

Randomized controlled trials join international register

WHO and online publisher, Current Controlled Trials Ltd, announced that from 2 April 2004, all randomized controlled trials approved by the WHO ethics review board will be assigned an International Standard Randomised Controlled Trial Number (ISRCTN) as part of a unique international registry of research.

The Register, launched in May 2003 and maintained by Current Controlled Trials Ltd, represents the first online service that provides unique numbers to randomized controlled trials in all areas of health care and from all countries around the world. Access to the ISRCTN Register is completely free and open to the public. It is hoped that this will make it easier for researchers, particularly in developing countries, to keep up-to-date with current research including unpublished trials and those with negative results.

"We are delighted that WHO are taking a lead in the registration of trials with an ISRCTN," said Anne Greenwood, Managing Director of Current Controlled Trials Ltd, part of the Current Science Group of companies with headquarters in London, England. "The ISRCTN scheme was conceived to address the confusion experienced by the research community. For controlled trials to be useful on a global scale, it is critical that research be coordinated. ISRCTNs offer a way to do exactly that."

Randomized controlled trials are considered the best way to compare — in an unbiased manner — the effects of particular interventions on people or populations either for health promotion, prevention, treatment or for rehabilitation. Despite being one of the main sources of medical knowledge, information about these trials has previously been difficult to find. This is because several trials may have the same title, one trial may be reported in several places under different titles, and many trials are never reported at all.

Information is even more difficult to find about those diseases which disproportionately affect poor and marginalized populations. Although WHO supports

and funds much of the research in this area, until now there has been no mechanism to make the information generated by the research easily available to researchers, particularly those in developing countries whom it affects most.

"The ISRCTN Register is an important first step within a wider context of the new emphasis on the need to increase international access to and utilization of health-related knowledge," said Dr Tikki Pang, Director of WHO's Research Policy and Cooperation Department. For a more in-depth perspective on the importance of public access to trial information, see related editorial in this issue of the *Bulletin* (2004;82:321).

As well as increasing knowledge sharing, access and utilization in low- and middle-income countries, the ISRCTN Register also tackles the problem of publication bias. By registering trials at the start of research, the register will include trials that are not published either because of negative findings, language barriers or inaccessibility of the researcher to journals.

As part of the first phase, all trials included in the HRP (UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction) trials register have now been included in the ISRCTN Register. Randomized trials in other major research areas such as infectious diseases, childhood diseases, vaccines and others will be added shortly.

Dr Timothy Evans, Assistant Director-General of WHO's Evidence and Information for Policy cluster warned against celebrating too soon: "Although trial registration is an important step on its own, it should not be seen as an end in itself," he said. "Only when these registers are efficiently used can they serve the purpose they are set up for... WHO will take steps to encourage its Member States to support the publication of research conducted within their countries and encourage the use of such registers."

Since its launch, the Register has assigned ISRCTNs to over 1800 trials and this figure is growing fast. Information about trials that have received an ISRCTN can be obtained from an online register maintained by Current Controlled Trials Ltd at <http://www.controlled-trials.com>. ■

Diabetes cases in Africa to double in next 25 years

The numbers of people with diabetes in Africa will more than double over the next 25 years, warned WHO and the International Diabetes Federation (IDF) during the joint WHO-IDF Workshop on Healthcare Coverage held in Dakar, Senegal, 1–3 April 2004. Representatives and diabetes experts from 13 French-speaking African countries attended the workshop in order to address the growing burden of diabetes in Africa.

"All African countries are struggling to care for the large number of people with diabetes, especially in urban centres," said Dr Nigel Unwin from WHO's Management of Non-communicable Diseases department. He also estimated that more than 80% of people with diabetes in Africa remain undiagnosed. In 2000, there were 7.5 million cases of diabetes in the continent. By 2030, this figure is expected to rise to around 18.2 million. "Despite this shocking trend, awareness about the importance of diabetes in Africa is poor," he added.

Low awareness amongst the public and primary health-care practitioners was highlighted as one of the major challenges faced by African countries in the prevention and cover of diabetes care. But as long as diabetes remains a low priority on national healthcare agendas, which in part reflects the low priority accorded by international funding bodies, this is unlikely to change. And the same can be said for the lack of funding and resources for national diabetes programmes, epidemiological studies and for the education and training of health care-personnel. Other obstacles to tackling the problem include a shortage of national insulin banks, diabetes specialists and centres in rural areas.

Leaving the problem unaddressed could be costly, warned Niek Sniekers, Vice President of Corporate Diabetes Programmes at Novo Nordisk, a health-care company with headquarters in Denmark, working with WHO and IDF to combat the disease.

"The increase in diabetes and its associated complications could have huge implications for the lay population in Africa and a massive impact