News

Chinese research register joins WHO network, raising hopes for improved clinical trials

China's acceptance, along with India, into the new WHO International Clinical Trials Registry Platform will help spur greater transparency and registration of research involving human's in the world's most populous country. But much work is needed to bring China's trial standards up to standard.

Chinese scientists for years have conducted unregistered clinical trials on humans that have raised concerns about the level of controls and transparency in place, as well as the kinds of safety standards available to trial subjects.

But the World Health Organization's July 2007 addition of recently launched Chinese and Indian registers into its new global clinical trial network has raised hopes that medical research standards would start benefiting from greater scrutiny.

> "[The Chinese Clinical Trial Register] aims to help trialists correctly report their trials to let the public know how the trial was planned and detail its results."
>
> *Taixiang Wu, administrator of the register.*

The WHO International Clinical Trials Registry Platform was launched in May 2006 to bring different clinical trials registers from around the world into one network. It aims to increase the transparency and accountability of clinical research conducted by companies and institutions, and thus boosts public trust and confidence in that research. The initiative follows a number of high-profile cases in developed countries, where negative research results were withheld from the public.

China's new state-backed registry, known as the Chinese Clinical Trial Register, was launched in 2005 in response to calls for greater transparency of the clinical trial process in the world's most populous country. It is run by the Chinese Evidence-Based Medicine Centre, sponsored by institutions such as the state-run Sichuan University and Chinese Ministry of Health, and was designated by the government to join the WHO platform.

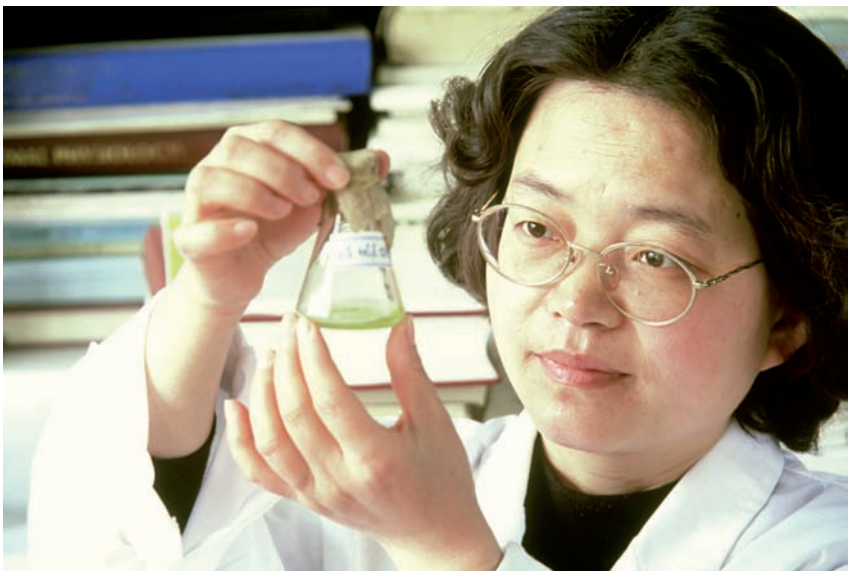
Associate Professor Taixiang Wu, administrator of the register, estimated at least 30 000 clinical trials were performed annually in China, but information on them is limited. Since 2006, some Chinese researchers have been registering their trials at http://www.ClinicalTrials.gov, a web site run by the United States of America National Institutes of Health, or at the International Standard Randomised Controlled Trial Number scheme sponsored by the Medical Research Council in England, which aims to simplify trial identification and improve reporting traceability. But despite this recent trend, most trials in China remain unregistered, Wu said. Fewer than 300 current Chinese trials have been recorded in international registers that contributed research to WHO.

The new Chinese register "aims to help trialists (i.e. researchers) correctly report their trials to let the public know how the trial was planned and detail its results", Wu told the *Bulletin*.

Its aim is to encourage widespread trial registration within China, a country where millions live in far-flung regions and where close scrutiny and consumer activism for improving medical procedures are weak. The Chinese register faced a "very big challenge", Wu acknowledged.

Dr Davina Ghersi, WHO platform coordinator, said bringing China and India into the network was "extremely important because of the vast populations in those two countries, the amount of research that is being done there, and the need to meet the needs of the populations of the two countries".

"The sketchiness of information relating to trials in China deprives both the public and scientific community of potentially valuable information", Ghersi said.



Keystone

The WHO International Clinical Trials Registry Platform has welcomed China's new state-backed registry, the Chinese Clinical Trial Register, into its network in a move to enhance transparency and strengthen standards surrounding clinical research in the world's most populous nation.

In some developed countries, editors of peer-reviewed medical journals have pressured researchers to publicly register their protocols and results. The International Committee of Medical Journal Editors, a group that represents the world's leading general medical journals, announced in 2004 that it would only publish results of clinical trials registered before the first patient's enrolment.

> "The sketchiness of information relating to trials in China deprives both the public and scientific community of potentially valuable information."
>
> *Davina Ghersi, coordinator of the WHO International Clinical Trials Registry Platform.*

The new Chinese register wants to build consensus for such a move by enrolling the editors of 52 key Chinese journals in the Chinese Clinical Trial Registration and Publication Collaboration, which was formed in 2006.

The collaboration was established by the Chinese Evidence-based Medicine Centre, the Ministry of Health, the Chinese Cochrane Centre and the International Clinical Epidemiology Network Resource and Training Centre of the West China Hospital. It aims to build an effective trial registration system by fostering agreement among key journals that only research relating to registered trials will be published. China has some 1100 medical journals.

Ghersi said China's government has supported involvement in the WHO platform to improve clinical trials. "Having a register in China supported by the Ministry of Health will give it the support needed to successfully identify all the clinical research being done in China," she said.

In many developed countries, consumer activism has led to transparency, registration of clinical trials and improved standards governing them. But this has not happened in China. Wu said that public consumer scrutiny of clinical trials helps promote these goals.

"Although consumer action in China is very young, I believe it will become stronger in the future", Wu said. "Joining the WHO (clinical trials) network will be very helpful in promoting such action to become a movement, and will feed back into promoting the rate of trial registration."

A Chinese advocate for patient involvement in improved clinical trials, Professor Mingming Zhang, said major obstacles, including large populations and poorly distributed health services, hindered public participation in efforts to raise research standards.

"The establishment of the Chinese Clinical Trials Register is a big step for those of us who understand why it is important", said Mingming, a member of the Cochrane Consumer Network Committee. "But Chinese patients know nothing about it at the moment, so raising awareness among the public is the first step." ■

Martin Adams, *Beijing*

Marburg fever outbreak leads scientists to suspected disease reservoir

Uganda's rapid response to the recent fatal Marburg haemorrhagic fever outbreak not only stopped the spread in its tracks, but also raised hopes the discovery of the disease's reservoir, possibly in a bat-infested jungle mine.

The news reached Dr Sam Okware via a text message from the United States Centers for Disease Control and Prevention (CDC). "Marburg virus isolation confirmed by CDC lab in Atlanta. More later", read Okware, a senior epidemiologist and commissioner of health services at the Ugandan Ministry of Health.

The 30 July confirmation was, at that time, the latest in a chain of actions initiated by Ugandan authorities to contain what investigators suspected was a rare outbreak of Marburg haemorrhagic fever.

The disease emerged in two labourers who worked at a gold and lead mine in the western Ugandan jungle. One miner died on 14 July, while the other remains in quarantine. The two are the outbreak's only confirmed cases.

Within hours of the CDC message, Ugandan Minister of Health Dr Stephen Mallinga issued a statement to Parliament. Uganda's health services director-general, Dr Sam Zaramba, issued another to the public through the media. On 9 August, Mallinga announced that the outbreak had been contained, but added that disease control activities would continue until the end of the month.

> "There is acceptability of WHO's capacity to respond [to outbreaks] in compliance with the International Health Regulations."
>
> *Melville O George, WHO country representative for Uganda.*

The World Health Organization (WHO) helped in the control effort through its Global Outbreak Alert and Response Network (GOARN) and the recently updated International Health Regulations (IHR), which led to neighbouring countries being alerted of the outbreak's threat. WHO also dispatched a team of experts to Uganda to help in the control and detection of the disease reservoir.

"There is acceptability of WHO's capacity to respond (to outbreaks) in compliance with the International Health Regulations", said Dr Melville O George, WHO country representative for Uganda. "So there was no need for panic."

Besides quickly containing the outbreak, WHO investigators believed they were close to discovering the outbreak's reservoir, a first in the history of Marburg fever. "We believe the chances are very good, but we need to undertake more studies to be sure", Dr Pierre Formenty of WHO's Epidemic and Pandemic Alert and Response (EPR) told the *Bulletin* during an interview in Kampala.

The hunt for the fever's host shone suspicion on 5 million bats, plus rats, ticks and other wildlife, living in and