

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it easier for researchers, particularly in developing countries, to keep up-to-date with current research including unpublished trials and those with negative results.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

on national healthcare budgets, due to loss of productivity," said Sniekers.

In order to tackle the burden of diabetes in Africa, WHO and IDE, with the support of Novo Nordisk, are currently pursuing various activities to combat the disease at all levels. The objectives of the Dakar workshop were to contribute to capacity building in the management of national diabetes control programmes and to update participants with the skills and knowledge required to assess the coverage and quality of care at country level and to outline an improved framework for this assessment.

Currently, there are three main initiatives under development. The *Declaration of Africa on Diabetes* aims to engage governments in African countries, nongovernmental organizations, industry partners, health-care professionals, and national diabetes coordinators in the fight to reduce the impact of diabetes. The draft document, originally prepared in May 2003, will be presented by national diabetes representatives to their national health ministers following peer-review. ■

Potential meningitis tragedy averted

A rare strain of meningitis known as W135 which re-emerged recently in Burkina Faso has been rapidly controlled thanks to the joint efforts of a number of international partnerships, and the rapid availability of stocks of a newly developed vaccine, according to WHO's Global Alert and Response unit.

"At last, we have the tools to contain small outbreaks like this one before they cripple an entire region," said Dr Michael J Ryan, coordinator of WHO's Global Alert and Response unit.

WHO has recently vaccinated around 135 000 people against *Neisseria meningitidis* serogroups W135, A, and C in Nanoro district, Burkina Faso.

The 2002 outbreak of W135 in Burkina Faso resulted in 13 000 people becoming infected, 1500 of whom died before the outbreak burned itself out. This was thought to be largely due to the difficulties faced by laboratories in identifying the disease when it first emerged in Africa two years ago, the lack of experience among field epidemiologists in tracking the disease and the absence of an affordable vaccine.

To address these deficiencies, WHO began galvanizing partnerships to build a "mass intervention delivery system" in the region aimed at combating W135. Laboratory workers and field epidemiologists were trained and supplied with materials so that the strain could be rapidly detected, tracked and confirmed. Regional monitoring was established at WHO's Subregional Multidisease Center in Ouagadougou, Burkina Faso.

At the same time, pharmaceutical partner GlaxoSmithKline developed a new vaccine which was rapidly tested and approved. Following negotiations with WHO, the company priced the vaccine affordably, at one euro per dose (around US\$ 1.8).

Following an urgent appeal issued in September 2003, WHO established an emergency stockpile of the vaccine with funding from the governments of Ireland, Italy, Monaco, the United Kingdom and from Médecins Sans Frontières, the Norwegian Red Cross, UNICEF and private individuals.

The containment of W135 provides an example of the potential that partnerships have in achieving successful public health interventions.

"Every part of the public health network pulled together to build this system," said Ryan. "Humanitarian organizations, industry, international agencies, lab trainers and private contributors have all worked together, and through their combined efforts an enormous tragedy in Africa may have been averted." ■

Vaccination campaign in the Americas kicks off in Haiti

Vaccination Week in the Americas which aims to reach some 40 million people began in Haiti on 24 April 2004. Coordinated by WHO's Regional Office for the Americas (PAHO), in collaboration with the US Centers for Disease Control and Prevention, the massive campaign is targeting women, children, the elderly and those living in rural border regions in 35 countries.

Vaccination Week "demonstrates our strong commitment to work together to improve the health of the people of the Americas, especially the children," said Dr Mirta Roses, director of PAHO.

Targets for the immunization effort in Latin America and the Caribbean include some 15 million children, 10 million adults, 10 million people over 60 years old, 1.4 million women of child-bearing age, and 1.7 million people in other risk groups. According to the US Centers for Disease Control, in the US alone, around 1 million children remain inadequately immunized.

Vaccination Week in the Americas aims to highlight the need for routine vaccinations to improve coverage, especially in rural areas, and it also hopes to promote access to health services. Most of the countries are vaccinating against measles, polio, rubella and congenital rubella syndrome; some are also vaccinating against influenza and neonatal tetanus. ■

Fifty-seventh World Health Assembly, 17–22 May 2004

Provisional agenda items:

- HIV/AIDS
- Surveillance and control of *Mycobacterium ulcerans* disease (Buruli ulcer)
- Control of human African trypanosomiasis
- Smallpox eradication: destruction of variola virus stocks
- Eradication of poliomyelitis
- Global strategy on diet, physical activity and health
- Road safety and health
- Health promotion and healthy lifestyles
- Family and health
- Reproductive health
- Health systems, including primary health care
- Quality and safety of medicines: regulatory systems
- Genomics and world health
- Human organ and tissue transplantation