Trial Steering Committee (TSC)

The role of the Trial Steering Committee (TSC) is to provide the overall supervision of the trial. Ideally, the TSC should include members who are independent of the investigators, their employing organisations, funders and sponsors. The TSC should monitor trial progress and conduct and advise on scientific credibility. The TSC will consider and act, as appropriate, upon the recommendations of the Data Monitoring Committee (DMC) or equivalent and ultimately carries the responsibility for deciding whether a trial needs to be stopped on grounds of safety or efficacy.

See MRC Guidelines for GCP for Clinical Trials 1998 for terms of reference and further guidance (Appendix 3).

GPRDVacancyapplicationLayMemberClinicalTrialSteeringCommittee

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The changing landscape of a

clinical trials unit: Working towards making PPI part of the culture of our organisation

Abstract: The Medical Research Council MRC Clinical Trials Unit (MRC CTU) at University College Longon (UCL) develops, runs and reports clinical trials and other research studies in areas including cancer, HIV and other infectious diseases. The MRC CTU Patient and Public Involvement (PPI) Group, which includes staff and patient representatives as members, has been working towards increasing the profile of PPI across the Unit to make PPI and integral part of our research culture.

We want to share the breadth of our recent experiences and achievements including:

- Developing and implementing a PPI policy at MRC CTU
- How we support our researchers in their PPI activities
- How we support our patient representatives in their research activities
- How we ensure PPI in all of our clinical studies.

We will also highlight some of our individual activities including:

- Improving patient information sheets for our clinical trials: a joint project between staff and patients
- Collecting case studies of PPI in our clinical research: sharing the learning using examples of impact
- The development of some short films about PPI in clinical trials.

We will discuss issues that we have experienced such as the challenges of supporting PPI across a broad spectrum of

activities and how we have tried to ensure consistent standards across all of our work. Our presentation will be codesigned and co-delivered by our staff and our patient representatives.

Download poster

Involving patients and the public from hard-to-reach groups in clinical trials

Abstract: The Medical Research Council Clinical Trials Unit at University College London (UCL) is committed to involving patients and the public in our research. We are increasingly focusing on challenging and innovative studies. This often means working with groups that have not traditionally been actively involved in research, such as:

- heroin addicts who have been recently released from prison
- gay men who are at risk of being infected with HIV in the UK
- adults living with HIV in Africa
- adolescents living with HIV in the UK
- lung cancer patients with very short life expectancy
- women in Africa who are at risk of being infected with HIV

These groups can be hard to involve in research due to stigma relating to their condition or lifestyle, age, literacy, and other factors. The most common approaches to patient and public involvement (having patient representatives as members

of the trial steering committee or trial management group) may not always be appropriate for these groups.

This presentation will explore how different trials have managed to involve these ‘hard-to-reach’ groups. Approaches used have included:

- working with voluntary organisations
- use of focus groups and community meetings
- webinars, workshops and conference calls with trial participants to inform future research plans
- use of social media

The presentation will reflect on some of the practical considerations involved in involving people from these groups, and the lessons we have learned so far from this experience. We hope this will encourage others to explore innovative and diverse approaches to involving people from ‘hard-to-reach’ groups in research.

Public involvement in the design and conduct of clinical trials: A narrative review of case examples

Abstract:
Clinical trials test the effectiveness of health care interventions. The public should be actively involved in the design and conduct of clinical trials. We searched the literature to find examples of public involvement in the design and conduct of individual clinical trials. This

presentation describes how the public were involved in the nine trials we identified through our literature search. We found that the public contributed to the design of trials by:

- reviewing consent procedures and patient information sheets
- suggesting additional trial outcomes
- reviewing a trial's data collection procedures
- making recommendations on the timing and location of follow-up data collection.

We found that the public can contribute to the conduct of clinical trials through membership of the Trial Steering Committee and by delivering the trial protocol after completing relevant training. We will discuss the concerns that researchers have raised about public involvement in the design and conduct of trials, as well as the good practice recommendations that have been put forward. This presentation will provide important evidence for researchers, the public and funders on how the public can make substantial contributions to the design and conduct of clinical trials.

I would like to acknowledge the contributions of Wendy Baird (Director of the NIHR Research Design Service for Yorkshire and the Humber) and Anthea Sutton (Information Specialist, University of Sheffield) to this work.

Developing a new approach to involve service users in a

multi-centred trial of a complex intervention in pre-hospital emergency care

Abstract:
Despite increasing service user involvement in health and social care research, it is still patchy in some areas. We present our experience of developing a model to actively involve service users in a multi-centred trial in pre-hospital emergency care.
The SAFER 2 trial is evaluating alternatives to A&E care for older people who repeatedly call 999. We include service users in this trial at different decision levels.

1. Trial Steering Group, Trial Management Group, Data Monitoring and Ethics Committee: these are the standard bodies which manage and oversee a trial
2. Management committees at local level: these take decisions about running the trial in each study site (Wales, London and East Midlands)
3. User groups: these groups of patients and carers meet with the site researcher to discuss issues affecting older fallers likely to be recruited into the study

Learning point: the different involvement forums allow service users, including elderly and frail people, to participate in and contribute to a multi-centred trial. Issues for discussion include: challenges of working with this user group; understanding and engaging in trials. Our model is based on the standard operating procedure for including service users, developed and adopted by our Clinical Trials Unit.

Summer 2015

In this issue:

- On the campaign trail
- The Patient Research Ambassador Initiative
- INVOLVE Coordinating Centre news
- Interesting articles and publications
- Payment and recognition for public involvement – issues and resources

Please note that benefits guidance and tax legislation been subject to considerable change/reinterpretation since 2019. Any INVOLVE documents referring to the payment of involvement fees may now be out of date and are pending a review during 2020. INVOLVE's guidance should not be substituted for professional advice, and INVOLVE accepts no liability for decisions or actions taken as a result of its guidance. You are always recommended to take your own tax, finance or legal advice.

- Dramatic approach to patient and public involvement
- Public members on Trial Steering Committees: interview study points way forward on guidance
- Diversity in public involvement
- Noticeboard

Involving 'seldom heard' groups in HIV research

By Annabelle South on behalf of the Medical Research Council Clinical Trials Unit (MRC CTU) at University College London

(UCL) Patient and Public Involvement (PPI) group*

There is a long-standing tradition of actively involving patients in HIV research. However, there are some groups of people affected by HIV who have not been actively involved. This article explores the experiences of two studies by the Medical Research Council Clinical Trials Unit at University College London (UCL) that have tried to address this.

Ask ALFIE

Adolescents and Adults Living with Perinatal *HIV (*AALPHI) is a study that follows a group of young people (aged 13-23) who were either infected with HIV when they were babies, or are HIV-negative and live with someone who is HIV-infected. This group is particularly hard to involve because of their age and the intense stigma around HIV. From the outset the study team worked with voluntary organisations that support young people with HIV to:

- pilot the interview with young people
- get young people to comment on the patient information sheet.

A group of HIV-infected young people rebranded the study as ‘ALFIE’, designing the logo and poster, and making a sock puppet video about the study. A young person is also on the study steering committee, and attends meetings with a mentor, meeting the chair beforehand to discuss how they want to contribute.

What difference has this made?

The input of young people made sure the questions and tests were acceptable and the study materials were appealing and understandable. Voluntary organisations have helped to promote the study to young people.

Lessons learnt

- Involvement has to start at the design stage to ensure acceptability
- Young people are a transient group, so involving a group rather than one or two individuals can provide stability while allowing for change
- Involving voluntary organisations that support young people affected by HIV is key – they have acted as a bridge between researchers and young people
- Involvement of young people must be on their terms, using the right language and avoiding tokenism
- Offer support and training to young people who are involved, and prepare them for any meetings.

PROUD

PROUD is an HIV prevention study for gay men at high risk of HIV. It is investigating what impact taking a drug called

Truvada (which can reduce the risk of HIV infection) has on gay men's sexual and risk behaviour, as well as HIV and sexually transmitted infections (STIs). This approach is called pre-exposure prophylaxis (PrEP) – taking a drug before exposure to the virus, to reduce the chance of becoming infected if exposed to it. This group has not traditionally been involved in research as they are not 'patients', and there is some stigma in the gay community around the use of PrEP. The researchers have involved the community in a variety of ways:

- The **Community Engagement Group** was formed at an early stage, and consists of voluntary organisations that support people living with HIV, and represent gay men and other men who have sex with men, and transsexual women. It advises the trial team on recruitment, communication, media activities and patient and public involvement (PPI) strategies.
- The **Trial Steering Committee** has three community representatives, one of whom is the joint chair.
- The **Independent Data Monitoring Committee** has a community representative as a member.
- **Participant involvement meetings** have been held (via teleconferences and face-to-face meetings) to get the views of some trial participants on study procedures and future trial priorities. These meetings were facilitated by community representatives, and were advertised by clinics and on the study website.

What difference has this made?

The Community Engagement Group helped to shape the whole trial from a very early stage. They provided advice about the acceptability of the study design and also advised on a change in the eligibility criteria.

Recruitment to the trial was initially slower than expected.

The Community Engagement Group met to discuss this, and as a result HIV charities released a joint statement outlining their position on PrEP. This resulted in considerable media coverage. The Terrence Higgins Trust also used GRINDR (a gay social networking app) to raise awareness of PrEP. This boosted recruitment.

Participant involvement meetings have helped to inform the development of a larger trial application, changes to the data collection tools, new recruitment materials, and identify the need for additional participant support such as social media platforms.

Lessons learnt

- Understanding your target audience is crucial for prevention trials
- Involve as many people as possible as early as possible, and keep the involvement dynamic
- Talking to participants and community groups may help to identify why there are problems with recruitment or retention, and how they may be addressed
- Community groups often have better channels of communication with potential participants than researchers do
- Researchers need to be politically aware, especially if they are doing research in an area that is potentially contentious
- Participants are keen to be involved and are well positioned to advise on ways to improve study conduct and help prioritise future research.

Conclusions

There is no ‘one size fits all’ way to involve ‘seldom heard’ groups. Study teams must consider the needs and preferences of their target groups, and design the involvement approach

around that. Doing so can result in involvement that has a real impact on the research.

Further information

* With thanks to those involved in patient and public involvement for the AALPHI and PROUD studies.

To find out more about patient and public involvement in the MRC CTU at UCL, visit **www.ctu.mrc.ac.uk/our_research/patient_and_public_involvement/**

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