RESEARCH VOLUNTEERS WORKSHOP

REPORT ON WORKSHOP PROCEEDINGS:

DISCUSSION, CONCLUSIONS AND NEXT STEPS

Research Volunteers Workshop

June 10th 2011
University College London

Report on Workshop Proceedings:

discussion, conclusions and next steps

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WORKSHOP ORGANISERS

The Research Volunteers Workshop was organised by:

Dr Norma Morris- Research Fellow at the Science and Technology Studies Department, UCL. Her research interests range from university-government relations to issues around human experimentation.

Dr Brian Balmer- Reader in the Science and Technology Studies Department, UCL. He has a broad interest in using historical and sociological approaches to understanding science, expertise and science policy, and has worked on the history and sociology of human experimentation in military research contexts. He is currently finishing a book on science and secrecy to be published by Ashgate.

Professor Jeremy Hebden- Head of the Department of Medical Physics & Bioengineering and Director of the UCL Biomedical Optics Research Laboratory. His research interests include development of novel optical techniques for functioning imaging of the brain and breast.

ACKNOWLEDGEMENTS

EXECUTIVE SUMMARY

The Research Volunteers Workshop provided the opportunity for a diverse group of stakeholders in biomedical research to come together and discuss the role of the research participants (or 'subjects') in contemporary research practice. Those invited included researchers, patients, patient groups, funders, managers and policy-makers. The objective was to try and assess practices in order to improve both the experience of the participants, and the quality of research findings. Well-managed volunteer involvement has the potential to generate research results that are better honed to public needs, and of more reliable quality. The findings of the workshop have wide-ranging implications for policy.

In order to take full advantage of the wide range of perspectives, the presentations were brief, and the focus of the day was on networking and discussion, as means to greater understanding between the different parties, increased collaboration and to form concrete recommendations for improving current practices.

Research Reports

The workshop began with presentations by researchers in both biomedical and social sciences and participating research volunteers. They gave some perspectives from the field about their experiences of working in partnership in research. The session was chaired by Professor Hugh Middleton, School of Sociology and Social Policy, Nottingham and NHS Consultant Psychiatrist, who introduced the short presentations.

The first presentation was from the organisers, about the study that was both the basis of an extended research project, and the origin of the workshop itself. The presenters were a group made up of a researcher from the Science and Technology Studies department, UCL, Dr Morris with Professor Jeremy Hebden who is developing new optical imaging techniques for the breast, and one of the research participants who had helped with the development of this new technology, Ms Fullerton. Together they gave an overview of what they had discovered about the potential for participants' roles in the research process, and the ways in which good working relationships were developed. Dr Leff and Mr Jarvis, gave a presentation of their innovative work taking research (and treatment) out of the lab, and onto the internet, and their observations of changing roles. Finally, Dr Teran gave an overview of some of the aims and new practices being developed at the Institute for Clinical and Translational Science, University of California

Irvine to promote a more reciprocal relationship between researchers and communities.

The discussion that followed raised questions about how to develop and maintain successful relationships between researchers and participants, particularly over longer-term projects, and how both communication and funding practices might affect these. There was also some discussion about the accreditation and ownership of research results where participants had become highly engaged in the research process.

The contribution of Patient Groups and PPI

This session was chaired by Dr Louise Wood, Deputy Director, R&D Directorate, at the Department of Health. The session aimed to examine how organised groups, whether patient- or researcher-led, may contribute to the research participant's experience. Dr Morgan, and Mrs Wilcox gave a presentation of the campaigning activities of the ICPV- Independent Cancer Patients' Voice group, which have included organising study days to promote researcher-patient/participant dialogue, and efforts to increase patient voice at structural levels in research organisations. Dr Shawe, supported by Forum member Erika Narkiewicz, gave an overview of the creation of the new Research and Innovation Forum that exists to give the local communities a greater role in organising and steering the research of the Margaret Pyke Centre for Sexual and Reproductive Health. Finally Dr Pfeffer gave an overview of her work with CERES (Consumers for Ethics in Research) a campaign group that had led the way in promoting participant empowerment, and good practice amongst researchers.

The session ended with debate on a number of issues including the diversity of the patient/research volunteer community, and consideration of how that could be best represented. There was also discussion of structures embedded within research procedures that were inhibiting patient involvement, these included power relationships, but also rules of confidentiality which may leave participants unable to seek support from peer groups.

Government, Sponsorship and the Participant

This panel, also chaired by Dr Wood, explored the role of the major institutional structures around research governance, regulation and sponsorship in shaping the research participant's experience.

The first presentation, given by Dr Jane Cope of the National Cancer Research Institute, gave an overview of how attitudes towards patient participation had changed during the course of her career and how different practices had evolved, particularly in relationship to governance. She drew attention to issues around assessing the level of regulation most beneficial to patients. The second presentation by Dr Susan Kerrison of the UCL/UCLH Joint Unit framed PPI within the context of the vast number and extremes of scale of studies that take place in this organisation each year. She highlighted the diversity of roles that research participants play in these.

The ensuing discussion debated the role of PPI in various kinds of research, and research environments, what it might contribute, how it should be evaluated its impact assessed different situations. Specific areas identified for action included the sharing of information, lack of regulatory attention to social and structural contexts affecting participation, and PPI in commercial trials.

Reflections and Exploration

The afternoon session of the Workshop followed a less traditional format than the morning's proceedings. It was designed to elicit the maximum contribution from all the participants, and consisted of three main sections, each aiming in different ways to promote reflection and deeper exploration of the themes emerging from the morning's presentations and discussions.

These three sections comprised:

1. Discussion in Break-out Groups
2. Afternoon Plenary address by Professor Stuart Blume on the social and political context of clinical trials
3. Reports from the Break-out Groups and concluding plenary discussion session

Both the plenary session and the Break-out Group reports raised issues that transcended the frame of the individual clinical study. They stressed the importance of understanding the meaning of medical research for potential volunteers and the range of roles that participants could play. Both explored the delicate balance between trust and regulatory safeguards, and weaknesses in current governance systems which concentrate too much on

the early stages of studies (initial patient information and consent) and lacked systematic attention to trial management and social issues of concern to participants. In the global context as well as closer to home, the local political economy of health shaped the choices available to potential volunteers, and could result in blurring of research and care. The final discussion included recommendations for reviewing, with patient input, the kind of regulation needed; for evolution of Ethics Committees practices and philosophy; and for recognising through regulatory systems that patient/participants needs went beyond 'protection', embracing issues such as information, access and appropriate research design.

Break-Out Groups

Each Group was assigned a topic for discussion, a broadly independent chairman, and someone with close knowledge of the particular area to start off the discussion. The groups debated the questions for about an hour and then drew together the main threads for report back to the plenary session after the tea break. A note-taker was provided for each group to help in this process.

The topics for discussion were as follows:

Group A: Does Patient and Public Involvement (PPI), as presently practised, affect the experience or level of involvement of actual 'research participants'?
Chair: Carolyn Morris (COMPASS User Involvement Group)
Opening the discussion: MaryRose Tarpey (INVOLVE)

Group B: Are the people enrolled in a clinical study best (or most accurately) described as participants, collaborators or research subjects?
Chair: Dr Brian Balmer (UCL)
Opening the discussion: Dr Oonagh Corrigan (Associate Professor in Sociology and Ethics, University of Plymouth)

Group C: Government policy plans to increase the proportion of patients taking part in research. What are the implications of this for patients and research participants?
Chair: Professor Ulf Schmidt (University of Kent)
Opening the discussion: Dr Janet Wisely (Director, National Research Ethics Service)

The final plenary session was chaired by Professor Graham Scambler (Professor of Medical Sociology, Research Department of Infection & Population Health, UCL). He outlined the format of the session and briefly introduced Professor Stuart Blume who had been invited to give the last formal presentation of the day. Professor Blume's presentation The Politics of Patient Participation brought out some of the wider political considerations for those dealing with medical research subjects and provided an excellent frame for beginning to draw conclusions from the day's proceedings.

Conclusions, Recommendations and Next Steps

The variety and richness of discussion at the Workshop made it impossible to draw together in the final discussion all the insights, observations and proposals for action that had emerged during the course of the day. With the advantage of more time, and documentation of the event, the organisers have however highlighted here some of the recurring themes and recommendations.

Biomedical research involving human subjects has developed rapidly over the last decades, as have understandings of the role and contribution of patients and research participants. The latter however remains patchy, and an overall priority is to increase public, patient and participant influence to address questions at both the micro level of the individual participant and individual trial and the macro level of global trends in healthcare and research, weaknesses in national and international systems of regulation, and pervasive issues such as trust and equity.

Specific recommendations made include the question of trust and how this intersects with appropriate levels of governance, and the negative effects of over-regulation and bureaucracy. Gaps were identified in current regulatory frameworks regarding social issues, such as complaints procedures, feedback and the availability of information for those who have taken part. We can overcome mere lip service to the involvement of public and participants in research by instating systems that require evidence of good practice in PPI and give due attention to practicalities such as funding. Commercial as well as publicly funded trials need to be drawn into this culture. Patients, patient groups and potential participants can make an important contribution to shaping such reforms.

At the micro level, the participants at the workshop identified a number of practical steps that could be taken. Ethics Committees and funding bodies could encourage the expansion of participant involvement to cover the whole process (engaging with them at the design stage, and through to the end of the studies), by making this a condition of approval. The same should apply to feedback from the researchers to participants about the results of the studies. The training of researchers could usefully include a more careful consideration of the roles of their participants, and the range of contributions that terms such as 'subject' or 'partner' might imply.

The conclusions and discussion from the Workshop are to be further developed in the Research Volunteers Forum which has a dedicated website (www.ucl.ac.uk/researchvolunteersforum), where more detailed information on the proceedings of the Workshop is to be found, including audio podcasts of all the presentations. The expectation is that individuals and organisations will have been motivated by these discussions to take up the themes most appropriate to their sphere, and create more developed plans of action.

ABOUT THE WORKSHOP

Current research strongly suggests that the quality of the relationship between the researcher and the researched subject is crucial for the achievement of both volunteer satisfaction and successful and reliable research outcomes. The organisers of this Workshop believe that such findings have policy implications for:

· the design and management of clinical trials and other experimental biomedical research using humans

· revisiting the concept of the volunteer that is embedded in research regulation and ethical codes

· the role of patient advocacy groups

· researcher training

· policy-makers, politicians and executives concerned with strategic priorities

The Workshop provided an opportunity to discuss such issues with a wide range of organisational and individual stakeholders in the research enterprise (including researchers, patients, patient groups, funders, managers and policy-makers). The format of the meeting placed an emphasis on sharing the expertise and perspectives of all participants. Presentations were kept very short, with extended provision for break-out groups, debate and networking. Together, these stakeholders reviewed the scope for joint and individual action and collectively suggested ways forward.

We have set up a dedicated website (www.ucl.ac.uk/researchvolunteersforum) where the links forged on the day may be maintained, and discussions and recommendations further developed. This site also provides access to both podcasts and transcripts from the workshop presentations. Please click on the icons (as below) to link directly to the relevant multimedia material on the website.

Listen to presentation 🔊

Read presentation transcript 📑

CONTEXT

WORKSHOP

Brian Balmer   / UCL

Stuart Blume   / University of Amsterdam/ Innovia Foundation

Sophie Broster-James / Medical Research Council

Victoria Cambridge   / Royal Society

Meg Clinch   / Cambridge University

Jane Cope   / National Cancer Research Institute

Oonagh Corrigan   / Peninsula Medical School, Plymouth University

Diana Dunstan   / Gt Ormond St Charity Trustee

Leila Eadie   / UCL

Sharon Fullerton   / Patient-Volunteer

Sophie Gasson   / Cancer Patients Research Group

Kate Harvey   / Nuffield Council on Bioethics

Jem Hebden   / UCL

Mark Jarvis   / Patient-Volunteer

Susan Kerrison   / UCL/UCLH

Anne Lancely   / UCL, Women's Health

Alex Leff   / UCL, Institute of Neurology

Karen Lowton   / KCL

Jackie Maull   / Association of Research Ethics Committees

Stephen Mawdsley   / Cambridge University

Hugh Middleton   / Nottingham University

Adrienne Morgan   / Independent Cancer Patients' Voice

Carolyn Morris   / COMPASS Consumer Liaison Group

Norma Morris   / UCL

PARTICIPANTS

Erika Narkiewicz   / St Mungo's

Naomi Pfeffer   / UCL

Vivienne Quirke   / Oxford Brookes University

Nadia Robb   / UCL

Graham Scambler   / UCL

Ulf Schmidt   / University of Kent

Jill Shawe   / UCL, Women's Health

Judith Stephenson   / UCL, Women's Health

Fiona Stevenson   / UCL

Maryrose Tarpey   / INVOLVE

Harriet Teare   / Cancer Research UK

Lorena Teran   / University of California, Irvine

Shana Vijayan   / UCL

Maggie Wilcox   / Independent Cancer Patients' Voice

Catherine Will   / University of Sussex

Janet Wisely   / The National Research Ethics Service

Louise Wood   / Department of Health

Zoe Wood   / UCLH

Rosamund Yu   / UCLH/UCL

CONTEXT

WORKSHOP

10.00 /Professor Malcolm Grant (UCL Provost) **Welcome**

10.10 /**Research Reports**

Chair: Professor Hugh Middleton, School of Sociology and Social Policy, Nottingham, and NHS Consultant Psychiatrist

Norma Morris, Jeremy Hebden, Sharon Fullerton and Brian Balmer (UCL)
Optical Imaging participant-involvement project: 'Just bodies' or partners in research?

Alex Leff Consultant Neurologist (UCL) and Mark Jarvis (participating patient)
Treating patients using the internet

Lorena Teran (University of California, Irvine)
Research participant engagement at University of California, Irvine

10.40 /Questions and discussion

11.00 /Coffee Break

11.30 /**The contribution of Patient Groups and PPI**

Chair: Dr Louise Wood, Deputy Director, R&D Directorate, DoH

Dr Adrienne Morgan, Maggie Wilcox (Independent Cancer Patients' Voice)
ICPV's role and policies

Dr Jill Shawe (Margaret Pyke Centre for Sexual and Reproductive Health)
The Research and Innovation Forum

Dr Naomi Pfeffer (UCL)
Reflections on 'CERES' (Consumers for Ethics in Research)

12.00 /Questions and discussion

12.20 /**Governance, Sponsorship and the Participant**

Chair: Dr Louise Wood, Deputy Director, R&D Directorate, DoH

Dr Jane Cope , Director, National Cancer Research Institute (NCRI)
Dr Susan Kerrison, (UCL/UCLH Joint Unit)
Research Governance and PPI - the view from a large Trust

12.45 /Questions and discussion

13.00 /Lunch

AGENDA

14.15   /**Breakout Sessions**

Group A

Chair: Carolyn Morris (COMPASS User Involvement Group)

Opening remarks: Maryrose Tarpey (INVOLVE)

Does Patient and Public Involvement (PPI) , as presently practised, affect the experience or level of involvement of actual 'research participants?

Group B

Chair: Dr Brian Balmer (UCL)

Opening remarks: Dr Oonagh Corrigan (Associate Professor in Sociology and Ethics, University of Plymouth)

Are the people enrolled in a clinical study best (or most accurately) described as participants, collaborators or research subjects?

Group C

Chair: Professor Ulf Schmidt (University of Kent)

Opening remarks: Dr Janet Wisely (Director, National Research Ethics Service)

Government policy plans to increase the proportion of patients taking part in research. What are the implications of this for patients and research participants?

15.30   /Coffee Break

16.00   /**Plenary Session**

Chair: Professor Graham Scambler (Professor of Medical Sociology, Research Department of Infection & Population Health, UCL)

Professor Stuart Blume (University of Amsterdam and Innovia Foundation)
The Politics of Patient Participation

Rapporteurs from the Break-out Groups
Reports from Break-out Groups

17.10   /Questions, discussion and where next

17.30   /Close

CONTEXT

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UCL Provost, Professor Malcolm Grant opened the workshop with a few words.

He commented that for UCL, (in common with many institutions) a primary goal is to ensure that mankind receives the benefits of its research. The strong connotations of the terms 'basic research' and 'applied research' have perhaps impeded this process. A university is publicly funded to do things that are of public benefit. This includes not only basic discoveries but also their translation into concrete results.

The notion of translation, finding a 'route out' of the laboratory into the population, has been key for UCL in discussions with organisations such as Cancer Research UK, the Medical Research Council and the Wellcome Trust who have funded the new medical research centre being developed at St Pancras. Partnerships between UCL and hospitals such as Great Ormond Street, Moorfields, UCL Hospital and the Royal Free are also immensely important because they allow us to ensure that teaching, research and clinical practice are more closely joined together. The success of this can be seen in last year's project looking at the treatment of strokes in the North Central London area. The incidence of lasting damage has been dramatically reduced and we hope to repeat that success with further work on cardiac and cancer treatment.

However, an important aspect of the 'translational pipeline' is that working with patient groups and human subjects is very different from working with mice! It is only when new discoveries come into contact with humans that we can understand their likely impact. This is a difficult and costly enterprise, in which we have been overtaken by the US and China. This workshop has the potential to make major contributions to our understanding of the use of volunteers and to developing better practices in clinical, translational research.

RESEARCH REPORTS

The workshop began with presentations by researchers in both biomedical and social sciences and participating research volunteers. They gave some perspectives from the field about their experiences of working in partnership in research. The session was chaired by Professor Hugh Middleton, School of Sociology and Social Policy, Nottingham and NHS Consultant Psychiatrist, who introduced the short presentations.

The first presentation was from the organisers, about the study that was both the basis of an extended research project, and the origin of the workshop itself. The presenters were a group made up of a researcher from the Science and Technology Studies department, UCL, Dr Morris, with Professor Jeremy Hebden who is developing new optical imaging techniques for the breast, and one of the research participants who had helped with the development of this new technology, Ms Fullerton. Together they gave an overview of what they had discovered about the potential for participants' roles in the research process, and the ways in which good working relationships were developed. Dr Leff and Mr Jarvis, gave a presentation of their innovative work taking research (and treatment) out of the lab, and onto the Internet, and their observations of changing roles. Finally, Dr Teran gave an overview of some of the aims and new practices being developed at the Institute for Clinical and Translational Science, University of California Irvine to promote a more reciprocal relationship between researchers and communities.

The discussion that followed raised questions about how to develop and maintain successful relationships between researchers and participants, particularly over longer-term projects, and how both communication and funding practices might affect these. There was also some discussion about the accreditation and ownership of research results where participants had become highly engaged in the research process.

'JUST BODIES?'

Dr Norma Morris, Professor Jeremy Hebden- members of the research team and Sharon Fullerton- research participant

Professor Hebden opened the presentation. He described the work of his research team who are developing a new optical imaging system to build images of the breast using harmless pulses of light. A first prototype was developed which required the patient to lean against a frame (Image 1). The testing of this prototype was done in collaboration with Norma Morris, who interviewed each of the volunteers after each study. These interviews generated interesting feedback that allowed the physicists and engineers to modify the system to be more patient-friendly. These modifications increased cooperation from the volunteers, and improve the quality of data. A second prototype was developed with a different system (Image 2). Further studies and interviews have led to continued refinement of the equipment.

Dr Morris described the key findings from her interviews with the participants and participant-observation of the optical imaging research. There were a few participants who described themselves as happy with the notion of being 'just bodies' as opposed to active participants, but at the same time felt ambivalent or hostile to the idea of being a 'guinea-pig'. More commonly participants sought an equal and active role, and felt themselves empowered by 'giving' to medical research in this situation where they could expect no direct benefit. Another volunteer described herself as a 'pioneer not victim,' i.e. as active, not passive, a reminder of the effort required for achieving and sustaining productive relationships in research.

Sharon Fullerton spoke as a participant in this study. She had come to be involved after successfully recovering from bilateral breast cancer. Her consultant surgeon had invited her to participate in the study in 2007. Sharon had agreed both from gratitude for the quality of care she had received but also due to her independent involvement with cancer charities.

She noted several ways in which she had been made to feel comfortable and valued as a volunteer. Prior to the study she had received detailed information beforehand about the tests. On the day itself she was met at the lobby, guided through the hospital and introduced to each person who was present. The closing interview by Norma Morris was a 'really nice way of

finishing the morning'. Sharon was also pleased to have received updates about the study by email, these leave her continuing to feel her participation was worthwhile.

The speakers left the audience with two key questions to be considered during the workshop:

What is it like to be a participant, a research volunteer in medical research? What scope is there to be more than a 'lab rat'- more than just a body?

Image 1: UCL optical mammography system, first prototype

Image 2: UCL optical mammography system, second prototype

TREATING PATIENTS USING THE INTERNET

Dr Alex Leff, consultant neurologist, UCL Institute of Neurology and Mark Jarvis

Dr Alex Leff has been developing a behavioural treatment for a condition caused by a stroke that affects people's vision, and in particular their reading. The treatment, Read-Right, is structured reading practice using text that is rolling across a screen. This exercise produces an increased speed of between 30-50% when the patient returns to static text.

The treatment was proven to be effective in a controlled clinical trial where the therapy materials (moving text at different speeds) was recorded onto videotapes and sent to patients' homes. However, after the trial finished the question remained of how to get it 'out there'. With funding from the Stroke Association and UCL Multimedia he decided to make the therapy freely available on a website.

This led to a new set of challenges. Initially these were related to developing a useful and attractive interface, but then the team decided to ask an additional, scientific question- does putting the therapy on the website have as good an effect as when it is done in a clinical trial? This made good web design all the more important. Finally the problem of distribution arose- how can you bring this therapy to the attention of patients? On these issues patient input proved to be crucial, and Dr Leff introduced Mark Jarvis, a patient who had collaborated with the research team on these questions.

Mark Jarvis explained how he had met Dr Leff. He was suffering from the condition of hemianopia- a loss of the field of vision in his right eye. Although he later learned that this only prevents 'pre-reading' (as those with stereovision are able to do), he initially thought he had lost the ability to read properly.

His role in helping to develop Read-Right. was to work with the design to improve his ability, as a patient, to use the website- for example, initially the controls were placed on the right hand side of the screen, where it was difficult for him to use them. They also changed colours and fonts to adapt it for people with the condition, and introduced a variety of different kinds of reading matter, books, articles, tabloid newspapers and so on. He found it really beneficial that his views, as someone with the condition, were

valued by the researchers, and put to use, and going out direct to the public and other patients by the website. His participation had also contributed to a greater sense of confidence. This partly came from understanding his condition better, that it was his visual impairment that slowed his reading, and there was nothing wrong with the 'reading' part of his brain. It had also however allowed him to go back to giving presentations. Public-speaking had been very difficult whilst reading had made him feel anxious.

Mark had also played a significant role in publicity and generating awareness. One key moment for the website was an article in the Mail on Sunday. This increased the number of participants, and Mark found himself inundated with emails and phone calls asking for more information about Read-Right. As a sufferer, he could appreciate that the loss of a skill that people had acquired from an early age was very frustrating for most people. Being able to assist people using the knowledge he had gained from participating in the research was a very fulfilling experience.
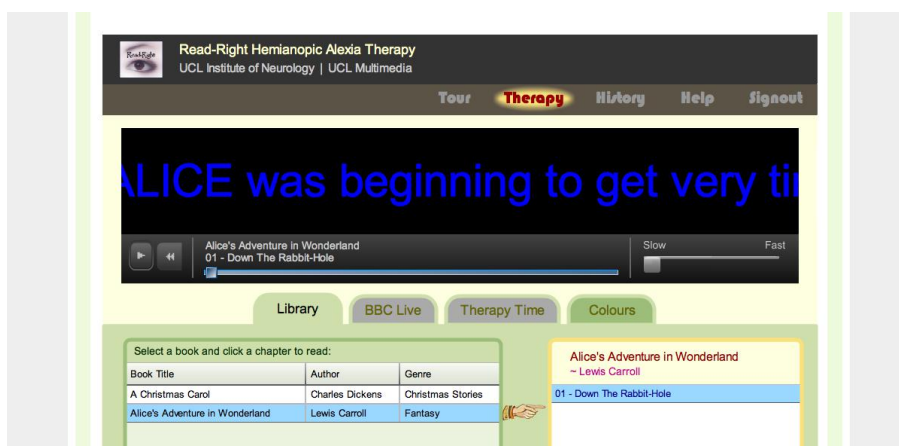
Screen shot from the demo version of Read Right / www.readright.ucl.ac.uk

RESEARCH PARTICIPANT ENGAGEMENT AT UNIVERSITY OF CALIFORNIA, IRVINE

Dr Lorena Teran, University of California, Irvine

Dr Teran gave an overview of the work underway at the University of California, Irvine in the Institute for Clinical and Translational Science. The department have recently set up a Community Engagement Unit (CEU). This unit creates a space for collaboration between students, scholars, researchers and community organisations on projects that have been generated by the community.

This unit is developing research practice based on the principles of Community-based Participatory Research (CBPR). These are founded on shared decision-making and shared ownership of research findings and knowledge benefits between all the partners involved. This style of working is new to UC Irvine, however, useful results have been gained from those few projects where the community has been involved, particularly in behavioural research.

Applying CBPR requires inventing new ways of working but generates benefits. In usual practice, research groups have to work to identify a patient population. As an example, there are many studies on obesity prevention, and a large Latino population in southern California. No one on the research teams however speaks Spanish or has a Latin background; the skills that would allow interaction with participants on their own terms. Involving the community and building the project together prevents this kind of problem.

This has an impact on research agendas. Typically these are based on clinical data, investigators' research interests or funding opportunities. Having more diverse research teams helps to identify and define clinical issues from the community's point of view. The community representatives are not only advisors, but also serve on decision-making bodies.

It also affects recruiting, which would traditionally be done through websites, local doctors or advertisements. The CEU are working to persuade research organisations to educate local community groups and hire individuals within the community as health outreach workers. These can in turn recruit volunteers.

They have also set up the Community Action Planning Group. The role of

this group is to act as an intermediary between researchers and community-based organisations. This group is involved in providing services such as blood pressure monitoring, or glucose testing and simultaneously disseminating findings beyond peer-review journals. The volunteers feel more involved and the community partners help with advocacy for policy change.

Direct benefits to the CBPR approach are that you have a better-balanced trial with more diverse patient populations, particularly those currently under-represented. You also increase patient trust, which has not always been sufficiently cared for in the past.

Finally, this communication between partners can be difficult, there are challenges to bridging the different perspectives. It can take many meetings and a lot of communication to get people on a level playing field. The CEU have two particular initiatives to address this. Firstly, the Campus Community Research Incubator Awards provide funding for the early stages of discussion between researchers and community organisations. Secondly they are working to motivate community groups and volunteers through award systems and stipends.

In conclusion, the work of the CEU using CBPR has produced interesting results and feedback from previously hard to reach populations.

The Community Engagement Unit at work-
they visit community health fairs and provide
participants with their BMI and blood
pressure for free

Research Reports: Questions and Discussion

Sustaining participation

The first question raised was about the challenge of sustaining an 'individual' relationship with participants in studies that extended over long period of time – six or seven years for example.

- One suggestion, from a patient and research participant, was that the key lay in maintaining regular contact through sending out information or updates to sustain interest and the sense of involvement

- Another suggestion was that participants might be invited to comment on how the trial processes might be improved in the light of their continuing experience. Although study protocols were not normally open to change, there was a case for considering more flexible approaches to design that permitted procedures to be modified in the light of participant feedback.

- A patient/participant also cited the Million Women Survey and Biobank as examples of how regular contact and information could successfully sustain participant commitment over a long period.

Levels of patient participation

Some divisions were observed at the strategic management level of large national studies with regard to volunteer research participant involvement (where provision of information was generally thought to be well-managed)

- Biobank, for example, had shown itself not to be open to an approach from a patient group to meet with managers to learn more about the governance of the study. This contrasted with, for example, a breast cancer-specific database launched by one of the cancer charities, where there were patients on the management board and on key committees, commenting on all aspects of the work

- Some of this difference might be accounted for by differences in the nature of the database and the participant population, i.e. the one a national DNA bank based largely on healthy volunteers, and the other a disease-specific tissue bank, necessarily patient-based.

Improving feedback to participants

Examples were given of poor practice (in major trials centres) regarding feedback of information on study progress to participants. This elicited suggestions for ways of improving this situation, drawing on practices already put in place by some individuals and institutions:

- Run courses on Participatory Research for both researchers and community or patient-based organisations (and make sure both come!)

- Use the Internet for both individual (eg test results) and study group feedback. Attention was needed to confidentiality and copyright (eg re scientific publications) issues, but these were surmountable problems

- Where the individual participant's voice is apparently not listened to, they could bring to bear added leverage by speaking as a member of a patient group

Practicalities of involving faculty and community

In response to a question regarding the involvement of faculty (ie researchers) on issues around active participation, it was noted that the proportion of those committed to this approach was still very small. Likewise it was easier to deal with organised groups rather than with unorganised patients. Nevertheless efforts were being made to widen the coverage, including the following:

- Holding workshops and courses

- At University of California, Irvine, a system of Incubator Awards – small cash grants available for work contributing to setting up partnerships

- Making training available for patients and community members to help them hold their own, play active roles within advisory or management committees, and communicate their valuable experience and views

- Ensuring patients as research participants felt confident enough to speak up with their comments or suggestions on the design and conduct of the research

Ownership of research results

The final topic raised in this discussion session was on the ownership of the results of research. How far might researchers (or their sponsors) be willing to share the fruits of research with the research participants? This provoked a range of comments and suggestions, including:

- Sharing information about results had already been identified as important to participants, should Ethics Committees therefore be encouraged to insist on this as a formal requirement?

- Extending the practice of co-authorship of publications with community/patient partners

- Sharing financial benefits (where there were any) was noted to be problematic in many ways, not least because of the ethical issues it raises. But the question remained open: should we find some way of "being like John Lewis" (ie a partnership that embraced all members of the enterprise, who all had some share in the profits)?

THE CONTRIBUTION OF PATIENT GROUPS & PPI

This session was chaired by Dr Louise Wood, Deputy Director, R&D Directorate, at the Department of Health. The session aimed to examine how organised groups, whether patient- or researcher-led, may contribute to the research participant's experience. Dr Morgan, and Mrs Wilcox gave a presentation of the campaigning activities of the ICPV- Independent Cancer Patients' Voice group, which have included organising study days to promote researcher-patient/participant dialogue, and efforts to increase patient voice at structural levels in research organisations. Dr Shawe, supported by Forum member Erika Narkiewicz, gave an overview of the creation of the new Research and Innovation Forum that exists to give the local communities a greater role in organising and steering the research of the Margaret Pyke Centre for Sexual and Reproductive Health. Finally Dr Pfeffer gave an overview of her work with CERES (Consumers for Ethics in Research) a campaign group that had led the way in promoting participant empowerment, and good practice amongst researchers.

The session ended with debate on a number of issues including the diversity of the patient/research volunteer community, and consideration of how that could be best represented. There was also discussion of structures embedded within research procedures that were inhibiting patient involvement, these included power relationships, but also rules of confidentiality which may leave participants unable to seek support from peer groups.

THE ROLE AND POLICIES OF THE INDEPENDENT CANCER PATIENTS' VOICE (ICPV)

Dr Adrienne Morgan and Maggie Wilcox (ICPV)

Dr Morgan began with a quotation from one of the founders of ICPV. "Research is improved by patients being partners with physicians and healthcare professionals, rather than passive recipients of healthcare." This outlines their philosophy as a patient advocate group led by patients, independent of established cancer charities, that has been working since 2009. Their aim is to bring the voices of the patient, carers and relatives into the cancer research community, and they have developed a number of strategies to do this. Dr Morgan outlined some of these; study days, members involved in clinical research, and an active Google group as a forum for discussion.

ICPV has been involved with a number of clinical trials that cover a range of issues. In addition they have also been involved with the new Breast Cancer Campaign tissue bank initiative. This has resulted in clinicians and pathologists having greater awareness of patients' willingness to consent to donate material. It has also led towards a change in attitude to tissue banking, the banks as custodians rather than owners of the material.

They have also organised four study days by approaching centres of excellence and researchers directly. Basic travel and accommodation costs have generally been supported by donations from the drug industry but otherwise the group has no source of funding. Discussions at the Study Days have tackled consent, pathology and tissue-banking, the breast cancer screening debate, and also the design of clinical trials. The most recent event took place at the Houses of Parliament where the ICPV hosted a 'Dragon's Den' style forum for researchers designing new clinical trials where there was also a discussion about the 23-hour pathway for breast surgery.

ICPV have also produced a variety of documentation from discussion papers to leaflets promoting the tissue bank initiative and a patient-to-patient leaflet explaining the benefits of participating in clinical trials.

Photograph from the National Cancer Intelligence Network (NCIN) conference
Photo credit: Adrienne Morgan

RESEARCH INNOVATION FORUM

Dr Jill Shawe, Margaret Pyke Centre for Sexual and Reproductive Health and Erika Narkiewicz, MPC Forum member and Regional Health Coordinator, St Mungo's NE London

Dr Jill Shawe is both researcher at UCL and clinician at the Margaret Pyke Centre. This centre is part of the Central Northwest London Trust and provides sexual health services for the whole area. When she joined the centre it became obvious that more patient involvement was necessary, and this eventually resulted in a Research Innovation Forum which was created with Dr Zara Haider, a colleague who was looking at setting up a community gynaecology service.

So why did they do this? Patient involvement was important for a number of reasons. Firstly that the patients themselves have great ideas for research, and it was important to find a channel for them. The centre was at the end of a trial for a contraceptive pill and the patients were actively seeking further ways to be involved. The Forum was seen as a useful place to think about the pathways that patients would use to access the proposed community gynaecology service and finally the centre wanted advice on their website from the users.

The Forum applied for funding from the UCL Public Engagement unit and that started things off. They used the Camden Community Information Service (CINDEX), contacted every community group and invited them to be stakeholders in the project. Two important partners emerged, the Fitzrovia Women's Centre that works largely with Asian women, and St Mungo's.

Erika Narkiewicz spoke on behalf of St Mungo's which is a large organisation for the homeless and runs several big hostels in the Camden area. She was happy to have been invited to join the forum as she usually has to approach the healthcare providers herself.

From September the patient forum will be chaired by one of the patients. An important problem to solve is how to get beyond email as a means of communication, whether Facebook or media completely outside of the internet, posters, flyers and so on. The patient pool for the organisations includes homeless people, asylum seekers, people from ethnic minorities and youth groups, and they want to widen participation. They are keen to gather

more information about what research is needed and how to improve services. A final outreach project is participation at a community fair, setting up a stall that is planned as an annual activity.

The latest news is that a forum-member has been involved with a grant-application process for funding using community pharmacists and therefore engaged in the project right from the start. A positive step for the Forum.

Flyer from the recruitment stage of the Margaret Pyke Centre Research Innovation Forum

REFLECTIONS ON 'CERES' (CONSUMERS FOR ETHICS IN RESEARCH)

Professor Naomi Pfeffer, UCL

Prof. Pfeffer described the work of CERES and some of the lessons learnt from participating in the organisation. The organisation was initially established in 1988 as the Standing Committee of User Organisations for Pregnancy, Childbirth and New Developments in Reproductive Technology.. From this CERES emerged but was campaigning around the patient role in medical research more broadly.

When the group was established, they undertook some research into the structure of medical charities. At this time these were most often structured very similarly; a scientific committee composed of eminent practitioners or researchers, and a lay group who were only involved as fundraisers. CERES aimed to act quite differently and was interested in raising consciousness and getting patients involved with drawing attention to the issues that were of immediate concern to them.

The group earned money through small grants and from the sale of publications. One of these was a booklet *Spreading the Word on Research*, funded by the North-East Thames Regional Health Authority advising investigators on how to produce comprehensive, comprehensible patient information. This was sold and used extremely widely. A second important publication was the *Medical Research and You* leaflet, ratified by the Plain English Campaign and also sold and distributed very widely. Other similar projects also produced publications, often providing information in various languages and also on tape.

Other activities included public meetings, as for example one held on research into Sickle Cell and Thalassaemia. These meetings brought up specific issues, such as the very poor quality of patient information material in clinical trials, and also the general interest from patients in more socially-oriented research into their conditions, investigating for example the factors that might provoke crises.

The organisation closed in 2006. There were several issues at that time. One was that *Medical Research and You* was being used inappropriately by a

company that was recruiting for healthy volunteers (and involved in a notorious incident in 2006 where several healthy volunteers required intensive care). Another was that patients were looking for more specific advice and support than CERES was able to give. Finally there had been a move to create an independent advice and information service for research subjects as a statutory requirement under the EU Clinical Trial Directive, although this was, in the end, dropped from the legislation.

The experience of working with CERES brought several lessons, which Dr Pfeffer invited participants in the Workshop to keep in mind during further discussions:

> There is no single research subject's view on medical research.
>
> There is no agreement on why researchers and their sponsors should take note of research subjects. Is it for:
>
>> better science?
>> better ethics?
>> easier recruitment of research subjects?
>> the development of more appropriate health care?
>> the creation of new markets?
>> confirming or monitoring investigators' compliance with regulations?
>
> Structural inequalities in power must be recognised.
>
> The landscape of clinical research changes, so there needs to be constant reassessment of what it means to have a patient voice.
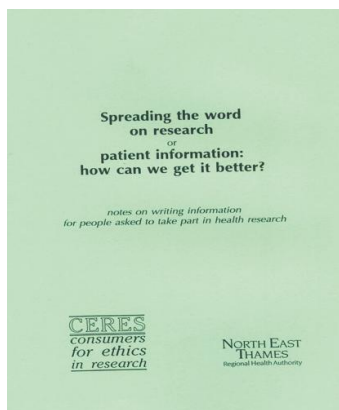
Spreading the Word on Research, CERES publication, 1994

Medical Research And You, CERES publication, 1994

The Contribution of Patient Groups and PPI: Questions and Discussion

Diversity of the patient community

The first topic raised was how far the patient body or community – often referred to in the morning's talks – was a coherent one. Were all voices equal in that body? And more specifically in terms of the history of patient groups did something special happen when doctors and medical scientists started to talk about their experience as patients, and could thus speak with a dual voice? Were there issues of structural inequality in the 'patient voice', which needed to be addressed? Among the points raised in the ensuing discussion were the following:

· There was great diversity and members of patient groups should be thought of as advocates – rather than representatives, as they could not and did not claim to be 'representative' of patients as a whole

· Scientists had to learn to be patients, as patients had to learn to be comfortable with science, and advocates had to earn their place at the table and earn respect by making valuable and relevant contributions

· Things had moved on since the pioneering early days. Both the AIDs community and the Women's Health movement had been important influences in winning acceptance for an active patient role, though inequalities of power of course remained at the level of both the individual and institutional influence.

Role and functions of patient groups

· Patient groups had a role in proactively seeking out patients with latent capacity for the advocate role and in sustaining momentum and energising their members through the enthusiasm and organisational enterprise of the collective

· Ensuring a range of perspectives through bringing in carers, young people, children and those patients totally dependent on care. (The work of NIHR's Medicines for Children Clinical Research Network and NRES in producing guidance on the involvement of children in research decisions was welcomed in this context.)

· Maintaining the morale and commitment of partnership groups through vicissitudes in funding (a role or responsibility shared with researchers)

· Drawing attention to the practical issues associated with the quest for diversity (e.g. lack of provision for the cost of carers' time)

Is there a space for the voice of research participants?

· Patient groups are held back from developing direct channels of communication with research participants because current rules of confidentiality deny them access. These rules need to be challenged so that more effective liaisons between patients on Management Groups and participants can be established

· Consideration could be given to inserting a clause into standard research forms regarding consent to further contacts. This might alleviate this situation

· Researchers and health professionals may still need reminding that they do not always know best what research participants and patients generally want and need

· It remains a concern that the total number of researchers actively involving patients – or participants – in the research is a very small proportion of the whole (a claim substantiated by figures collected by 'INVOLVE' up to 2010)

CONTRIBUTION OF PATIENT GROUPS & PPI

GOVERNMENT, SPONSORSHIP & THE PARTICIPANT

This panel, also chaired by Dr Wood, explored the role of the major institutional structures around research governance, regulation and sponsorship in shaping the research participant's experience.

The first presentation, given by Dr Jane Cope of the National Cancer Research Institute, gave an overview of how attitudes towards patient participation had changed during the course of her career and how different practices had evolved, particularly in relationship to governance. She drew attention to issues around assessing the level of regulation most beneficial to patients. The second presentation by Dr Susan Kerrison of the UCL/UCLH Joint Unit framed PPI within the context of the vast number and extremes of scale of studies that take place in this organisation each year. She highlighted the diversity of roles that research participants play in these.

The ensuing discussion debated the role of PPI in various kinds of research, and research environments, what it might contribute, how it should be evaluated and its impact assessed in different situations. Specific areas identified for action included the sharing of information, lack of regulatory attention to social and structural contexts affecting participation, and PPI in commercial trials.

PATIENT AND PUBLIC INVOLVEMENT AT THE NATIONAL CANCER RESEARCH INSTITUTE

Dr Jane Cope, Director, National Cancer Research Institute

Dr Cope presented some personal reflections on nearly 30 years' experience of research involving patients. This began in her work setting up AIDS research in the UK in 1980s. The patients here were mostly young, gay men who were very vocal about their involvement. This followed on from the culture of AIDS research in the US where patients had actually re-organised a trial because they found a placebo-controlled method to be unethical given the prognosis of the condition. At that time cancer research in Britain had very little patient involvement, to the extent that patients in trials did not necessarily know the nature of their condition, or that they were participating in a trial. This changed hugely over the following 30 years, and cancer research trials are now at the forefront of patient involvement, a change that in itself makes an interesting subject for study.

An example of recent good practice would be a trial for treatment of prostate cancer (ProtecT). The research group wanted to compare three different treatments, surgery, radiotherapy and active monitoring, but didn't know whether patients would be willing to be randomised into one of these. One of the principal investigators is a social scientist and ran focus groups that dealt with the delivery of information, consent processes, and the trial has proved very successful.

The NCRI use the term consumer. This is controversial, however they have found that patients, users, survivors, service-users, all these terms are loved and hated by different people. This emphasises that there is no single consumer viewpoint and equally no single formula for doing involvement correctly.

This situation poses problems when it comes to research governance. Advocating governance is obviously done with a concern for patient safety, but does more governance lead to more benefit to patients?

It has been assessed that the EU Clinical Trials Directive has doubled the cost of academically-led trials which probably means that the number has been halved. Is that in patients' best interests?

Another issue that has emerged is that certain patients are beginning to think of themselves as having a 'right' to be involved in trials. Evidence suggests that patients on trials, or in hospitals that have a research culture have better outcomes. Therefore more people are requesting to be involved. The NCRI had a letter from a breast cancer patient complaining that her tissue had been thrown away, but she was unaware of the paperwork required to regulate access if it was to be preserved.

There is a line to be drawn as to what levels of regulation and governance are most beneficial to patients.

RESEARCH GOVERNANCE AND PPI- THE VIEW FROM A LARGE TRUST

Dr Susan Kerrison, Head of Risk and Regulation, Joint UCL/UCLH and Royal Free Research Office

Each year around 500 research studies on patients or their data are registered at UCL-UCLH. Rather than talking about the diversity of the patients, Dr Kerrison focused on the diversity in studies and implications of this for involving patients. She looked at three factors, funding arrangements, study objectives and study size.

Funding for medical research in the UK comes from three main sources, from medical research charities, through public funding, or through commercial research (or sometimes a combination of all these).

Medical research charities have the highest level of public involvement. As Michel Callon showed in his studies of patients with muscular dystrophy, the long term engagement of patients in research into their condition, can lead to a co-production of research, with increased funding and development of new treatments. Patient engagement is therefore crucial for those interested in investigating rare conditions.

Public funding is another source of financing. Public involvement in decision-making is now in vogue for all parts of the NHS including research. An application for public funding now requires the applicants to state how they will involve the public in the funded research. This has promoted the involvement of patients.

Finally there is commercial research. Making patient involvement a reality in commercially sponsored studies seems to be more of a challenge. Figures from the MHRA obtained under the Freedom of Information Act show that commercial sponsors run about four times as many trials each year as academic sponsors. Companies undertaking trials in UK may be global players –based outside the UK. Are UK polices for patient involvement likely to be influential on their activities? A trial may be conducted in many different countries simultaneously. How does meaningful public involvement work in this situation?

Research methods may also set the parameters for patient involvement. A trial for a promising therapy where there is no other treatment will offer a very different patient experience from one that is non-therapeutic. Some studies require multiple examinations and hospital visits – others may pose few demands other then signing a consent form. Some research subjects may be single players e.g. having gall bladder removed or repeat players ie those with long term conditions. All these issues may have bearing on capacities for and type of patient involvement.

Finally, there is the question of the size of the study, this may range from ten subjects, to screening studies that involve hundreds of thousands of people. Addressing patient involvement in these two situations offers very different challenges, conceptual, financial and organisational. If these studies are also taking place globally in many different centres then that adds another layer of complexity. Patient involvement may only be possible with certain types of studies, under certain circumstances. Looking at the diversity of studies raises complex conceptual issues about how patient involvement might work with different types of studies.

New Research Studies UCLH 2010
n ~ 500

Commercial clinical trials 11%

Non commercial clinical trials 12%

Questionnaires, qualitative research, data analysis, laboratory studies 60%

Intervention studies eg scanning, procedures 17%
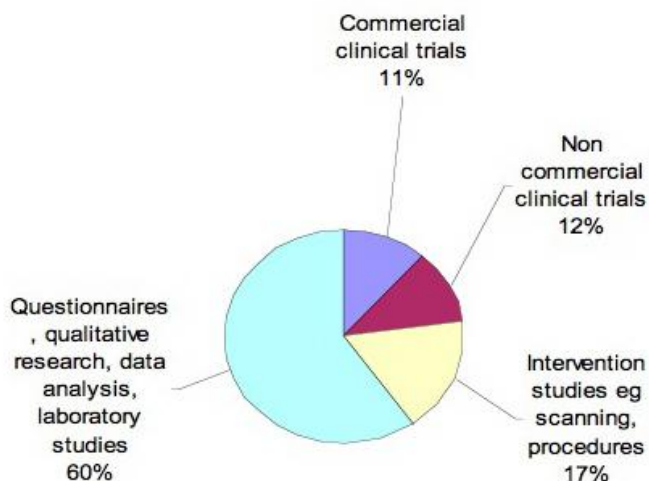
Government, Sponsorship and the Participant: Questions and Discussion

Impact of patient involvement and related programmes

Initial discussion turned around the impact of the creation of the National Institute for Health Research (NIHR) on research design, funding allocation, and the development of the Patient Benefit programme. Among the points made were:

- While some measurable progress had been made in establishing PPI in clinical environments, it was hard to see its effects in laboratory-based research which commands a very high proportion of medical research funds
- Robust measures of evaluating PPI content were needed. This would be helped by structuring grant application forms so that they required strategies for public involvement (separately from strategies for engagement, which is not at all the same thing)

Regulatory matters

A second theme concerned the regulatory framework for clinical trials, especially commercial trials. Issues raised included:

- Attention to social issues was largely absent from current regulatory frameworks. Areas to address might be the sharing information with participants through regular feedback, availability of treatments post-trial, the artificiality of trial conditions and assumptions about participants' roles
- When Patient Groups do get a seat at the table for regulatory decisions they could best serve the community by attending to the fundamental issues of trial structuring and social responsibility, rather than accepting the framework uncritically or taking it as a given. An example of the latter was given in discussion of a European Union directive
- While the important role of commercially funded trials was fully acknowledged, it was equally important to pay attention to their deficiencies in matters of public involvement and to variable scientific standards. This latter topic in particular needed to move up the public agenda

Returning to questions of impact

Returning to the theme of the slow spread of PPI, the debate explored issues around the role and contribution of 'involved' patients and public, and how funding policies exerted influence.

· It was noted that doubts were sometimes raised as to the contribution that patients/publics could make on design and conduct of more abstruse and technically demanding (typically laboratory-based) research studies. The counter-argument however was that technical competence – or the advantages of a health professional or scientific background – should not be over-valued, since the patient advocate role was primarily to bring to bear a 'public' perspective on the research and to speak to social and political issues, which required other kinds of competencies

· While it was commonly believed that funding was a driving force in promoting PPI, might it not rather be a force for promoting lip service to PPI? To address this, funding policies should be accompanied by policies to raise the status of PPI as an activity ('INVOLVE' was cited as running schemes and awards to this end). However peer review remains dominant in funding decisions and it is questionable whether the quality of PPI carries much or any weight in that process

· A separate aspect of funding was the scale of provision for PPI activities within a grant proposal. This constituted a minute proportion of total funding and was usually inadequate for the purpose. For example, (and as referred to earlier) consumers have to bear their own costs for attending meetings (despite having no institutional resources to draw on). This discriminates against the less well-off and those whose health care needs add to costs of travel

· A way forward for the furtherance of genuine PPI might be through building a requirement for well-planned, good quality PPI into regulatory and ethical frameworks

REFLECTIONS & EXPLORATION

The afternoon session of the Workshop followed a less traditional format than the morning's proceedings. It was designed to elicit the maximum contribution from all the participants, and consisted of three main sections, each aiming in different ways to promote reflection and deeper exploration of the themes emerging from the morning's presentations and discussions.

These three sections comprised:

1. Discussion in Break-out Groups
2. Afternoon Plenary address by Professor Stuart Blume on the social and political context of clinical trials
3 Reports from the Break-out Groups and concluding plenary discussion session

Both the plenary session and the Break-out Group reports raised issues that transcended the frame of the individual clinical study. They stressed the importance of understanding the meaning of medical research for potential volunteers and the range of roles that participants could play. Both explored the delicate balance between trust and regulatory safeguards, and weaknesses in current governance systems which concentrate too much on the early stages of studies (initial patient information and consent) and lacked systematic attention to trial management and social issues of concern to participants. In the global context as well as closer to home, the local political economy of health shaped the choices available to potential volunteers, and could result in blurring of research and care. The final discussion included recommendations for reviewing, with patient input, the kind of regulation needed; for evolution of Ethics Committees practices and philosophy; and for recognising through regulatory systems that patient/participants needs went beyond 'protection', embracing issues such as information, access and appropriate research design.

THE POLITICS OF PATIENT PARTICIPATION

Professor Stuart Blume, University of Amsterdam and Innovia Foundation

Professor Blume opened by saying that he had been asked to talk about 'the big picture'. For this he would draw on his experience over many years of looking at questions around new health technologies. What problems or questions did they solve, what did they not solve, or create? His picture would not be particularly a UK one since he lived and worked outside the UK.

One of the issues raised by discussions of the role of volunteers and medical researchers was that of recruitment, which had formed the subject of very large numbers of academic papers. Many of these centred on recruitment strategies (recruitment now being a very professionalised, and commercialised, activity) and in methods and content differed sharply from a smaller number of studies where researchers went out and talked to people and enquired about why they participated or did not participate in research. Findings from the latter kind of study underlined known deterrents to participation, such as randomisation, or threw up interesting observations like the value placed by African-American men (but not women) on having information about who paid for a study. A Danish study had demonstrated the struggle between the wish to add to the common good through participation and the (more compelling) need to assure their personal benefit from treatment. In the case of healthy volunteers the determining factor – as shown by a meta-analysis of 13 studies in different countries – was the financial incentive, with the single exception of a study in Malawi where the principal reason for enrolling was access to health care. This point would be returned to.

Referring to his title 'The politics of patient participation' Professor Blume suggested that to consider in what sense all this is political we had to stand back and think about the rules and conventions governing how research is conducted and the sources of people's expectations and anxieties. Trust was crucial, and the kind of thing that could undermine trust was (to use an example from the Danish study) doubts about the physicians' or researchers' ability to withstand the influence of the pharmaceutical industry. This could lead to political demands for higher degrees of regulation of trials. Another

study found widespread distrust – a sort of communal distrust, historically based – of the medical profession among African-Americans. The common general point here is that participants' reasons extend beyond specific details of the trials, to concern trust in the people doing the study.

Additionally, there has been overt politicisation of clinical trials, through patient activism such as shown by the HIV/AIDS community, which led to changes in the regulatory framework for trials in the US. Again in the US there was a change of policy around the issue of who – what sectors of the population should be invited to participate in clinical trials, leading to greater inclusion of eg ethnic minorities and women. The effects of this are controversial, and may have far-reaching implications for popular understanding of research and health care, for questions of access to health care and the blurring of boundaries between research and care, especially where resources for care are being cut. This recalls the example of the population in Malawi, and the finding in other African countries that people enrol, or enrol their children, in trials as a means of accessing health care.

In summary: to appreciate the inherently political nature of medical research, we have to understand its meaning for potential volunteers, their assessment of the likelihood of its benefiting themselves, their children or their community and the ways in which the local political economy of health shapes the choices available to them.

Questions and Discussion

One of the questions raised in the discussion following the talk was how far cultural differences and religious issues might affect participation and whether this had been much studied or considered in patient groups – a matter that had come up for discussion in one of the afternoon's Break-out groups (Group C). While it was agreed that these were likely to be important, it was felt that the subject was under-represented in the literature. Studies in population genetics had led to discussion of the significance of genetic difference for people's cultural perceptions of identity, but the cultural context itself was highly relevant to the implications of research, as Professor Blume's work on the issues around cochlear transplants where there was a strong deaf community had shown.

Reports from Break-out Groups

A: Does Patient and Public Involvement (PPI), as presently practised, affect the experience or level of involvement of actual 'research participants'?

Chair: Carolyn Morris (COMPASS User Involvement Group)
Introducing the discussion: MaryRose Tarpey (INVOLVE)

This group's discussion embraced two main themes. Firstly, what was the role of PPI in making the experience of being a participant 'more beneficial'? Secondly how far PPI had developed a role and a voice in influencing research at the strategic level? At the study level there was no clear pattern discerned in interactions between PPI activities and participants. There was a frequent lack of clarity regarding roles and expectations – whether publics or patients (the two 'Ps' of PPI), participants or researchers. However these were all matters that needed further thought.

The governance framework for research could be unhelpful. The system is front-loaded with more intense scrutiny being given to preliminary and early stages of a study. PPI activities had also fallen into this pattern. Though it was important that PPI influence should be brought to bear on individual studies at the earliest possible stage in the project, that influence needed to be sustained through the rest of the experience. More focus is needed on, for example, improving systems to deal with complaints and tackling patients' fears about voicing problems. There is also room for positive action here – through simple mechanisms that acknowledge the participants' contribution, thank them and feed back information on results. Payments to participants were also discussed here, but this notion elicited mixed views, with some voicing the opinion that they could get in the way.

The bureaucratic nature of research governance was also discussed; it was felt this should be replaced by patient (and participant?) thinking about what is actually required to protect patients and participants, their interests and rights. Specific criticism was levelled at protective measures seen as disproportionate to the risks involved – it being argued that you don't necessarily need the same processes for a piece of qualitative research as you do for brain surgery. Thus the Group's discussion led to consideration of many broader issues that lay outside the purview of any single study and underlined the need for PPI influence at the strategic and policy level. While views may differ on how much that influence is already felt (depending

probably on the fields or types or research one is most familiar with) there was consensus in the group that more of it would be to the advantage of all concerned.

B: Are the people enrolled in a clinical study best (or most accurately) described as participants, collaborators or research subjects?

Chair: Dr Brian Balmer (UCL)
Introducing the discussion: Dr Oonagh Corrigan (Associate Professor in Sociology and Ethics, University of Plymouth)

Dr Brian Balmer, as Chair, introduced the Group's report. He commented that discussion had shifted from the question of a correct title (collaborators, participants and so on), onto a discussion of why these terms did or not matter. The Group's conclusion was that these terms were context-specific, and need to be seen as occupying a range of positions along a spectrum of human agency, with collaborators being the most empowered. The list could be extended to include other terms, such as user, partner, healthy volunteer, however all these are equally complex and loaded. They were not able to resolve the issue, only to show the complexity of the terms in discussion.

Dr Balmer gave an instance of 'why it matters' and how changing the terminology might have the effect of making the experimenter think about the meaning of participation from the participant's point of view. The process may well be different from the point of view of the experimenter than from that of the research volunteer. An example could be taken from the work of Simon Cohn who found that participants perceived by the clinical team as wonderfully altruistic healthy volunteers, themselves cited reasons for participation relating to personal health issues. Volunteers from the imaging study presented in the morning session, had fully understood that the test they undertook would be of no personal health benefit. They nevertheless held the thought that as research (by definition) throws up new things, it may yield new information which would add to knowledge of their disease or health status. Thinking about terminology might encourage thinking about assumptions. The group also called attention to the wide diversity of research situations, from relatively harmless procedures to manipulating the treatment of life-threatening conditions. A broad spectrum of relationships and interactions are encompassed between those two extremes. As such, the title and contribution of lay-people in research processes is likely to vary. In addition, these boundaries may shift throughout any individual study.

A question arose as to what term could be used for lay people (patients or publics) involved in policymaking decisions and activities. A corollary was how doctors tend to categorise all members of 'the public' as patients (since everyone is on a GP's list) but, interestingly, with varying degrees of abstraction. Comparing the usage of a range of committee members of medical professional bodies, there seemed to be a possible correlation between presence of substantial lay membership on such bodies and less abstract, more meaningful talk about 'patients'. Dr Adrienne Morgan recounted how as a cancer patient involved in a number of clinical trials she had experienced a number of roles. Through IPCV she had been involved as a *collaborator*, helping design trials from the outset. On another occasion she had been a *research subject* in a huge randomised clinical trial, turning up every so often to have the injection, with very little information. She had also been a *participant* when filling in an annual form once a year about her diet. But how should she categorise a request from her surgeon to use her lymph node for research ? Would she or her lymph node here be the *participant*?

C: Government policy plans to increase the proportion of patients taking part in research. What are the implications of this for patients and research participants?

Chair: Professor Ulf Schmidt (University of Kent)
Opening the discussion: Dr Janet Wisely (Director, National Research Ethics Service)

Professor Schmidt reported that the group had held a lively discussion, which had looked at the politics of research from different perspectives. They addressed issues of information-sharing and transparency, including communication and cooperation between different groups, control of data, and gate-keeping of data for protection of participants. The group had also discussed the market, taking into account that UK policy fully recognised that the medical research industry was not just health-creating, but also wealth-creating, and as such was of great interest to politicians. Finally, the Group had touched on the following in more detail.

Ethical caution and its consequences
One of the issues arising in the group was a sense of living in a risk-averse culture, in which people might shy away from research. Not only was ethical committee review given prominence but institutions, funding bodies and researchers had concerns about legal liability. There was a lot of discussion about the possibly excessive caution shown by ethics committees over

approaches to patients about research. One example was whether, having given a patient details of a study, it is reasonable and permissible to follow-up any non-responders to ask if they have decided, and whether precluding such approaches constitutes a barrier to these patients becoming part of the trial (see advice issued by the National Research Ethics Advisors' Panel NREAP/02 at http://www.nres.npsa.nhs.uk/aboutus/nrea/ which recommends a more balanced and contextual response).

Who does regulation protect? And issues of trust
A member of the Group had raised the issue of whether the framework put in place by the Government protects the patient, or mainly protects the care-giver. This linked to Stuart Blume's comments on how we have reconceptualised trust. So rather than trust being a relationship that occurs between individuals, patients and doctors and so on, this definition has been displaced by a need on the professionals' part to prove that they are trustworthy, and subsequently, much box ticking. As such it is legitimate to ask, when a government or any other official body seeks to put a code of ethics in place, just what the functions of that code are. These changes also mean that people are required to play new sorts of games to get their research projects launched. Added to this was the further bureaucracy associated with funding, R&D approval from hospital trusts, and a general lack of transparency.

Implications of cultural diversity
Another important issue, which was briefly raised earlier in the day, was that of cultural, religious or ethnic difference. Knowledge is lacking about how different communities might feel about research participation. This potential diversity of viewpoints did not appear to be represented among the participants of the workshop.

REFLECTIONS & EXPLORATION

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Final Workshop Discussion

What kind of regulation?

A number of contributions focused on the issue of the kind of regulation that would better fit with current needs, and the linked issue of trust – an essential corollary, but one which, perversely, the system at times tended to displace. The question was raised as whether self-discipline might be preferable to systems of largely external, and inevitably bureaucratic regulation. Are we now sufficiently inculcated with ethical ways of thinking to govern ourselves both rigorously and efficiently? Acting as a counter to this was the difficulty of judging whether the practice of research was indeed more or less ethical than before (practice had changed but so had society) and practical considerations as to the sustainability of a self-policing system, given the 'fade' effect over time and the constant influx and outflow of researchers needing training and mentoring. The general consensus was that clinical research practice – in terms of thinking about patients' and participants' needs and about ethics – had changed, but ethics committees were still needed to maintain patients'/participants' trust, and to provide for the transparency in the system that had frequently been called for during the meeting. This was not to endorse the regulatory system as it operated at present unquestioningly: it does not cover all the patient/participant needs that had been identified during the workshop and risked promoting only formal compliance rather than actual good practice.

Practice and functions of the ethics committee system

It was pointed out that only 20% of applications to Ethics Committees got a favourable opinion first off: around 50% got provisional approval. A major function of the committees was to scrutinise how studies were presented to participants, rather than suitability of the research design. The National Research Ethics Service saw more scope for trust in the system, and scope for more limited review for some kinds of studies. Ethic Committees would still provide the important safeguard of an independent assessment of the accuracy of patient information compared against protocol; they could look at proposals from the point of view of the participant – something it was more difficult for clinicians or researchers to do.

Picking up on the theme of 'who does the ethics system protect?' raised by Break-Out Group C, it was noted that some of the components of the system were clearly being used for purposes other than the protection of participants. This applied particularly to Informed Consent, where the forms to be signed were often more like contracts, including waiving any participant

rights to tissues or intellectual property. This detracted from the clarity of the Ethics Committees' function of serving participants' interests, and it was suggested that some separating out might be needed. This was another instance of how the ethical review system needed to adapt its practices to changing times and social developments.

Going beyond 'protection'

Patients and participants wanted information – about the trials they were in, and (increasingly) about trials that were available. Some patients felt strongly that clinicians tended to be restrictive about access to trials. This they felt was disadvantageous to patients who were interested in taking part in research or desired access to experimental treatments. Various publicly-supported initiatives were mentioned that are developing public information resources on ongoing and planned trials so that patients might proactively seek enrolment in appropriate studies. There was also a public interest in publishing details of trials that had had negative results or proved inconclusive (as well as potential benefit to other researchers in the field). Funders were said to be increasingly requiring that researchers register their trials and register the results. There were international efforts to ensure that commercial trials also were similarly registered. Additionally in the UK Ethic Committees would put this question to applicants (including commercially sponsored trials) and also had adopted the practice of publishing a summary of the research and the committee's suggestions, unless good reasons could be advanced for delay.

The pressures for access to trials (particularly among activist patient groups) and for more information (a widespread desideratum among both patients and publics) should not lead to neglect of other, and partly countervailing, patient needs. There were those patients who did not desire participation in research, wanted a more conventional doctor-patient relationship and preferred to trust in the 'tried and tested' treatment. There appeared to be incipient conflict between the 'old' principle of patient choice, and national policies and social pressures to enrol in medical research studies. A further issue was the inadequacy of the clinical trial formula – particularly in its randomised, controlled trial format – to deal satisfactorily with some kinds of diseases or conditions (especially those that were long-term or complex, like complications from diabetes, or people with mental health problems). This was beginning to be appreciated in policy circles – possibly helped on by appraisal of their high costs and very high proportion of inconclusive outcomes. Public, patient and participant influence could help to inform this debate or educational process.

REFLECTIONS & EXPLORATION

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A final wry point made was that we should be wary of patient empowerment being used as just another rhetorical device: "It's something you have to agree with but often in the health domain it means empowering patients to do what we have pre-decided is in their best interests and ours, which looks a lot like disempowerment."

CONCLUSION & NEXT STEPS

The variety and richness of discussion at the Workshop made it impossible to draw together in the final discussion all the insights, observations and proposals for action that had emerged during the course of the day. With the advantage of more time, and documentation of the event, the organisers have however highlighted here some of the recurring themes and recommendations.

The conclusions and discussion from the Workshop are to be further developed in the Research Volunteers Forum which has a dedicated website (www.ucl.ac.uk/researchvolunteersforum), where more detailed information on the proceedings of the Workshop is to be found, including audio podcasts of all the presentations. The expectation is that individuals and organisations will have been motivated by these discussions to take up the themes most appropriate to their sphere, and create more developed plans of action.

CONCLUSION & NEXT STEPS

Our general conclusion was that the question of research on (or with) human beings must involve consideration at both the macro and micro levels. Here, macro was understood as the level of the social and political., including issues of 'the politics of clinical trials', the inequalities of power embedded in social structures, the assumptions and characteristics of systems of research governance, and the immense diversity of both clinical studies and research participants which made generalisation difficult. The micro level embraced the experience and expectations of the individual research participant (still a relatively under-investigated topic), as well as the scrutiny of individual clinical studies which makes up much of the day-to-day work of research regulatory systems (via ethics committees), and patient or consumer liaison groups. The division is of course notional, in practice the micro and the macro are embedded each in the other. The distinction becomes useful however when considering matters like the actual or potential role of public, patient and participant involvement in ameliorating or reforming current policies and practice.

Micro level issues

Professor Blume, in the conclusion to his address pointed to the need to understand issues at the individual level to appreciate the underlying politics: 'In summary: to appreciate the inherently political nature of medical research, we have to understand its meaning for potential volunteers, their assessment of the likelihood of its benefiting themselves, their children or their community and the ways in which the local political economy of health shapes the choices available to them.'

Comments and recommendations for action:

1. Steps lying mainly in the purview of patient organisations and partnership groups

- Many of those active in public/patient involvement (PPI) felt the lack of any clear pattern for relationships between the PPI groups and participants: there was a lack of clarity about roles within the groups and about what was expected of the different parties involved. This needs to be explicitly addressed.

- PPI activity, following the pattern of regulation and funding for research, tends to be front-loaded. This has reduced the capacity of PPI groups to follow through the complete participant experience and

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give attention to matters such as the operation of complaints systems or participant anxieties. PPI groups need to extend their involvement with individual clinical studies to include these areas.

· Patient groups have been held back from developing direct channels of communication with research participants because current rules of confidentiality deny them access. These rules need to be re-thought in order to establish more effective liaisons between patients on Management Groups and individual participants.

· In some situations, those involved in trial design could alleviate this problem by inserting a clause into standard research consent forms that permits this kind of communication.

· It was widely agreed that giving feedback to research participants on results and acknowledging their contribution were important steps, but often omitted. There was scope for encouraging Ethics Committees, professional bodies or umbrella organisations to make observance of this courtesy a condition of approval or membership. Approaches should be made to carry this forward.

2. Steps for increasing understanding of the different meanings of 'research participation'

It was suggested that better understanding in this area was a key to forging productive working relationships between researchers and participants, to the benefit of both parties. This should include:

· Recognition of the different roles of research participants. These occur along a spectrum of empowerment (ranging roughly from 'research subject' to 'collaborator') and can potentially evolve during the course of a project. Participants find themselves situated in a huge range of research projects from those with a relatively trivial impact on the volunteer, to others with life and death consequences, and involve participants in differing states of dependency on health care.

· Recognition that the participants' expectations, assumptions and interpretations of what is going on in the research may be different from those of the researchers.

· Use of a reflection on terminology (subject, collaborator, partner, guinea pig etc) as a framework (a) for researchers to look critically at their own practice and question their assumptions about volunteers' expectations or understandings, and (b) for participants in

assessing the quality of their experience and the contribution they were allowed to make.

Macro level issues

In the course of the discussions, the workshop participants identified a number of general principles or issues they considered of greatest importance for a sound clinical research system and ensuring a positive experience for all participants, in whatever capacity.

Trust

Trust was agreed to be crucial but typically depended on matters extending beyond the confines of any individual study. It included participants' general perceptions of the medical profession, and of the power and motives of the pharmaceutical industry. It framed their questions about whether the process of informed consent was there to protect physicians and health providers or to protect the participants. There was also a delicate relationship between trust and regulation. Lack of trust led to demand for more regulation; but additional regulation might lead to formal compliance only (the tick-box mentality) and give false reassurance. Recommendations about changes to regulatory systems and bureaucracy (see below) attempted to address this question.

Gaps in regulatory system

Of major concern were the areas not covered by current UK regulatory systems, the workshop identified two major deficits:

· Current regulatory frameworks focus on participants' immediate physical and emotional wellbeing and fail to address important social issues. These issues include sharing information with participants through regular feedback, availability of treatments post-trial, artificiality of trial conditions, assumptions made about participants' roles, complaints procedures. Patient and participant input could be of crucial importance here.

· There is a lack of attention to the deficiencies of commercial trials in matters of public involvement and of variable scientific standards. It was agreed that this topic needed to move up the public agenda.

Bureaucracy

There was concern at what was perceived as unnecessary or inappropriate regulation. Suggestions for action included:

· Thinking through the whole system afresh starting from what participants/patients need. This radical proposal was well supported but could not be extensively developed in the course of the meeting. It has been noted as a key point for follow-up.

· Encouraging NRES to take further their initiatives in matters such as proportionate review, and to review restrictions on access to participants or potential participants.

· Continue to improve system transparency.

Knowledge-sharing

The workshop participants addressed the question of knowledge-sharing from different angles. There was discussion on the sharing of intellectual property, though this was not pursued in depth. At the workshop, the main issues about knowledge-sharing concerned the kind of information that is needed to meet the expectations of proactive patients, patient groups and potential participants. These included:

· Feedback from trial organisers to research participants (as identified earlier) and recognition of their contribution to the research and status as partners, rather than 'subjects'.

· Putting information into the public domain about available trials for those who would be interested in enrolling. Recent progress in making such information available was noted but there was still room for making it more patient-friendly.

· Availability of information about clinical trials that had negative or inconclusive results. It was emphasised that active patients and patient groups with an interest in research valued such information and considered it a benefit, as much as the professional research community.

· The development of Ethics Committee practice to encourage these trends and require publication of summaries of research was welcomed, and would be followed with interest.

Patient choice

Three main points for vigilance and policy influence were noted under this heading:

· Social structural, and national policy influences that could restrict patient choice will require further debate beyond the workshop. These include the lack of alternative health care, the blurring of research and care borders (research as higher quality care), and social pressures to enrol.

· Physicians' restrictive or selective approach to eligibility or suitability of entrants to clinical trials (or other clinical studies) could be construed as limiting patient choice. Addressing these practices was seen as a high priority by some workshop participants.

· Enthusiasm as to the benefits of research participation or arguments about social responsibility still needed to be balanced against the principle of individual patient choice.

Expansion of public, patient and participant involvement and influence

The essential role that could be played by the trio of publics, patients and research participants in maximising the benefits of the research system was a key theme of the meeting. The discussions identified a number of core issues that need to be addressed, in some cases indicating possible courses of action, in others identifying the questions as an agenda for the future.

· Extending current mechanisms of PPI (this term to be understood as in practice 'PPPI', ie to include a clear research participant voice) into a wider range of clinical studies. It needs to be more than a niche market, yet figures showed that, despite its positive results (for both research and patients), PPI covers only a very small proportion of the totality of clinical research.

· Extending PPI's remit further into the strategic field- to address, in partnership with other research actors, those issues identified earlier (such as trust, social structures, limitations of regulatory systems) that transcended the bounds of any single study or group of studies.

· Using the public/patient/participant voice at the policy table to articulate the kinds of research, the kinds of ethical review and the structures of research governance that met those constituencies' needs.

- Similarly, for the public/patient/participant voice to join and influence debates on topical or timely issues. Contemporary examples would be the differences in practice between public and commercial trials, or the limitations of the RCT (randomised controlled trial) especially for long-term and complex conditions.

- Extending public and patient influence and the partnership concept into the area of laboratory-based research (which accounts for the major share of medical research resources).

- Developing robust methods of evaluating the PPI content of research proposals and benefits of PPI partnerships to help in achieving the above objectives.

- Among these grand designs, not to lose sight of the costs of running partnerships of the type envisaged. These should be budgeted for within research proposals and recognised as legitimate by funding bodies. Publics who cannot count on institutional resources to cover the costs of their time, carers' time and travel expenses, should not be expected to pay the bill themselves, with all the inequities this implies.

Next Steps

The collective conclusions and recommendations from the workshop have drawn up a formidable agenda for action but say little about ways and means. The expectation is that individuals and organisations will have been motivated by these discussions to take up the themes most appropriate to their sphere, and create more developed plans of action. Some themes may be taken forward through joint action in partnership with contacts made at the Workshop. The Forum facility on the Research Volunteers website hosted by UCL www.ucl.ac.uk/researchvolunteersforum has been created to provide both an information resource and a continuing forum for debate and exchange of views.

GLOSSARY OF ACRONYMS

ABPI / Association of the British Pharmaceutical Industry

CBPR / Community-based Participatory Research

CERES / Consumers for Ethics in Research, UK patient advocacy group

DCIS / Ductal Carcinoma In Situ

ICPV / Independent Cancer Patients Voice, UK cancer patient advocacy group

KCL / King's College London

MHRA / Medicines and Healthcare products Regulatory Agency, UK

MRC / Medical Research Council, UK

NCRI / National Cancer Research Institute, UK

NIHR / National Institute for Health Research, UK

NREAP / National Research Ethics Advisors' Panel, UK

NRES / National Research Ethics Service, UK

PPI / Patient and Public Involvement

ProtecT / Prostate testing for cancer and treatment study, UK

RCT / Randomised Controlled Trials

UCL / University College London

UCLH / University College London Hospital

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Current research strongly suggests that the quality of the relationship between the researcher and the researched subject in biomedics is crucial for the achievement of both volunteer satisfaction and successful and reliable research outcomes. The organisers of this Workshop believe that such findings have policy implications for:

- *the design and management of clinical trials and other experimental biomedical research using humans*
- *revisiting the concept of the volunteer that is embedded in research regulation and ethical codes*
- *the role of patient advocacy groups*
- *researcher training*
- *policy-makers, politicians and executives concerned with strategic priorities*

The Workshop provided an opportunity to discuss such issues with a wide range of organisational and individual stakeholders in the research enterprise (including researchers, patients, patient groups, funders, managers and policy-makers). The format of the meeting placed an emphasis on sharing the expertise and perspectives of all participants. Presentations were kept very short, with extended provision for break-out groups, debate and networking. Together, these stakeholders reviewed the scope for joint and individual action and collectively suggested ways forward.

Please visit www.ucl.ac.uk/researchvolunteersforum for more information and for podcasts of the event.