Women’s health trials in developing countries: under-registration is the keyword?

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Merriel et al. analysed the WHO International Clinical Trials Registry Platform (ICTRP) for trials that are within the broad remit of obstetricians and gynaecologists, and conducted in low- and middle-income countries between 2012 and 2014. They identified 509 registered trials evenly distributed across obstetrics and gynaecology. The question we must ask is whether the numbers represent a low level of interest in women’s health in general or under-registration. Merriel et al. found 47 (91 overall) trials registered in India and 51 (103 overall) trials registered in Iran on maternal health. Both are listed as primary registries of the WHO Registry Network (www.who.int/ictrp/network/primary/en). Although the Brazilian registry is also a primary registry, it is surprising that Brazil does not appear among the top four active countries for research.

Given that MDG4 and MDG5 motivated huge levels of funding both for research and programmes in the past 15 years, the numbers picked up must surely be an underestimation of the scope of research in this field. The WHO ICTRP was set up following the Ministerial Summit in 2004 through World Health Assembly (WHA) resolution 58.34 in 2005. Over the years, a lot of effort has gone into improving trial registration, raising awareness about the importance of publication bias, and encouraging the pharmaceutical industry and countries to register their trials in a timely and comprehensive manner. The registration status 10 years after the ‘Mexico Statement’ on health research is clearly not at an acceptable level. Much of the criticism and media interest about trial registration have focused on the pharmaceutical industry; however, from the numbers demonstrated by Merriel et al. it is clear that under-registration is widespread beyond the pharmaceutical industry-sponsored trials. It is important to note that BJOG and most other biomedical journals made commitments to reject unregistered trials. There is clearly a need to disseminate this information widely, and to educate and advocate for trial registration globally and nationally. It would also be important to highlight the proportion of unregistered trials received by major biomedical journals to understand the scale of the problem better.

The scientific community is discussing cutting-edge issues in scientific communication and knowledge sharing, including improving open access, different measures of article metrics, and how publication of results of trials within a given time period can be secured. Although these initiatives are certainly welcome, the efficiency of trial registration must also be improved. The registration must include sharing the protocol, and the research results must be reported within a reasonable time frame. The AllTrials initiative (www.alltrials.net) is a welcome programme to improve public understanding about the importance of accessing research that is funded and conducted.

The fact that 72 and 89% of obstetrics and gynaecology trials, respectively, had less than 500 participants suggests that many of those trials are unlikely to provide conclusive results. The need for consistent and standardised reporting of core outcomes in these trials could at least be of help to make sense of the knowledge generated by the trials. The CROWN initiative to develop and report core outcomes in women’s health (www.bjog.org/view/0/crown-initiative.html), supported by BJOG and other major professional and research organisations in the field of sexual and reproductive health, will be key in this respect.

Disclosure of interests

I have no conflict of interests to declare with regard to this article.