Involving patients and the public in the work of the Medical Research Council Clinical Trials Unit

By members of the MRC CTU PPI Group*

When INVOLVE published its guidance on public involvement in clinical trials in March 2012 (see above), the Medical Research Council Clinical Trials Unit (MRC CTU) had already done some work to ensure that patients, carers and community members have positive impacts on the quality and usefulness of our research.

Involvement at an organisational level

At an organisational level, we had:

- set up a working group on patient and public involvement (PPI), with input from patient representatives into the terms of reference for the group as well as membership of it
- produced guidance for researchers working on cancer clinical trials about how to actively involve people affected by cancer
- produced an induction pack for people affected by cancer who get actively involved in our trials
- held meetings with patient groups to discuss progress of our trials, results and implications, and future

research priorities
- ensured we have PPI in our Protocol Review Committee, which looks at the plans for each of our trials including any written information for people who take part in research
- undertaken and published a survey about PPI in our research.[1]

Involvement in individual trials and other studies

Many of our researchers had also worked in partnership with patients, carers and community members to ensure that individual trials and other studies reflected the needs and priorities of patients. For example:

- A lot of our research about HIV and TB takes place in African countries. We have worked in partnership with people in local communities in these countries to make sure that the research works well and is about topics that are important to people.
- Patients and patient representatives have been actively involved in our trial management groups (TMGs), and patient representatives have been involved in writing our guidance notes both for researchers and for PPI representatives on TMGs.[2]
- We have explored ways to involve patients effectively in a meta-analysis. This type of research does not involve any direct contact with patients – instead it looks at the results of research that has already taken place. That makes involvement more challenging.[3]

Development of a policy on PPI

Our experience meant that we were asked by INVOLVE to help to write their guidance on public involvement in clinical trials

(see above). Working on the guidance enabled us to learn more about PPI in other trials units. We were impressed by the systematic approach to PPI in some clinical trials units – for example the Wales Cancer Trials Unit and the University of Leeds Clinical Trials Research Unit. As a result, and with the support of senior managers, we have been working on an overall policy for PPI for the MRC CTU. We hope this will mean that PPI will become a normal part of how we do our research.

The policy recognises the central role of patients and the public in research at MRC CTU. Our aim is for CTU researchers to build partnerships with patients and the public that help to shape decisions about research, including setting priorities, developing relevant questions and disseminating results. This policy covers all research projects being led by the MRC CTU, with the exception of some methodological research. It commits us to ensuring PPI within individual clinical studies, across programmes of clinical research and at a strategic level.

The policy was developed in partnership with patients and has recently been approved by our senior management team. Our next challenge is to ensure it is implemented!

Please email us for a copy of the policy – contact details are at the end of this article.

Lessons learned

The key lessons we have learned so far are:

- set up a PPI group – it helps to have peer support, share the workload and set deadlines
- ensure you refresh the group every few years – it helps introduce new ideas
- get senior level support – we have had active support from our Unit Director, Max Parmar
- work in partnership with patients and patient

organisations
- develop and support relationships between researchers and patients, and between your organisation and patient organisations
- find out what PPI is already happening, and build on that
- remember that trials are complex and have to run according to legal guidelines – people need to understand this before they agree to get involved
- it's helpful to evaluate what you've done, so that you can learn lessons and improve PPI in the future.

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[1] You can download this for free from the Trials open access journal – the link is www.trialsjournal.com/content/13/1/9 and the reference is: Involvement of consumers in studies run by the Medical Research Council Clinical Trials Unit: Results of a survey by Claire L Vale, Lindsay C Thompson, Claire Murphy, Silvia Forcat and Bec Hanley. *Trials* 2012, **13**:9

[2] You can find these on our website www.ctu.mrc.ac.uk/resources/patient_involvement.aspx

[3] We wrote about this work in an article which you can access free of charge. The link is www.systematicreviewsjournal.com/content/1/1/23 and the reference is: Evaluation of patient involvement in a systematic review and meta-analysis of individual patient data in cervical cancer treatment by Claire L Vale, Jayne F

Tierney, Nicolette Spera, Andrea Whelan, Alison Nightingale and Bec Hanley. Systematic Reviews 2012, 1:23 doi:10.1186/2046-4053-1-23