EXECUTIVE SUMMARY

SCOPING STUDY TO EXPLORE THE MOST APPROPRIATE WAY TO PRODUCE AND DISSEMINATE INFORMATION ON THE QUALITY OF RANDOMISED CONTROLLED TRIALS FOR POTENTIAL PARTICIPANTS
known as
PACT (Participants' Assessment of Clinical Trials)

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INTRODUCTION
New treatments and technologies should be evaluated before they are introduced into the NHS. The randomised controlled trial (RCT) is the best way to assess the effects of most new interventions, but researchers often find it hard to recruit enough participants to these trials. At the same time, some people who would like to enter RCTs are not offered the opportunity to do so.

It has been suggested that a centralised resource could help potential participants to identify which trials are ongoing, and / or find information about the quality of these trials. At present, although there are a few registers of trials available, there is no central information resource about ongoing UK-based RCTs specifically designed for the public.

Purpose of the scoping study
Consumers in NHS Research commissioned the Health Services Research Unit to inform the development of such a centralised information resource by assessing the types of information that are important to potential trial participants and appraising the ways in which that information could be provided.

METHODS
We sought information from the following sources: published academic literature; lay media, interviews and focus groups, and use of e-mail discussion.

We recognised that different people would have different perspectives on information needs and on the appropriate presentation of that information. Reflecting this we elicited views from: a) people considering participating in a trial; b) people who are currently, or have recently been, participants in trials; c) representatives of national consumer groups; and d) researchers involved in the design and conduct of trials.

Over the course of the scoping study we interviewed a number of individuals on a one-to-one basis and elicited the views of many others in a focus group or group discussions context. We formally interviewed: nine potential trial participants; six consumer representatives; nine researchers, and one industry representative.

In addition, the views of 24 further consumer or patient advocate groups were elicited at national meetings of consumers involved in research. A number of those

consumer representatives had personal experience of involvement in clinical research and trials, as did some of the researchers, and these formed the basis of the views of 'actual' trial participants.

INFORMATION NEEDED TO DESCRIBE A TRIAL

People who are considering participating in a trial might need information about:

- *the quality of the trial* – including: the importance of the research question being asked; the nature of the difference that the trial could make; the scientific or methodological quality of the trial; the robustness of the knowledge it would generate; and the ethical integrity and acceptability of the trial.
- *the interventions being compared* – particularly information about: the processes involved in the interventions; how the interventions were thought to work; the benefits it is hoped they would bring; and, what is already known about their effects (both positive and negative).
- *the implications of the trial for participants* – this covered the more practical issues around participation including: any extra visits or tests associated with the trial; how long individuals would be followed up for; and, how long the trial would run for. Respondents also felt that the processes describing how, when and what would happen if they subsequently withdrew should also be spelt out.
- *contact details for someone to talk to about the trial* – respondents stressed the importance of having access to someone to talk to about the trial, so that any misconceptions could be corrected and personal concerns could be addressed.

FACILITATING UNDERSTANDING OF INFORMATION

We considered two basic options to help people consider information about trials and decide whether to participate:

- *Star/quality rating scheme* – there was a mixed response to the provision of information which had been star/quality rated. A number of concerns were raised including: the validity and meaning of such a system; who would do such a rating; whether such a system might be too 'cryptic'; and personal weightings on different 'facts' could not be incorporated. However, there was acceptance that an overall rating or 'kite mark', which would indicate that certain key features were in place for a trial, would be desirable.
- *Self-appraisal guide* – there was general enthusiasm for the suggestion that, as part of the central resource, there would be a 'guide' to help people appraise key elements of trials for themselves. It was suggested that some existing checklists might be modified for more general public use.

DESIRABLE FEATURES OF A CENTRAL INFORMATION RESOURCE

There was widespread support for the concept of a centralised information resource for clinical trials. Desirable features for such a resource included:

- *Standardised structure for the reporting of trial information* - Information within the centralised resource should be reported in a standardised manner. However, the system should be flexible enough to allow optional links to other resources, for example links to the individual trial sites.
- *Up-to-date information* - It was acknowledged that the information needs of people do not stop at the 'decision-to-enter' stage, and that up-to-date information should be available for people for the duration of the trial.
- *A general information section* - This section could include: general information explaining clinical trials; a glossary of commonly used terms in research; links to

organisations who would be willing to provide generic support and information about clinical trials; and a 'guide' to help people appraise elements of the trial for themselves.

- *A structured or layered database* - This would allow people to choose what kinds of information they would like to see, and in what level of detail.
- *A searchable database* - People would like to be able to enter their personal details (eg health condition, age, gender, geographical location etc), and ask the system to filter out all the trials directly relevant to their health condition and to their wider personal profile. This search facility should also be easy to use.

Presentational issues

The packaging of information was seen as very important. Information presented should be in simple language with the use of scientific terms kept to a minimum. The information provided should also be short in nature. People would also like greater use of visual aids; for example, use of diagrams or video-clips.

POTENTIAL MODELS OF PROVISION

Two main aspects were considered – firstly the platform, or host, for such a resource, and secondly the best ways of accessing it.

- *Potential platform or host* – there are a number of registers of ongoing trials available, primarily accessed via the Internet. Many of them contain some of the elements of information required for a resource for potential participants, but they have not been developed directly from the information patients want. The three main sources identified were: *meta*Register, the NiH register and an HIV / AIDS trial register.
- *Potential means of accessing the resource* – There was widespread support for the provision of a centralised information resource via the Internet. Access to the Internet is not possible or desirable for some people, however, and as such people would also like to be able to access the information by other means, for example by telephone. Many respondents felt that NHS Direct / 24 might be an appropriate vehicle to access information about ongoing trials, whilst another popular view was that trials relevant to specific conditions be available via the appropriate consumer groups.

*Suitability of meta*Register *to host the centralised information resource*

Discussions were held with the developers of *meta*Register (*m*RCT) around the feasibility of providing the types of information, and searchable structure, our respondents had identified. The *m*RCT acts as a repository for information generated via a number of disparate research registers. Hence, if extra items of information are required to be collected, it is likely that the individual source registers will have to be liaised with directly to facilitate this. However, in principle, the developers of *m*RCT supported the concept of developing a more sophisticated search facility, and facilitating access to supplementary information / media.

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

- There was widespread support for the concept of a publicly available resource containing information about ongoing clinical trials designed for use by potential participants.

- When considering information about trials, people want to know about the quality of the trials, the interventions being compared and what participation would mean for them personally.
- People prefer to have access to someone to discuss their potential involvement in a particular trial.
- There was widespread support for the provision of a 'guide' to help people self-appraise aspects of a clinical trial.
- People would like to be able to choose which information elements they wanted to see and the level of detail to see them in.
- People would like to be able to search the central resource using a combination of relevant criteria.
- People would like to be able to access the central resource both via the Internet and by other means.
- On an Internet-access version, people would like to be able to transfer or link directly from the central resource to other relevant information sites. For example, they would like to be able to 'click through' to specific trial information sites.
- The gathering of all the information seen as desirable for the centralised resource might be practically difficult.
- A considerable investment would be needed to develop the kind of search engine and interface seen as desirable.

Recommendations

There are a number of clearly desirable features of a centralised information resource for clinical trials. Whilst we accept that the provision of some of these features may be impractical, and that each will have resource implications, we recommend serious consideration of the following:

- Provision of a 'guide' to help people appraise key elements of trials themselves.
- Provision of a 'kite mark' (as an indicator that a trial has passed a minimum quality threshold) to trials for which 'the key things are in place'.
- Provision of a flexible system to allow:
  - people to focus on what information they want, and in the level of detail they want;
  - people to search the central resource using a combination of relevant criteria;
  - the incorporation of visual aspects such as diagrams or videoclips; and
  - links to other relevant information sites eg specific trial sites.
- Provision of a resource not only via the Internet, but also by other means of access, such as via NHS Direct / NHS 24 and / or via consumer organisations.
- Initiation of discussions with a primary register of trials (eg the National Research Register) to investigate more fully the feasibility of gathering all the information elements seen as desirable.
- Initiation of discussions with *meta*Register and a primary register of trials (eg the National Research Register) to develop a more sophisticated search engine and interface.