Information about ongoing clinical trials for patients

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It is often difficult for patients who want to take part to find information. **Fiona Godlee** and **Iain Chalmers** argue that their needs can and should be met

Cancer patients face many challenges, but in two respects they may be more fortunate than patients with other conditions in the United Kingdom. CancerHelp UK provides them with access to specially written information about clinical trials of cancer treatments in the UK and a dedicated telephone helpline that they can use to discuss potentially relevant trials with specially trained oncology nurses.[1] Why do patients with other conditions not have similar facilities?

The demand from patients for information about ongoing trials has been clear and growing for many years. They want this information for various reasons, including a wish to participate in research.[2-6] Their motives for participation include wanting access to treatments that are only available within the context of research; an altruistic wish to help others; and as a way of dealing with uncertainties about which treatment option to choose. Furthermore, a recent review of evidence about the impact of participation in clinical trials found that it helps to ensure the acceptability of clinical trials and to increase recruitment to all types of research.[7]

The continuing lack of information to help people decide whether and how to take part in research is surprising. The government has put great emphasis on patient choice, and the Department of Health declared five years ago that because "health research is conducted for the benefit of patients, users, care professionals, and the public in general . . . there should be free access to information about ongoing research . . . presented in a format understandable to the public."[8] And three years later, the secretary of state for health, in a summit hosted by the prime minister, set out new plans to ensure that "patients from every part of the country, with any illness or disease [should be] made aware of research that is of particular relevance to them, so that they are able to take part in clinical trials if they meet the criteria."[9] Given government support for these principles, why have they not been translated into practice?

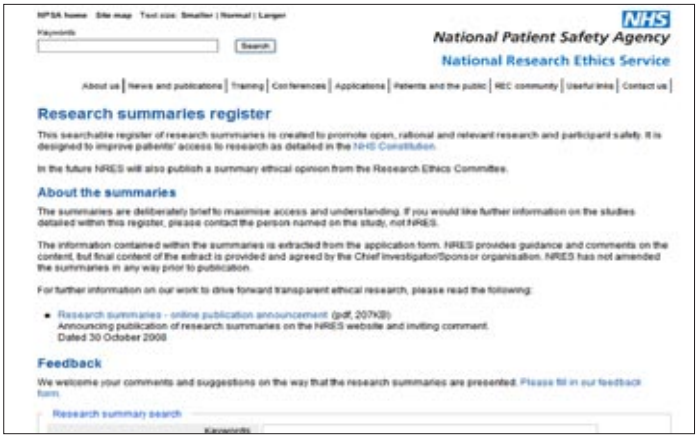
Requirements for registration on WHO international clinical trials registry platform (www.who.int/ictrp)

- Name of primary registry and trial identifying number
- Date of registration in primary registry
- Secondary identifying numbers
- Source(s) of monetary or material support
- Primary sponsor
- Secondary sponsor(s)
- Contact for public queries
- Contact for scientific queries
- Public title (in easily understood language)
- Scientific title (as registered)
- Countries of recruitment
- Health condition(s) or problem(s) studied
- Intervention(s)
- Main inclusion and exclusion criteria
- Study type
- Date of first enrolment
- Target sample size
- Recruitment status
- Primary outcome(s)
- Main secondary outcomes

Availability

Standard information about all clinical trials in the UK already exists, but it is too often neither publicly available nor patient friendly. Janet Wisely, director of the National Research Ethics Service, estimates that at least 400—and probably many more—trials recruiting in the UK have still not been publicly registered (personal communication). This seems to have little to do with active resistance to registration among researchers: thousands already register their trials on the UK based ISRCTN Register or on ClinicalTrials.gov in the United States. The main problem seems to be confusion about who should register the trial, how to do it, and which register to use.

Unlike governments in some other countries, successive UK governments have not made trial registration mandatory. But the latest iteration of the Declaration of Helsinki states that all clinical trials "must be registered in a publicly accessible database before recruitment of the first subject."[10] As it happens, all 20 items required to register a trial on the World Health Organization's international clinical trials registry platform (box)[11] can be derived from the Integrated Research Application System (IRAS)—a bureaucracy busting facility used by UK researchers to submit documents to research ethics committees and regulatory bodies. With minor modifications, IRAS could also send the 20 items required to achieve complete public registration of all trials in the UK.



The WHO 20 item dataset can hardly be characterised as patient friendly, but it could link through to existing information that has been written specifically for patients, such as the information on CancerHelp UK. How big a job would it be to generate similar information on all UK trials? Developing quality information for patients costs money. CancerHelp UK employs the equivalent of five full time editors and develops information on about 180 new cancer trials a year. Extending a similar service across all conditions would require substantial investment, but a significant proportion of the needed investment is already being made. The National Research Ethics Service, which oversees research ethics committees in the UK, now creates lay summaries of all clinical trials that have received ethical approval and, with the consent of the researchers, publishes them on its website.[12] With input from writers trained to prepare material for the public, linkage to these summaries could rapidly extend the amount of information for patients at less cost than starting from scratch.

Resource efficient solution

So all the elements of what patients have been asking for already exist. What would these various pieces of the jigsaw look like if they were put together properly? Trialists would enter their information once only in IRAS, from which a complete UK clinical trials register could be automatically derived. Using trial identifiers, a clinical trials gateway would pull information together from this UK register and from sources of information written for patients. This aggregated information would then become available through the NHS patient website, NHS Choices. Patients could register their interests and be alerted to clinical trials that are recruiting locally and relevant to them. Because patient friendly information is often also profession friendly, this aggregated information would also be relevant to professionals using the information portal NHS Evidence.

By joining up existing resources the NHS could create a one stop shop for researchers registering their trials and another for patients, members of the public, and professionals seeking information about ongoing trials. But this will require political will and an end to fragmented leadership. Within England alone, the key publicly funded organisations responsible for parts of the jigsaw—the National Institute for Health Research, the National Research Ethics Service, NHS Choices, and NHS Evidence—report to different officials in the Department of Health. A champion of sufficient seniority should now be appointed and given responsibility for ensuring that these bodies work together more effectively, not only with each other but also with the health departments in Scotland, Wales, and Northern Ireland. Patients who want to take part in clinical trials, both because of the potential health benefits and because they want to help others, have longstanding information needs.[13] If progress in meeting these needs cannot be achieved without legislation, then the latest revision of the Helsinki declaration should be used as a basis for changing the law.

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Good doctors here and abroad

PANORAMIC/GETTY IMAGES

Guest blogger Louise Kenny is back in the UK after a recent lengthy stay in Guatemala working at the Hospitalio Atitlan. She is finding it harder to adjust to life in Gateshead than she first did on her arrival in Guatemala. "I've been back for 3 weeks now, and I'm missing the drama and variety of Guatemala. I scrape the ice off my car every morning, saddened by the thought that there is no chance of me delivering a baby, extracting a machete, draining an abscess, or frantically googling 'how to deal with a lightning strike,'" she writes. She hopes to return to Guatemala soon, but is waiting to secure funding for her trip. Does anyone know of any organisations or foundations that provide funding for international work?

Helen Jaques looks at what makes a good doctor. A previous study found that competence, caring, compassion, and commitment are the most important core professional values for practising medicine. Now a new study in the *Journal of Medical Ethics* has found that cheerfulness needs to be added to the list.

Emily Spry is finding that her work in the Pikin Hospital, Sierra Leone, is stretching her to her limits and way beyond what she has been taught at medical school. "How often in your UK practice have you designed an emergency patient trolley from scratch and given your drawings to the welder? Only to find that caster wheels with brakes cannot be sourced in Freetown," she says.

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