

Leprosy vaccine

Large-scale trials begin in India

New Delhi

THE first large-scale clinical trial of the anti-leprosy vaccine derived from armadillos will begin two months from now in India. This follows closely on the announcement of a similar trial in Malawi (see *Nature* 316, 183; 1985). The vaccine has been developed under the aegis of the World Health Organization (WHO), but the Indian trial is being mounted by the Indian Council for Medical Research (ICMR). This international project will thus take place soon after the clinical trial of the Indian anti-leprosy vaccine developed at the Cancer Research Institute.

The trial of the WHO vaccine will be mounted, once the Drug Controller of India has given formal clearance, in the Chingleput district of Tamil Nadu in south India. Both leprosy and tuberculosis are endemic among the 4 million people living there. The director-general of ICMR, Dr V. Ramalingaswami, says that the council's Jalma Institute of Leprosy will be responsible for planning and carrying out the trial, and that it is hoped to vaccinate up to 300,000 apparently healthy contacts of leprosy patients.

The first objective is to assess the prophylactic efficacy of the vaccine, by comparing the vaccinated group with those among the population who are not vaccinated. There will also be a comparison of the value of the WHO vaccine with and without accompanying Bacille Calmette-Guérin (BCG). The groups involved will be followed for ten years.

Ramalingaswami says that ICMR has agreed to test the vaccine only on condition that WHO will also supply the technology for manufacturing the vaccine locally. What this means is not clear, for ICMR does not have facilities for maintaining an armadillo colony. All but two of

the six animals imported by the Jalma Institute of Leprosy four years ago have since died. It is believed that ICMR will import the *Mycobacterium leprae* harvested from armadillos and set up processing facilities in India using the WHO technology. Meanwhile, vaccine for the Chingleput trial will be supplied by Burroughs Wellcome of Britain.

This may be the first time that India has insisted on technology transfer as a condition for testing a WHO product. In the past, many in India have complained that multinationals have tested their products under WHO auspices and have then exploited the Indian market without offering price concessions or transferring, on easy terms, know-how for manufacturing the products. For the leprosy trial, ICMR has been under pressure to test the WHO vaccine and had to choose between that and an Indian vaccine which has already completed phase-I trial and been given clear-

ance from the toxicology angle by the Drug Controller.

Ramalingaswami said ICMR had decided to try both vaccines. A trial of the vaccine developed by the Cancer Research Institute (CRI) in Bombay was begun on 2 October (Mahatma Gandhi's birthday) at Wardha in central India. This vaccine is made from gamma-ray-inactivated cultivable mycobacterium (belonging to the *M. avium* group) isolated from human leproma and showing extensive cross-reactivity with *M. leprae*. The number of people to be vaccinated in Wardha will be the same as in Chingleput. But the CRI vaccine will be given to leprosy patients as well as to contacts, for the phase I trial showed therapeutic potential as well as prophylactic effect.

India has four million leprosy cases — one-third of the world's total — and there are 300,000 new cases a year. ICMR says it will be several years before the results of the two trials are known, so chemotherapy will continue to be the main plank for achieving India's goal of eradicating leprosy by the year 2000. **K.S. Jayaraman**

US standards bureau

Emergency measures required

Washington

A CONGRESSIONAL committee has heard dire warnings that the national measurement system could face "total breakdown" unless urgent steps are taken to reverse the decline of the National Bureau of Standards (NBS). Edward Nemeroff, president of Datron Instruments, told the House of Representatives' science, research and technology subcommittee that many users of NBS's calibration services were unable to meet the needs of their organizations because NBS could not provide necessary measurement standards and services.

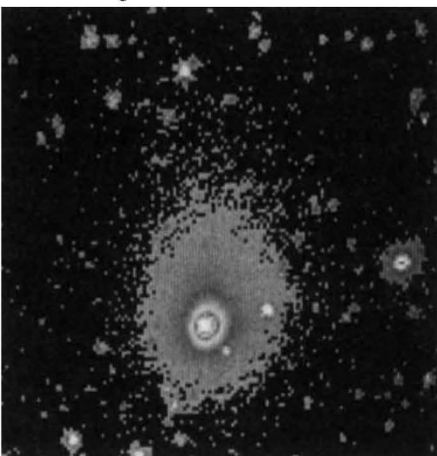
To be fair to NBS, other witnesses called to the special two-day hearing earlier this month on the future of NBS had kinder things to say about the bureau's work of developing and providing measurement standards for industry in fields as different as microelectronics and fire safety. But the hearing provided a forum for growing concern that the Reagan administration's perennial attempts to cut NBS's budget (always partly restored by Congress) could seriously increase measurement costs for industry. Despite attempts in Congress earlier this year to add \$20 million to the administration's proposed \$120 million appropriation for NBS in fiscal year 1986 (which started 1 October), the figure is likely to end up at no more than the authorized \$124.5 million — a decrease in real terms, since the appropriation has hovered at \$120 million for the past four years. The number of staff employed at NBS — of whom a high proportion are scientists — has fallen by 16 per cent since 1980.

Behind the unrest is the fact that NBS has sought to keep up with advances in technology within a shrinking budget by cutting back in more pedestrian areas. High priority targets for expansion include supercomputers; high performance ceramics (which will be shortly aided by a new cold neutron guide hall); optical electronics; and biotechnology. In order to finance these new activities, consumer product measurements have been reduced and the administration has for each of the past four years proposed closing NBS's building technology and fire research laboratories, so far without success. Even NBS's director, Ernest Ambler, admitted that "we've got our backs to the wall".

NBS is currently administered by the Department of Commerce. One proposal that has surfaced many times in the past is that NBS should be found a more suitable home, perhaps with the National Science Foundation in a new Department of Science and Technology. But Ambler shows little enthusiasm for the idea, and the Commerce Department is thought unlikely to want to surrender NBS, which accounts for a substantial fraction of its budget. Without President Reagan's personal support for the plan it now appears unlikely to go ahead. And that, according to congressional staff, means there is no easy end in sight for NBS's tribulations: because it is classified with the Commerce Department, NBS is denied the influential support of the champions of scientific research and development in the Office of Management and Budget who have successfully defended the science budget in the past.

Tim Beardsley

Halley's Comet



The forming tail of Halley's Comet, as seen from the 60-inch telescope at Palomar Observatory on 25 September.