NHS
Health Research Authority

PCWP meeting

Guidelines on the summary of clinical trial results for laypersons

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HRA – Non-Departmental Public Body Status – January 2015

- Care Act places our functions on a statutory footing
- Greater authority and policy responsibility
- Extends remit to adult social care
- Gives duties to the HRA and to others
- Duty to promote transparency

Development of guidelines on the clinical trial results for laypersons

- Development of guidance to be led by the UK
- Good fit with previous guidance
- Builds on our experience of working with a range of stakeholders

Transparency – HRA approach

- Transparency as a global issue
- Pragmatic and proportionate approach to support UK competitiveness
- Question on ethics application form since 2008
- Registration identified as a specific REC condition - 2013
- Deferral option for early trials
- Using the sponsor declaration as a compliance check point – 2014, extended 2015

Public views on transparency Sciencewise

HRA has worked with Sciencewise - the UK's national centre for public dialogue in policy making involving science and technology issues

Public dialogue 2013 - Methodology

1. The Public view – Public Dialogue workshops conducted by MORI
   - 8 workshops

2. The Patient/participant view
   – 8 workshops

Patient workshops included:

- Diabetes
- Parkinson's
- Mental Health
- Stroke survivors
- COPD
- Cancer
- Children and Young people
- Phase 1 participants

- Each group was 3 hour workshop, 5 with researchers

Perceptions of health research

- General public have little or no understanding of health research; some of it derived from fiction
- Differences between views of public and patients but consensus on transparency issues
- Public shocked that results are not automatically made available
- Study participants disappointed that the results are not shared with them.

Transparency

- Both patients and public were not happy with the lack of publication

  "It should all be published because information is knowledge; if you are educated you can make an informed decision" (London2)

- Both patients and public wanted the HRA and ethics committees to take a stronger line with researchers that did not publish their findings

  "Publishing results in the public arena is a moral obligation" (Cancer Patients group)

- Patients were aware that even if results were published, they may not be able to access them and wanted them made available in a public space

- Patients suggested lay 'research summaries' on an accessible website

Guidance on information for participants at the end of a study - April 2015

- Information should be given to participants as their time in a study comes to a close
- Applies to all interventional studies including clinical trials and diagnostic studies
- Excludes Phase 1 studies of healthy volunteers
- Does not require ethical review as long as it complies with the initial PIS

Guidance on information for participants at the end of a study

Information should include:

- A thank you for taking part
- What will happen to them at the end of a study including arrangements for treatment
- How summary study findings can be accessed by participants
- How those who would rather not see the findings can opt out of this process.

Building on existing work by INVOLVE/NIHR

- Lay summaries of protocol at the beginning of a study
- Initial review and assessment of plain English summaries in NIHR funded research
- Development of guidance on how to write a plain English summary

Building on work undertaken by Harvard MRCT

Namely:

- guidance
- templates

Next steps

- Detailed work plan for delivery of draft guidance by early November 2015
- Set up taskforce
- Build on good work undertaken so far
- Work closely with interested stakeholders

Task force

- Patients and consumers in form of sub-group from PCWP
- Industry representatives
- EUDRACT representative?
- Academia