

## Report calculates value for money of US vaccine R&D

Almost four years after it was commissioned by the National Institute of Allergy and Infectious Diseases (NIAID), the Institute of Medicine (IOM), a branch of the National Academy of Sciences, has released a report analyzing which vaccines give the best return per R&D investment dollar. It concludes that vaccines for cytomegalovirus, influenza, insulin-dependent diabetes, multiple sclerosis, rheumatoid arthritis, group B streptococcus and *Streptococcus pneumoniae*—classified as Level I vaccines—have the best all-round R&D investment value.

"NIAID asked us to look into the future of where science will lead us, and to estimate costs of vaccine development, implementation and cost savings of premature morbidity and mortality," explains chair of the IOM Committee to Study Priorities for Vaccine Development, Robert Lawrence, Johns Hopkins School of Hygiene and Public Health.

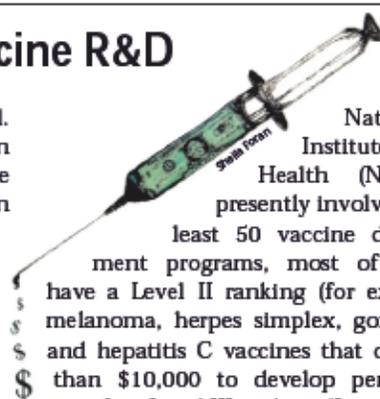
The report, "Vaccines for the 21st Century: A Tool for Decisionmaking," stratifies 26 vaccines into four levels based on development cost versus the

quality-adjusted life years (QALY) saved. This quantitative model operates within a computer spreadsheet and can be adapted to any candidate vaccine. It can be obtained free of charge from the IOM in Washington D.C.

Under its congressional mandate, the committee was restricted to evaluating vaccines of importance to the US rather than those that are beneficial on a worldwide scale: "We would have liked to examine disease burden in the developing world as well, but diseases such as schistosomiasis and malaria were off limits," says Lawrence.

Also off limits was an assessment of the value of developing an HIV/AIDS vaccine. Apparently the panel was not to appraise this type of vaccine because NIAID has already made substantial commitment to HIV vaccine research. However, Lawrence expects somebody outside the committee will quickly determine its cost-effectiveness now that the software for the model is in the public domain.

According to Adis International's R&D Insight drug development database, the



National Institutes of Health (NIH) is presently involved in at least 50 vaccine development programs, most of which have a Level II ranking (for example, melanoma, herpes simplex, gonorrhea and hepatitis C vaccines that cost less than \$10,000 to develop per QALY saved) or Level III ranking (for example, rotavirus and streptococcal A vaccines that cost between \$10,000 and \$100,000 per QALY saved). As a rule of thumb, explains Lawrence, "a therapy under \$100,000 is usually a good buy in the US healthcare environment, so commitment to vaccines in all three of the first levels is justified."

The NIH is also working on at least three of the less favorable Level IV vaccines, which cost more than \$100,000 per QALY saved. These include shigella and *Escherichia coli* vaccines. A summary of the report is available at <http://www2.nas.edu/hpdp>

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## The sun sets on the CVI

Many delegates attending a mid-March closed meeting led by the World Bank in Bellagio, Italy expressed emotions from disgust to amazement at what seemed to be the destruction of, rather than the transformation of, the Children's Vaccine Initiative (CVI). The meeting sounded the termination of the CVI, along with the contracts of its 14 staff by year's end and its replacement, at least in the short-term, by a much smaller secretariat acting purely as a clearinghouse of information between its partners—the World Bank, the World Health Organization (WHO), the Rockefeller Foundation and UNICEF.

The CVI, a nine-year-old multi-agency program, had been working towards the addition of new vaccines, such as hepatitis B, haemophilus influenzae B, rotavirus and the potentially new pneumococcal vaccines, to the existing world vaccination schedule (*Nature Med.* 4, 136; 1998). If delivered to 80 percent of the world's children, these four 'new' vaccines could save four million young lives each year.

Although many believe that shutting

down this organization would be detrimental to global immunization programs, the Dean of Public Health at the University of Harvard, Barry Bloom—a passionate advocate for children's vaccines—says he is "thrilled" at the outcome. The Bill and Melinda Gates Children's Vaccine Program, founded in December last year with \$100 million from the William Gates Foundation, is also clearly satisfied with the arrangement and has promised "a lot of program money" to develop a new initiative for improving the existing vaccination system.

Bloom's upbeat position is based on the argument that CVI has achieved its goal, and that its continued existence actually discourages its member organizations and associates from getting involved first-hand in new vaccine development and distribution. According to fans of the new deal, these organizations are now ready to make real commitments to buying and distributing new vaccines. The partners, including representatives from the pharmaceutical industry and donors but notably lacking delegates from countries

needing the vaccines most, left Bellagio to forge a strategic plan to be ready by September. The goal is to achieve what they are calling "sunrise"—finally vaccinating the world's children with the new vaccines. A commitment to this objective is what thrilled Bloom.

However, some insiders believe that the dissolution of the CVI is a purely political maneuver. Under its new confident and technocratic leader, Grö Harlem Brundtland, the WHO is actively re-taking control of areas such as vaccine distribution, where its power had been slipping. "This is because WHO's capacity in immunization has grown tremendously in the time since CVI has been established," explains Bruce Ayleward, head of the WHO's polio eradication initiative, adding that "under the re-organization of WHO's activity here in Geneva, things have been changed."

And it seems that things are still changing at WHO headquarters, with internal rumblings over which cluster will gain ultimate control over vaccine programs: either the Health Technology and Drugs cluster, headed by Michael Scholtz,

