Resource material: Patient and public involvement in research

This patient’s viewpoint and the experience of seeking to understand research issues, following invitation to take part in a clinical trial – and refusing - eventually led to the formation of a joint professional/patient working group, the Consumers’ Advisory Group for Clinical Trials. (CAG-CT)

Improvements in treatment are achieved by testing them in well-planned randomised controlled trials, often by comparing the standard treatment with the ‘new’ treatment, or by comparing different timings, dosages or combinations of therapies. Other types of studies may also be undertaken to supplement this approach.

Speed of progress is dependent both on clinicians’ ability and enthusiasm to become involved in running trials and on patients’ willingness to be recruited as partners in the enterprise. Speed of progress also depends on the choice of hypothesis; on seeking appropriate outcomes through well defined relevant endpoints; on the quality of methodologies; accessibility of good quality information; on education of both public and health professionals and on the attitude of all those involved.

Neither health professionals nor patients are a homogenous group. All can contribute to improving the quality and speed of research by different types of contribution to the research process. Either party, alone, will achieve nothing. Both have an interest in producing good quality evidence so that it may be used to continually improve the delivery of healthcare. Each party needs encouragement by the other.

Patients’ experiences of participating in clinical trials can be either as participants in a trial or as a collaborator in the whole design/management process, or both. Either way, their contribution is as vital as it is varied! Contributions from collaborating patients can be formal or informal; as individuals or in groups; using various methodologies to provide insight into the best way to choose and develop research questions. Such patients will have a desire to see that findings resulting from such activity are clearly and promptly reported, disseminated and used. The James Lind Alliance, launched April 2004, takes the partnership further.

354:siv48
5 http://www.lindalliance.org
Patients’ experiences of participating in clinical trials will be affected by:
- their understanding of the trial/trial concepts/randomisation;
- their perception of the need for research;
- the manner and timing of their approach/invitation;
- their acceptance of the uncertainty principle;
- the attitude of the trial team;
- the ability of their team to communicate effectively;
- the ability of their team to satisfy the prospective patient’s information requirements - great or small;
- their sense of partnership in the enterprise;
- their own values and preferences;
- their perception of mismatch of experience with expectation;
- their ability to appreciate and understand risk, probability and ‘chance’.

**Systematic Review of Patient and Public Involvement in research**


**A European overview of literature and a survey report:**

Overview literature of patient involvement in clinical trials:  

Report on good practices on patient involvement in clinical trials from the patient perspective (End 2008)  

**A set of interviews on public involvement in healthcare,**  
featuring among other items, an interview with Janet Wale from the Cochrane Consumer Network, 27th April 2010  

Website of: Health Innovations in Context. (Canadian)

**Evaluation/review of patient involvement in research: published papers/reports**


3. Telford R, Boote JD, Cooper CL. **What does it mean to involve consumers successfully in NHS research? A consensus study.** Health Expect 2004; 7: 209-20


5. Review: Crawford M, Rutter D, Thelwell S. **User Involvement in change management: A review of the literature. 2003.** NCC SDO (National Co-ordinating Centre Service Delivery and Organisation) (And other SDO ‘user involvement’ reports on SDO website [www.sdo.lshtm.ac.uk](http://www.sdo.lshtm.ac.uk))


**A paper describing an example of `participatory research`**

D. Wright, J. Corner, J. Hopkinson and C. Foster. *Listening to the views of people affected by cancer about cancer research: an example of participatory research in setting the cancer research agenda.* Health Expectations 2006; 9:1:13-24

**UK Clinical Research Collaboration ACTIVITIES LOG**

www.ukcrc.org/index.aspx?o=3043 A database that captures and shares information about current activities that are in some way researching, evaluating or reflecting on the impact of patient and public involvement in research. Form available to complete from philippa.yeeles@ukcrc.org for those engaged in such activities.

**A `model` (a “Template”) of patient involvement in a multicentre randomised controlled trial**

This is a detailed account of an integrated relationship between the organisers of a clinical trial and a consumer organisation in the PRISM trial – a UK multicentre, randomised controlled trial comparing treatment strategies for Paget’s disease of the bone.

**Model framework for patient and public involvement – Australia and N.Zealand**


**Useful Publications:**

*Involving the public in NHS, public health, and social care research: Briefing Notes*
This is an introductory document designed for researchers with no previous experience of involving members of the public as active partners in research.


English, Arabic, Chinese and Spanish texts are now available without charge under a Creative Commons Attribution 3.0 Unported Licence on the James Lind Library website  www.jameslindlibrary.org


**Toolkit:** *Patient and Public Involvement Toolkit.* Julia Cartwright, Sally Crowe, Carl Heneghan (Series Editor), Douglas Badenoch (Series Editor) Rafael Perera (Series Editor. ISBN: 978-1-4051-9910-0 www.toolkitbookseries.com/

**Book:** Morrow E, Boaz A, Brearley S, Ross F. *Handbook of service user involvement in nursing and healthcare research.* Wiley-Blackwell, Chichester, UK. 2012

**Useful sources of information for Health Professionals wishing to engage with members of the public in research**

www.peopleinresearch.org

Website (launched January 2007, piloted for 3 months) developed by the UK Clinical Research Collaboration, INVOLVE, and others. The original idea for this web resource came from two frequently asked questions: members of the public asking ‘How can I get involved?’ and research organisations or projects asking ‘How do we find people who want to get involved?’


NIHR – Patients and Public. http://www.crncc.nihr.ac.uk/cci
User involvement in research: a route map

The route map for user involvement in research is a resource for staff in health research charities and other organizations that commission research who wish to involve service users in their work.

Developed by Kristina Staley and Bec Hanley of TwoCan Associates with support from the Association of Medical Research Charities (AMRC)

www.twocanassociates.co.uk/routemap

Some examples of research studies with patient involvement in which I (HT) have been involved, alone or with others – both as groups and as individuals

(See also INVOLVE website: www.invo.org.uk/Database.asp)

   This describes the CAG-CT research project “Using a consumers’ advisory group to increase accrual into trials”, funded by the NHS R&D (Cancer) Programme (NCP/D18) in 1995/6, based on a feasibility study which led to the multicentre U.K. Randomised Trial of Hormone Replacement Therapy (HRT) in Women with a History of Early Stage Breast Cancer. ISRCTN 29941643
   (See INVOLVE website database.)

   (See INVOLVE website database)

3. The ATAC (Arimidex, Tamoxifen, Alone or in Combination) Trial.
   An early example, (minimally) involving the Consumers’ Advisory Group for Clinical Trials (CAG-CT) (See INVOLVE website database.)

   (See INVOLVE website database.)


9. **PRE-EMPT.** (Preventing disease through opportunistic, Rapid Engagement by Primary Care Teams using Behaviour Change Counselling.) ISRCTN 22495456. This is a National Prevention Research Initiative (NPRI) funded project. It is an efficacy cluster randomised trial evaluating use of a training intervention - Behaviour Change Counselling (BCC) - during GP consultations on four different health behaviours: smoking, risky drinking, unhealthy diet and lack of exercise.

1. **Trial Registers:**

   - **Current Controlled Trials:** metaRegister of ongoing controlled trials; all trials registered are given an ISRCTN - International Standard RCT Numbers. [www.controlled-trials.com](http://www.controlled-trials.com) and [http://www.controlled-trials.com/ukctg/](http://www.controlled-trials.com/ukctg/)

   [NB: As yet there is no fully comprehensive worldwide register of trials. There are initiatives underway to try to bring this about.]

   See also:


   - **International Clinical Trials Registry Platform (WHO)** [www.who.int/uctrp](http://www.who.int/uctrp)

   See also the

   - **International Federation of Pharmaceutical Industries and Associations** (IFPMA) Clinical Trials Portal at: [clinicaltrials.ifpma.org](http://clinicaltrials.ifpma.org/) and the
2. Getting patients involved in research

- **INVOLVE** – [www.invo.org.uk](http://www.invo.org.uk) - is the website of the UK NHS organisation for consumer involvement in research. It has many useful publications and other resource material.
- **Cochrane Collaboration Consumer Network** [www2.cochrane.org/consumers/cinc.htm](http://www2.cochrane.org/consumers/cinc.htm)
- **UK Clinical Research Network** [www.ukcrn.org.uk](http://www.ukcrn.org.uk/)
- **James Lind Alliance** [www.lindalliance.org](http://www.lindalliance.org)
- **NHS National Library for Health: Patient and Public Involvement Specialist Library** (managed by the King’s Fund) [http://www.library.nhs.uk/ppi/](http://www.library.nhs.uk/ppi/)
- **NHS Choices** [www.nhs.uk/Conditions/Clinical-trials](http://www.nhs.uk/Conditions/Clinical-trials)
- **People in Research** [www.peopleinresearch.org](http://www.peopleinresearch.org)
- **Patient Partner Project**. [www.patientpartner-europe.eu](http://www.patientpartner-europe.eu) An EU programme ‘Identifying the needs for Patients Partnering in Clinical Research’ (European Forum for Good Clinical Practice)
- **NIHR – Patients and Public**. [http://www.crincc.nihr.ac.uk/ppi](http://www.crincc.nihr.ac.uk/ppi)

3. Understanding clinical trials

- **James Lind Library** – [www.jameslindlibrary.org](http://www.jameslindlibrary.org)
- **MRC Clinical Trials Unit** [www.ctu.mrc.ac.uk/Trialinfo.asp](http://www.ctu.mrc.ac.uk/Trialinfo.asp)
4. Sources of information about evidence-based treatments:

- **The Cochrane Library**, an online reliable source of evidence in healthcare, including *The Cochrane Database of Systematic Reviews*.  
  www.thecochranelibrary.com

- **BMJ Clinical Evidence** is “one of the world’s most authoritative medical resources for informing treatment decisions and improving patient care.”  
  http://www.clinicalevidence.com/ceweb/index.jsp

5. Training for lay people:

- **INVOLVE** See  www.involve.org.uk and search for ‘Training’.

- **Critical Appraisal Skills Programme**;
  http://www.phru.nhs.uk/Pages/PHD/CASP.htm

- **Health Knowledge** – learning how to find and critically appraise evidence  

- **Macmillan Cancer Support** - Cancer Voices  
  http://www.macmillan.org.uk/Get_Involved/Cancer_Voices/Training.aspx

- **Cancer Care Study Days and Conferences**, Royal Marsden Hospital, London

- **UKCRN and NCRN study days and courses**:  
  http://www.ukcrn.org.uk/index/training.html

- **Folk.us** runs workshops for service users and carers. They provide practical support and assistance with involving service users and carers in research projects.  
  http://www.projects.ex.ac.uk/folk.us/whoweare.htm#Workshops,%20Training,%20%20&%20Advice

- **Project LEAD**. US National Breast Cancer Coalition’s “*Innovative Science Programme for Breast Cancer Activists.*” An extensive 4-day programme for advocates.  
• United States Cochrane Centre Web course: Understanding Evidence-based Healthcare: A Foundation for Action. “…designed to help consumer advocates understand the fundamentals of evidence-based healthcare concepts and skills.” http://apps1.jhsph.edu/cochrane/CUEwebcourse.htm

University Courses:
MSc Clinical Research: Patient and Public Involvement (PPI) in Research Module The University of Hertfordshire is one of seven universities in England to offer the first wave of the part-time modular master’s degree programme in Clinical Research which includes a module on PPI in research. This programme is jointly funded and supported by the NIHR and Chief Nursing Officer (CNO). The University of Sheffield also offers this course with PPI module.

A module on Patient and Public Involvement in Health and Social Care Research is also offered at King’s College, London, to provide post-graduate training.

6. How to produce or assess good quality information for cancer patients:


Producing Patient Information: How to research, develop and produce effective information resources Updated 2nd ed.
Duman Mark
King's Fund, 2005 £25.00 ISBN 1857174704
Read more about this publication here http://www.kingsfund.org.uk/publications/kings_fund_publications/producing.html

Criteria for the assessment of patient information leaflets (of all kinds) are to be found on the British Medical Association website http://www.bma.org.uk/ap.nsf/Content/LIBBMAPatientInformationAward


NB: please note that this collection of information is not comprehensive: it has merely been assembled as a useful guide for anyone wishing to find out more about patient and public involvement in research.

Hazel Thornton
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