Randomised trials in developing countries

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Professor Trevor Duke and colleagues at the Centre for International Child Health, University of Melbourne, have made a remarkable contribution to international child health. Over the past 11 years, they have undertaken annual structured searches for published reports of controlled trials of interventions addressing child health in developing countries, and assembled summaries in a compendium that is easily accessible to clinicians, policymakers and research funders. They present an analysis of the controlled trials that have been included in these annual compendia.

The results are encouraging: there has been a sevenfold increase in the number of trials published each year, providing a significant expansion in the evidence base for many common conditions, most notably the prevention and treatment of malaria. New knowledge of effective interventions from these trials has been generated alongside political will arising from the Roll Back Malaria initiative.

During the 11 years reviewed, there has been an increasing proportion of trials for which the corresponding authors are based in developing countries, suggesting that local capacity to undertake trials is being enhanced. Importantly, the evidence for interventions resulting from clinical trials is frequently taken up into policy first in the countries where the trials have been conducted because of the engagement that they generate and obvious local applicability of results. Examples include bacterial conjugate vaccines and treatment of malaria with artemisinin derivatives.

However, in developing countries, there is often limited opportunity for local clinicians to gain the skills needed to conduct high-quality trials. Participation in large multicentre clinical trials has played a significant role in generating local capacity. In Africa, the recent RTS,S malaria vaccine trials and large trials of antimalarial treatments have enhanced skills and facilities in local centres. There are several initiatives that support local investigator-led clinical trials. Organisations such as the Global Health Trials Network (https://globalhealthtrials.tghn.org/) currently provide resources for career development for clinical trials professionals including trial coordinators, data managers and monitors, as well as resources including standardised protocols and data collection tools. Open source software is available for capture and managing data for trials that meets international regulatory standards. Support for capacity building in clinical trials is provided by the European & Developing Countries Clinical Trials Partnership (EDCTP) and other funders. Local networks, such as the East African Consortium for Clinical Research (EACCR), based in Entebbe, Uganda, provide regional facilities for training in grant writing, trials design and management, good clinical practice, ethics, and organise cross-trial monitoring between participating centres, which decreases reliance of more expensive external commercial monitoring and other outsourcing services. There is considerable need to further develop national and regional clinical trials support units throughout the developing world.

An important issue that is highlighted in the article is that all too frequently, interventions with strong evidence of efficacy and cost-effectiveness are not adequately taken up into policy or adequately implemented in practice. Examples include some of the simplest and least expensive interventions, such as zinc and oral...
rehydration solution, for diarrhoea and cord care for newborns. Research is needed at a national policy level, at districts and health facilities, and among individual clinicians to induce behaviour change. There are also areas where clinical trials of efficacy are not needed, including universal access to free healthcare, access to essential medicines, and ensuring food security. Trials that focus on health systems and cross-cutting strategies are essential in order to identify the best ways of implementing these.

In the next 11 years, it is likely that the number of clinical trials will continue to increase. The annual compendium of controlled trials in developing countries will therefore be an increasingly valuable resource... Long may it continue.

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