work with governments and nongovernmental organizations to expand supplement distribution programmes in countries that already have them and develop new ones in those that don't.

The report also launches an information campaign that is targeted at government agencies, media outlets and food producers in at-risk countries, highlighting the damage caused by vitamin and mineral deficiencies and emphasizing the affordability of the solutions.

Whilst fortification and vitamin distribution would have a significant impact on micronutrient deficiencies in poor countries, most public health professionals agree that these strategies alone are not enough to eradicate the problem, said Bruno de Benoist, Acting Director of WHO's department of Nutrition for Health and Development. "Supplementation is important but it won't solve the problem without concurrent improvement of diet, sanitation and infectious disease control," he said. ■

Judith Mandelbaum-Schmid, *Zurich*

US and Thai Governments defend HIV/AIDS vaccine trial in Thailand

Public health officials and scientists from the US and Thai Governments have countered accusations by a group of HIV/AIDS researchers who questioned the scientific rationale behind a Thai and US Government-backed trial of an HIV/AIDS vaccine in Thailand.

The phase III trial is testing a vaccine combination that critics say has no "reasonable prospect" of protecting anyone. In an article in *Science* magazine (2004;303:316), 22 HIV researchers contend that scientific evidence for the vaccine is "extremely weak," and they "doubt whether these immunogens have any prospect of stimulating immune responses anywhere near adequate for these purposes." They also argue that any new scientific knowledge that the trial might produce is not worth the US$ 119 million cost and effort.

However, in a rebuttal published in *Science* (2004;303:961), John McNeil and other scientific officers from the sponsoring agencies argue that the decision to proceed with the trial is "scientifically justified, morally correct and strategically important." In the same issue of *Science* (2004;303:954-5), Charal Trinvuthipong, Director General of the Department of Disease Control in Thailand's Ministry of Public Health which is co-sponsoring the trial, pointed out that the critics' argument was flawed and that "there is no such thing as wasting time or money in researching an AIDS vaccine."

In September 2003, the first of 16 000 young, heterosexual volunteers began receiving the vaccine which comprises Aventis-Pasteur's live canarypox virus vector ALVAC combined with VaxGen's genetically engineered HIV surface protein gp120. The Aventis-Pasteur vaccine is designed to stimulate cellular immunity by promoting the growth of cytotoxic T cells. VaxGen's gp120 vaccine aims to induce antibodies against HIV. According to the critics, phase I and II clinical trials revealed that the ALVAC vector alone was poorly immunogenic, and trials in the US and Thailand indicated that the gp120 component was "completely incapable of preventing or ameliorating HIV-1 infection." The "prime-boost" combination vaccine was designed to strengthen cellular and humoral immunity to prevent and or control HIV-1 more than either vaccine does alone.

The critics argue that "there are no persuasive data" to support this idea. "I don't think there's anyone who thinks this will be protective," said Beatrice Hahn of the University of Alabama in the US, a co-author of the critique in *Science*. For a phase III trial to be justifiable, there should be a "reasonable prospect" that the vaccine will benefit the study population but this prospect is lacking, argue the authors.

The article accuses the National Institutes of Health (NIH), the agency of the US Department of Health and Human Services backing the trial, of not consulting closely enough with independent experts. The authors fear that the study's failure could erode public and political confidence in HIV/AIDS vaccines and deplete the reservoir of willing participants in future HIV/AIDS vaccine trials. "Our opinion is that the overall approval process lacked input from independent immunologists and virologists who could have judged whether the trial was scientifically meritorious," they said.

However, McNeil and colleagues from the National Institute of Allergy and Infectious Diseases (NIAID) — the research component of NIH, and the Walter Reed Army Institute of Research in Washington which has also been involved in the project, point out that the combination vaccine was reviewed and endorsed by 11 international governmental and academic scientific, ethical and regulatory review bodies in Thailand and the US and by WHO and the Joint UN Programme on HIV/AIDS (UNAIDS). They also argue that the "prime-boost" combination did seem to increase immune responses in small phase I and phase II studies and since there is no suitable animal model, the only way to test the method further is a large human trial.

Trinvuthipong argues that the basis of the criticism is flawed "in that it uses data from efficacy trials of a single vaccine concept to predict the results of a prime-boost combination vaccine study. Only by conducting the trial will we be able to determine if the combination of two candidate vaccines will induce both cellular and humoral immunity and protect against HIV infection."

Trinvuthipong also said that even if the trial is not successful, it will still give rise to important benefits. "Regardless of the efficacy of the results, Thailand is benefiting from conducting this trial in several areas," he said, pointing out the importance of the experience for scientists, health workers, Thailand's laboratory infrastructure and specimen archiving systems. "Another important benefit," he added, "is the intensified HIV/AIDS awareness campaign around the trial, which directly benefits the local communities in Chon Buri and Rayong.

Modifications to the trial's design are currently under way. "We certainly are looking at ways to improve the design," said Anthony Fauci, Director of NIAID. "And we are going to be doing further immunological monitoring, so that we can get a better handle early on if [the vaccine] isn't giving at least the immunological effect that we're looking for," he added. Additional scientific rationale for the trial will be published soon.

Dr Saladin Osmanov, from the WHO–UNAIDS Vaccine Initiative said that "no one can guarantee that this trial will result in an efficacious vaccine, but what we can guarantee is that if we do not conduct clinical trials, we will never have an AIDS vaccine." ■

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