they are prepared to learn from each other’s experiences, both good and bad. There is now no shortage of evidence on how clinical services and health policies can reduce suicide. What we lack is an effective forum where a rigorous examination of international evidence can take place, with the findings translated into actions across the many countries where deaths from suicide are now on the rise.

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The global spread of clinical trials

David Skuse

There has been considerable publicity recently in the UK concerning the threatened contraction of the country’s pharmaceutical industry. The UK currently has the third highest share of global pharmaceutical research and development expenditure (after the USA and Japan), but the costs of conducting research in the UK are rising.

In February 2011, Pfizer announced it would be closing its entire research and development (R&D) facility in Sandwich, Kent, with the loss of 2400 jobs. Nature (1 February 2011) commented that UK governments had repeatedly been warned that the country is perceived as being unfavourable to medical research, although Pfizer claimed its decision was not made on those grounds. The Academy of Medical Sciences recently produced a report expressing concern that it is exceptionally difficult to get ethical approval for clinical trials in the UK (Academy of Medical Sciences, 2011). It made recommendations for reform of the ‘much maligned’ European legislation on the matter.

While the number of clinical trials approved in the UK has not dropped significantly in recent years, the UK’s global share of patients in trials plummeted from 6% in 2004 to just 2.5% in 2008. It takes an average of 621 days in the UK from the award of a research grant through to the first patient entering a trial, compared with 30–60 days in Canada, because of the complexities of the current system. The chair of the Academy working group that produced the report, Michael Rawlins, highlighting the difficulty getting permission for a funded trial to be enacted, commented: ‘at the moment nobody knows half the time where to go and what to do’ (quoted in the same issue of Nature).

In light of the problems encountered here, and to a similar degree in the USA, it is hardly surprising that ‘Big Pharma’ has turned to low- and middle-income countries to conduct trials. The attraction of countries where legislation on ethical
Challenges of clinical trials in low- and middle-income countries

Akwasi Osei

Clinical trials have been conducted almost wholly in high-income countries until recently, yet their results may not always be valid or applicable in middle- and low-income countries. A welcome recent development is the increasing number of clinical trials being conducted in the latter areas. Growth in the number of trials and their increasing costs in high-income countries are combining with globalisation to shift clinical trials to less wealthy countries (Rowland, 2004). Glickman et al (2009) have shown that about a third of clinical trials conducted by the 20 largest US-based pharmaceutical companies are now conducted outside the USA, many in low-income countries.

Such globalisation of clinical trials obviously confers some benefits to the host countries, including the sharing of experiences and knowledge. It also increases the local availability of the medicines under trial, as well as familiarity with them. The trials bring revenue to the host countries while cutting costs to the pharmaceutical companies by around 10–50%. Clinical trials in India, which is emerging as a favoured global destination for research and outsourced clinical trials, was expected to have earned that country US$1.5 billion of revenue by 2010 (Federation of Indian Chambers of Commerce and Industry, 2005).

As welcome as this development is, it brings in its wake challenges, provoking the debate over whether clinical trials in low-income countries are as valid as they are intended to be. Many factors come together to determine the validity of clinical trials, including the number of participants who can be recruited, the affordability and local availability of the medicines, informed consent, and ethical approval from an institutional review body or the agency accredited by the local ministry of health, among others. Ethical approval is a very important consideration, to ensure that nobody is exploited in the course of the trial and that the drug is properly shown to be safe in general application.

In the light of these considerations and challenges, two key questions arise.

- Are clinical trials accurate and reliable in low-income countries?

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