US plans large scale environmental study

The US National Institute of Child Health and Human Development (NICHD), the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA) are planning the most ambitious study thus far to look at the effects of environmental factors on children's health. If everything goes according to plan, 100,000 participants will be recruited before birth, probably in the first trimester of pregnancy, and data will be gathered until they reach age 21.

The project was borne out of the Executive Order on the Protection of Children from Environmental Health, signed by President Clinton in 1997. The order requires that all federal agencies assign a high priority to addressing health and safety risks to children, coordinate research priorities on children's health, and ensure that their standards take into account special risks to children. Congress has authorized $18 million per year from 2001 to 2005 for the planning and pilot stages of the study.

Although the details still have to be worked out, the study aims to collect samples and medical information on an ongoing basis to identify and quantify environmental risks to children's health, determine whether there are critical windows for exposure, and look for interactions between genetics and environment. In addition to physical environment, the study will also be concerned with social environment—primarily the family.

Ethical considerations are a major concern. Peter Scheidt, co-chair of the coordinating committee that organizes and directs the study's operations, says that a specific subcommittee has been given the charge of addressing various issues: How do you get consent for a yet unborn child? Who should have access to the data?

Enrolment will begin in 2004. Data will be collected at multiple sites to reflect a cross-section of the national population. Once assimilated, this data would become a national resource for other investigators. Results of the first complete analyses of the data are expected in 2030.

Laura Bonetta, Bethesda

First HHMI meeting of international scientists

Thomas Egwang has become the first Ugandan scientist to be awarded a scholarship by the Howard Hughes Medical Institute (HHMI). The new funding of $225,000–450,000 over five years dwarfs Egwang's previous grants from groups such as the World Health Organization. A further bonus is that the money is unrestricted. The funds can be used for supplies, travel to meetings, training graduate students and other needs.

Thomas Egwang

Egwang's first port of call was Vancouver where all 132 international HHMI researchers from 29 countries met for the first time last month to discuss their research projects. Whereas HHMI has previously chosen scholarships based on geographical region—for example, last year's competition focused on scientists from the Baltics, Central and Eastern Europe— Egwang's competition round was the first to be selected by disease area, in this case infectious and parasitic diseases.

As a Senior Research Scientist in the Department of Medical Parasitology at the Medical Biotechnology Labs in Kampala, Egwang is conducting basic research on the biochemical drug targets in *Onchocerca volvulus*, the causative agent involved in river blindness, and *Plasmodium falciparum* with the aim of developing a new generation of antifilarial drugs based on protein prenylation. His team is also collaborating with the Ministry of Health to map antimalarial drug resistance in Uganda.

Stephanie Irvine, Denver

Gene therapy researchers bemoan dual regulations

Gene therapy researchers in the US expressed their unhappiness last month with what they see as "excessive government oversight" of their field of research. Meeting at the fourth American Society of Gene Therapy (ASGT) conference in Seattle, they renewed their call for a single set of rules for reporting of adverse events rather than the two separate systems currently in place.

Investigators conducting gene therapy clinical trials need to report both to the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), and the two agencies' reporting rules differ. The FDA requires immediate reports of serious, unanticipated events. The NIH, guided by the recently reinvigorated Recombinant DNA Advisory Committee, demands that researchers report all adverse events in a trial, not just those believed to be triggered by gene therapy.

"When you have conflicting guidelines, it's ripe for non-compliance," says Kenneth Cornetta, chair of the ASGT's clinical and regulatory affairs committee. He admits that the field has received a lot of bad press for not reporting adverse events to the NIH, but believes that the problem has been confusion over precisely what to report, not non-compliance *per se*.

The FDA and the NIH are working on addressing the researchers' concerns, according to Philip Noguchi, director of the FDA's Division of Cellular and Gene Therapies. "I was surprised at the amount of discussion on this [at the meeting]," he told *Nature Medicine*. "We are striving mightily to harmonize the guidelines." But he added that because the two agencies have unequal authority over clinical trials, there are bound to be some differences. For example, the FDA deals with clinical trial sponsors—usually drug companies—not investigators, and has the authority to shut down clinical trails. The Recombinant DNA Advisory Committee has more of a monitoring role.

At this point, gene therapy appears to be no more risky that other experimental drugs according to ASGT president Malcolm Brenner, a researcher at Baylor College of Medicine in Houston, Texas. "I don't see why it has to be treated differently," he says. "We've had to treble our regulatory affairs staff. None of this comes without cost to the patient."

Tinker Ready, Boston