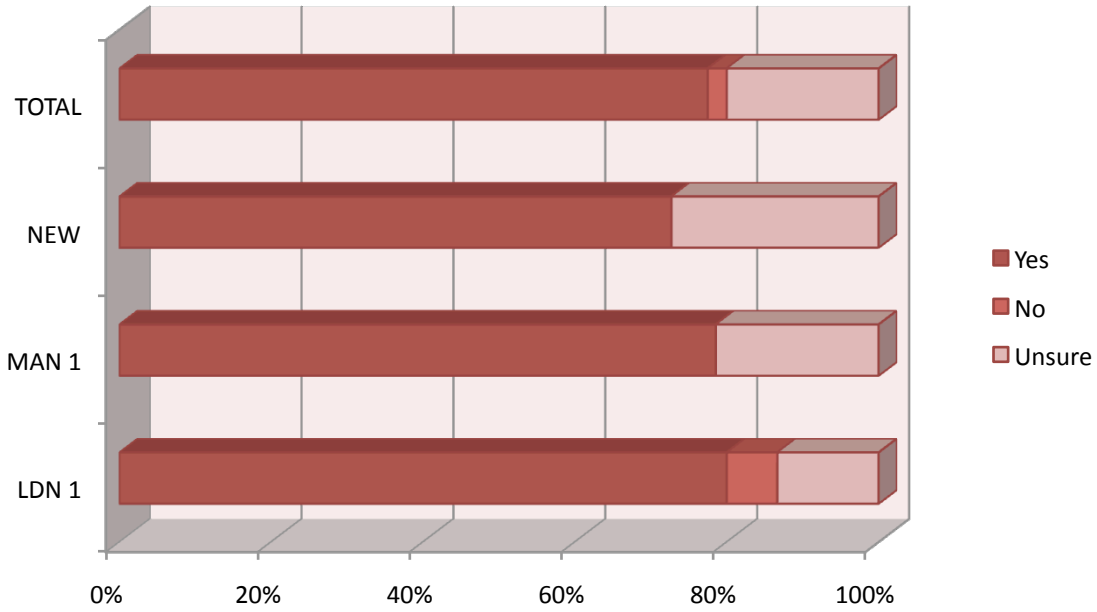


DISCUSSION

93% of respondents at the first-round workshops at London, Manchester and Newcastle stated that the aims of the workshop, and the whole process of which the workshop was a part of, had been made clear from the outset of the workshop. Furthermore, not one respondent stated that aims had not been clear.

Question 4: *Do you think the public participants involved were appropriate for the workshop?*

Location	LDN 1	MAN 1	NEW
Yes	**n=12**	**n=11**	**n=8**
No	**n=1**		
Unsure	**n=2**	**n=3**	**n=3**



DISCUSSION

78% of respondents at the first-round workshops in London, Manchester and Newcastle stated that the public participants involved in the workshop had been appropriate. 20% of respondents surveyed at these events stated being unsure.

Question 5: *Who do you think was missing from the event, if anyone?*

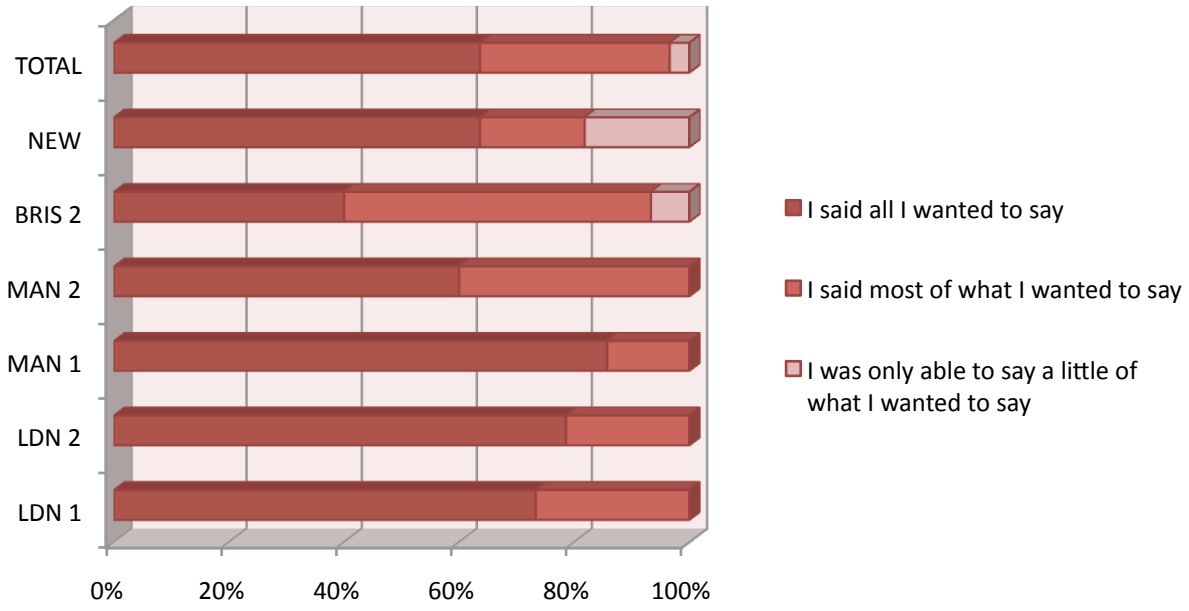
Medical professional- medical-legal expert (frequently cited)
Both evenings have been different - the researchers who joined us had interesting views to share
Doctor – GPs, hospital staff etc. – would be good to have had a mix of preselected critical and supportive voices from within the medical profession giving presentations on pros and cons of proposals
Someone who has been in a medical trial (frequently cited)
Patients who have been in a research programme (frequently cited)

DISCUSSION

Whilst the majority of respondents from across all the dialogue workshops observed by the evaluation team, tended to skip and/or leave this question blank, a good number made reference to those with expertise or prior experience of clinical trials and medical research. Interestingly, respondents suggested that the workshop would have benefitted from the inclusion of patients, who we know as being subject to a separate if synchronous dialogue process.

Question 6: *During the workshop, did you have the opportunity to have your say?*

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRIS	NEW
I said all I wanted to say	n=11	n=11	n=12	n=9	n= 6	n=7
I said most of what I wanted to say	n=4	n=3	n=2	n=6	n=8	n=2
I was only able to say a little of what I wanted to say	-	-	-	-	n=1	n=2
I didn't get a chance to say anything	-	-	-	-	-	-
Non complete	-	-	-	-	-	-

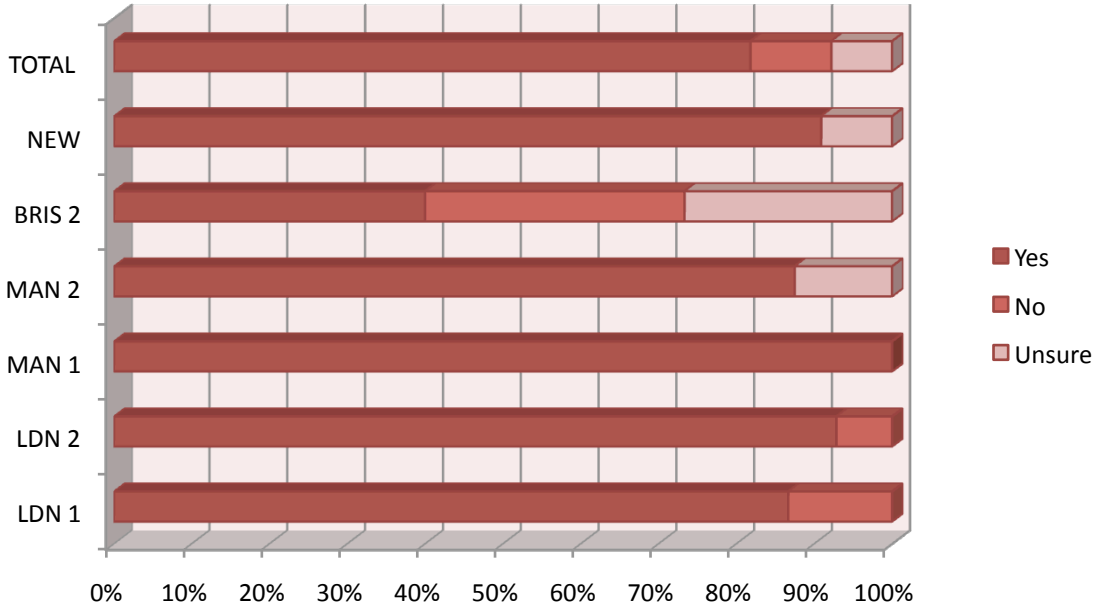


DISCUSSION

More than 60 per cent (64%) of respondents from across the six workshops surveyed stated that they had been provided an opportunity to say *all* that they wanted to say. Only three respondents out of the 88 responding this question stated that they had only able to say a *little* of what they had wanted to say. Zero respondents stated *not being able to say anything*.

Question 7: *Was there sufficient time in the workshop to discuss all that needed to be covered?*

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRIS	NEW
Yes	n=13	n=13	n=14	n=7	n=6	n=10
No	n=2	n=1	-		n=5	
Unsure	n=	-	-	n=1	n=4	n=1



DISCUSSION

82% of respondents at the reconvened dialogue workshops in London and Manchester, and workshops in Bristol and Newcastle stated that there was sufficient time to discuss all that needed to be covered. In Bristol however, 36% of respondents, or 5 from 12, stated that there was insufficient time to discuss all that needed to be covered.

Question 8: *Do you think there were any important issues that were NOT discussed in the workshop, but which should have been? What were these?*

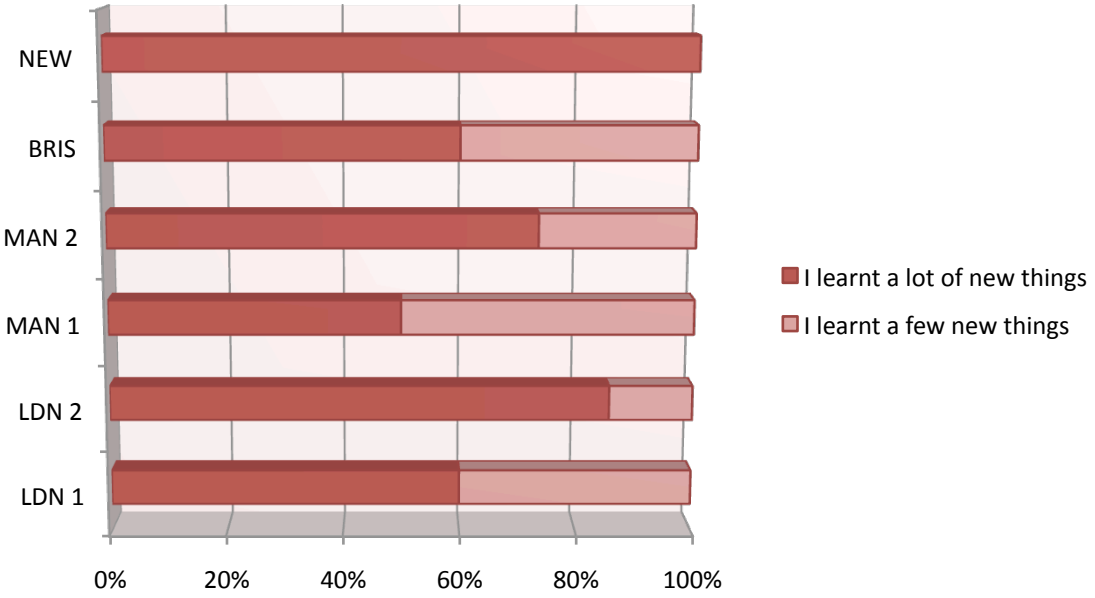
Animal testing, children consent, what are Pharmaceutical companies, how do they work – corrupt or not – what countries are they from
Corruption
Mutation
Didn't discuss clinical trials gone wrong
No time
Euthanasia
The role of the NHS in making the availability of trials to the public
Specific unethical practices within trials. Why? How? How to negate
Some were only briefly touched upon and not talked out to a satisfactory conclusion

DISCUSSION

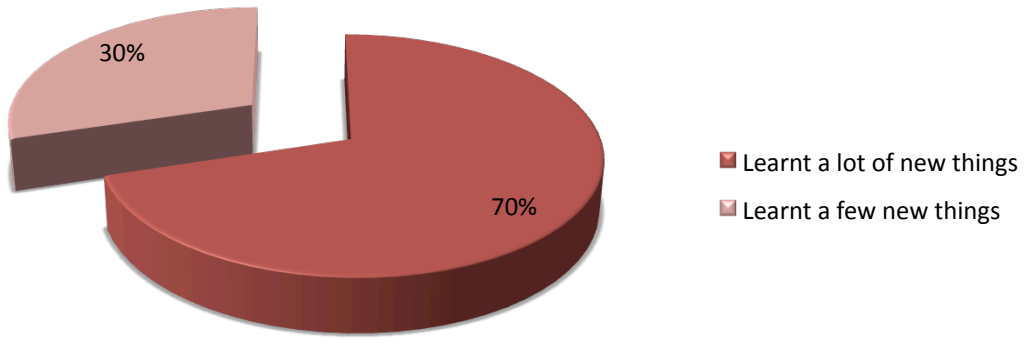
The overwhelming majority of respondents skipped this question. Those that did respond stated – as above – that a) time was a factor prohibiting discussion of other issues b) issues missing from discussion included those which focused on the negative aspects of clinical trials and the practice of pharmaceutical companies.

Question 9: *Did you learn anything new from the workshop?*

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRISTOL	NEW
I learnt a lot of new things:	n=9	n=12	n=7	n=11	n=9	n=11
I learnt a few new things:	n=6	n= 2	n=7	n=4	n=6	-
I'm not sure I learnt anything new	-	-	-	-	-	-
No I didn't learn anything new	-	-	-	-	-	-



Total number of surveyed participants:
Did you learn anything new from the workshop?

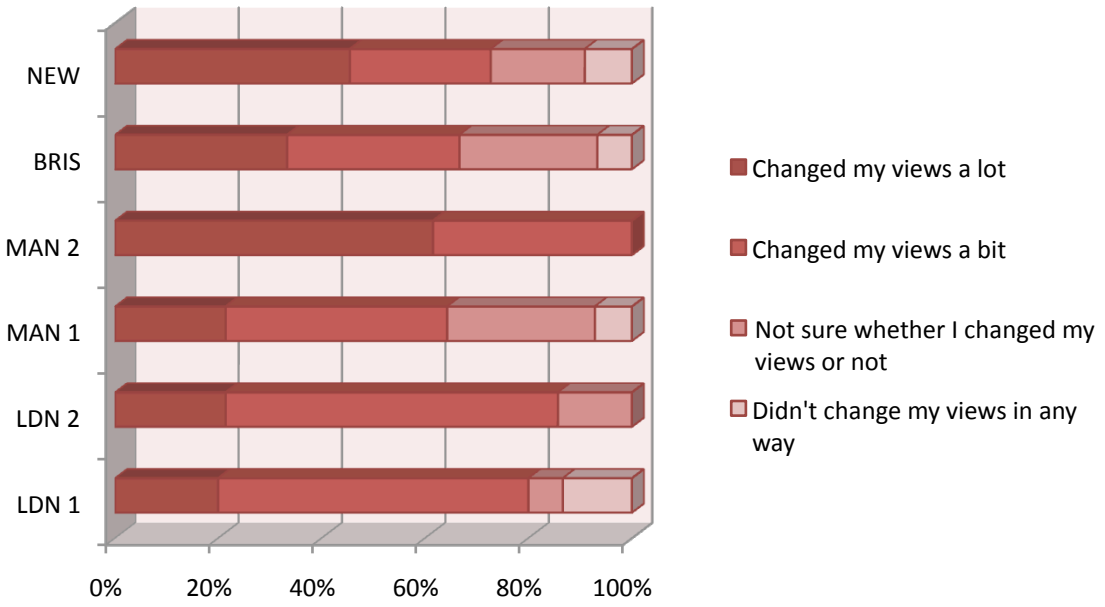


DISCUSSION

Every respondent surveyed across the workshops in London, Manchester, Bristol and Newcastle attributed some level (*a lot* and/or *a few*) of learning from the workshop experience. Of 84 respondents to the question, 59 or 70% stated having learnt *a lot* of new things. At the first Manchester dialogue workshop there was parity between respondents stating they had learnt *a lot* (n=7) and *a few* (n=7) new things.

Question 10: *Did taking part in the workshop change your views on the issues in any way?*

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRIS	NEW
Yes, I changed my views a lot	**n= 3**	**n=3**	**n=3**	**n=8**	**n=5**	**n=5**
Yes, I changed my views a bit	**n=9**	**n=9**	**n=6**	**n=5**	**n=5**	**n=3**
I'm not sure whether I changed my views or not	**n=1**	**n=2**	**n=4**	**-**	**n=4**	**n=2**
No, I did not change my views in any way	**n=2**	**-**	**n=1**	**-**	**n=1**	**n=1**



DISCUSSION

The majority of respondents answering this question (78%) stated that their views had changed to some extent (a lot n= 27 *a bit*: n=37) as a consequence of the workshop experience. A minority (6%) of respondents stated that the workshop experience had not caused any change in their views.

Question 11: *What information (from speakers, from written material, from other participants etc.) made the greatest impression on your views?*

INFORMATION (speakers, information, participants)

- *Some of the slides*
- *The clinical researchers – the views from the researchers*
- *Not just talking to the middlemen but the people doing the research*
- *Some of the information on ethics*
- *Group discussion*
- *Powerpoint presentations*
- *Video at start*
- *Speaker- about children doing studies*
- *All information was informative and very useful and allow understanding and enabled discussions and broadened my views*
- *Written material – the possibility you could have the drug taken away*
- *Most impression from attending health professionals*
- *Research conducted by myself between sessions*
- *Mental health professor, ethics panel client (also a dentist)*

THEMES

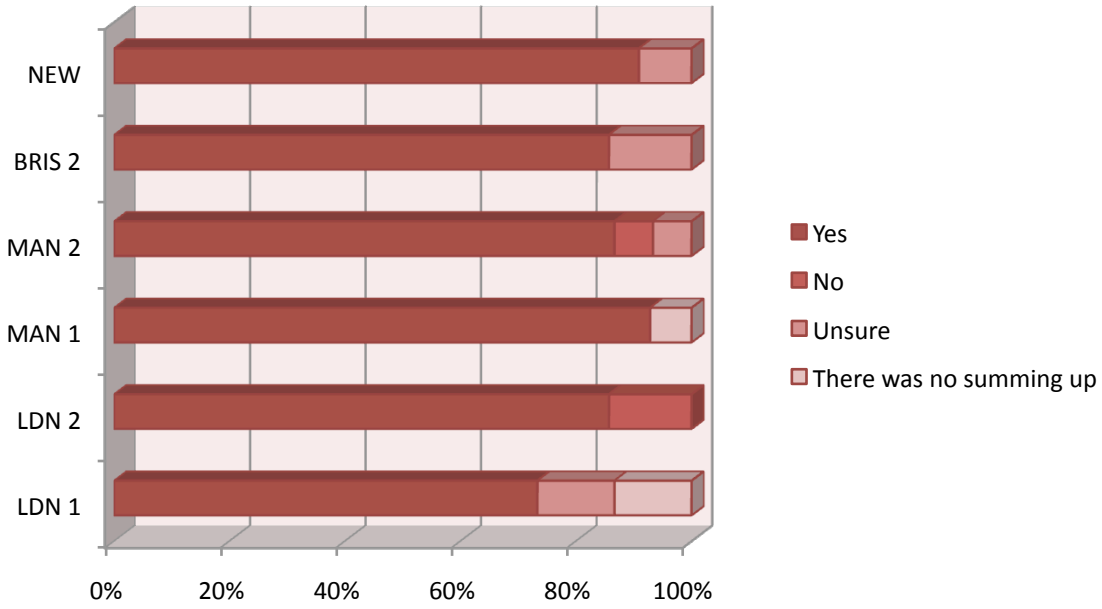
- *Process involved in research*
- *How the processes currently work and difficulties in order to get a starting point*
- *Differences in male and female views regarding therapy and counselling*
- *Child research*
- *Placebo surgery - what placebos are etc.*
- *Not having a huge understanding of ethical medical – these evenings helped open up my interest*
- *The importance of clinical trials*
- *Whether members of the public should be involved in discussions about how research is conducted and also how much research is published*
- *Clearly illustrated how low risk clinical trials actually were*
- *Reflection on personal perspectives*
- *That the results of the studies might not be published depending on what they are*
- *Shortening and streamlining the process*

DISCUSSION

Respondents identified a number of information sources as making an impression on their views. These included, as above, aspects of stimulus materials (written and visual i.e powerpoint) and more significantly, though perhaps unsurprisingly, the participation in the workshop of those involved in health research and its ethical (de)construction. 'Information' was also interpreted by some respondents to include specific topic themes such as information focused on research and research approval processes and the role of placebos in clinical trials.

Question 12: *Do you think final summing-up accurately reflected what was discussed at the workshop?*

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRIS	NEW
Yes	n=11	n= 12	n=13	n=13	n=12	n=10
No	-	n=2	-	n=1	-	-
Unsure	n=2	-	-	n=1	n=2	n=1
There was no summing up	n=2	-	n=1	-	-	-



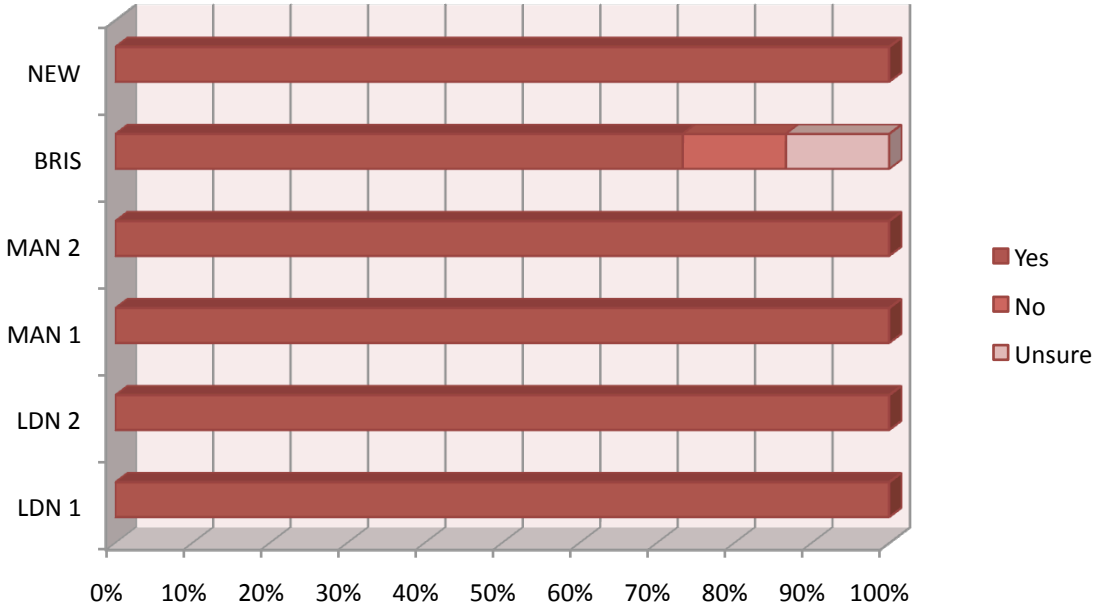
DISCUSSION

The overwhelmingly majority of respondents (86%), attending both sessions of the London and Manchester workshops and Bristol and Newcastle events, and answering this question stated that they felt summing-up accurately reflected what was discussed at the workshop. Conversely, 4% stated that summing-up did not accurately reflect what was discussed at the workshop and a further 4% suggesting that there was no summing at all.

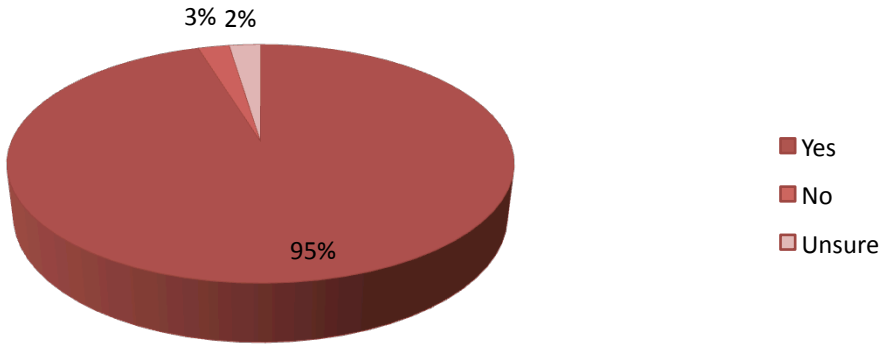
Question 13: *Overall, do you think the workshop was well run?*

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRIS	NEW
Yes	n=15	n=14	n=14	n=15	n=11	n=11
No	-	-	-	-	n=2	-
Unsure	-	-	-	-	n=2	-

Commentary
Better buffet would be better; poor food offering
Timing



Total Number of Surveyed Participants:
Do you think the workshop was well run?



DISCUSSION

A significant majority of 95% of respondents drawn from across six of the public dialogue workshops stated that the workshop was well run.

Question 14: *Overall, what was the best thing about the workshop?*

Knowledge, learning, education and opinions
Discussions on the table
Overall communication and participation
Group interaction
Having your say
Nice participants – polite
The main speaker was very clear in her explanation
It was thorough
Lively discussion
The videos and talking to the researchers
The presence of researchers for questioning
Talking to the ethics committee

The way 'X' was able to sum up what I was trying to say. I am not good at speaking
Talking to the committee and 'HCA'
Discussion in groups
Case studies
Information provided
Learning and being able to ask questions when unsure
Well organised, structured, gave me a clearer view of what research studies actually entail – the pros and cons, side-effects, and not knowing what's in the drugs you're taking
The way it was delivered - was very timely, systematic and organized
Having the opportunity to discover my views on a subject I wouldn't have normally considered
friendly atmosphere
Questions, feedback as went along, hearing others' point of view and breaking down each section all the different opinions and feedback
Being presented with opinions other than my own to think about
Heated discussions
Talking to health professionals
Expert guests- good insight; opportunity to discuss interesting issues
That the public took part
The people – everyone had different opinions and came from different backgrounds
Talking with the HRA representative and the researcher present
The experts and their insight
Educational aspect getting opportunity to discuss issues raised with others
Time for discussion
We were well informed/got enough information, we had opportunities to say and state what we thought, well timed
Meeting the Ipsos Mori team and sitting with different members and ages of the public
Learning new things, having debates about the matters discussed
The way the research is done

DISCUSSION

This text-based question returned a healthy response from surveyed participants as evidenced above. Responses, which reflected repetition on a theme, were for obvious reasons, redacted. Responses focused on the quality of the process, environmental conditions and personal impacts of the dialogue: an opportunity to speak and be heard; to be involved and 'included' in discussion with other lay-participants and specialists; exposure to the heterogeneity of public opinion; and the dialogue as a learning experience.

Question 15: *Overall, what was the worst thing about the workshop?*

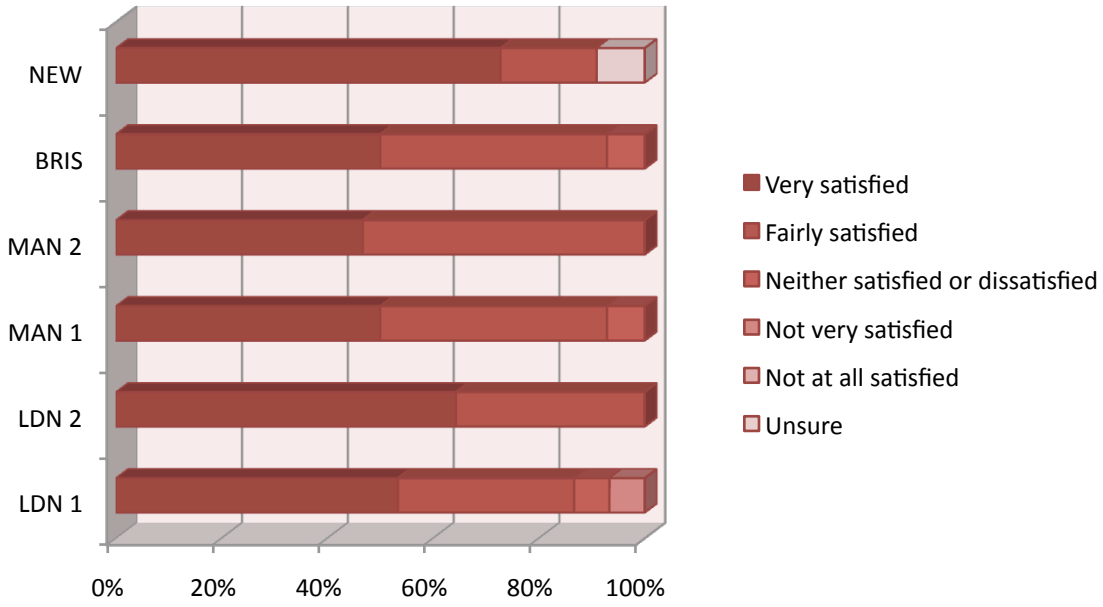
Room very hot – no cakes
Stale sandwiches
The food was not labelled – for vegetarians/non-vegetarians
Not enough time
I didn't think I had lot of free thinking, felt slightly judged of what I was saying
Power point presentations;
More time to complete the form
Short break
Maybe a longer workshop
Poorly facilitated – initial presentations were too long and poorly delivered
You could not hear some of what was being said because of the size of the room and the amount of People taking part i.e needed tables further apart
People over talking one another
There was no negativity on the workshop
Had to make decisions on things with insufficient information about how things worked

DISCUSSION

In comparison, to eliciting the *best* things about the workshop, far fewer responses were returned by surveyed participants, when asked what they considered to be the *worst* aspects of the dialogue workshop. Those that did focused on issues of time and the food. One other insight came from one respondent who commented on the lack of contestation regarding the proposed changes – or that the changes under proposal were depicted as inherently better than the existing system.

Question 16: *How satisfied were you with the workshop overall?*

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRIS 2	NEW
Very satisfied	n=8	n=9	n=7	n=7	n=7	n=8
Fairly satisfied	n=5	n=5	n=6	n=8	n=6	n=2
Neither satisfied or dissatisfied	n=1	-	n=1	-	n=1	-
Not very satisfied	n=1	-	-	-	-	-
Not at all satisfied	-	-	-	-	-	-
Unsure	-	-	-	-	-	n=1



DISCUSSION

95% of respondents from London (x2), Manchester (x2), Bristol and Newcastle workshops stated to be in some way satisfied with the workshop (*very*: 56%; fairly: 39%). Only one respondent from across these workshops, from the first London workshop, stated being not very satisfied with the workshop overall.

Question 17: *How do you think an event like this could be improved upon in the future?*

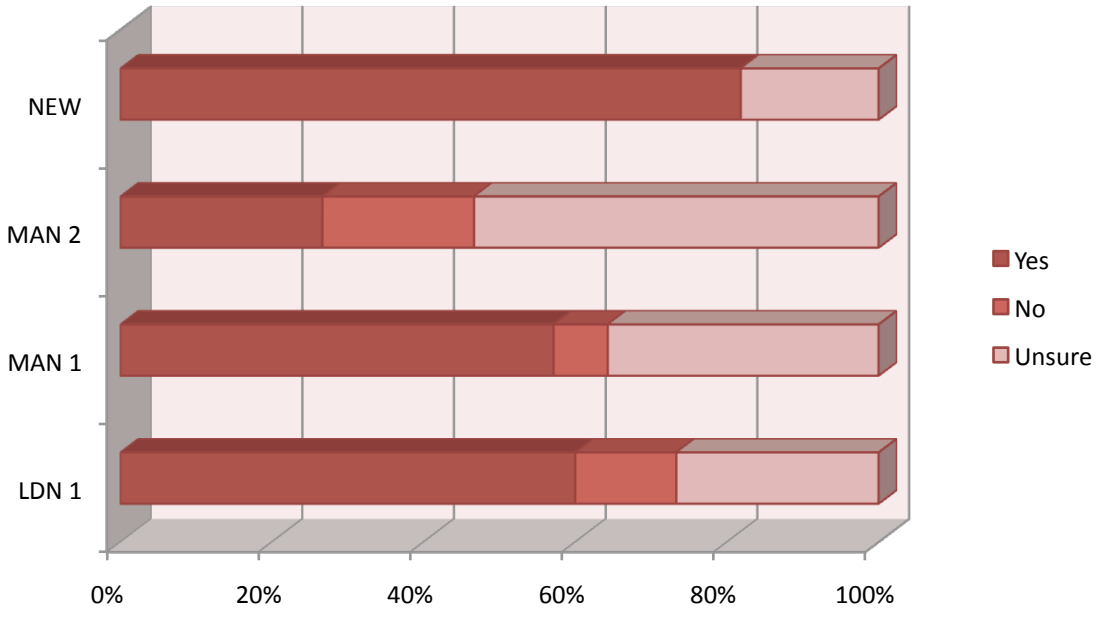
A little bit more organised
Sole interviews on some touchy subjects and then a group interview
By having a better incentive and better quality food
Have more women
Air conditioning
Food, venue
A well-advertised public community meeting open to anybody to take part and with more meetings running for a shorter duration
Maybe earlier starts to ensure more time to discuss matters in more depth; was a bit rushed
More professionals with the knowledge
Smaller break-out groups
Take a more diverse sample of respondents
Slightly shorter – not so late in the evening
More time, facilitators with better understanding of minor details and explanation of finer details. Also experts should feel more allowed to correct any objectively incorrect things/uses of terms
Q&A with researchers, previous and post-discussion – not during

DISCUSSION

Ideas for improving the dialogue workshop, suggested by respondents from across six of the sessions, focused on *structural* issues such as the length of the workshop, timing and size of groups, physical organisation of the workshop room/venue; *informational* issues such as the subject expertise, or lack thereof, of the facilitators; *relational* issues such as the precise role of experts and protocol for their interfacing/supporting participants; and *representational* issues such as the heterogeneity of participants recruited. As is often the case of exit-poll analysis of this variety, respondents also suggested that the food provided could be better.

Question 18: *Do you think this project is likely to have any influence on the HRA's approval process?*

	LDN 1	MAN 1	MAN 2	NEW
Yes	**n=9**	**n= 8**	**n=4**	**n=9**
No	**n=2**	**n=-1**	**n=3**	**-**
Unsure	**n=4**	**n=5**	**n=8**	**n=2**



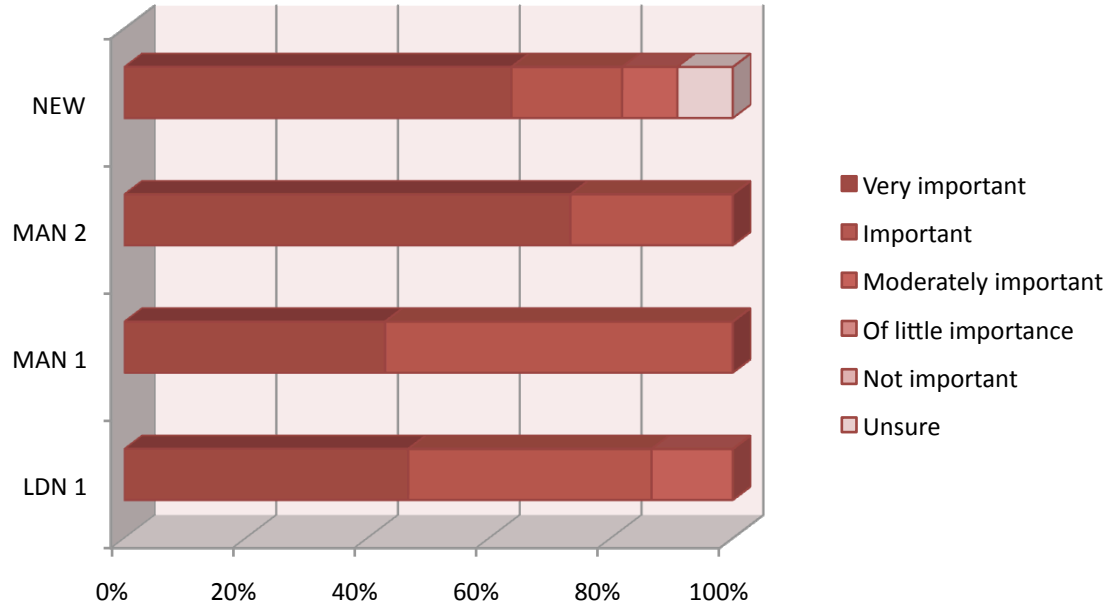
Comments
There were lots of good points
They told us it would
I would like to think it would
Because this was a diverse group of people so they should hopefully get a good mix of the publics' views
Lots of feedback
Not sure what they will take on board
The researcher seemed to not show that our view would make a difference. I thought it felt like an information meeting.
I think we are reaching similar conclusions to most similar groups
It will depend on what others have said. If it all contradicts each other
II would hope that the HRA can use our views and opinions to maybe improve their systems
Lots of issues were raised about the ethics committee and the NHS
Assuming the point of the focus group is to get information that can be used to better processes and help in decision-making
It would be foolish not to

DISCUSSION

Of the participants surveyed at the first London session, Manchester (x2) and Newcastle, a slim majority (55%) considered that the dialogue project would have an influence on the HRA's approval process. A further 35% expressed uncertainty, while 11% stated that they felt the project would have no influence on the approval process. In the second Manchester workshop, eight out of fifteen respondents answering this question, stated being doubtful of the project's influence on the HRA, with half of this number (n=4) stating that they felt the project would influence the HRA's approval process. The majority of additional comments made also suggested that participants were more hopeful than certain that the project would be influential, in these terms.

Question 19: *How important do you think events like these are in helping the HRA protect and advance the interests and welfare of patients and the public in health research?*

Location	LDN 1	MAN 1	MAN 2	NEW
Very important	**n=7**	**n=6**	**n=11**	**n=7**
Important	**n=6**	**n=8**	**n=4**	**n=2**
Moderately important	**n=2**	**-**	**-**	**n=1**
Of little importance	**-**	**-**	**-**	**-**
Not important	**-**	**-**	**-**	**-**
Unsure	**-**	**-**	**-**	**n=1**



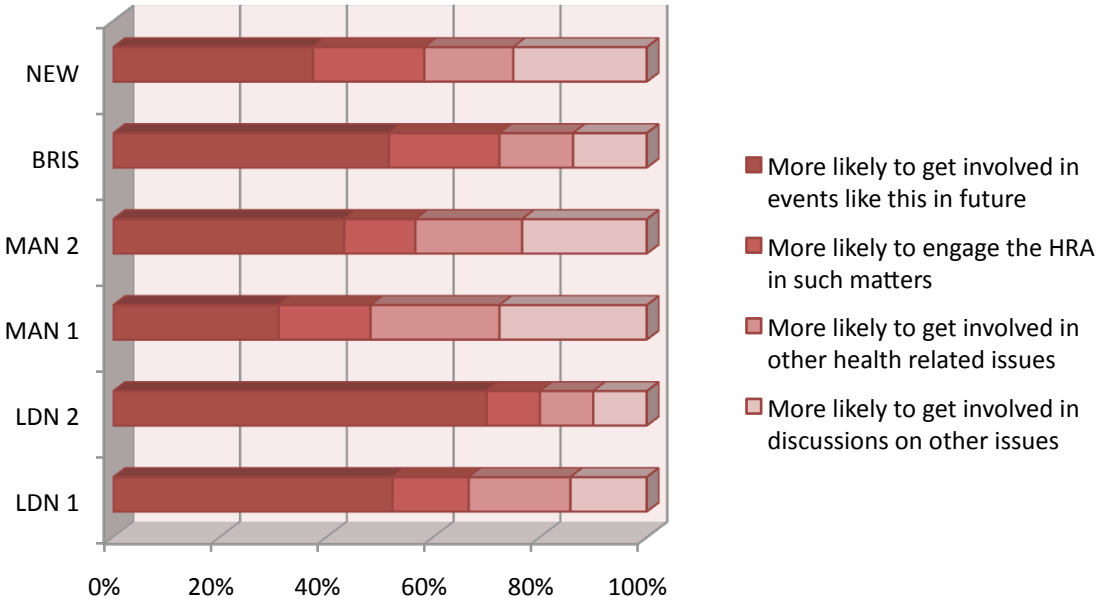
Commentary
I would like to see change in clinical trials
Peoples views matter
Because sometimes you hear things and jump to the wrong conclusion but when you have it explained to you it completely changes your views
Giving members of the public the opportunity to express their views
Clears common misconceptions
In order to understand what most people think
Hearing everyones view gives a wider perspective and understanding
To gain other peoples' honest opinion
Anything that can help our future health is important
May have some impact on how trials are run
Very important as the public should be able to have their say
It's always good to stay up to date with public opinion and get a fresh perspective
Because the publics' views are important and give an unbiased view
The general public have a right to know who the HRA are and what their role is

DISCUSSION

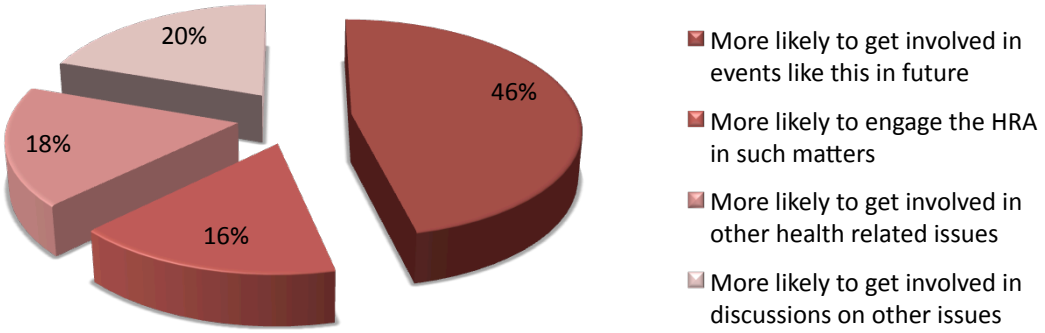
Respondents at London, Manchester (x2) and Newcastle, were largely unanimous in declaring that interventions of this sort were necessary in helping the HRA protect and advance the interests and welfare of patients and the public in health research. Of 55 survey responses to this question, only one respondent stated being unsure of the importance of interventions, like the project, in safeguarding patient interests and welfare in health research. The remaining 54 responses revealed that surveyed participants at London, Manchester (x2), and Newcastle were in some way convinced of the importance of intervention: 54% stating intervention was *very important*, 36% stating intervention was *important*, and 5% stating intervention was *moderately important*. Respondents rationalised the importance of the workshop according to a need for transparency; democratic governance; and scientific enrichment and safeguarding through public involvement.

Question 20: *Has your experience of taking part in the project, resulted in any of the following impacts on you personally?* (Put a cross in as many boxes as are relevant to you, or leave all the boxes blank)

Location	LDN 1	LDN 2	MAN 1	MAN 2	BRIS	NEW
I am more likely to get involved in events like this in future	n=11	n=14	n=9	n=13	n=15	n=9
I am more likely to engage the HRA in such matters	n=3	n=2	n=5	n=4	n=6	n=5
I am more likely to get involved in other health related issues	n=4	n=2	n=7	n=6	n=4	n=4
I am more likely to get involved in discussions on other issues	n=3	n=2	n=8	n=7	n=4	n=6



Total number of surveyed participants:
Personal impact from dialogue workshop



DISCUSSION

In the final question of the workshop exit-poll, respondents were asked to reflect on personal impacts derived from the workshop experience. Participants from across London (x2), Manchester (x2), Bristol and Newcastle were asked to consider whether they would be:

- More likely to get involved in events like this in future (46%)
- More likely to engage the HRA in such matters (16%)
- More likely to get involved in other health related issues (18%)
- More likely to get involved in discussions on other issues (20%)

In response, 71 respondents stated that they would as a result of the workshop experience be *more likely to get involved in similar events in the future*; 25 stated that they would be *more likely to engage the HRA in such matters*; 27 stated they would be *more likely to get involved in other health related issues*; while 30 stated that would be *more likely to get involved in discussions on other issues*. Evidently, (in the context of these impact categories) the greatest personal impact derived by respondents from the workshop experience was their increased openness to be involved in other public engagement/dialogue based activity.

Conclusion

From the participant perspective the public dialogue workshops were a success. Respondents reported benefits and impacts from the workshop such as new learning/knowledge and a greater likelihood of future participation in engagement, deliberation and consultative events. Respondents also registered a belief that the workshops had been well run and that findings would likely be influential to the HRA's strategy for research approval. Dialogue events were posited as important aspects in the helping the HRA protect and promote public and patient interests in healthcare research. Finally, respondents stated to have had sufficient time with which to discuss all that was needed to be covered; had been provided an opportunity to have their say; had to some degree had their views changed by the dialogue and were largely satisfied with the overall workshop experience.

4. *Patient* Dialogue Workshops: Exit-Poll Analysis

Overview

This chapter considers the exit-poll data gathered through the administering of an exit-poll questionnaire by the evaluation team at three of the eight patient dialogue workshops. Exit-poll results reflect respondent impressions from workshops conducted with mental health patients in Birmingham, patients suffering from Parkinson's Disease (London); and Diabetes patients (also London). Each of these workshops was also attended and observed by the evaluation team, with a full observational account provided in Chapter 5.

At the end of each of the three dialogue workshops attended by the evaluators, patient participants, exactly as their public counterparts, were asked to complete an evaluation questionnaire which asked for their honest reflections on the workshop experience. The questionnaire for patient participants was largely the same as that provided for public participants, with some minor alterations to reflect the different participants in the group. Questions were focused on eliciting from participants their thoughts on: how well organised, structured and facilitated the workshop had been: what they identified as its strengths and weaknesses; what they had gained from the workshop, such as in the way of any new learning; what they would recommend changing in re-running and improving the workshop; and what they considered the impacts of the workshop would be to the sponsor and themselves as prospective/future participants of other public dialogue exercises.

Headline Findings

- A clear majority (87%) of respondents stated that information sent prior to the workshop made it clear what it would be about and made it clear why they had been invited.
- A clear majority (75%) of respondents stated that the aims of the workshop and the overall process of which the workshop was a part of had been made clear.
- A clear majority (92%) of respondents stated that the participants selected for the workshop had been appropriate.
- 54% of respondents stated saying that they had been able to say *all* of what they had wanted to say. 38% stated having been able to say *most* of what they had wanted to say.
- A majority (71%) stated that there was sufficient time to discuss all that needed to be covered.
- 54% of respondents stated learning a *lot* of new things.
- 54% of respondents stated that the dialogue had changed their views *a bit*.
- 54% of respondents stated that final summing-up accurately reflected what was discussed at the workshops.
- A clear majority (87%)of respondents stated the workshop was well run.
- Respondents stated that some of the best things about the workshop were: an opportunity to be involved, to listen and to be heard.
- Respondents stated that some of the worst things about the workshop were: the dominance of other workshop participants and the size and lay-out of the workshop room space.
- A clear majority (92%) of respondents stated being satisfied with the workshop experience.
- Respondents' ideas for improving the workshop focused on: time and space management and bigger group numbers.

- A clear majority (75%) of respondents stated believing that the project would influence the HRA's approval process.
- 100% of respondents confirmed the importance of dialogue events in helping the HRA protect and advance the interests and welfare of patients and the public in health research.
- Like their public counterparts, patient respondents stated that the project experience had increased the potential of their being *more likely to get involved in events like this in future*; *more likely to engage the HRA in such matters*; *more likely to get involved in other health related issues*; and *more likely to get involved in discussions on other issues*.

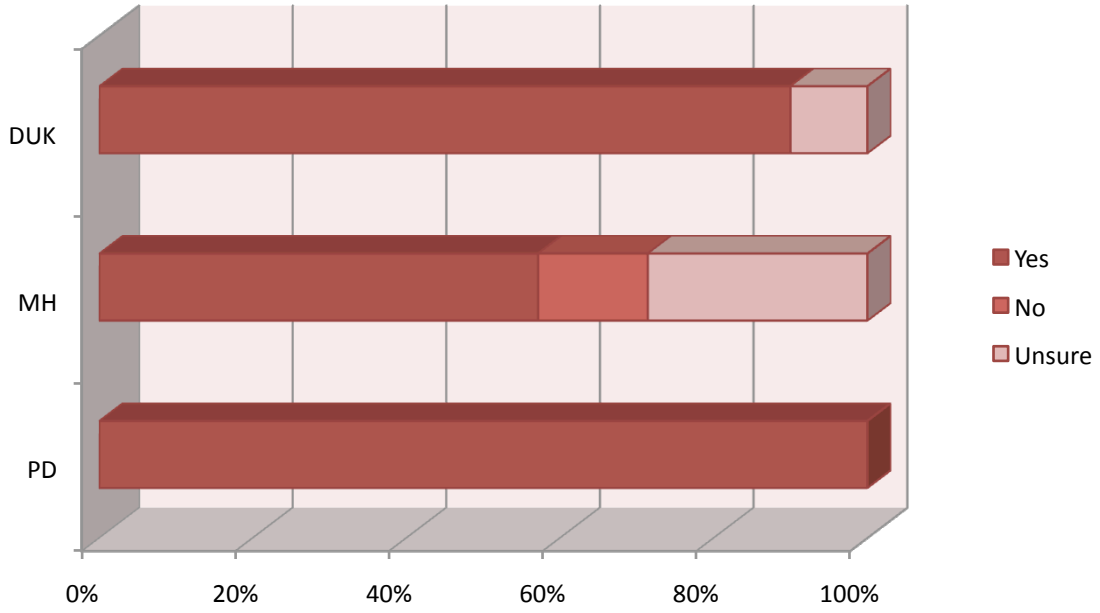
Analysis

NOTE: In the accounts below: PD is used to reflect the *Parkinson's Disease* Patient Workshop; MH is used to reflect the *Mental Health* Patient Workshop; and DUK is used to reflect the Diabetes Patient Workshop.

Question 1: *Was it clear from the information you were sent before the workshop what it would be about?*

N= number of responses to question; % calculated to nearest decimal point

Group	PD	MH	DUK
Yes	n= 7	n=4	n=9
No	-	n=1	n=
Unsure	-	n=2	n=1

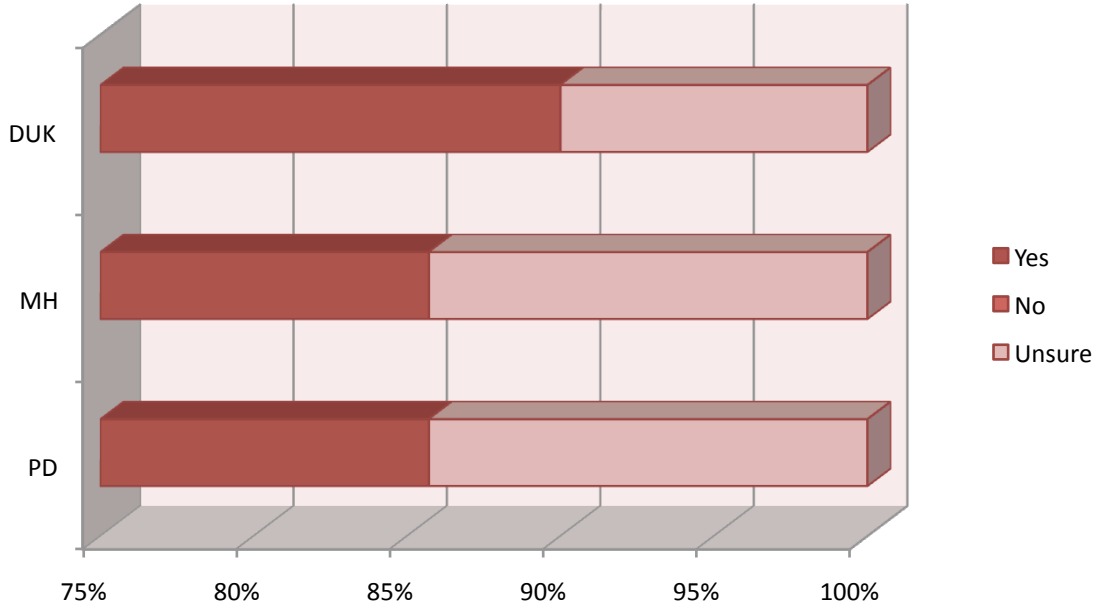


DISCUSSION

The vast majority or 87% of patient respondents from across the three patient workshops surveyed stated that information sent prior to the workshop had made it clear what it would be about. Only one person felt this was not clear.

Question 2: *Was it clear to you from the information you were sent prior to the workshop why you were invited?*

Group	PD	MH	DUK
Yes	n=6	n=6	n=9
No	-	-	-
Unsure	n= 1	n= 1	n=1

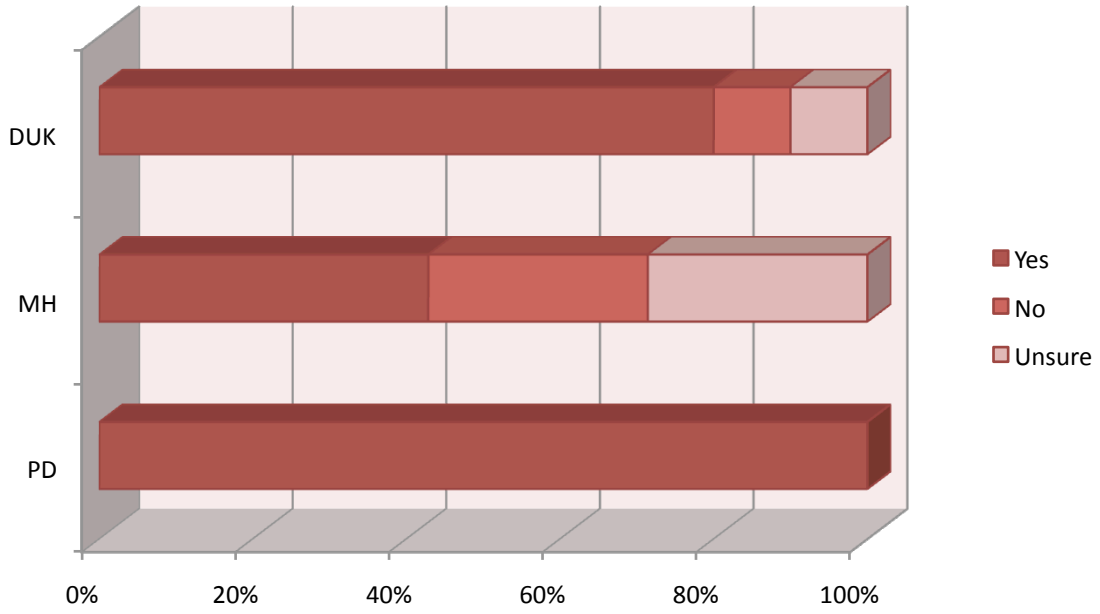


DISCUSSION

The vast majority of respondents (87%) from across the workshops also stated information sent prior to the workshop had made it clear why they had been invited. No-one thought it was not clear.

Question 3: *Were the aims of the workshop, and the whole process of which the workshop is a part of, clearly explained from the outset?*

Group	PD	MH	DUK
Yes	n= 7	n=3	n=8
No	-	n=2	n=1
Unsure	-	n=2	n=1

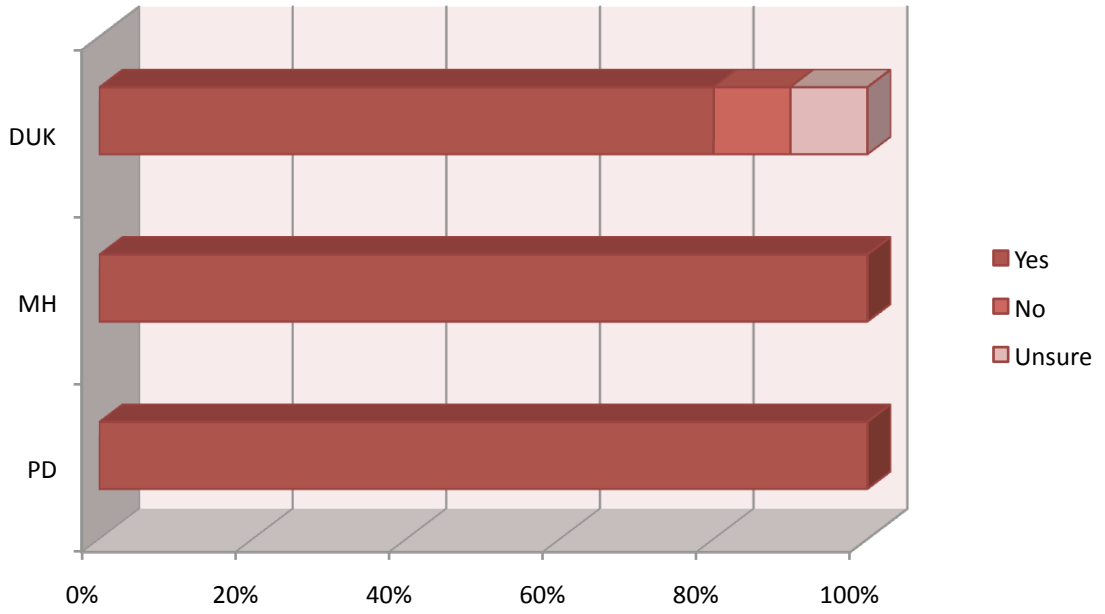


DISCUSSION

75% of respondents stated that the aims of the workshop and the whole process of which it was a part of, had been clear at the start. 12.5% of respondents across the workshops stated that the aims and overall process of the workshop had not been made clear. A similar 12.5% of surveyed respondents were unsure.

Question 4: *Do you think the participants involved were appropriate for the workshop?*

Group	PD	MH	DUK
Yes	**n=7**	**n=7**	**n=8**
No	-	-	**n=1**
Unsure	-	-	**n=1**



DISCUSSION

The overall majority of respondents (92%) stated that they believed that the participants selected for the workshop had been appropriate. There was complete consensus on this view in both the Mental Health and Parkinson's Disease workshops.

Question 5: *Who do you think was missing from the event, if anyone?*

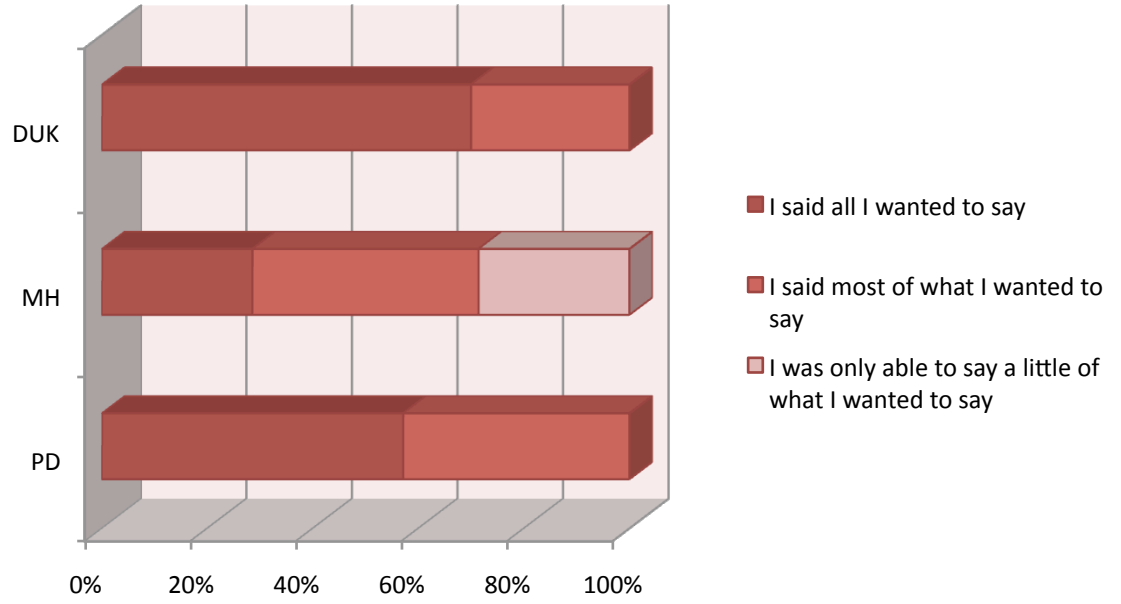
PD
▪ *Other stakeholders* ▪ *Researchers* ▪ *Charities* ▪ *Pharma* ▪ *Regulators*
MH
▪ *People from minority, ethnic backgrounds* ▪ *Mental health service-user focus – would have helped to have other impairments included* ▪ *Less academic research participants – service users*
DUK
▪ *Young people* ▪ *Non-white patients* ▪ *Doctor or consultant*

DISCUSSION

Respondents made suggestions, in reference to who was potentially missing, of a broader demographic including youth and BME populations. They also pointed to the need to include other kinds of stakeholder groups such as pharmaceuticals and medical practitioners

Question 6: *During the workshop, did you have the opportunity to have your say?*

Group	PD	MH	DUK
I said all I wanted to say	n=4	n=2	n=7
I said most of what I wanted to say	n=3	n=3	n=3
I was only able to say a little of what I wanted to say	-	n=2	-
I didn't get a chance to say anything	-	-	-

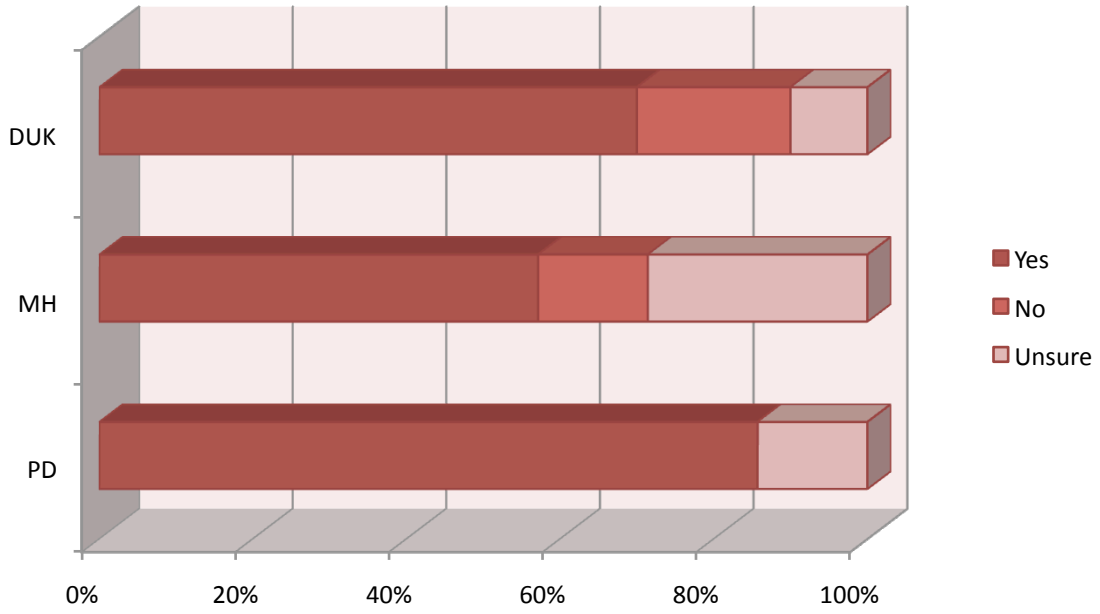


DISCUSSION

The majority of respondents stated that they were able to say either *all* (54%) or *most* (38%) of what they wanted to say. Two out of twenty four respondents claimed that they had only been able to say little of what they had wanted to say.

Question 7: *Was there sufficient time in the workshop to discuss all that needed to be covered?*

Group	PD	MH	DUK
Yes	n=6	n=4	n=7
No	-	n=1	n=2
Unsure	n=1	n=2	n=1



DISCUSSION

While 71% of respondents stated that there was sufficient time in the workshop to discuss all that was needed to cover, 12% stated that there was not and 17% were unsure.

Question 8: *Do you think there were any important issues that were NOT discussed in the workshop, but which should have been? What were these?*

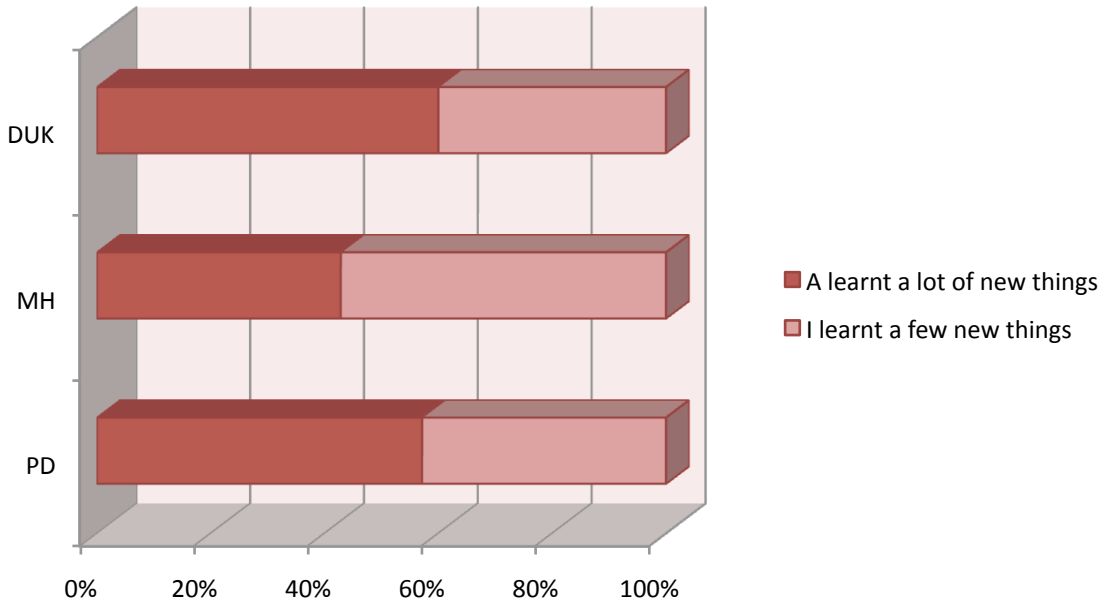
PD
▪ *Researchers considering where they do the researcher – needs to be closer to patients' home/surgery/hospital*
MH
▪ *I would have liked more discussion of the role of ethics committees and HRA in promoting follow-up research, particularly on pharmaceutical products to establish long terms issues that are not noted in the original research*
▪ *Discussion on what constitutes meaningful patient involvement in research*
▪ *More legal and philosophical debate about need for ethics*
DUK
▪ *Diet research including questioning 'received wisdom'*
▪ *Genetic aspect of research*

DISCUSSION

In considering important issues that had not been covered in the workshop, surveyed participants identified aspects of research and research approval process and specific research thematics (see above).

Question 9: *Did you learn anything new from the workshop?*

Group	PD	MH	DUK
I learnt a lot of new things:	n=4	n=3	n=6
I learnt a few new things:	n=3	n=4	n=4
I'm not sure I learnt anything new	-	-	-
No I didn't learn anything new	-	-	-

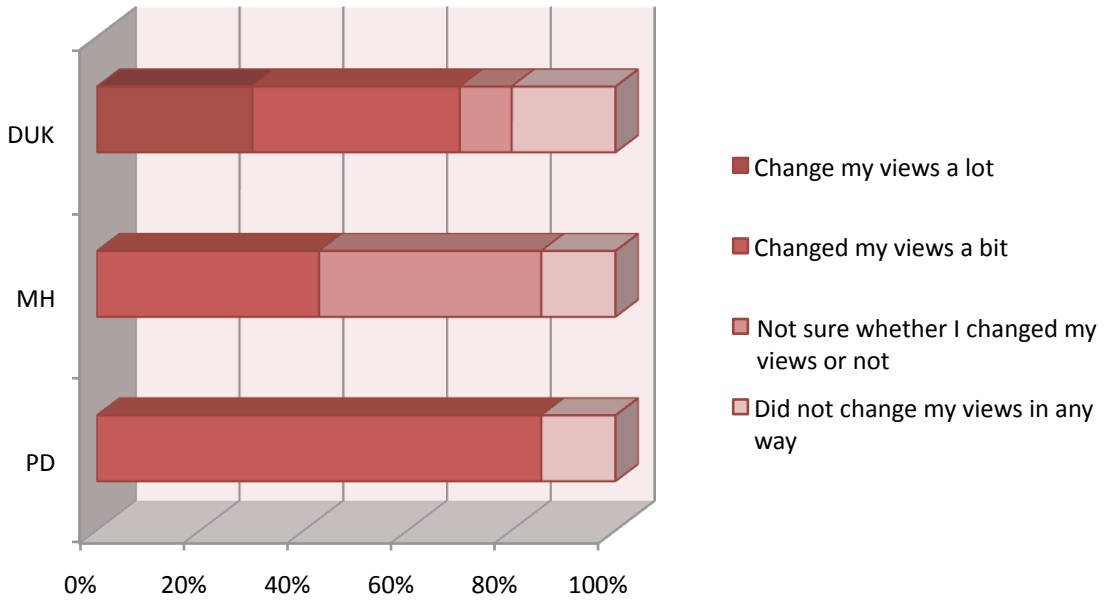


DISCUSSION

Respondents stated having learnt either a lot (54%) of new things or a few (46%) new things, suggesting that overall, all three workshops had a strong educative dimension.

Question 10: *Did taking part in the workshop change your views on the issues in any way?*

Group	PD	MH	DUK
Yes, I changed my views a lot	-	-	n=3
Yes, I changed my views a bit	n=6	n=3	n=4
I'm not sure whether I changed my views or not	-	n=3	n=1
No, I did not change my views in any way	n=1	n=1	n=2



DISCUSSION

A small majority (54%) of respondents across the workshops stated that the dialogue experience had changed their views *a bit*. A further 17% of surveyed participants were unsure whether the experience had changed their views or not, or stated that the workshop had not caused to changed their views in any way.

Question 11: *What information (from speakers, from written material, from other participants etc.) made the greatest impression on your views?*

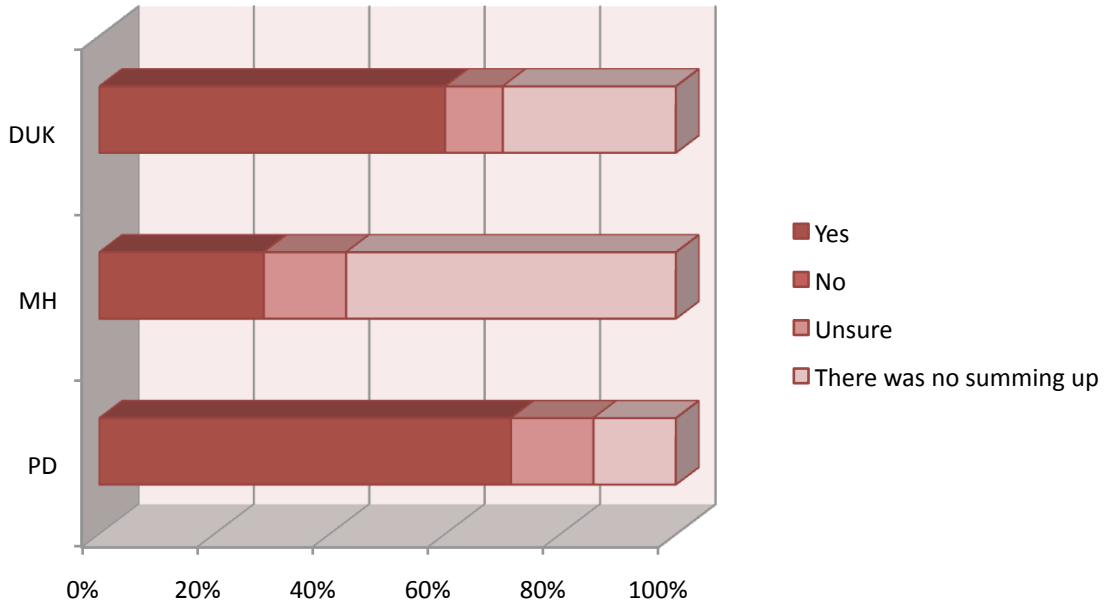
PD
▪ *What HRA is* ▪ *A good presentation in general* ▪ *General view that patients not involved enough in proposals for research*
MH
▪ *Examples from real life research helpfully expanded in points raised* ▪ *General details of NRES process* ▪ *Information about details of ethical approval process* ▪ *The slides were brilliant* ▪ *Understanding the problems of getting approval from all separate NHS sits – also recognising that all research May not be relevant for publication*
DUK
▪ *The basics of research* ▪ *How research currently works, the current issues and hopes for improvements* ▪ *Impact of other participants rather than leaders* ▪ *Hearing from researchers* ▪ *The importance and role of PPI in research* ▪ *HRA and demise of R&D* ▪ *The whole to and fro discussions made an impression – it was interesting to hear views and see the visual information – good to have both*

DISCUSSION

Respondents were largely complimentary in their characterisation of the dialogue process and the opportunity to speak with and learn from other stakeholders – especially researchers. They also commented on information relating to the research and research ethics/approval process making a significant impression.

Question 12: *Do you think final summing-up accurately reflected what was discussed at the workshop?*

Group	PD	MH	DUK
Yes	**n=5**	**n=2**	**n=6**
No	-	-	
Unsure	**n=1**	**n=1**	**n=1**
There was no summing up	**n=1**	**n=4**	**n=3**



DISCUSSION

54% of all respondents from across the patient workshops stated that final summing-up undertaken accurately reflected what was discussed at the workshop. However 33% of surveyed participants stated that there had been no summing-up. This was especially so for the Mental Health patient workshop where four of the seven surveyed participants responding to this question stated that no summing-up had occurred.

Question 13: *Overall, do you think the workshop was well run?*

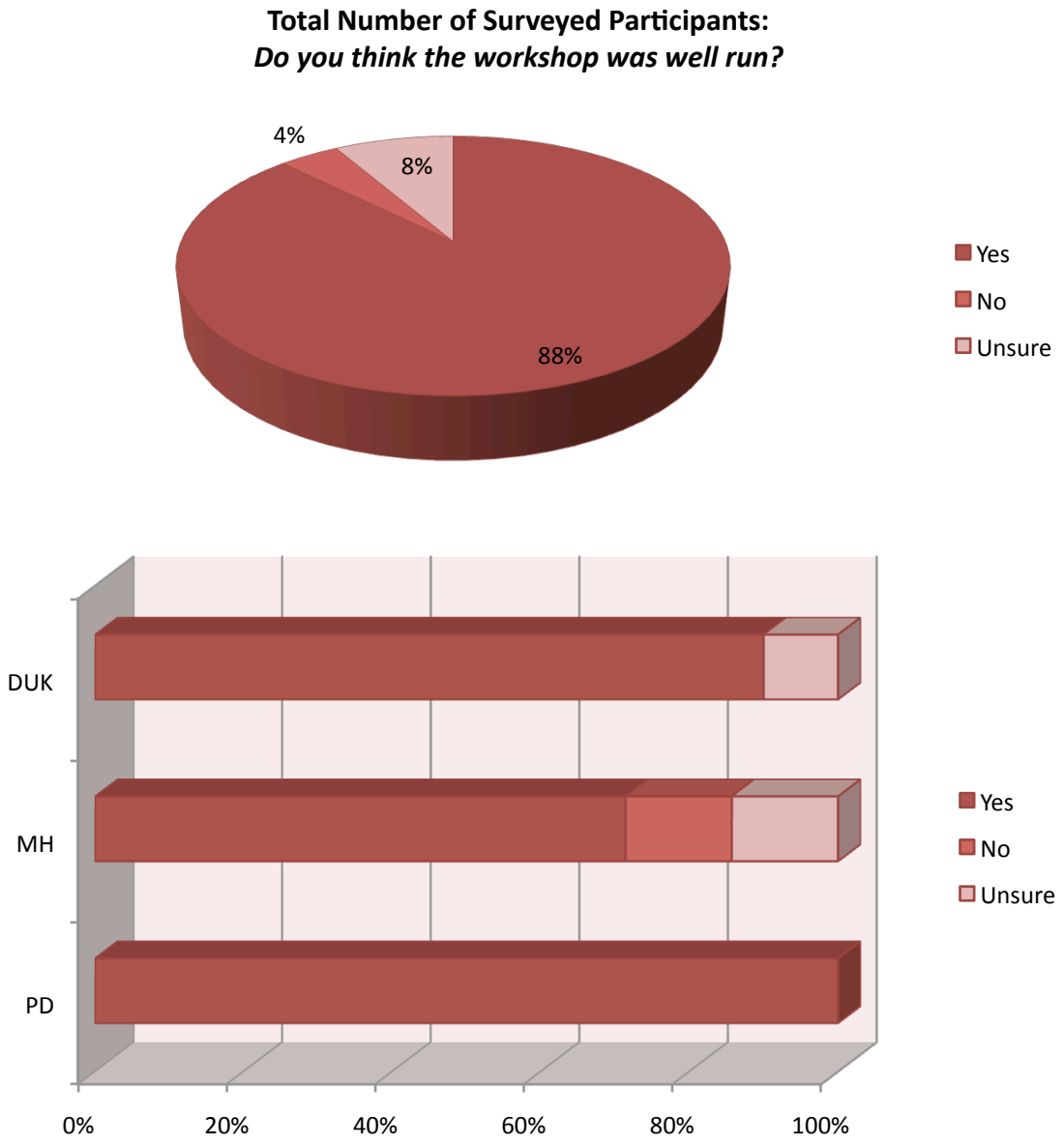
Group	PD	MH	DUK
Yes	n=7	n=5	n=9
No	-	n=1	-
Unsure	-	n=1	n=1

Comments

There were no ground rules – some people dominated, one person said nothing at all and people continually talked over each other

It was always the same people talking – little opportunity to explore opposing views

Could have benefitted from separate and stronger chairing



DISCUSSION

The vast majority (87%) of respondents from across the workshops stated that the workshop was well run. Only one from a total of 24 surveyed participants responding to this question stated that the workshop was not well run. Despite a general consensus that the workshops were successfully

co-ordinated, some reference was made by respondents to a need for stronger facilitation and/or chairing. Criticism of the dialogue moderation from respondents, however, appears isolated and one-off, and as transpires in the findings of Question 14, negated where other respondents identify the moderation/chairing as one of the strengths of the workshop process.

Question 14: *Overall, what was the best thing about the workshop?*

PD

- *To promote patient involvement in research process*
- *Listening to others peoples' experiences and see participants had their say – no one was subdued or failed to make a point*
- *Opportunity to feel that some changes would be made that would reflect patient involvement in research proposals for the future*
- *Different opinions*
- *Having the opportunity to have some input*
- *Information on HRA*
- *Our views were listened to*

MH

- *Venue, hospitality, slides, leaflet on research sent through the post*
- *Being consulted*
- *The lunch*
- *Just getting to talk about this stuff – it was clear, well-structured and appropriate for the people attending sharing views*
- *Having a discussion about the ethics approval process*

DUK

- *Sense of helping to change things for the better*
- *Hearing different viewpoints*
- *Enthusiasm to make changes for all-round improvements*
- *The structure and the engagement of everybody by the careful chairing*
- *Acquiring a better understanding of the HRA's role*
- *Participation of all the group*
- *Having the opportunity to be involved*
- *Understanding the background of research and the ethics to accompany it*

DISCUSSION

Respondents opined that the engagement process itself was among the most positive aspects of the workshop: as an opportunity to be involved, to listen and be heard.

Question 15: *Overall, what was the worst thing about the workshop?*

PD

- *Couldn't understand all the questions*
- *Room very restrictive – difficult for people with disability*
- *Noise from road*

MH

- *Needed more time for complicated subject*
- *The facilitation*
- *Listening to the same people get on their soap-boxes*
- *I found it difficult to break into voice my thoughts*
- *Not enough time*

DUK

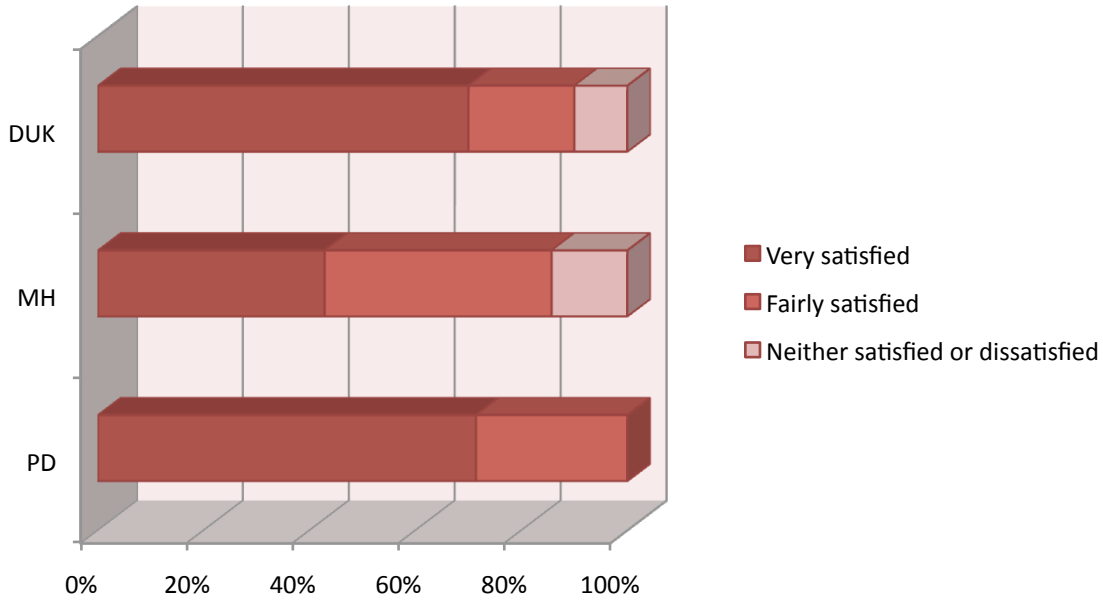
- *Not sure that all people were aware of the focus of the meeting*

DISCUSSION

Respondents pointed to a few *structural* deficiencies impeding the dialogue such as the size and lay-out of the workshop room; and *social/interactional* issues such as the dominance of other workshop participants.

Question 16: *How satisfied were you with the workshop overall?*

Group	PD	MH	DUK	TOTAL
Very satisfied	n=5	n=3	n=7	n=15
Fairly satisfied	n=2	n=3	n=2	n=7
Neither satisfied or dissatisfied	-	n=1	n=1	n=2
Not very satisfied	-	-	-	-
Not at all satisfied	-	-	-	-
Unsure	-	-	-	-



DISCUSSION

The vast majority of respondents (92%) from across the workshops stated being satisfied with their overall workshop experience: 63% stated being *very* satisfied and 29% *fairly* satisfied.

Question 17: *How do you think an event like this could be improved upon in the future?*

PD

- *Public discussion and resources reaching out to other stakeholders*
- *More participants*
- *Better venue*

MH

- *Better facilitation, ground rules, control and inclusion: I wasn't sure what the purpose of the workshop was and I received venue and date details at the last minute, a semi-circular table would have been more conducive to discussion and post-it exercises would have gathered views more inclusively*

DUK

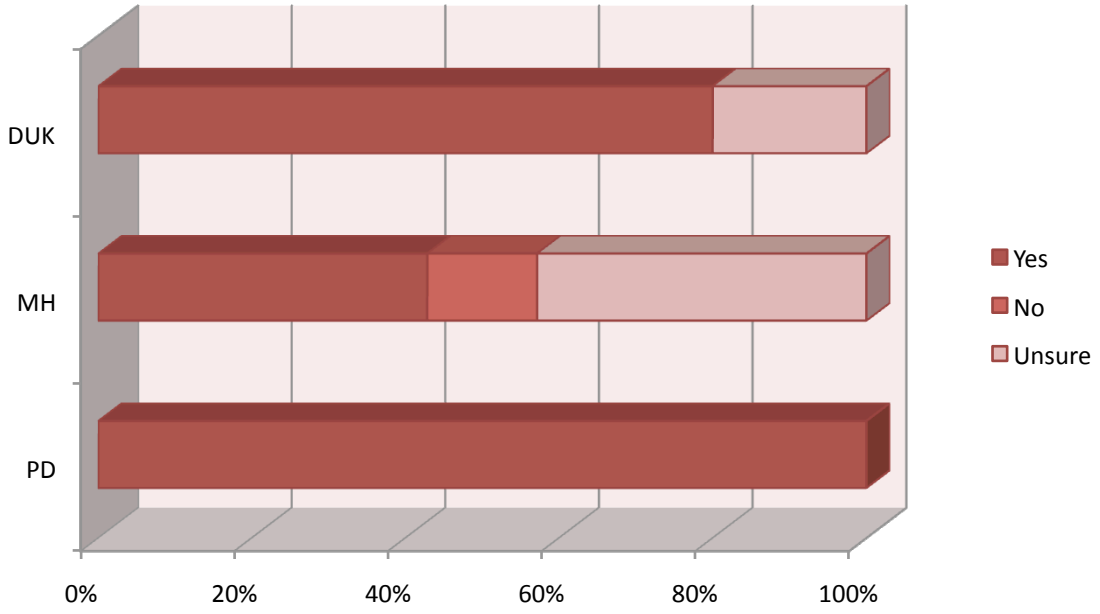
- *Ensure that all invitees are fully aware of what the meeting is for*
- *A little more space*
- *Held more often*
- *A longer time – a full day*

DISCUSSION

Respondents pointed towards improvements in time management, space selection and management; better signposting; and a larger number of participants as key aspects for follow-up/future workshops.

Question 18: *Do you think this project is likely to have any influence on the HRA's approval process?*

Group	PD	MH	DUK	TOTAL
Yes	n=7	n= 3	n=8	n=18
No	-	n=1	-	n=1
Unsure	-	n=3	n=2	n=5



Comments

Our views were listened to

It was clear that they must LISTEN an act if possible

I hope so but am not sure how receptive they will be to feedback from this meeting

A lot of good suggestions were made

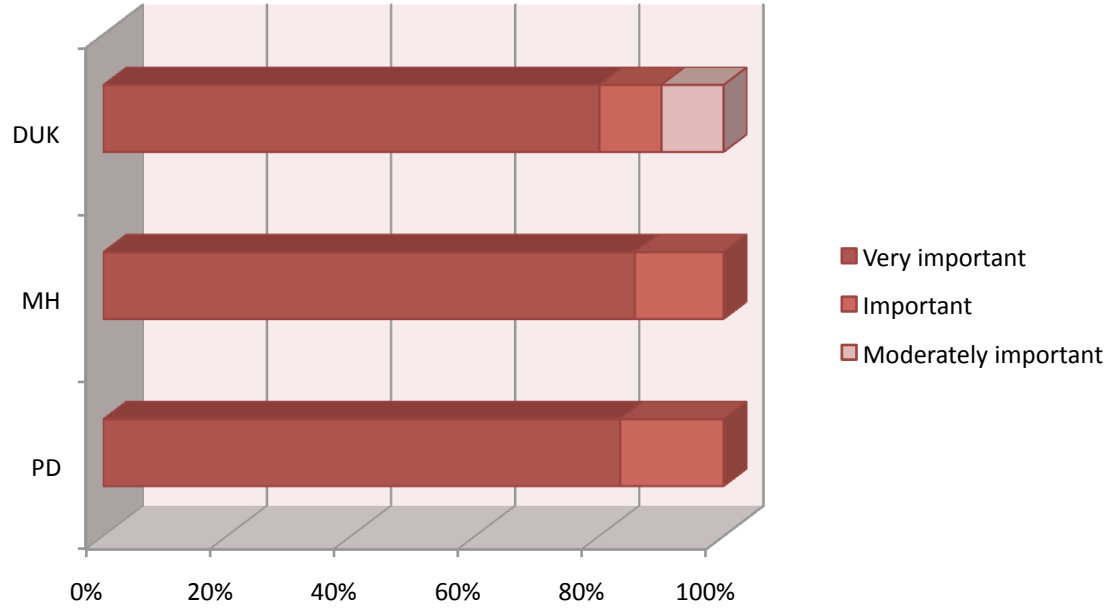
I believe it will represent PPI involvement in clinical trials and research
A wide consensus of views and careful recording of views
I think original information was raised and appeared to be welcomed
I hope so! I am not yet fully confident that service-user views are listened to
I don't know whether the event was tokenistic or not

DISCUSSION

A clear majority of respondents (75%) from across the workshops stated that they believed the project would bear influence on the HRA's approval process. Concurrently, 21% of all surveyed participants responding to this question stated being unsure, while one of the 24 responding participants felt that there would be zero influence from the project on approval processes.

Question 19: *How important do you think events like these are in helping the HRA protect and advance the interests and welfare of patients and the public in health research?*

Group	PD	MH	DUK	TOTAL
Very important	**n=6**	**n=6**	**n=8**	**n=20**
Important	**n=1**	**n=1**	**n=1**	**n=3**
Moderately important	-	-	**n=1**	**n=1**
Of little importance	-	-	-	-
Not important	-	-	-	-
Unsure	-	-	-	-



Comments

Vitally important that service-users are involved in decisions and changes
Health research involves patients and patients need a voice
I think it is very important to use every opportunity to get our views across and bring us into the process
It is about us that's why – nothing about us without us
Need for more volunteers in clinical trials
Changes are needed
We need more research

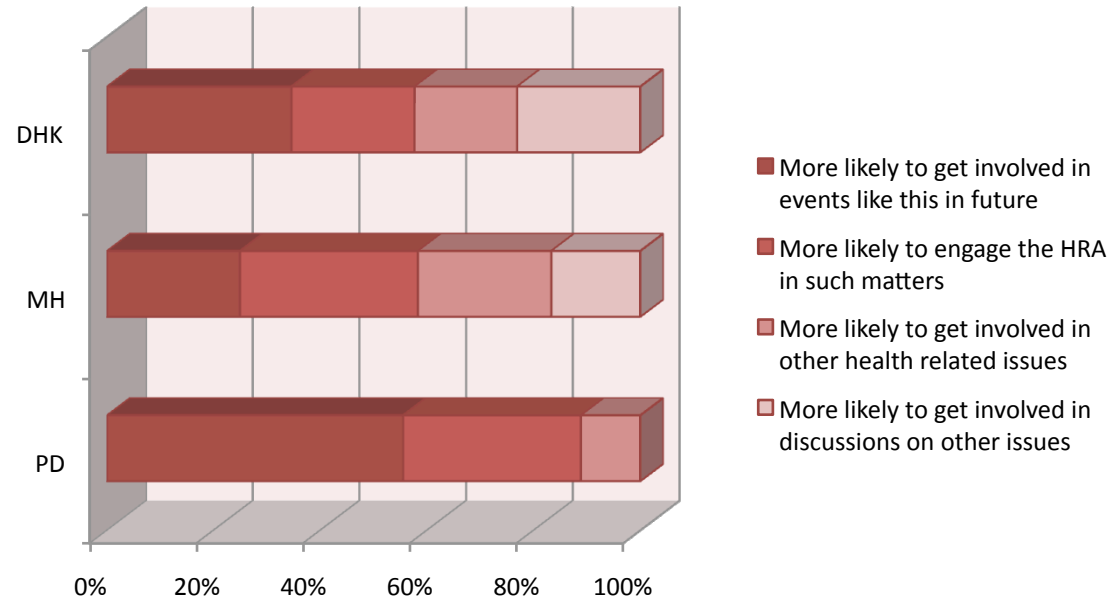
Such research will help us to channel research in a positive direction
It is very important that there should be PPI involvement at all stages when appropriate
By giving the assurance that patients taking part in various research are protected
It is very important to participate in research as a professional person who is a patient of diabetes
Diabetes is big and getting bigger – costs to the NHS etc. – More research is vital and wider range of patient participation

DISCUSSION

100% of respondents from across the workshops confirmed the importance of dialogue events in helping the HRA protect and advance the interests and welfare of patients and the public in health research. Of these, 83% stated that dialogue events are *very important*, 13% stated *important* and 4% stated *moderately important*. PPE activity, as evidenced in the quotes above, is therefore seen as integral to safeguarding and promoting patient interests in health research.

Question 20: *Has your experience of taking part in the project, resulted in any of the following impacts on you personally?* (Put a cross in as many boxes as are relevant to you, or leave all the boxes blank)

Group	PD	MH	DUK	TOTAL
I am more likely to get involved in events like this in future	**n=5**	**n=3**	**n=9**	**n=17**
I am more likely to engage the HRA in such matters	**n=3**	**n=4**	**n=6**	**n=13**
I am more likely to get involved in other health related issues	**n=1**	**n=3**	**n=5**	**n=9**
I am more likely to get involved in discussions on other issues	**-**	**n=2**	**n=6**	**n=8**



DISCUSSION

This question provided a mixture of answers in so much as in the MH and PD workshops, respondents selected only one impact in their response, whereas in the DHK workshop, respondents selected multiple impact options. Nonetheless, we are able to evidence a variety of personal impacts gained by respondents as a consequence of their dialogue experience. The number one impact identified by respondents related to their new enthusiasm for participation in future/prospective dialogue events. Furthermore, 54% of respondents from across the patient workshops claimed that their workshop experience had resulted in a greater likelihood for future engagement with the HRA.

Conclusion

From the patient perspective the patient dialogue workshops, much like their public equivalent were a success: results are near analogous. Respondents reported benefits and impacts from the workshop such as new learning/knowledge and a greater likelihood of future participation in engagement, deliberation and consultative events. Respondents also registered a belief that the workshops had been well run and that findings would likely be influential to the HRA's strategy for research approval. Dialogue events were posited as important aspects in the helping the HRA protect and promote public and patient interests in healthcare research. Finally, respondents said they had sufficient time in which to discuss all that was needed to be covered; had been provided with an opportunity to have their say; had, though to a lesser extent than their 'public' counterparts, changed their views as a result of the dialogue and were very satisfied with the overall workshop experience.

5. Public and Patient Workshops: Ethnographic Observations

Overview

This chapter records our ethnographic observations of eight of the project's dialogue workshops – those which we attended and observed: four of the public events in Bristol, London, and Manchester, and four of the patient events in Birmingham and London.

The public events were organised into two cumulative sessions, one building on the other. Workshop one operated on an instructional level, providing participants with an informational foundation enabling confident and meaningful discussion and 'informed' deliberation, which would be the focus of the second workshop.

In workshop #1 participants were provided a 'crash-course' in clinical research (the variety of health research, the stages of clinical trials, the use of a 'placebo' or control group) and ideas of research governance. The second session, reconvened a week later with the same participants, concentrated on a discussion of the changes to the research governance proposed by the HRA, drawing on first-hand accounts from clinical researchers.

The 'expert' input at the first round of public events was provided by the HRA, although the instructional responsibility was largely left to the facilitators who provided extensive information on both the nature of clinical research and the structure of research governance frameworks, with the HRA answering questions when required. The second round of public events were mostly attended by three senior researchers who provided expert input.

The patient events were single session workshops, with participants recruited by appropriate patient organisations. The number and nature of 'expert' contributions to these patient workshops varied widely, from no clinical researchers (the workshop involving patients with lung disease), to a workshop in which the contribution of expert participants was significant (the workshop involving patients with diabetes).

Public Workshop #1

At the first session, as the participants sat down, but before any real introduction, they were invited to complete a simple quiz. The facilitators stressed that the quiz was light-hearted. It contained questions such as who cannot take part in a clinical trial, to which the answer was The Doctor [Who]: not being human. The quiz prompted some discussion; all the groups expressed surprise, for example, at the fact that children could take part in clinical trials.

The facilitators introduced the workshops by saying that 'we want to have a discussion about health studies and health research' (Bristol). A rough outline of the two sessions was laid out, and the event was clearly set up as being deliberative – 'we're here to answer specific questions' (London) – with the facilitators stating that they wanted to identify and explore participants' ideas and for recommendations for future regulations. The facilitators stressed that the workshop was 'not about loads of knowledge, but using common sense' (Bristol) and that the topic was 'a subject not many people know about […] we're not expecting you to be experts' (London).

The facilitators stressed that clinical trials are relevant to all if not most people. Unsurprisingly therefore a focus on clinical trials, over other forms of health research, provided the mainstay of discussion. The facilitators laid the ground for equal, collective participation in the discussion; emphasised that participants' expression of views and attitudes would be subject to anonymity; encouraged the asking of questions and participants' consideration and sensitivity to their quieter counterparts.

The workshop *proper*, began with an introduction to the clinical trial process presented by the facilitators. This set the scene for the discussions by explaining the role of the HRA as having been set up to streamline and simplify the research approval process, and that the dialogue was to debate the implications of these changes with the public. The facilitators said, 'we need your help' in trying to 'balance the scales' (a metaphor reinforced by an image during the presentation) between 'red tape' and safety. The idea that regulation was 'red tape' – a particularly negative term – was returned to multiple times across the workshops. The presentation included the screen grab of a *Telegraph* headline bemoaning the obstruction of 'red tape'. There was a mention of the 'laborious' nature of the ethical and R&D review process. 'It could be quicker, more streamlined', said the facilitators, 'but what would be lost?' To encourage conversation, the facilitators stressed that everyone might have different views and 'balance the scales differently'.

In all of the workshops, the role of the HRA in protecting patients was described, as was the HRA goal of making the approval process more straightforward for researchers.

This introduction was followed by participants swapping their answers to the quiz and engaging in a generic ice-breaking exercise. The exercise worked well, with participants engaging with little awkwardness with their neighbours. Each person was subsequently asked to introduce their partners to the rest of the table, before the quiz answers were provided and discussed by the group as a whole.

A video extolling the virtues of clinical trials – the 'greatest medical advance of the century' – was presented. The participants were then invited to discuss clinical trials – 'think about your impressions of clinical trials, what has surprised you…', first in pairs and then across the table, but were typically given no guidance or focus to their discussion.

Together with discussions of ordinary healthcare, it was evident that the participants were not clear what they should be discussing. Indeed, the facilitators struggled to keep the distinction between clinical trials, other kinds of health research, and general health care. When the facilitator asked 'what if something drastically goes wrong', the discussion often jumped to failures in health care and pharmaceuticals that had been licensed for use. At all these workshops, the HRA either had to step in to correct developing misunderstandings, or the facilitators had to ask the HRA to answer questions.

The facilitators presented the basics of randomised control trials to the whole group. Participants were asked to 'think about this process… each of the elements'. Again, the participants were provided with little focus to guide their thoughts or discussion. Facilitators then asked the group about who can, or should, be able to contact potential participants in health research. Regrettably, they themselves appeared unclear on the way in which people might be recruited.

A video then followed of Ben Goldacre (British physician, academic and best-selling science writer) discussing the placebo effect. The focus of this video on the use of placebos diverted participants from the main focus of discussion. As part of this, blind, double blind, and triple blind research was outlined. However, as an informational strategy, the focus on placebos appeared more *off* than *on* topic and of only cursory relevance to a discussion of the approval process for health research, or the HRA's proposed changes. Instead there was sustained discussion on whether the placebo effect is real, the power of positive thinking, mind over matter, etc. Further digression from the core topic of discussion ensued with instructions for participants to share their 'top of the mind thoughts about what you've just heard' (London).

When the facilitators did focus the discussion onto a specific issue, such as what the participants perceived as being the risks of taking part in health research, there was often confusion. At the London workshop, for example, discussion of 'risk' was undermined by participants' confusion over the difference between the clinical trial phases and the difference between taking a drug as part of a clinical trial and being prescribed a licenced drug in an ordinary health care setting. During these discussions of clinical trials and the placebo effect, the facilitators expressly delayed discussion of informed consent in some instances. Though it was the next topic of discussion, this left some participants struggling to understand the ethical basis on which health research is conducted even as they were asked to discuss their 'top of the mind thoughts'.

Taking part in health research was then discussed: 'We now want to talk about the specifics […] deciding whether to take part […] what the clinical trial team should tell you' (London). The discussion of these topics at the London workshop was one of the most effectively focussed sections of the public workshops, with direct, relevant questions such as, 'what are the three to four things that you want to make sure that you're told, and who should tell you?' The participants discussed the sort of information that they would like, and it was clear from the feedback on the flipcharts that they covered much of the ground that Research Ethics Committees (RECs) demand be covered in patient information sheets; risks, ending participation, possible outcomes, monitoring, and aftercare, were all common topics of discussion.

The facilitators then showed the group long and short versions of the information sheets, and asked participants to discuss them.

The facilitators provided a few 'case studies', vignettes describing a health research project/clinical trial and a prospective participant in the research. This could have been a really strong part of the workshop. However, discussion often diverted to the topic of whether or not the participants *themselves* would take part. In fact, 'would *you* take part?' was the question asked explicitly by facilitators. A better question, also asked by this facilitator, was 'what questions would you have?' However, even this question could have worked better if it had been, 'what questions should [fictionalised person described in the vignette] ask?'

One vignette that could have produced a very informative discussion, but in practice produced little of value, described a clinical trial involving children. The participants discussed whether or not they would allow their own child to take part in a clinical trial and whether or not giving a child drugs, designed for adults, works. Given that this discussion produced – when it was not addressing questions outside the technical competence of *everyone* at the table – answers such as, 'I wouldn't let my children take part in a clinical trial', this discussion did very little to assist the development of

a research governance system that would satisfy the parents of children who *are* taking part in health research.

By choosing topics such as clinical trials involving children and research into grieving, participants were encouraged to focus on the emotive aspects of the vignettes. The case studies helped the participants understand the wide range of issues which might be considered by a REC.

Research Ethics Committees (RECs) were discussed before the case studies and closely linked to discussion of those case studies. The session concluded with a reminder that the question at hand was about a 'balance between risk and possible reward'. The current system was expressly discussed as a burden and an obstacle to research. By the time of the London workshop there was good focus to the task, with the facilitator asking the question, 'if you were on a REC, what would you ask a researcher? What would help you trust that the project would be done safely and well? What should be in the proposal?' However, the facilitators were unable to answer questions from the participants about how RECs actually work.

At the end of the session, the participants were given a 'homework' exercise; to go away and work further on the case studies, and to find something about health research in newspapers, on television, or on the Internet.

Public Workshops #2

The second session of the public workshops took place a week after the first. Again, the 16 participants were sat at two tables, each with a facilitator and a note-taker. At these sessions, health researchers ('experts') were introduced. The facilitators briefed the experts at the start of the session, asking for the experts to be balanced and to avoid bias, while asking them to contribute examples from their experience.

The second session opened with a recap of what the participants thought were the key things that they learned about the research approval process. Participants wrote key points onto *Post-It* notes, which were then arranged according to theme by the MORI facilitators. In the Bristol workshop, one of the experts interrupted a discussion to correct misunderstandings generated by the first session. A second expert joined in, helping explain placebos and the stages of a clinical trial.

The session continued with an ice-breaking exercise identical to the one that started the first session. This tended to prompt some complaints from participants because it seemed to them to be repeating their earlier experience. However, by locating participants in different seats it provided the expert/s at each table the opportunity to introduce themselves. With the rest of their tables, the participants were then asked to discuss the results of their 'homework'. As might be expected, not all of the reading chosen by the participants related to the issues at hand. At the Bristol workshop, one participant began discussing a documentary about the genetic modification of human foetuses, which other participants had seen.

After the 'homework' and the *Post-It* assisted recap, the session was brought back to the 'big question', 'balancing the scales'. How could the regulation of health research be made more efficient, cutting 'red tape', while keeping it ethical and maintain rigorous review?, the participants

were asked. The aims of the second session were set out, with an emphasis on the fact that it would draw on the experience of the experts in the room.

The facilitators introduced RECs. At the Bristol workshop, a participant interjected to remark that 'it seems like a lot of "red tape"'. This was the phrase that the facilitators had already used to describe the existing system. To her credit, the facilitator said, 'well, we can discuss that. It might be the right amount of red tape to protect people'. However, when presenting on RECs the MORI facilitators were clearly talking beyond their expertise; at one point in the Bristol session, the facilitator looked at the experts and said, 'if I'm wrong…', and later, when the facilitator was guessing at the answers to the questions of participants, the expert had to interrupt and provide an answer. At the London session, one of the experts was having a side discussion with two participants, leading them, with confidence and clarity, through the review and governance procedure for health research. The facilitator appeared to be unaware of this, and quietened the group to provide his own summary of the ethics and review procedure, asking the expert to, 'correct me if I'm wrong'. In this instance, it could have proved more profitable for the facilitator to have referred to the expert in unpacking specificities of the review and governance process (of which the facilitator had only a superficial grasp). What could be effortless on the part of the expert was a great labour for the facilitator, as he struggled with concepts and procedures with which he had limited familiarity.

The facilitators moved on to discuss R&D approval. At the Bristol workshop there was a noticeable lack of focus and guidance from the facilitators, with participants invited to discuss, in their pairs and then with the rest of the table, what they had just been presented with. However, the experts on each table provided a focal point. At the London workshop there was more focus, with participants asked a relevant question; 'do you think the process is doing enough to protect patients?' This question was followed up by question such as, 'How much do you trust this system, as potential users as well as potential participants?'

During the London workshop one of the experts presented a description of R&D. He described his frustration with the system, especially the delays, and explained where some of these delays might originate (highlighting the problem of understaffed pharmacies in hospitals, for example). The HRA provided the example of the survey researcher who was asked to submit to x-rays, vaccinations, and multiple CRB checks before being granted access by a number of R&D departments. The expert talked about health trust R&D departments 'quite rightly' looking at the practicalities and resource implications of proposed research projects. Later in the workshop, when this expert had moved tables, he provided a similar view of R&D departments, discussing, in detail, the 'bottlenecks' within hospitals set up to provide health care, not to manage research. Interestingly, one of the participants contributed to this discussion, disagreeing with the expert by offering a rephrasing of the description of R&D departments as making unfathomable demands.

The facilitators reported on the discussions at each table using flipcharts. At the Bristol workshop it was clear that a lack of focus had led each table to engage in very different discussions, covering very different ground. At the London workshop, at which there was a much tighter focus, and at the Manchester workshop, it occasionally seemed like the summary had also been better prepared, with points (that we might expect to figure in the discussion) finding their way onto the flipchart even if the participants only mentioned/touched on that point in passing.

The workshop moved on with the facilitators presenting the HRA's proposed system, before going back to discussion at the tables again. Participants often raised technical points on which they were provided no information. At the Manchester workshop there were discussions of whether the proposed system would prove more cost-effective. At the London workshop there was some discussion – prompted by the experts – of what the 'black box' of the HRA dealing with local site approval will contain. Rather than involve the expert and check facts with the HRA representative, the facilitator invited the participants to speculate on what might be involved in the HRA managing local site approval.

At Bristol and London the participants were then asked to stand and arrange themselves in a line between two points in the room, one labelled 'fit for purpose' and one labelled 'unfit for purpose', describing their impressions of the HRA's proposed changes to research governance. Typically, participants would cluster up around the 'fit for purpose' end of the imaginary line. The facilitators would ask people why they had chosen to stand where they had. Responses varied, with some participants appearing apathetic or disenchanted with the exercise: 'because there wasn't any more space over there' (London); 'I don't think that after twenty minutes discussion I can come to a view' (Bristol). Other participants, such as one in London, provided a more meaningful rationalisation justifying his (physical) position in reference to the anecdote of R&D departments making unfathomable demands. Participants' reticent and limited response to this exercise suggests that it was improperly sequenced and might have generated a more substantive and usable finding had it occurred later in the session.

The workshop then moved onto a discussion of reporting. It was typical that during these discussions at both the public and patient workshops that participants appeared insufficiently supported in distinguishing between academic publications; wider dissemination plans; the release of raw data; and reporting to RECs and funding bodies. This led to confused discussions at both public and patient workshops. The problem was more pronounced at the public workshops where the difference between these forms of scientific communication, and the interests of the HRA, did not appear to be entirely clear to the facilitators themselves. In the public workshops, the benefits of having experts present came to the fore where they were able to step in to explain, for example, the fact that there are a variety of reasons why the results of research might not be published (not all nefarious), and that academic priorities, peer review, and editing determines the content of academic journals. At the London workshop, one of the experts, listening to the participants and facilitator speculate, said, 'can I bring a bit of reality?'

The final part of the public workshop was a discussion of public engagement and patient involvement in research governance. Typically, this was extremely rushed. At the Bristol workshop there were only three or four minutes of discussion, at London less than ten, leaving little time for anything approaching a deliberative discussion.

Patient Workshops

In the workshops with Parkinson's disease and lung disease patients, no health researchers (experts) were present. At the workshop with mental health patients, a professor of nursing provided insights into health research. At the diabetes patient workshop, several experts were present who – as deeply invested stakeholders – became participants in, even facilitators of, the workshop.

The patient workshops took place in a number of different settings; at the headquarters of a patient organisation, at a suite of commercial meeting rooms, and at the Friend's Meeting House in London, a regular host of meetings arranged by the NHS. Unlike the public workshops, at which the participants were seated at two different tables, during the patient workshops, the participants sat around a single table.

As with the public workshops, the patient workshops improved with practise. As described above, the particular diseases that formed the basis of the participants shared experience (including their experience of health research) was different at each event, and the role played by experts (when present) also varied. However, the workshops involving the mental health, Parkinson's disease, and lung disease patients were very similar in structure and execution. Despite holding to a similar formal order, the diabetes patient workshop was markedly different in practice due to the role played by a number of experts taking part in the discussion.

It is important to note that at the patient workshops it was usual for many of the participants to know each other from their membership of a range of patient organisations. Even if they did not know each other personally, they often had common acquaintances, and certainly had experiences in common with each other. Patient workshops, therefore, tended to begin with the participants re-introducing themselves to each other and swapping stories of their healthcare, access to benefits and services, and their patient 'activism'. For example, many of the participants at the lung disease patient workshop were organisers of British Lung Foundation Breath Easy support groups.

The workshops began with 'formal' introductions, where participants told the rest of the group a little about themselves. Typically, the facilitator asked the patient participants to describe any experience that they had of clinical trials or other health research, and as well as taking part in research, some participants had been involved in recruiting other patients into research, helping draft patient information sheets, etc.

Next was a 'quiz' exercise, similar to that used in the public workshops. While in the public workshops the participants 'sat' the quiz as a 'test', writing their answers down and having the answers revealed later, during the patient workshops the questions were delivered to the group as part of the presentation, each question discussed by the group in turn.

The facilitator then introduced the HRA and the National Research Ethics Service (NRES). The current system of research governance was described as deterring research. The facilitator described the goal of the HRA as streamlining the research approval process without loss of rigour. The facilitator explained the relevance of the patient workshops, stating that in the past, only researchers would have been consulted, but given the HRA's role in protecting patients, their involvement in consultation was necessary.

The basics of clinical trials were discussed. The facilitator pointed out the benefits of taking part in a clinical trial, including the placebo effect, the extra care and monitoring that participants (a participants at the lung disease patient workshop likened this to a 'free MOT') in clinical trials receive, and the fact that hospitals involved in research tend to have better outcomes in general. The patient participants were generally knowledgeable and well informed, asking pertinent, insightful questions. For example, at the Parkinson's disease patient workshop, one of the

participants raised the issue of patient groups campaigning against the use of placebos, citing the case of HIV activists in the 1980s.

There was a brief overview of Research Ethics Committees (RECs), during which the facilitator showed a pie-chart that demonstrated the variety of proposals that are seen by RECs. Typically, patient participants were keen to discuss the potential for patient participation at this stage. The facilitator would return to the topic of RECs later in the workshops, typically after the coffee break.

The facilitator then introduced the topic of recruiting participants for clinical trials and other health research. She clearly set out the current practice, and the restrictions on who can 'trawl' records for potential research participants. These restrictions were presented as an obstacle to research. This tended to prompt a discussion from participants of the other ways in which patients could be recruited into research – through adverts, by patient organisations, setting up voluntary databases, etc. The facilitator brought these discussions back to address the question of who should have access to medical records, in which circumstances, and how potential research participants should be approached.

The workshops then moved onto the topic of informed consent, asking the question of who should seek consent. After the facilitator presented the existing system, participants would typically say something along the lines of, 'that sounds like a real stumbling block' (lung disease patient workshop). Some of the patient participants had experience of recruiting patients into research, and were able to contribute their expertise to the discussion. The patient participants demonstrated a 'deep engagement' with the issues under discussion, and so had the awareness to raise issues such as power differentials between medical professionals and patients. This was followed by a discussion on who should provide advice when potential participants were considering whether or not to take part. In particular, there was discussion on who would be in a position to provide neutral advice.

The facilitator then discussed patient information sheets, distributing short and long versions of patient information sheets. Patient participants tended to discuss the idea that patients, or patient groups, should have a role in writing or editing patient information sheets. Patient/service user involvement in the design of research was a topic that was returned to time and time again during the patient workshops.

The discussion then moved onto RECs (often after a coffee break). The facilitator presented a pie chart that showed the frequency of the different decisions made by RECs, saying, 'we'd like to reduce the number of "provisional" judgements'. Again, patient participants were keen to discuss the idea of patient/service user involvement. The facilitator presented a slide on the proportion of applications to RECs that declare (and can demonstrate) patient involvement in research, describing patient involvement in research as something that 'smooths the path' of proposals, strengthening the credibility of researchers in front of RECs.

After the participants discussed RECs, health trust 'research and development' (R&D) approval – in all its variety – was introduced. The burden of the process was stressed. The facilitator used the same example as used in the public workshops to present the demands of R&D as extensive; a researcher conducting a questionnaire study, who various R&D departments demanded receive vaccinations, chest X-rays, multiple CRB checks, etc. before being granted approval. When experts were present they often joined in at this stage, stating that their frustration with R&D is 'why I'm

here today' (mental health patient workshop) and that R&D stands for 'Rubbish and Delay' and 'From a researchers' point of the view the HRA are brilliant as it stands a chance of getting rid of R&D, an obstacle to research' (diabetes patient workshop). That said, some patient participants with some experience of research had a negative opinion of R&D departments, with one participant describing the process as an 'enormous waste of time' (Parkinson's disease workshop). The role of R&D was explained and patient participants raised baffled questions such as 'are these stumbling blocks there as stumbling blocks?' R&D was described as making 'unreasonable demands all the time' and as something that is 'well intentioned' but that has turned into a 'Frankenstein's monster', stressing the length of time taken to receive R&D approval; and the implication of this for time-limited research funding.

The new system proposed by the HRA was then presented, in summary, as involving early assessment by an ethics officer, a full review by a REC, and the HRA granting a study-wide decision. It was further explained that there would then be local site approval, but the trust would be unable to consider ethics, or other aspects of the study that had already been considered by the REC and the HRA. This met the total approval of participants across all the patient (and public) workshops.

The concept and role of a Researcher Passport, and what it covers, was then explained, as well as how individual Trusts allocate the passports. Participants were asked whether they thought it would be appropriate for the HRA to take on the provision of researcher passports on a national basis.

The facilitator then moved discussion onto what happens at the end of a study. Patient participants discussed whether individuals should be allowed to continue taking a trial drug

The discussion then focused on the topic of patient and public involvement in research and what role the HRA should play in encouraging this. Discussion covered how hard a line the HRA should take in enforcing this, what the downsides of this might be and whether they should prioritise particular types of studies for patient and public involvement

The facilitator then moved the discussion onto the subject of the publication of results. Patients were easily able to differentiate between the wider dissemination of the published findings and the concept of feeding back findings to the participants of a study. The concern for most participants was that the public should have access to comprehensible information on the results of research. Annual reporting to the REC was discussed, with the facilitator stating that 'few people read the annual reports of process not research findings, we'd like to replace them with shorter electronic reporting with something more comprehensive at the end.'

Wider questions were also asked such as, 'What things need to be in place for you to have trust in the overall system?' (mental health patient workshop), or 'How can the HRA help you feel protected? What should we be doing?' (Parkinson's disease patient workshop).

At the end of the workshop, there was discussion on how the HRA itself should involve patients and the public at a strategic level to inform its own policy and practice.

6. Lessons

This section discusses the lessons that emerged from our observations of the public and patient workshops, explores what worked well, what worked less well and provides suggestions for future dialogue practice.

Time

As is so often the case in participatory deliberations, time was an issue. This was especially true in the context of this project, where the informational aspects of the workshops were so significant that the amount of time available for more extensive and expansive deliberation among participants suffered. Attributing equal time and focus to these two dimensions of public dialogue is self-evidently a significant challenge, yet one which might be more ably solved through the earlier and continuous inclusion of experts, whose mastery of specialist knowledge might provide for more fluent and seamless transitions and more equal allocation of time than facilitators with insufficient knowledge to provide information quickly and easily. We would suggest that, in this instance, too much was expected of the facilitators, where the information to be introduced and debated was extensive. Furthermore, we would argue that too great an expectation on facilitators as quasi-experts detracts from their facilitation role, in stimulating, scaffolding and safeguarding equitable collective discussion. Finally, we observed occasional moments of hesitation and uncertainty among the facilitators, not least where they were challenged to present to public participants, information they themselves had little familiarity with, especially given the lack of consistency in attendance by the facilitator team. We would suggest from the experience of this project that where dialogue exercises have weighty informational components, substantive lead-in and familiarisation time is essential, maximising the capacity and confidence of facilitators in supporting participants; stimulating discussion, and synchronising 'informational' and 'conversational' responsibilities. Furthermore we would recommend against congested workshop timetables. Trying to fit too many sessions, in multiple locations, within a short period of time, can compromise the quality of a dialogue process by not allowing sufficient recovery and reflection time for facilitators.

Delineation of roles

Our experience of observing these public dialogue workshops has also led to the opinion that clear delineation of roles of facilitator and expert is essential, not least in making explicit to participants the respective function of both, and in providing an interactional road-map stipulating the rules and expectations of engagement for all parties. A firmer definition, or be that division of roles, may then allow for more harmonious interaction between the facilitator and expert, with a greater awareness of the parameters of their involvement. This kind of clarification will likely also better orient public participants through the dialogue process, where they are knowledgeable for instance, of whom to direct questions specific to informational content at, and allow therefore for more fluid exchange. In other words, we would make a firm appeal, for future public dialogues to make explicit the extent and quality of contribution anticipated from each party and that this is known and agreed upon by all those responsible for the delivery of the dialogue in addition to public members.

A protocol for experts was established by the facilitators, in written form and on the day of Workshop #2. It is questionable however, quite whether this was sufficient in establishing a sound etiquette between the session's facilitators and experts. Not unusually, we observed instances, where experts became too involved and too influential over the course of the dialogue, which necessitated the frequent intervention of the facilitator; in turn unnecessarily punctuating

discussion. Managing expert input and supporting public participant input is a vital role for facilitators. We would suggest that a code of conduct for dialogue be established by facilitators with experts, not only through reference to written guidance but by verbal negotiation. Experts themselves, may quite plausibly be as un-initiated to public dialogue as public participants themselves, and require a similar degree of scaffolding.

The extent of expertise and personal experience demarcating 'patient' from 'public' participants, might be viewed as respectively enabling or inhibiting factors for dialogue processes focused on yielding new insights for policy, where respective informational wealth or poverty, stimulates or curtails laypersons' involvement. In the context of these public dialogue workshops, participants' low threshold of knowledge matched with the complexity and weight of the topic under discussion, made for an informational component preceding deliberation all the more necessary. It also meant that where public participants were brought 'up-to-speed', their new knowledge and understanding of health research governance was not only quantitatively different but qualitatively distinct from the kind of knowledge and understanding mobilized by patient participants. For example, public participants' knowledge and understanding of health research governance was fused through 'transmissional' and internal (formed within the workshop) learning, and different from the type of knowledge wielded by 'patient' groups, which would be predominantly 'experiential' and external (formed outwith the workshop). It is arguably therefore very important that in weighting the significance of public and patient accounts that consideration be given not only to the relative levels of expertise but how this expertise has cultivated. For instance, publics' perspectives of health research governance may be less contaminated by prior experience and therefore potentially more objective and non-partisan than patients' perspectives. In contrast, patients' perspectives may be more rounded and 'global'. Cognisance not only of the quantitative but qualitative divide in knowledge and understanding separating public and patient groups is therefore necessary in the development of dialogue materials and in the analysis of participant contributions.

The necessity of quality hospitality and hosting

The public workshops were troubled by organisation and (related) timekeeping problems. At the first session of the Bristol workshop, participants began arriving just before 6pm, under the impression that the workshop was to start at 6pm. These participants were told to wait in the lobby of the hotel. This clearly frustrated some of the participants, and might well have played a role in the fact that at the second session of the Bristol workshop several participants arrived late.

The necessity of rehearsal when using audio-visual (AV) equipment in the 'informational' needs of public dialogue

The facilitators' struggle with their presentation also included playing the videos. At the Bristol workshop there was a prolonged period during which the facilitators struggled to adjust the volume, while at the London workshop the facilitator started the video within the *powerpoint* editing mode several times, before a participant offered advice. If nothing else, these had an effect on both timekeeping and, again, the authority of the facilitators.

Providing for those with physical impairment and disabilities

The patient workshops generally ran to time and were well organised. However, there was possibly not enough consideration made to the needs of patients with chronic illness – an issue which was raised by the participants at the Parkinson's disease patient workshop who pointed out that an

event such as the one arranged could only be attended by those patients who were relatively active. Providing for participants with disabilities in the context of PPI dialogues evidently needs careful thinking in terms not only of access but providing for conditions that might delimit the extent to which traditional dialogue methods might be applied.

Focused discussion – keeping on topic – managing the tangential

Whilst digression in dialogue activity is to be expected and at times encouraged for revealing other and/or unanticipated insights or themes for investigation, the stricture of time causes for precise management and stewardship of discussion so that it does not become too far removed or disconnected from central topics and lines of questioning. Public workshops might have benefitted from stricter marshalling of dialogue to save, for instance, a focus on health research being subjugated by participants' interest and discussion in health care. This kind of slippage of focus might be avoided by the more precise use of experts and their greater integration as 'content' supervisors within the process of dialogue, avoiding the pitfall of public participants becoming confused, lost, disinterested and disengaged in discussion. As previously advised, a clearer explication to participants of the roles of facilitator and expert, would also add to the fluency of dialogue and avoid the scenario of participants asking unreasonable 'content' questions to dialogue facilitators as 'process' experts. Furthermore a clearer sense, and agreement, of the roles and expectations of those involved in moderating/stimulating the dialogue may also add to the comparability of findings, where the deliberative aspects of workshops involve break-out into smaller groups, and where the chance of deviation in terms of the kinds of discussions, level of intervention and such between groups, augments.

Maintaining consistency and uniformity in a team of dialogue facilitators is also key, not least where the practise of dialogue within a given subject provides facilitators with a fuller grasp of informational content, prospective lines of discussions and questions and an ability to regulate and respond to these respectively. A lack of consistency of key personnel was something of a weakness of the public workshops, which hampered the fluidity of the dialogue process and provoked, on occasion, the frustration and consternation of public participants.

The kinds of intelligence gleaned from facilitating dialogue is what improves the dialogue process and enables, where there is consistency in dialogue personnel, facilitators to incorporate modifications to content and structure that might greatly improve and/or add to further dialogue sessions. This kind of reflective practice for dialogue facilitators however might only occur where they are involved from inception to conclusion of a dialogue process and not where there involvement is sporadic or one-off.

This said, we observed some improvements in the co-ordination of the public workshops as they progressed and a clear sense of reflective practice from the delivery team, who prior experiences were learnt from and responded to, not least in the management of more disruptive and/or dominant participants prone to rupture or fragment lines of conversation. The facilitation teams' ability to spot and cauterize the potential for dialogue diversions or derailment, and their capacity to safeguard equal and inclusive dialogue, improved as the public sessions progressed.

Issues in feedback

We observed issues in the way participants' views were reported and fed back and the way this was then used, or not used, to sponsor further discussion – in break-out groups of in plenary. In the

public dialogues, feedback occurred in plenary and without initial feedback or opportunity for individuals in groups to verify or contest that which had been scribed. This, we would recommend as an essential phase preceding whole-group presentation of dialogue findings and further discussion. It may be less about finding consensus within a (break-out) group, and more an opportunity for participants to comment directly on the likeness of what has been interpreted and reported to that, which they initially articulated.

Balance and bias

There is arguably an issue of balance and bias in the context of the patient workshops where these were co-ordinated and delivered by the HRA as a dialogue sponsor. The degree of detachment and impartiality of the facilitator is in this instance questionable, and despite the very best intention and commitment of the facilitator to neutrality, there is the inherent and arguably, unavoidable risk of bias, leading questions and invested influence, that might compromise the integrity and robustness of the dialogue findings. This is not to say that a sponsor should not be allowed an opportunity for interacting with participants in the course of a dialogue, but that these interactions might be, as was in the case of the public workshops, 'informational', rather than 'conversational'. Indeed, we would suggest that the high visibility of the HRA as a sponsor throughout the public workshops, was of significant added-value, not least as an informational resource for the facilitators. In fact, if only on the terms of organisational learning in respect of the value of PPE in dialogue contexts, we would recommend that more than one representative of the HRA might have attended the workshops. This might also allow for wider direct experience and thereafter distribution, at an organisational level, of the learning of participatory and deliberative public (and patient) dialogues.

Another aspect of potential bias is that attributed to experts, particularly experts who bring a specific, and as may be unflinching and inarguable (certainly from their own point-of-view) perspective to dialogue. Where these perspectives are introduced by experts but then left to public participants' discussion and deliberation, then the contribution is valuable and uncomplicated by bias. Where however, the dialogue is co-opted by an expert as a platform to proselythize and convert non-experts to their way of thinking and/or where their influence is more instructional and informational, balance is lost. This danger increases where the contribution, or be that, intervention of the expert within the dialogue exceeds that of the public participants, and where a combination of expertise and erudite argument, diminishes the capacity, confidence or willingness of a non-expert to disagree or propose another way of thinking. At the diabetes patient workshop for example, the experts present spoke of the right to participate in research, and went on to suggest that patients expecting care from the NHS had a duty to take part; 'If you want to take from the NHS, you have to give something in return'. At the same workshop, an expert talked about the 'dream, and I hope everyone is working towards this being for access to medical records to be opened up to researchers'. We would advise that dialogue co-ordinators need to be highly selective in their choice of experts and provide their experts with clear briefing on the parameters of their involvement.

Expectations on participants

Whilst, a dialogue as an exercise in participatory deliberation is intended to challenge and stretch the team-working, problem-solving, creative and imaginative capacities of public participants, deficiencies in an informational framework and in the kinds of resources that stimulate and guide such work, can make unreasonable demands of participants' that might provoke their withdrawal or ire. We witnessed a few such instances, where participants felt inadequately supported by the

facilitators and informational and stimulative materials, which culminated in their feeling disenfranchised from and disenchanted with the dialogue process. The right pitching of material to public participants is a special challenge and one with which facilitators might not always enjoy success. However an ability to reflect on and improve aspects of a dialogue's content, structure and process will greatly aid this process. In the context of both public and patient dialogues we recognised a willingness to be flexible in project design and implementation, which caused to significantly increase the fluency of the dialogue as it progressed and therein participants' own sense of satisfaction and fulfilment as able and equal contributors.

That said, there were instances where the content of questions made impossible demands of the non-expert participants. For instance, at the Bristol workshop, discussing publication and release of raw data, the participants were asked, 'what would be the consequences of publishing everything?' This is self-evidently is an expert question, requiring knowledge of the organisation, economy and reward structure of science to even begin to answer. It is a question for technically competent people. It is also a question, which threatens to alienate respondents by being ill-aligned. Simple tweaking and reorganisation of the question, for instance by structuring around experts might yield a far more meaningful and inclusive exercise. For example, a more valuable exercise might take the shape of if an initial expert presentation focused on what might happen if researchers were required to publish everything or release their raw data and an account of expected costs and expected consequences, This could then provide the basis for non-expert participants to more ably discuss the key issue and by interrogating the expert.

Appropriate lines of questioning and informational resource are essentials for inclusive and meaningful dialogue, and dialogue that fulfils its aims and potential by fully exploiting the wealth of insight from public citizens as *social* experts.

An exercise in consensus-making

It appeared during some workshops that some participants had the impression that their role as dialogue participants was in legislating for and legitimising decisions rather than being engaged in critical discussion of 'pros' and 'cons'. When discussing annual reporting to RECs, one of the participants at the Bristol workshop said, 'Doesn't that just add to the red tape we're trying to get rid of?' This reflected the complexity of the basis for the dialogue, which was to consider the implications of proposals to streamline and simplify the regulation of health research. In some cases, a lack of focus in setting out the questions and a tendency for them to be leading by nature gave the appearance of the workshops as an exercise in consensus-making for a streamlined research governance process rather than an open discussion. However, some participants' fears of dialogue as rubber-stamping exercise was not a significant issue overall, given that no-one raised it as an issue about the conduct of the workshops, and the majority of respondents (55%) gave positive feedback about the the likely influence of the process on HRA decision making in future (see pages 33-34).

Sequencing of expertise

We have previously commented that the limited availability of experts in the first public workshop was problematic, with only one HRA representative present to answer questions. The use of a video as a substitute was insufficient, even though there was extensive discussion after the video was shown and the HRA was able to answer questions at that point. The use of supplementary materials

like a video, should , in our opinion, be complemented with more in situ experts, able to make sense of what participants have been shown and work with participants in drawing insight.

Integrating expertise

We have already noted some of the benefits of incorporating experts in the dialogue process. The most prominent and pervasive perhaps though is their role as a rapid informational resource, supporting the 'conversational' role of the facilitator. In the mental health patient workshop, for example, the expert was able to very quickly provide clear information about the way that drugs with side-effects can reach the market despite rigorously conducted clinical trials. This prevented the discussion becoming side-tracked into a discussion of the regulation of health care in general, which was not the issue of concern for these workshops, and concentrated the discussion on the governance of health research and clinical trials.

In wielding their scientific authority however, there was a danger that experts could simultaneously not only drown out the voices of the public and patient participants but those of the facilitators themselves. Two workshops in particular suffered from this problem. At the second session of the Bristol public workshop the contractor had arranged for three experts to attend. This led to two experts sitting at a single table. It appeared, at first, that this would produce an educational discussion, clarifying points of fact and contributing specialist knowledge by way of dialogue between experts rather than direct instruction and correction. However, as the session progressed it became clear that the participants were content to listen to the discussion between the experts, which encompassed both questions of fact and the deliberative questions that the public participants had been asked to discuss. The facilitator did little to intervene – the authority of expertise was possibly as intimidating for him as it was for the public participant – until it was too late. By the time public participants were invited to offer their views on the questions that had already been addressed by the experts, their contributions tended to stretch to little more than approval of the views of the experts; 'yes, it all seems to make sense'. Another said that she was 'content to listen', while a third talked about 'sitting on the outside'. When the facilitators reported on this section of the workshop, using flipcharts, most of the points written onto the sheet were points drawn from the discussion between the experts; the experts had become the participants, to some degree displacing the public participants.

At the diabetes patient workshop there were several experts (a professor and several other research professionals), making up significant proportion of the attendees. With that many experts, the diabetes patient workshop was more of a diabetes research stakeholder workshop. There was no distinction between the experts and the patient participants – except, perhaps, inadvertently, as several of the experts sat together at a prime point in the arrangement of the room – and the experts completely dominated the discussion, to the degree that the experts took it upon themselves to facilitate the discussion. Again, the authority of expertise and experience being brought to bear on deliberative questions shut out many of the patient participants from the discussion until the matter had the appearances of being conclusively settled.

The problem in both these cases was not the presence of experts, or that they were heavily involved in the workshop. Indeed, as we have described, the problem of the public workshops was that there was too little genuine expertise involved in the presentation of specialist knowledge in the first

sessions, and insufficiently strong facilitation at later workshops to manage the discussions effectively.

At several events, experts moved beyond playing the role of participant in the discussion and ended up filling the role of facilitators, directing the discussion. This was the case in several of the public groups, where experts would ask the participants questions that would focus the discussion. It was also the case in the diabetes patient workshop, at which an expert took a dominant role in the discussion. As well as playing the role of participant – he was a stakeholder in the issues under discussion – he directed the discussion, asking the patient participants questions such as 'how offended would you be if you received a letter out of the blue, from a researcher, asking you to take part in research?', or 'What does everyone feel about that [prospective participants being able to speak to people already taking part in the research]?' After effectively running this discussion, the expert would turn to the facilitator and say something such as, 'one of the things you can take back to the HRA is…' In other words, the expert assumed the authority to frame the discussion from question to summary. We might not be surprised that experts, particularly those who hold positions of superiority, used to taking the lead in their professional life, would assume such a role.

We return to our initial point that the integration of experts into public dialogue exercises requires sensitivity in the initial selection of experts and expertise and experience in managing their involvement. Clustering experts at tables of public participants, is for instance likely to crowd out the potential for non-experts to voice their opinion if the facilitation of the discussion is not sufficiently strong. We would always recommend that experts form the minority of participants (as was the case here) and, concurrently, that there is recognition that the moderation of experts in dialogue situations requires very strong facilitation skills. We would recommend in such scenarios that only the most experienced and seasoned facilitators are charged with such a responsibility.

7. Impacts and issues

This chapter considers a range of impacts and issues characterizing and attributable to the project. The information on these impacts has been provided by those involved in the management and oversight of the project.

We identified, with the help and advisement of the HRA, a select group of individuals (n=6) able to authoritatively comment on the project process – from cradle to grave – and its achievements. Those that we identify herein as 'stakeholders' comprised representatives from the HRA and the HRA project team; members of the project's oversight group (OG); and a Sciencewise (SW) representative. We undertook interviews with each of these individuals, not long after the final oversight group meeting and prior to our presentation of the report to the HRA and Sciencewise. Interviews were conducted by phone and followed a schedule (located in the appendices), which sought to identify what stakeholders regarded as the overall impacts and contribution of the project.

For purposes of anonymisation – an assurance made to interviewees and that we adhere to as an integral feature of responsible social research – we purposely avoid attributing ownership to any verbatim quotes beyond an indication of which stakeholder interest group they represent.

As Figure 5 illustrates, our conversations with project stakeholders revealed five impact themes: the project resulting in impacts on policy and decision making within the HRA and more widely; the increased legitimacy of dialogue based activity and the establishment of PPE as a core activity in the overall context of the HRA's portfolio of work and specifically in the context of health research approval and governance processes; new learning and competencies resulting from the direct experience of the dialogue process; the enlarged perspective gained from an inclusive and democratic approach to decision making processes in health-research; and finally, the new emergence of the HRA as a role-model in patient and public engagement.

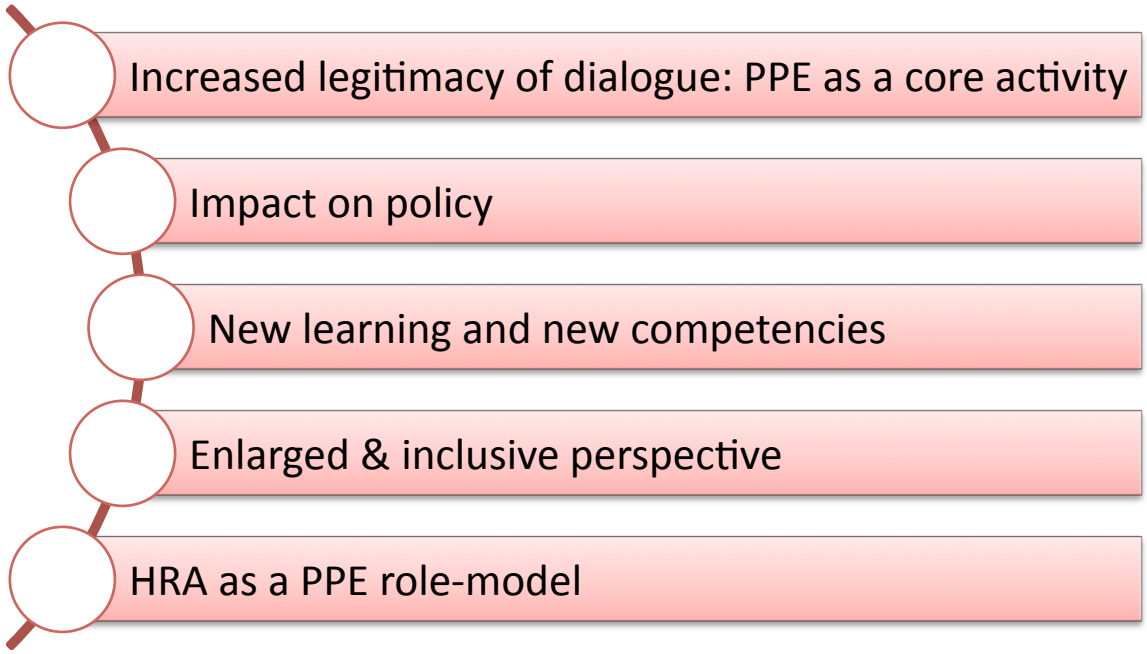


Figure 5: Impacts identified by stakeholders

The dialogue project has already achieved significant impacts on policy and decision making. The results of the dialogue were presented by the HRA to the House of Commons Select Committee on Science and Technology inquiry on clinical trials in July 2013[2]. The dialogue was also referred to by the Department of Health and the Academy of Medical Sciences in their own evidence to the Committee. The Committee report refers directly to the evidence on the findings of the dialogue, and it has recommended that the HRA take a much stronger role in encouraging transparency through the publication of research findings. The impact of the dialogue results on the HRA work on transparency has perhaps been the project's greatest achievement to date. The HRA has continued to work closely with stakeholders, including the pharmaceutical industry, to take this work forward and develop guidance and regulation on this issue.

The dialogue results have also fed into the HRA development of guidance at the end of 2013 for researchers on Information for Patients at the End of a Study, which was consulted on in early 2014. Dialogue findings have also been incorporated into the development of a template for patient information sheets, to encourage researchers to consider patient and public involvement at an early stage.

In addition, the results will be incorporated into the Research Governance Framework which will be revised in 2014, as well as being fed into other projects including HRA guidance following the Caldicott report. Longer term, the results will feed into the revision of the Governance Arrangements for Research Ethics Committees.

Internally, the HRA has drawn on the results of the dialogue in developing its own public involvement strategy. More widely, having seen the results of the dialogue, the National Institute for Health Research is revising its plans for training materials for patients.

The project was also seen as pivotal to the strategic direction of the HRA as a relatively new organisation seeking to establish a precedent of openness and the centralisation of patient and public views in its strategic decision-making:

> *'It's been really refreshing to see the HRA prioritize on patient and public engagement from the outset.'* (OG member)

The project was also seen as an effort to redress a deficit in understanding and gap between how patients *and* the public view health research regulation:

> *'The project was kind of unique in focusing on what both patients and publics think about research. Talking with patients on these terms is not something particularly new. We have quite a bit of experience in this. Talking with the general public in this kind of face-to-face way was, however, something different and really valuable.'* (HRA)

It was felt that the project had demonstrated the worth of engaging both patients and public constituencies, where both brought, different perspectives on the research process, characterised respectively as informed, decided and closed (or less flexible) and un-informed, undecided and open (or more flexible):

[2] House of Commons Science and Technology Committee. (2013) *Clinical trials. Third Report of Session 2013-14*. Published by HMSO 9 September 2013. Additional written evidence, published 3, 5 and 17 June 2013. House of Commons Science and Technology Committee. (2013) *Clinical trials: Health Research Authority Response to the Committee's Third Report of Session 2012-14*. Published by HMSO 16 October 2013. Department of Health (2013) *Government Response to the House of Commons Science and Technology Committee Inquiry into Clinical Trials*. HMSO, November 2013. HRA (2013) *Transparent research*. Paper for information and comment. May 2013.

'What the public said really had merit and was coming at the issues from a different space. I think that if you're less accustomed in these things, you're likely to approach them in a different way and without the baggage of past experience.' (SW)

'It was really interesting to see the participants in the public groups approach and tackle these issues for the first time. I think this whole process provided a fresh pair of eyes.' (OG member)

'This was an opportunity to add to the views of very experienced patient cohorts already bought-into research by talking to those people who haven't yet been involved.' (HRA)

This sense of the public's 'topic-neutrality' – they're attending the dialogue sessions without preformed ideas – was felt to be especially important and underpinned the basis of 'collaborating with the public in this way'. The basis of the public's topic neutrality was however, seen not only to stem from their relative lack of exposure to the issues pertaining to health research governance but their lack of experience in the collective deliberation and discussion of these:

'It seemed that few, if any, of those in the public sessions had much prior experience of discussing these kinds of issues; certainly in this kind of way.' (SW)

Accordingly, the project was also considered for its contribution in opening up and democratising the decision-making process apropos decisions in health research, including public and patient groups or in other words those whose status as patients is 'dormant' and 'active' respectively.

'We saw both ends of the spectrum, which surely is essential in making decisions around something that affects everybody, even if many of those don't know it yet.' (OG member)

At an organisational level, the project was seen to have made a significant contribution to the HRA's knowledge and understanding of *public* views of the approval and governance process in health research. This experience of PPE and the new knowledge it provided was seen as integral to organisational intelligence and the further and future development of the HRA's PPE strategy:

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

The project's learning was seen however to have spread beyond the HRA. Two respondents for instance, spoke of how the learning emanating from the PPE project was prompting discussions in their own organisations in respect of patient and public engagement:

'It's definitely made us stop and think about our own commitment to public engagement and how to do it. It's really helped in that respect.' (OG member)

The PPE project was seen to have established the HRA as a front-runner in public and patient engagement:

'The HRA has set out its stall and shown that it is an organisation committed to engaging and being engaged by the 'public'.' (OG member)

In terms of organisational development, the project was also seen as an effective way of centralising and building around a tenet of PPE rather than latterly introducing PPE into organisational philosophy:

'The HRA has built-in PPE from the beginning, which is much better than introducing it as an unknown organisational philosophy later down the line.' (OG member)

The PPE project was consequently perceived as significant not only in influencing and potentially defining the way with which the HRA will work but in showcasing this approach and this level of investment to other similar organisations:

> *'I'm sure there'll be a trickle effect. Others will sit up and take note of what the HRA has achieved.'* (OG member)

It was similarly felt that the external view and reputational status of the HRA, would it be significantly boosted by this PPE and future PPE investment:

> *'. . . no doubt the project has given the HRA a lot of credibility.'* (OG member)

At the same time the project had resulted in the HRA achieving the status of role-model for PPE and with this greater exposure, greater accountability:

> *'I'm not sure if it's a good or bad impact but the HRA now has the new responsibility of being a role-model for patient and public engagement in health research.'* (OG member)

The longevity of the HRA's public image as a public-facing and engaging organisation was predicated on its continued investment and commitment to PPE:

> *'The worst thing that might happen is that this project is a one-off. It should be the start not end of a longer process.'* (OG member)

The HRA is also continuing to invite participants to contribute to different elements of their work.

As a learning-journey (and exercise in capacity building), those we spoke to with no previous experience of a dialogue approach to patient and public engagement, recommended the project for being learning rich and for having been won over to the dialogue approach:

> *'. . . it was overall sold to me as an approach to take forward.'* (OG member)

That said, whilst respondents commended the deliberative elements of the consultation they felt that the incorporation of a survey poll was a significant addition, which lent quantitative weight and statistical significance to the richness of the dialogue's qualitative (small sample) findings.

Overall however, it was felt that the experience of the project rendered a rationalisation against PPE in health research largely unfeasible:

> '*You need to find reasons and excuses not to be doing this kind of thing.'* (HRA)

Overall the project was viewed as having set an important precedent for health research, where it was felt far too little time, effort and money was invested in improving communication with patients and the public:

> '*This has set the bar for an area in which we have historically not done enough.'*
> (OG member)

In a related way, the project was seen to have catalysed and confirmed stakeholders' 'renewed' respect and confidence in the Sciencewise mission/portfolio.

In terms of a growing awareness of public understanding of clinical trials and the research approval process, the project was seen to provide an important barometer of 'where the public are' and the kind of communication role/strategy the HRA should adopt.

The project has also benefitted from significant external dissemination (in addition to the presentations relating to the Select Committee identified above):

- at the European Forum for Good Clinical Practice in London on 24 June 2013
- at INVOLVE (the health participation organisation)
- at the International Clinical Trials Day in Liverpool on 20 May 2014
- at the Great Ormond Street Hospital study day on 30 October 2013
- at the Norfolk Public and Patient Involvement Group on 3 December 2013
- at the Clinical Trial Service Unit, Participant Panel Meeting, University of Oxford on 4 December 2013
- at the Department of Health
- at the UK Research Ethics Development Group (UK REDG) covering England, Scotland, Northern Ireland and Wales on 20 August 203
- to R&D champions across the NHS in England

The project was also referred to in Pharma Times Online on 21 May 2013: 'NIHR says "it's okay to ask" about clinical research', by Peter Mansell.

Internally, presentations about the dialogue project were made to the HRA Board, the HRA Confidentiality Advisory Board and at a half-day workshop in September 2013 to staff and Research Ethics Committee members.

Finally, we were informed that participants (for whom contact details were available) were invited to attend one of three workshops in September 2013 in London, Manchester and Newcastle to hear the findings of the dialogue projects and the survey.

Project co-ordination and delivery

Whilst not an impact *per-se*, respondents were keen to endorse the success of the project in terms of it fulfilling its aims and objectives.

In terms of the project's overall co-ordination and delivery, the common view from those we spoke to was that most aspects had been successfully managed. The HRA was especially also praised for guiding the project to a successful conclusion and as an effective information gatekeeper and steward, signposting and scaffolding process transparently.

> *'The HRA did a fantastic job of co-ordinating the various aspects of the project especially given the limitations of time.'* (OG member)

Indeed, as mentioned above, this contribution was considered to be especially note-worthy given the scale of the project.

It was also felt that the oversight group had provided, if in a limited way, an important contribution drawing on a relatively broad membership able to comment on and provide steer to the project.

It was felt by respondents that the project ought to be commended for the honesty and transparency by which it was conducted and managed.

The investment from Sciencewise was in a similar context seen to add to the integrity of the project: providing the PPE with 'an independence, good structure and external evaluation'.

An issue of time

Whilst our conversations with stakeholders mainly focused on what they perceived as the project impacts, we endeavoured to find out if they identified any specific issues or shortcomings in the project's execution.

Overall, respondents found the project to be largely unproblematic. What issues they did identify were nearly all related to restrictions of time.

A frequently observed challenge of public engagement activity is a struggle to contend with restrictive timeframes and/or a project's overall paucity of time. This particular project was seen to be no different. A lack of time at the very outset had made any contingency planning nigh on impossible and the timeframe for deliberative activities too tight and potentially over-rushed. A case was made by respondents for more generous and flexible time allocations, not least to allow for changes in project design and scope:

> *'It felt like the project morphed and more things were added . . . topic guides were being amended on the day of the workshop . . . it all felt too close to the bone.'* (SW)

Another factor, seen to be accentuated by restrictions of time, was the relative lack of face-to-face time among the entire project team, including the oversight group, which was compensated for with 'heavy traffic of e-mail messages'. This was seen to cause occasional confusion in terms of the project's organisation and a sense of how best to deliver on its aims and objectives. It was felt that had there been a more generous time allocation, which might have for instance increased the involvement of the oversight group, issues of confusion and difference in the project approach may have been more easily resolved:

> *'We would have been more effective ironing out differences in the philosophical approach to the task at hand.'* (OG member)

8. Conclusion

This PPE project has proven to be an overall success in its role and contribution in mobilizing not only the *patient* but *public* voice in matters of health research approval and governance. In so doing the project is testament to the feasibility and legitimacy of the publics' dialogical involvement in, and contribution to, decision-making processes – in this instance, in the context of health research. Furthermore, the project has shown not only the value to be gained from a broad and inclusive approach to patient and public engagement, but has revealed the potential in embedding a commitment to PPE within the early stages of an organisation's development. In this respect, the HRA now occupies, what we understand (based on our consultations), to be a unique position as a role-model for PPE in health research contexts.

This project has also produced huge amounts of new learning in respect of the challenges involved in the delivery of successful dialogue based engagement. If a spot-light is to be focused on any one of these lessons, it is perhaps in the handling of expertise and experts within public dialogues, where the nature and quality of specialisation can cause to erode the equality and inclusivity of dialogue and potentially cause to marginalise, or worse disenfranchise, non-expert participants. That said, we cannot overstate the contribution of this project in terms of progressing knowledge focused on the practice and delivery of PPE in health related contexts, and thereafter public dialogue for research and policy purposes more generally.

We are also cognisant of the multiple realised and prospective impacts the project has and will continue to propagate. Not least among these has been the influence of the project in engendering enthusiasm and new/further motivation among those who have come into its ambit for involvement in deliberative exercises as related to health research and beyond. The project is also significant for revealing a quality of 'hope' and a greater conviction among participants – than is arguably typical among many public engagement for policy initiatives – in the dialogue process as a means of connecting user, research and policy communities and dialogue as a means of mobilising influence and change, and as itself an impact-driver affecting elite, executive and policy decision-making. The project has also provided an important precedent for doing PPE in health research and in concretizing the significance of dialogue not only with patient but public groups.

Drs. Watermeyer and Barlett, March 2014.

Annex A: The Observation Schedule

Observational Schedule

NB The following schedule suggests aspects to observe that are related to the 'translation' concept. The schedule is expressed in the form of various questions: the observer should seek to answer the questions and provide explanation/ evidence for their answers.

Information Comprehensiveness *(Do the sponsors provide full information to participants?)*

- Do the sponsors clearly state the aims of the event at the outset?
- Do the sponsors clearly elaborate on an agenda?
- Do the sponsors clearly explain to participants what is expected of them (defining their task)?
- Do the sponsors explain how they have selected participants/ why they are there?
- Do the sponsors explain what will follow from the event (i.e. what feedback they might expect and what will happen with the output from the event)?

Information Appropriateness/Fairness *(Do the sponsors fairly frame the problem or is there any evidence of bias in terms of information provision/ recording/ translation?)*

- At the outset, do the sponsors provide a fair summary of the subject being considered, or do they provide a particular slant, bias or frame that might lead some perspectives to be focused upon at the expense of others?
- Does the way in which information is collected suggest any particular bias (beyond, say, randomness)?
- Is the process managed in such a way that bias is introduced in terms of the information that is considered or recorded (e.g. participants with one position allowed to speak at the expense of those with another position)?
- In any summing up, is there any bias in the reporting of the output from participants?
- Is participation fair, or do some participants have much greater opportunity to speak and influence than others (whether due to facilitator bias or event logistics)?

Process Limitations to Effective Translation

- Is there sufficient time for participants to consider all the necessary information, provide all necessary information, and think about this information? Are certain debates unneccessarily cut short because of time limits?
- Are there any information resource limitations that hinder the effective consideration of the topic of debate? That is, are participants asked to discuss an issue or solve a problem on which it is clear that extra information might have been made available (report findings, academic evidence)?
- Are there sufficient resources (personnel, tape recorders etc.) to enable the full output from the event to be recorded, or do such resource/logistic deficiencies ensure that there is only a partial recording of output, or imperfect recording of information?

Information synthesis

- How is the various information outputs synthesized, and are there any apparent inefficiencies? For example, how are competing priorities compared and contrasted? How are pro and con arguments set against each other? How is such information displayed to participants – and is it in a way that may help or hinder them from synthesizing different points of view? [For example, are there whiteboard or computer screen displays of pro and con lists? Are accurate 'minutes' taken? Is there any form of voting process to confirm participants' aggregate views?]

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Evaluation Questionnaire: Health Research Authority (HRA) PPE

Dear Participant,

Thank you for having taken part in the workshop. We would now like to ask you a few questions about it as part of our evaluation of this project, and we would be extremely grateful if you could complete this questionnaire. Please be assured that your responses will be treated anonymously. Although we ask for your name (below), this is so that we can characterize those who respond to this questionnaire. Your name will not be cited in any evaluation report or associated with any comment you make herein.

Thanks for your cooperation.

Dr Richard Watermeyer and Dr Andrew Bartlett (Cardiff University Evaluators)

1. What is your name? .....

2. Was it clear from the information you were sent prior to the event what the workshop would be about?
   - Yes ☐
   - No ☐
   - Unsure ☐

3. At the start of the workshop, were the aims clearly specified?
   - Yes ☐
   - No ☐
   - Unsure ☐

4. Was it clear to you from the information you were sent prior to the event why you were invited?
   - Yes ☐
   - No ☐
   - Unsure ☐

5. Was it made clear to you how the participants for this event were selected?
   - Yes ☐

No ☐
Unsure ☐

6. Do you think the public [interchangeable with *patients*] participants involved were appropriate for this event?

Yes ☐
No ☐
Unsure ☐

If there were there any notable absentees at the event, who were these?

.....
.....
.....
.....

7. During the event, did you have the opportunity to have your say?

I said all I wanted to say ☐
I said most of what I wanted to say ☐
I was only able to say a little of what I wanted to say ☐
I didn't get a chance to say anything ☐

8. Was there sufficient time to discuss all that needed to be discussed?

Yes ☐
No ☐
Unsure ☐

9. Do you think there were any significant issues that were NOT discussed, but which should have been? What were these?

.....
.....
.....
.....

10. Did you learn much from the workshop?

I learnt a lot of new things ☐
I learnt a few new things ☐
I'm not sure I learnt anything new ☐
No, I did not learn anything new ☐

11. Did participation in this event change your views on the issues in any way?
    - Yes, I changed my views considerably ☐
    - Yes, I changed my views to some degree ☐
    - I'm not sure whether I changed my views or not ☐
    - No, I did not change my views in any way ☐

12. What information (from speakers, from written material, from other participants, etc.) did you think was particularly influential on your views?

    .....
    .....
    .....
    .....

13. Do you think the summing-up accurately reflected what was discussed at the workshop?
    - Yes ☐
    - No ☐
    - Unsure ☐
    - There was no summing up ☐

    If not, what do you think was missed or improperly reported?

    .....
    .....
    .....
    .....

14. Overall, do you think the workshop was well run?
    - Yes ☐
    - No ☐
    - Unsure ☐

    If you said 'no', what was the main problem?

    .....
    .....
    .....
    .....

15. How satisfied were you with the event overall?
    - Very satisfied ☐
    - Fairly satisfied ☐
    - Neither satisfied nor dissatisfied ☐
    - Not very satisfied ☐
    - Not at all satisfied ☐

Unsure ☐

16. Do you think this event is likely to have any influence on the HRA's approval process involving *research and ethics review*?

Yes ☐
No ☐
Unsure ☐

Please explain your response.

.....
.....
.....
.....

17. Do you think this event is likely to have any influence on the HRA's approval process involving *research governance review*?

Yes ☐
No ☐
Unsure ☐

Please explain your response.

.....
.....
.....
.....

18. Do you think events like this are an essential part of the HRA's mandate of protecting and advancing the interests and welfare of patients and the public in health research?

Yes ☐
No ☐
Unsure ☐

Please explain your response.

.....
.....
.....
.....

19. As a result of this event, which of the following impacts, if any, do you think it is liable to have? (put a cross in as many boxes as are relevant to you, or leave all boxes blank)

I will be more likely to get involved in events like this in future ☐
I will be more likely to engage with the HRA in such matters ☐

20. Overall, what was the best thing about the workshop?

……
……
……
……
……

21. Overall, what was the worst thing about the workshop?

……
……
……
……
……

22. How do you think an event like this could be improved if something similar was run in the future?

……
……
……
……
……

Finally, we would like to phone a few people afterwards to ask them some more detailed questions about the event. Would you be prepared to talk to us again in a short 30 min. telephone interview? (Please note: saying 'yes' does not mean we would definitely phone you, as we will only re-contact a small sample after the event.)

Yes ☐
No ☐

If you said 'yes', please provide the details below:

Home phone number (including area code): ……

What is your email address: ……

What is your postal address: ……

What is the best time to phone you (e.g. weekends, after 6pm):

……

Would you like to receive other information from Sciencewise-ERC, including possibly opportunities to be involved in other debates on these sorts of topics in future?

Yes ☐

No ☐

Once again, thank you for your time.

Annex C: Interview schedule: *project stakeholders*

Interview schedule: Project stakeholders

- What do you think was most special and interesting about this public dialogue project?
- What do you identify as the strengths in the project approach?
- What do you identify as the weaknesses in the project approach?
- How well did the public and patient dialogue workshops link together to meet the objectives?
- Has taking part affected your own views on: a) the issues discussed and b) public engagement in policy on these sorts of issues? Please say why / how.
- How has the dialogue affected / improved what you were going to do / recommend (or not)? Please give details.
- Will you use the results of the project in your own work in future? Yes/No. Please say how [as specific as possible].
- What do you identify as the main short-term impacts of this project?
- What do you identify as the likely main long-term impacts of this project?
- What is the legacy of this project: for the HRA; for the research approval processes; for public engagement in health/research/policy contexts?
- As a whole, do you think the project has been a success? Please say why or why not.
- Finally, is there anything else you would like to say about this project?