United States General Accounting Office

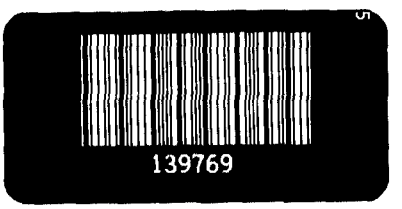
GAO

Report to the Honorable
Daniel K. Inouye, U. S. Senate

October 1989

FOREIGN AID

AID's Malaria Vaccine Research Activities



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GAO
United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

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October 17, 1989

Senator Daniel K. Inouye
United States Senate

Dear Senator Inouye:

This report responds to your request for our review of the Agency for International Development's (AID's) malaria vaccine research project. The primary recommendation in our report is that AID not make any long-term funding commitments until management deficiencies are corrected and the results of a major evaluation of malaria control activities and options by the National Academy of Sciences is completed.

The report also discusses a number of management weaknesses in the areas of planning, procurement, implementation, and evaluation. We found that AID has taken steps to correct many of the deficiencies we noted during our review; however, we recommend that additional actions be taken to improve the planning and implementation of future activities and to ensure adequate oversight of project funds.

We will send copies of this report to the Administrator of AID and other interested parties. We will also make copies available to others upon request.

This report was prepared under the direction of Nancy R. Kingsbury, Director for Foreign Economic Assistance Issues. Other major contributors are listed in appendix I.

Sincerely yours,

Frank C. Conahan
Assistant Comptroller General

Executive Summary

Purpose

Malaria is a leading health problem in developing countries, with an estimated 150 million to 200 million cases and 1 million to 2 million deaths each year. The Agency for International Development (AID) has supported a directed research program and obligated about $96 million since 1966 to develop vaccines against malaria.

Beginning in 1987, serious questions have arisen both within and outside AID about its management of the vaccine research project and whether its continued funding was appropriate. At the request of Senator Daniel K. Inouye, then Chairman of the Subcommittee on Foreign Operations, Senate Committee on Appropriations, GAO reviewed the management of the AID malaria vaccine research project, including the selection, oversight, and evaluation of research and support subprojects.

Background

AID initiated the vaccine research project in 1966, when it was apparent that a worldwide effort to control malaria through insecticides and drugs had failed. The project initially supported research in one university laboratory; it now provides funding to 12 institutions, which form a "network" of 15 research and support subprojects. Although no vaccine for malaria has been developed, AID officials report that AID-funded laboratories have made significant breakthroughs which facilitated research progress.

Results in Brief

From 1982 through mid-1987, the AID malaria vaccine research project was not well managed and substantial funds were misused or wasted. AID's systems for planning, implementing, monitoring, and evaluating the project and controlling project funds were inadequate. GAO found deficiencies in (1) subproject selection and awards, (2) subproject monitoring, (3) financial oversight, (4) overall project planning and evaluation, and (5) planning for procuring, housing, and caring for research monkeys.

Since 1987, AID has taken several steps and planned others to improve project management. In GAO's view, these changes, if successfully implemented, will eliminate some of the deficiencies noted. However, additional actions are still needed to ensure the objectivity, adequacy, and openness of external review; improve control over project activities and funds; and remedy problems with management of the large inventory of research monkeys.

Principal Findings

Irregularities in Subproject Selection and Awards

Subproject selection during 1982 through early 1987 was characterized by limited concern for competition and costs. GAO reviewed the records of all current subprojects, 11 of which had been funded as either contracts or cooperative agreements awarded during 1982 to 1987. GAO found that competition had been waived for 10 of these 11 subprojects and the waivers had been based in part on inaccurate documentation sent from the technical office responsible for the malaria vaccine research project to AID procurement officials. In addition, GAO found that AID funded at least three research proposals that received negative preaward evaluations of their budget and/or technical merit.

Inadequate Internal Oversight and External Review of Project

AID did not maintain sufficient supervisory oversight over malaria vaccine research project staff and activities. As a result, questionable funding actions, management practices, and financial transactions were not detected.

Prior to 1987, AID relied on network members and a limited number of external experts to review the performance of subprojects. The practice of using network members raises questions about the adequacy and objectivity of external review during this period. GAO also found that AID had not ensured adequate oversight and audit of project expenditures.

AID Did Not Adequately Plan for Acquiring, Housing, and Using Research Monkeys

AID acquired more than 1,400 research monkeys with no comprehensive management plan to coordinate their purchase, housing, and care. The lack of an integrated plan resulted in AID's purchasing monkeys with limited use for malaria vaccine research; providing inadequate housing for some monkeys; wasting funds to acquire, house, and care for monkeys; and maintaining demographic and biomedical databases on its monkeys that had limited use for network researchers and did not provide complete census information for inventory accountability purposes.

Recent Actions Taken to Correct Deficiencies

As awareness of the problems occurring in the vaccine research project grew in 1987, AID took the following corrective actions.

- Expanded the number of external consultants asked to review project activities.

- Improved subproject selection and monitoring processes.
- Established external committees to provide advice related to research and development issues, field studies and trials, and research monkeys.
- Audited the records of four network institutions and questioned or suspended almost $450,000 in costs paid to those institutions.
- Initiated several investigations of specific allegations of fraud involving a former AID project officer and several network institutions and turned over evidence involving that project officer to the Department of Justice.
- Reassigned and replaced this project officer in April 1987, following allegations that he was harassing employees of a network member and later placed him on administrative leave pending a criminal investigation of his activities. He has been on paid administrative leave since October 1987.

Additional Improvements Are Still Needed to Ensure Adequate Oversight and Accountability for Project Funds

AID's actions over the past 2 years go a long way toward correcting the deficiencies GAO noted during its review. However, additional steps are needed to ensure adequate oversight of project activities. For example, AID has not developed adequate guidance for the selection of external reviewers or redesigned a primary project monitoring tool to ensure that it is both useful and safeguards confidential scientific data. Also, several subprojects have not been audited, including the project's technical services contractor, whose records include numerous questionable costs. In addition, despite the fact that a significant portion of project funds have been and will be spent to acquire, house, and care for a large inventory of research monkeys, AID still has not developed a comprehensive primate management plan.

Future Funding for Malaria Vaccine Research Under Debate

AID management is debating the merit of continued support for malaria vaccine research, and proposals to fund a new $45-million malaria vaccine research project and a $15-million clinical and field trials project are being considered. AID has requested the Institute of Medicine of the National Academy of Sciences to conduct a comprehensive evaluation of global malaria control activities and options, including vaccine research and AID's role as a donor for such research. However, this study may take 2 years to complete. In the meantime, AID must decide whether to continue funding malaria vaccine research and, if that decision is affirmative, whether to approve interim funding until the evaluation results are known or make long-term commitments to these activities.

Recommendations

GAO recommends that AID (1) make no long-term funding commitments for malaria vaccine research activities before correcting the management deficiencies noted in this report and analyzing the results and recommendations of the Institute of Medicine's evaluation of global malaria control efforts and options and (2) develop a management plan for the future acquisition, housing, care, and disposition of its research monkeys. GAO also recommends that the AID Inspector General conduct financial audits of all subprojects that it did not audit in 1988. GAO also makes several recommendations addressing management issues discussed in its report.

Agency Comments

As requested, GAO did not obtain formal agency comments on its draft report. However, the draft was discussed with agency officials and their comments are reflected throughout GAO's final report.

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Abbreviations

AID	Agency for International Development
AIBS	American Institute of Biological Sciences
BRI	Biomedical Research Institute
CDC	Centers for Disease Control
FDA	Food and Drug Administration
GAO	General Accounting Office
MIVR	Malaria Immunology and Vaccine Research
NIH	National Institutes of Health
OIG	Office of the Inspector General
PAHO	Pan American Health Organization
PPP	Peruvian Primatological Project

Introduction

Malaria is one of the world's leading health problems. Over half of the earth's population lives in areas where malaria is endemic, primarily in Africa, Asia, and Central and South America. An estimated 150 million to 200 million cases of malaria occur each year, causing about 1 million to 2 million deaths annually, mostly in children under the age of 5. Malaria is the suspected cause of 25 percent of all childhood deaths in Africa.

The Agency for International Development (AID) became interested in developing a malaria vaccine in the mid-1960s, when it became clear that a worldwide effort to control malaria had not succeeded because mosquitoes were becoming resistant to insecticides and the malarial parasite was developing resistance to widely used drugs. AID began shifting funds from field programs to research laboratories, seeking a method of control independent of drugs and insecticides. The first AID-funded malaria vaccine research was initiated in 1966 at the University of Illinois. It demonstrated that artificial immunity against malaria could be stimulated in laboratory animals.

In 1974, AID and the National Academy of Sciences sponsored a workshop to review the state of malaria vaccine research. Despite some disagreement as to approach, the participants agreed that further research was warranted. In 1975, a panel of experts convened by AID approved AID's proposed research strategy and advised AID to expand its support to more than one laboratory. AID selected four additional laboratories, laying the foundation for what has become known as the AID malaria vaccine research network.

Malaria Vaccine Research Goals

Human malaria is caused by any of four species of the blood parasite Plasmodium. All four species cause a clinical condition known as malaria, which is characterized by fever, chills, and headache. Untreated infection by the most virulent species can lead to severe anemia, kidney failure, respiratory failure, hemorrhage, shock, and coma. Severe malaria carries a risk of death of between 20 and 50 percent.

The malaria parasite has a complex life cycle, with stages occurring in both humans and mosquitoes. Infected mosquitoes carry a form of the malarial parasite, called sporozoites, in their salivary glands. Sporozoites are left behind in the bloodstream of humans bitten by infected mosquitoes and quickly migrate to the victim's liver, where they change form. Parasites, now in a form called merozoite, again enter the victim's bloodstream, where they invade red blood cells and multiply and continue to invade new cells. Some parasites change form again and are

included in the blood ingested by another feeding mosquito. The parasites again change form and, as sporozoites, they travel from the mosquito's gut to its salivary glands where they can be transmitted to another human victim.

Vaccine research has been loosely grouped into categories defined by the life stages of the parasite: sporozoite, blood stage, and transmission. At the time of our review, AID did not fund transmission-blocking research, which is directed toward preventing further development of the parasite within infected mosquitoes.

As described by the Office of Technology Assessment, the path from the laboratory to the successful control of malaria through vaccination will be long and is uncharted.

> "The challenges ahead include: developing a polyvalent (multiple component) vaccine, demonstrating that it is safe and effective, conducting large field trials in developing countries, producing the vaccines in quantity, and delivering it to the populations at risk."[1]

AID adds that the ideal vaccine should also be effective in a wide variety of epidemiological situations, economical, feasible for mass programs, stable, and preferably effective as a single dose.

AID believes that the AID-funded network has made progress toward achieving a vaccine against malaria, pointing to the following breakthroughs achieved in network laboratories.

- The discovery of a system for continuous cultivation of the red blood stage of P. falciparum in the laboratory.
- The discovery of a tissue culture system for growing liver stage parasites in the laboratory.
- The discovery of the major sporozoite surface protein for P. falciparum, which was critical to the development of the first generation of sporozoite vaccines.
- The description of the first method for cloning a gene for a malarial antigen, which demonstrated the possible use of biotechnology for malaria vaccine production.
- The demonstration that candidate vaccines are safe and immunogenic in man.

[1]U.S. Congress, Office of Technology Assessment, "Status of Biomedical Research and Related Technology for Tropical Diseases," 1985.

Project Organization and Administration

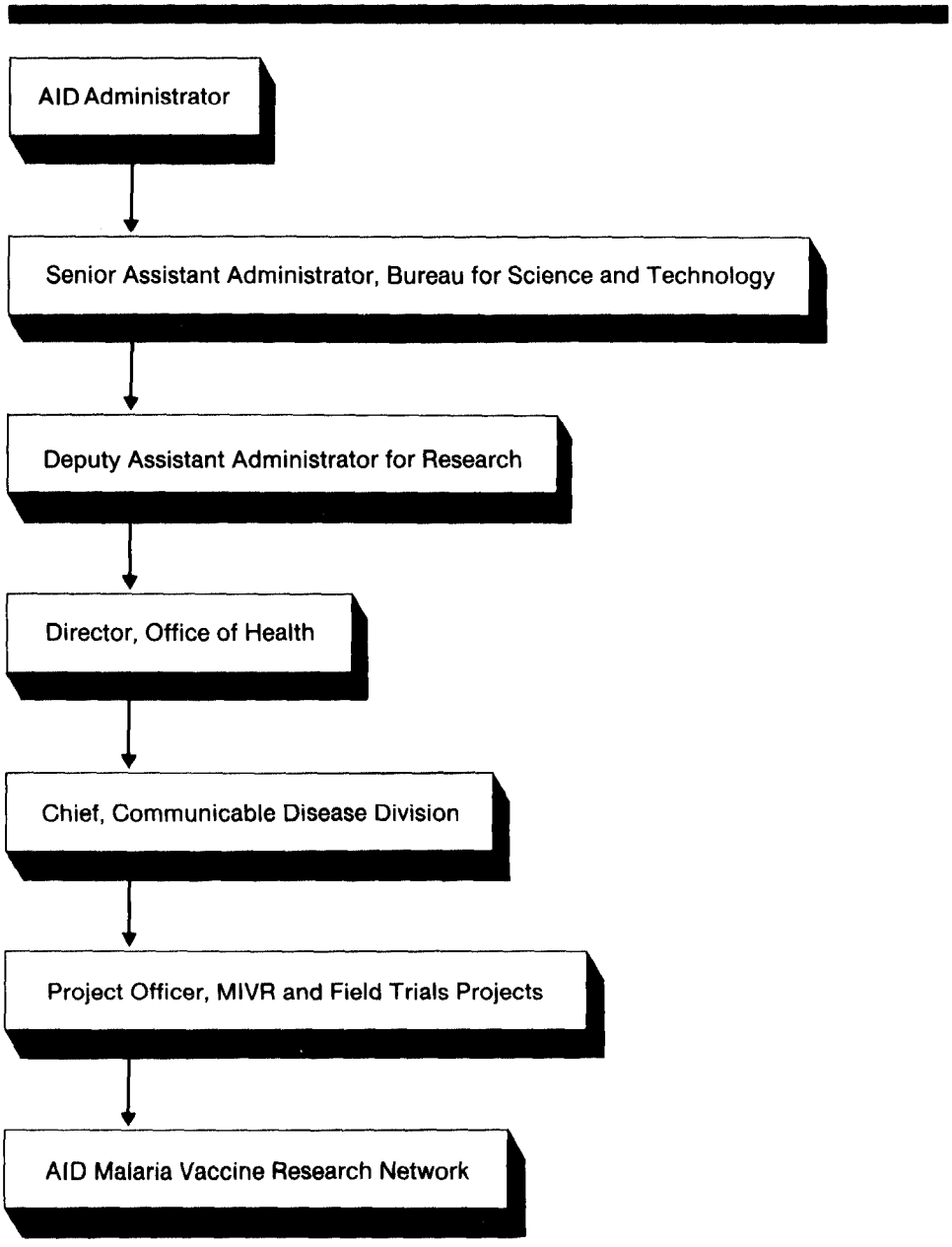
AID selects, funds, monitors, and evaluates malaria vaccine research and supporting activities through its Malaria Immunology and Vaccine Research (MIVR) Project. Development of a malaria vaccine field trials facility in Papua New Guinea is administered through an interrelated Malaria Field Trials Project. AID is designing a project to succeed the long-lived MIVR project. The new project will be known as the Malaria Vaccine Research and Development Project. It will no longer include a component for clinical testing of vaccines on U.S. volunteers. This activity will be shifted to the field trials project and will form a new Malaria Vaccine Epidemiology and Evaluation Project. AID is considering whether to begin these projects in fiscal year 1990.

Figure 1.1 shows the chain of offices involved in the administration of AID's malaria vaccine research and field trials projects. Day-to-day management and oversight of both projects is the responsibility of the AID project officer, assisted by a staff of three professionals. The project officer also receives technical and administrative support through a contract with the American Institute of Biological Sciences (AIBS). Although AIBS is a member of the research network, it has a distinctly different role than that of other members. AIBS assists AID by

- providing technical assistance through in-house expertise or hiring short-term external consultants, subject to AID approval;
- planning and arranging evaluations of project activities,
- managing a portfolio of small research subcontracts;
- organizing meetings and workshops; and
- paying transportation fees, some housing costs, and other expenses associated with AID's inventory of research monkeys.

The MIVR project has been managed by four project officers during its 23-year life. The first served from 1966 until he retired in 1982. The second was involuntarily reassigned in April 1987, pending resolution of various allegations of mismanagement. The third project officer served in an acting capacity until September 1988, when the current project officer, an active duty Army officer with malaria vaccine research experience, was appointed.

Figure 1.1: Chain of Responsibility for MIVR and Field Trials Projects.



AID's Research Network

Membership in AID's research network has varied at different points in time. During our review, the project consisted of 15 subprojects at 12 institutions conducting 4 distinct but interrelated activities.

1. Develop potential vaccines.

2. Acquire and manage research monkeys.

3. Set up clinical trial centers for testing vaccines first in monkeys and later in humans.

4. Provide project support services.

These subprojects were funded as contracts, grants, cooperative agreements, or interagency agreements. Table 1.1 lists the institutions receiving AID malaria vaccine research funding in fiscal year 1988, their primary work objectives, and when they joined the network. Three members were brought into the network in 1984 during a major acceleration and expansion of project activities caused by AID's belief that the goal was within reach. The expansion included plans for the purchase of more than 2,000 South American monkeys for research, facilities for primate housing and vaccine trials, a center for testing U.S. volunteers, and a global search for field testing sites. The optimism proved premature, as early primate and human trials were not as successful as expected.

Table 1.1: Members of AID Vaccine Research Network in Fiscal Year 1988

Institution	Year Joined the Network	Subproject Focus
Agouron Institute La Jolla, California	1987	Blood stage parasite research.
American Institute of Biological Sciences Washington, D.C.	1982	Technical and management support to coordinate project activities.
Battelle Memorial Institute, Pacific Northwest Laboratories Richland, Washington	1984	Management of primate database systems.
Battelle Memorial Institute, Pacific Northwest Laboratories Richland, Washington	1986	Housing, care, and breeding of research monkeys.
Biomedical Research Institute Rockville, Maryland	1980	Liver stage parasite research and production of infected mosquitoes.
Biomedical Research Institute Rockville, Maryland	1984	Blood stage parasite research.
Case Western Reserve University Cleveland, Ohio	1984	Blood stage parasite research, electronmicroscopy, and monkey pathology.
Centers for Disease Control Chamblee, Georgia	1982	Vaccine testing in monkeys. Development of monkey models of human malaria. Field studies in Kenya.
DNAX Research Institute Palo Alto, California	1988	Blood stage parasite research.
National Institutes of Health Bethesda, Maryland	1984	Support for conservation activities and breeding programs for monkeys of interest to malaria vaccine research, through an agreement with the Pan American Health Organization and its agreement with the Peruvian Primatological Project.
National Institutes of Health Bethesda, Maryland	1985	Vaccine trials on U.S. volunteers, through a subcontract with the University of Maryland's Center for Vaccine Development.
New York University Medical Center New York, New York	1975	Sporozoite stage parasite research.
University of Hawaii Honolulu, Hawaii	1975	Blood stage parasite research.
University of Illinois Urbana, Illinois	1966	Blood stage parasite research.
University of Southern California Los Angeles, California	1986	Cell mediated immunity research.

Also, in 1987 AID began to provide funds to the Institute of Medical Research in Papua New Guinea, through the Malaria Vaccine Field Trials Project. The Institute will collect epidemiological data, construct field facilities, and conduct field trials.

Project Costs

AID has obligated about $96 million for malaria vaccine research and field trials activities. Table 1.2 shows program funding since 1966.

Table 1.2: Obligations for Malaria Vaccine Research and Field Trials Projects

Dollars in millions

Fiscal Year	Malaria Immunology and Vaccine Research Project	Malaria Field Trials Project
1966-74	$3.974	$0
1975-79	10.532	0
1980	2.674	0
1981	4.189	0
1982	5.817	0
1983	5.770	0
1984	7.912	0
1985	13.446	0
1986	9.465	0
1987	9.753	2.000
1988	9.256	1.838
1989	8.500	.662
Total	**$91.288**	**$4.500**

Source: AID

Other Agencies Also Support Research

According to a 1985 survey by the Office of Technology Assessment, the biggest contributors to malaria vaccine research were AID and the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH). The next largest were the World Health Organization's Special Program for Research and Training in Tropical Diseases, cosponsored with the U.N. Development Program and the World Bank; the Department of Defense; the Centers for Disease Control (CDC); and the Rockefeller Foundation. AID coordinates its activities with other U.S. agencies through the Federal Malaria Vaccine Coordinating Committee. It also sends representatives to international conferences, including those sponsored by the Special Program. AID estimates that it contributes about 30 to 35 percent of the global resources currently committed to malaria vaccine development.

Objectives, Scope, and Methodology

At the request of Senator Daniel K. Inouye, then Chairman of the Subcommittee on Foreign Operations, Senate Committee on Appropriations, and currently Chairman of the Subcommittee on Defense, Senate Committee on Appropriations, we reviewed the management of AID's malaria vaccine research project. Our review focused on the period from late 1982 through early 1989. Our objectives were to determine whether

- the procedures and processes used to select research and support subprojects ensured that high-quality, relevant, cost-conscious subprojects were funded;
- an effective, impartial system to monitor performance had been instituted;
- the relevance, impact, and management of the malaria vaccine research project had been periodically evaluated; and
- project expenditures had been subject to adequate financial oversight and audit.

We reached an agreement with AID's Office of the Inspector General (OIG) to ensure that our review would not impede ongoing investigations by that Office. We agreed to focus on broad management issues, while the OIG would continue to investigate more specific criminal allegations. We coordinated our efforts with the OIG throughout our review.

Our review was conducted in accordance with generally accepted government auditing standards between June 1988 and September 1989, primarily at AID offices in the Washington, D.C., area. We interviewed former and current MIVR project staff and the principal researcher or manager of each current subproject and two former subprojects. We reviewed AID policies, procedures, and regulations governing project design, monitoring, and formal evaluations to obtain an understanding of the internal control systems applicable to management of the MIVR project. Because most MIVR subprojects are implemented by contractors or recipients of cooperative agreements, we reviewed agency and federal regulations applicable to the evaluation, selection, and award of contracts, grants, and cooperative agreements.

Because the project relies on the advice of external consultants to evaluate research proposals, review subproject performance, and provide advice and recommendations on overall project management and strategy, we reviewed the project's compliance with agency and federal guidelines pertaining to advisory committees and conflicts of interest.

We reviewed records for all current subprojects. We reviewed the files of the 11 which were funded through contracts or cooperative agreements to determine how they had been selected and awarded. We also reviewed documents pertaining to the selection of one former network member. To evaluate the extent to which project funds were audited, we reviewed copies of all audit reports on file with the OIG for any institution receiving MIVR funding.

To determine the relevance of the MIVR project to AID's mission, we reviewed AID policy statements and Bureau for Science and Technology strategy statements and workplans and analyzed a number of internal and external reviews of the Office of Health's project portfolio, which included the MIVR project. We attended meetings and reviewed the minutes of AID's scientific consultant groups for malaria research, field trials, and monkey management issues to determine what advice and recommendations AID was receiving from external experts. We also interviewed AID officials and researchers not connected with the network to determine their views on the project's management, relevance to AID's mission, and contributions to malaria vaccine research.

As requested, we did not obtain formal agency comments on our draft report. However, we did discuss our findings with project officials and their comments are reflected throughout the final report.

Problems in MIVR Project Management Between 1982 and 1987

Our review of major MIVR project activities disclosed that, primarily during 1982 to 1987, the project lacked financial and program accountability because of inadequate agency oversight and failure to exercise effective management controls. Generally, project management did not assure that high-quality, efficient, research or support activities were funded or that poor performance was identified and corrected. We found (1) irregularities in the subproject selection process and questionable contract and grant awards, (2) inadequate internal oversight and external review of project activities, and (3) inadequate financial management. We also found evidence of fraud, waste, and misuse of project funds.

Selection and Award Irregularities

At the time of our review, there were 15 MIVR subprojects, 11 of which had been funded through contracts or cooperative agreements awarded during 1982 to 1987. We reviewed files pertaining to these 11 subprojects to determine how they had been selected and awarded. We found that

- competition was waived for 10 of the 11 awards;
- with one exception, AID did not formally announce the availability of funds or otherwise request proposals for research or services;
- the basis for waiving competition in all 10 instances was questionable;
- two subprojects were funded despite negative pre-award evaluations of their technical merit; and
- in at least two instances, including one of the subprojects mentioned above, the Office of Health did not advise the Office of Procurement that external reviewers had commented unfavorably on the estimated budgets of research proposals that the Office of Health had selected for funding.

We also reviewed documents pertaining to a grant awarded without competition in 1985 to an institution which is no longer in the network. In this case also, the subproject was funded despite negative pre-award evaluations of its technical merit and the basis for waiving competition was questionable.

Project Officer Not Adequately Supervised

We found that the Office of Health did not adequately supervise the MIVR project officer and the lack of supervisory and internal controls prevented AID from identifying weaknesses in the selection and oversight of MIVR subprojects. According to AID officials and our review of MIVR files, the MIVR project officer from 1982 to early 1987 had more

influence than any other individual over the direction and day-to-day management of the malaria vaccine research project, and he initiated many of the questionable actions we identified. During most of this period, the project officer was also the Chief of the Communicable Disease Division. This dual role eliminated the level of supervisory review most likely to identify performance deficiencies at the project level. The Deputy Director of the Office of Health was the immediate supervisor for division chiefs and, therefore, for the MIVR project officer. She told us that she relied on him to evaluate the relevance, technical merit, and estimated costs of proposals submitted for MIVR funding. She said that the project officer drafted the memorandums the Director of the Office of Health sent to the Office of Procurement recommending specific awards or waiver of competition, but neither she nor the Director suspected that the documents might contain misleading or inaccurate information and, therefore, they had not verified the accuracy of the information.

The Office of Procurement was responsible for reviewing awards proposed by the Office of Health for MIVR project funding. Because of their limited technical expertise, procurement officials relied on the MIVR project officer to evaluate the technical merit and costs of these awards. However, we found that MIVR project documentation sent to the Office of Procurement in support of specific procurement actions was incomplete, misleading, or inaccurate.

Receipt of flawed data influenced the decisions of the Office of Procurement to waive competition and to process specific awards. The weaknesses we identified in the proposal evaluation and selection processes raise questions about the merit and cost of awards made during this period. Specifically, it is not certain that AID always identified and selected the best sources for high quality malaria vaccine research and whether the research was conducted at a reasonable cost.

Competition Generally Waived

There are numerous federal and AID requirements applicable to the solicitation, evaluation, and selection of proposals for contracts, grants, or cooperative agreements. Although competition is encouraged in the award process, it can be waived under certain conditions. Requests and justifications to waive competition originate in the various technical offices and are reviewed by the AID Office of Procurement.

Competition was waived for all current MIVR research subprojects and for all but one of the service-type subprojects. Eight current subprojects

resulted from unsolicited research proposals. The Office of Health submitted the eight proposals to external reviewers for comment. However, the Office of Health misrepresented the nature of the review comments to support its requests to the Office of Procurement for waivers and justified its requests, in part, on the fact that external reviewers said the research could not be obtained from alternate sources. However, we found that none of the reviewers discussed whether the research was available from other sources.

The Office of Health also requested that competition be waived in selecting two institutions to provide technical services to the network, but justifications to support these waiver requests were vague, overstated, or inaccurate. These justifications are discussed below.

- In 1984, AID entered into a $750,000, 3-year cooperative agreement with Battelle-Northwest to develop, monitor, and coordinate primate data for the research network. The agreement was awarded without competition. The request that competition be waived stated that Battelle-Northwest was the most appropriate institution to perform this work but did not indicate how this conclusion was reached.
- In 1985, AID awarded a 5-year, $8.377 million, follow-on contract to AIBS for administrative and technical services. The Office of Health requested that competition be waived for this award for several reasons, including a statement that soliciting other bids would disrupt the research program because AIBS had developed and copyrighted protocols for clinical and field trials which would take 2 years to reconstruct. However, when we asked the executive director of AIBS why AID could not have used copyrighted documentation developed at AID expense, he told us that AIBS had not copyrighted any MIVR project documentation.

Limited Competition May Have Affected the Quality and Cost of Awards

The Deputy Director of the Office of Health told us that competition had not been emphasized during 1982 to 1987, because AID's strategy was to concentrate its investments in a limited number of institutions believed to be leaders in malaria vaccine research. The MIVR project officer assigned to the project in April 1987 told us that in his opinion some research funded by the MIVR project was not high-quality or sufficiently focused. He also said that limited competition had led researchers to expect AID funding and that budgets approved prior to 1987 appeared to be inflated. In his opinion, competition would have forced network members to submit realistic budget estimates. He believed that overstated budgets had given some researchers the flexibility to pursue objectives of secondary importance without the need to collaborate. He added that,

in some cases, secondary objectives might have been accomplished at lower costs by other institutions with pre-existing expertise and equipment.

Negative Evaluations of Technical Merit Reported as Positive

AID funded at least two current MIVR network members despite negative pre-award evaluations of the technical merit of their unsolicited proposals. In addition, at least one former network member was selected despite similar negative pre-award review comments. In each case, the Office of Health misrepresented the negative review comments as positive in documentation it sent to the Office of Procurement asking that the award be implemented. The Deputy Director of the Office of Health told us that the Office would not have funded proposals receiving negative technical reviews if it had been aware of the negative reviews. Two of these awards are discussed below.

University of Illinois

The University of Illinois submitted an unsolicited proposal to continue its malaria vaccine research for 3 years beginning in 1983. The proposal was one of seven evaluated by a panel in early February 1983. According to the minutes of the meeting, the panel recommended that the proposal not be funded because it was "more like a pre-proposal".

The panel's negative recommendation was reported as positive in a document dated June 24, 1983, drafted by the MIVR project officer, asking the Office of Procurement to negotiate a noncompetitive contract with the University of Illinois. The request stated that the proposal had been "reviewed and approved by AID's external panel of expert consultants at their February 1983 meeting" and that the panel had endorsed the scientific methodology and the exceptional qualifications and experience of the researchers and had concluded that no other institution could do the research. AID awarded a $2.38-million contract to the University for the proposed research.

KT&R Laboratories

In 1985, AID awarded a 3-year, $736,801 grant to KT&R Laboratories, St. Paul, Minnesota, to conduct the work outlined in its proposal. Unfavorable pre-award reviews of the proposal were reported as favorable in documentation sent by the MIVR project officer to his superiors and in documentation sent by the Office of Health to the Office of Procurement. This grant was terminated by AID in 1987 after the (1) Office of Health evaluated subproject performance and found major deficiencies and unreasonably high expenditures given the subproject's limited accomplishments and (2) OIG audited subproject records and found

KT&R's accounting systems to be totally inadequate. More than $430,000 had been disbursed under this award.

The AID OIG investigated allegations that neither action was an "arms length" transaction and that the project officer and the researchers acted improperly. The OIG turned over evidence developed during these investigations to the Department of Justice.

Negative Evaluations of Proposed Budgets Not Disclosed

In two instances, the Office of Health did not disclose to the Office of Procurement the fact that external consultants believed the estimated budgets of research proposals were excessive. The Office of Procurement subsequently reduced these estimated budgets only a minimal amount during budget negotiations with the research institutions. The Deputy Director of the Office of Health told us that the negative comments should have been disclosed to the Office of Procurement.

Biomedical Research Institute

A 1983 proposal submitted by the Biomedical Research Institute (BRI) had an estimated 3-year budget of $2.077 million. Two external reviewers evaluated the proposal. The first was "dismayed" by the "excessive" budget proposed. The second was "shocked" by the budget proposal.

Nevertheless, the Office of Health did not raise cost as an issue in documentation it sent to the Office of Procurement requesting that BRI's proposal be funded. The Office of Procurement negotiated the final award with BRI and accepted a final budget of $2.03 million, only $46,691 less than proposed. The first year's budget was $950,016, far exceeding one reviewer's recommendation that $100,000 would be reasonable. The amount budgeted for equipment, which both reviewers had singled out as highly inflated, was reduced by only $587, or 1.4 percent.

University of Hawaii

The University of Hawaii first received MIVR funding in 1975. In 1984, the University submitted an unsolicited proposal for a 3-year extension with a proposed budget of $1.65 million. AIBS records indicated that there were two evaluations of this proposal. The first reviewer found the proposal "overly ambitious". He questioned whether the University had modern animal facilities, termed proposed budget increases "overwhelming" and "excessive", and gave the proposal a mediocre score. The second reviewer described the proposal as "totally unrealistic in terms of time, money, and availability of material" and found the budget to be "outlandish" and "outrageous".

The Office of Health, in requesting that a noncompetitive award be made to the University, did not advise the Office of Procurement of the reviewers' negative comments on the proposal's technical merit and budget. The proposal was approved and fully funded.

Inadequate Oversight and Review of Project

The AID project officer has primary responsibility for monitoring performance under the contracts, grants, cooperative agreements, or interagency agreements used to fund MIVR subprojects. The primary monitoring tools of the MIVR project have been (1) semiannual progress reports submitted by each network member and (2) onsite reviews of performance by the project officer and a team of external consultants. AID also monitors performance through technical presentations at periodic network conferences and feedback from other federal and international organizations conducting or sponsoring malaria vaccine research.

Our review of the internal monitoring mechanisms used during 1982 to 1987 disclosed significant weaknesses, which raised questions about the (1) usefulness of progress reports, (2) integrity and usefulness of external reviews, and (3) project officer's ability to objectively monitor the performance of one network contractor.

Doubts about the value of progress reports and onsite reviews raise concerns about their purpose and actual impact on project decisions. Questions about the project officer's objectivity also raise questions about the adequacy of oversight over funds expended by one network member.

Progress Reports Had Limited Utility

Network members were required by the terms of their agreements with AID to submit semiannual progress reports. The project officer was expected to review the reports and discuss any deficiencies and recommended courses of action with network members. Our review indicated that these reports generally were submitted as scheduled. The Deputy Director of the Office of Health told us that she had not reviewed these reports nor discussed their contents or use with the project officer in charge between 1982 and 1987. However, she was advised by the project officer appointed in April 1987 that they did not contain information needed to evaluate project performance.

Two network researchers said they did not include current data in their reports because AID circulated the reports to other network members and they believed this jeopardized their unpublished findings. A team of external reviewers reported in early 1989 that none of the 13 network

researchers they interviewed could recall receiving any feedback from either AID or AIBS, and 7 researchers were sufficiently concerned about AID's practice of disseminating their reports that they only reported information that had already been published or accepted for publication.

Criteria for Selecting Onsite Review Team Members Questionable

Onsite reviews may have had limited utility because many review team members appeared to lack the independence or expertise needed to provide objective, competent advice to AID on the performance of network subprojects.

AID guidance emphasizes the importance of acquiring first-hand impressions of a contractor's or funding recipient's progress and identifying problems which may adversely affect its performance. AID guidance also encourages the use of external experts to evaluate projects. The Assistant Administrator for Science and Technology noted that the use of external experts brings to AID's research projects and programs "a level of scientific expertise not available in our own ranks and provides a technical input not obtainable through regular in-house project evaluation."

We found that during 1982 to 1987 the project officer made periodic site visits and routinely asked AIBS to put together teams of reviewers to accompany him and evaluate subproject performance. These teams then gave the project officer a consensus report of their findings and recommendations. The Deputy Director of the Office of Health and the current AIBS project manager told us that during this period efforts were made to avoid actual or apparent conflicts of interest in selecting team members. However, the focus was on intellectual rather than financial interests and the fear that non-network reviewers would steal the ideas of network members if they were included on review teams. As a result, only a limited number of trusted consultants and network members were asked to join onsite review teams.

We reviewed the composition of eight teams formed during July 1984 through March 1987 and found that at least one network member was included on six of these teams and that team members reviewed each other's institutions. In three instances, the only members of review teams were the network's two primate experts. For example, a September 1986 onsite review team visiting the University of Hawaii consisted of the AID project officer, AIBS project manager, and the two network experts on animal care and primate trials. It is unclear whether these

individuals had sufficient expertise to evaluate all aspects of the research being reviewed. Their report appeared to be primarily a description of activities rather than an evaluation of performance or objectives, its recommendations focused on primate trials and animal facilities and appeared somewhat peripheral to the actual research being conducted. In comparison, a team visiting the University of Hawaii in February 1988 consisted of a malariologist, a parasitologist, and a molecular biologist.

Relationship Between Project Officer and AIBS Employee Raised Questions About Objectivity of AID Review of AIBS

We found evidence that, beginning in late 1982, the AID project officer had a romantic relationship with the AIBS employee hired to manage the AIBS contract. The Deputy Director of the Office of Health told us that she became aware of this relationship in April 1985 but when she confronted the project officer he told her the relationship had ended and the AIBS employee would be leaving the project. She said she relayed this information to the new Director of the Office of Health in July 1985 asking him to determine whether it was appropriate to proceed with a noncompetitive procurement with AIBS because of the appearance of favoritism in selecting AIBS. The Director of the Office of Health determined that the procurement was appropriate and requested the Office of Procurement to waive competition. The Deputy Director said that she was unconvinced that the waiver was appropriate and, in December 1985, informed the Deputy Assistant Administrator and Senior Assistant Administrator of the Bureau for Science and Technology of the relationship and her concerns. The Director was instructed to conduct another investigation and again found the procurement to have been appropriate. During neither review did the Director detect the fact that some information contained in the waiver request was inaccurate. The AIBS employee involved in this relationship told an investigator from AID's personnel office that the relationship continued until early 1987. The AID investigation did not resolve this discrepancy with the MIVR project officer's claim that the relationship had ended earlier.

The Office of Health reassigned the project officer in April 1987, after AIBS complained that the project officer was harassing its employees, including the project manager with whom he had the relationship. Soon after AIBS made its charges, the Office of Health asked the OIG to investigate a number of allegations involving several network members. When these investigations appeared to implicate the project officer, he was placed on administrative leave in October 1987, pending the outcome of the OIG investigations. He remains in a paid leave status.

AID's personnel office initiated an investigation of AIBS' allegations of harassment in the spring of 1987. In November 1987, as a result of this review, AID penalized the project officer one week's pay for misconduct, specifically the appearance of favoritism and/or loss of impartiality caused by his relationship with the AIBS employee. In the fall of 1987, the OIG turned over the results of its parallel investigations involving the former project officer and several network members to the Department of Justice, which directed subsequent OIG investigations on these matters.

Lack of Financial Accountability

During 1982 to 1987, AID did not ensure adequate control over or accountability for MIVR project funds. We identified the following fiscal and financial irregularities.

- Evidence of misuse of government funds.
- Questionable costs billed to AID by AIBS and other network members.
- Irregular reporting practices by AIBS.

In addition, the OIG identified evidence of fraud involving several network institutions.

Evidence of Fraud and Misuse of Government Funds

The OIG reviewed project funds disbursed to the University of Hawaii and, in December 1988, the Office of Procurement informed the University that the OIG investigation indicated

> "an apparent systematic diversion and theft of funds as well as the submission of false claims and other documents intended to cover up the actual use of the funds that were under the control of the University's Principal Investigator....there is evidence to support allegations that the Principal Investigator apparently diverted to his and his secretary's personal use, (funds) in excess of $50,000. An additional $10,000 was used to refurbish his offices at the University and apparently these construction costs were charged to the Grant as consultant payments."

AID advised the University that it was no longer acceptable for the researcher to have responsibility for AID funds and gave the University 10 days to resolve the matter. According to an AID official, the University appointed a new administrator for the subproject. In September 1989, the researcher was indicted in Hawaii for theft of funds awarded to the University by AID.

The OIG also has information that the principal researcher of the University of Illinois had diverted AID funds to personal use. University auditors are investigating the researcher's activities.

We found other indications of fraud in an AID-funded research project at the National Institute of Health in Bogota, Colombia. This project was administered as a subcontract by AIBS at AID's request. In June 1982, AID awarded AIBS a 3-year contract with an estimated budget of $709,375. On September 29, 1982, AID amended the contract to authorize AIBS to enter into a 33-month subcontract with the Institute and increased the contract budget by $1.53 million to cover the research costs and AIBS' overhead. AIBS and the Institute had already signed a subcontract on September 8, 1982, which was approved retroactively by the AID contracting office in February 1983. Although the Colombian program had research components, AIBS' executive director told us that AID's primary motive in approving the subcontract was a hope that Colombian monkeys would become available for vaccine testing, either at the Institute or by export to the United States.

In May 1984, the project officer and AIBS staff visited the Institute to clear up numerous billing and financial irregularities, including checks sent by AIBS to the Institute's Malaria Unit that had been deposited in Swiss bank accounts. The team found the program's finances to be in complete disarray. They found three sets of records, none matching billings to AIBS. The institute's principal researcher was unable to account for all project funds. In January 1985, a local audit firm hired by AIBS to examine the subcontractor's records reported that financial information was "completely disorganized, incomplete, and non-summarized". They found that U.S. dollar checks mailed by AIBS to the malaria unit had been converted to local currency "through channels forbidden by the national monetary authorities" and there was no way to ascertain that the exchange rates used were reflected in the income of the project. AIBS has alleged that the principal researcher of this project defrauded the U.S. government of about $147,000 by submitting false claims to AIBS.

The Institute's Director told the review team that he had been unaware of problems in the malaria research program and was interested in continuing a joint research effort but was not interested in only raising monkeys. The Institute, AID, and AIBS agreed to suspend further activities until the financial problems could be resolved. Although AID hoped that the Institute would propose another research project, no further work was performed during the remainder of the contract period.

AID has not sought to recover any expenses from either AIBS or the Institute. The executive director of AIBS attributed this decision to "sensitive relations" between the United States and Colombia on other issues. Officials in the Bureau for Science and Technology denied this assertion. They told us that in May 1988 they requested the OIG to audit the AIBS contracts to determine whether there has been misuse of AID funds but this audit has not yet been scheduled. The Deputy Director of the Office of Health said she has also asked the AID Office of Procurement to look into this matter.

Although work was not resumed after May 1984, AIBS continued to bill AID for subcontract costs through the end of the contract period. Our review disclosed that AIBS mislabeled more than $553,000 spent for other project activities as subcontract expenses on its monthly vouchers to AID. AID did not amend the AIBS contract to reflect the fact that work had stopped under the subcontract nor did it revise the budget estimates for other project activities to reflect their increased costs. The unexpended funds budgeted for the subcontract apparently became a large discretionary account, with limited accountability and control.

Conclusions

During 1982 to 1987, AID failed to exercise adequate oversight over project staff and activities. Subprojects were selected under questionable circumstances, their performance was not subjected to adequate evaluation, and inefficient poor quality research may have been tolerated. Although there was the appearance of external review, it is questionable whether review teams always had sufficient independence or expertise to provide objective, useful advice. Because some research proposals were selected and fully funded despite negative pre-award comments on their technical merit and budgets, the extent to which external advice was used as the basis for project decisions is also questionable. Finally, there is evidence of waste of government funds and fraud.

Recent AID Actions To Improve Management of Malaria Vaccine Research

As awareness of the problems in the MIVR project increased after March 1987, AID took steps, including those below, to bring the project back in line with agency project management guidance.

- Improved the subproject selection process.
- Improved the onsite review process.
- Established advisory groups to provide external guidance on research and development, field studies and trials, and use of research monkeys.
- Audited the direct costs billed by 4 of the 15 network subprojects.

However, we identified some deficiencies that were not corrected, such as inadequate guidance on conflicts of interest, noncompliance with regulations implementing the Federal Advisory Committee Act, lack of recent financial audits for most MIVR subprojects, absence of approved design documentation for the field trials project, and failure to arrange for an external evaluation of the MIVR project before designing its successor project.

AID must also resolve significant internal disagreements as to whether it should continue to fund malaria vaccine research and/or field trials activities. AID has arranged for an external evaluation of the current state of malaria vaccine research and an assessment of other malaria control alternatives. This evaluation could be useful in making future funding decisions.

Changes in Selection and Award Process

AID significantly improved the subproject selection process by improving the quality of the pre-award evaluation process and by insisting on high-quality proposals from institutions seeking vaccine research funding. However, because AID did not announce the availability of fiscal year 1989 funding for new MIVR subprojects it cannot be sure that it received the best proposals and research available. AID did, however, issue a general solicitation for proposals to be funded in fiscal year 1990.

External Review of Proposals Is Formalized

The Office of Health improved the pre-award evaluation process by using an expanded list of consultants to review proposals and exercising greater supervisory involvement and oversight of the process. Early in 1989, the Office of Health received 10 unsolicited proposals for MIVR project funding. New procedures to evaluate these proposals included the use of an 18-member panel of external experts. The MIVR project

officer told us that the panel was designed to include at least one member from each scientific discipline included in the proposals to be evaluated. Panel members were asked to sign statements that they would abstain from reviewing any proposals with which they had known conflicts of interest and would not disclose any confidential information obtained during the review. Network members were not asked to serve as reviewers, a change from past practice.

The Office of Health told us that large pre-award evaluation panels to review proposals and applications for MIVR funding will be a permanent feature of the MIVR project and its proposed successor, the Malaria Vaccine Research and Development Project.

Competition Delayed

Lack of competition remained a problem during the spring 1989 selection cycle. Federal regulations emphasize the importance of competition, but AID did not advertise or otherwise formally announce the availability of fiscal year 1989 funding for new MIVR network research subprojects. Therefore, it is not surprising that only 2 of the 10 proposals received were submitted by non-network members. The current MIVR project officer told us that he did not have time to advertise for new proposals prior to the spring 1989 cycle because several subprojects were reaching their termination dates and decisions about continued funding had to be made. AIBS did announce the availability of limited fiscal year 1989 funding for a program of small research projects which it administers as subcontracts for AID.

In May 1989, AID announced the availability of fiscal year 1990 funding for new malaria vaccine research subprojects. Proposals received pursuant to this solicitation will be reviewed in late 1989. The Deputy Director of the Office of Health told us that the review would indicate whether network laboratories were still leaders in malaria vaccine research.

Oversight Can Be Strengthened

During 1982 to 1987, the usefulness of the two primary monitoring tools, onsite reviews and progress reports, was questionable. In 1988, AID redesigned the format of the semiannual progress reports, improved the quality of onsite review teams, and used review reports and recommendations to focus scientific performance and make budget decisions. Some additional changes, including improved agency guidance on conflicts of interest, would further strengthen these monitoring mechanisms.

Expanded List of Experts for Onsite Reviews Poses New Problems

It has proven difficult for AID to balance its need for thorough and comprehensive reviews of subprojects with the need to avoid actual or apparent conflicts of interest. During 1982 to 1987, some MIVR project reviewers appeared to lack sufficient independence or expertise to provide high-quality, objective advice. After mid-1987, AIBS expanded its list of external consultants to allow the selection of reviewers with more relevant expertise. However, in some cases the expertise appeared to be so closely related to the research being evaluated that it caused allegations of conflicts of interest and bias from the scientists being reviewed.

AID sent onsite review teams to 12 subprojects in fiscal year 1988. AIBS was evaluated in early 1989. We reviewed the composition of each review team, their reports, and AID's use of the reports and recommendations and found that AID significantly increased the number of consultants asked to become members of such teams and used the reports to make significant budget decisions. However, two researchers alleged that teams included members with conflicts of interest.

AID sent review teams to Agouron Institute in November 1987 and to BRI in May 1988. The researcher at BRI complained that a member of the review team was "pursuing precisely an identical line of research to ours." The reviewer also indicated some hesitancy to participate on the review team because others might perceive a lack of objectivity on his part. AID decided that the researcher's objections did not have sufficient merit, in part because the reviewer's familiarity with the BRI research was considered to be an advantage and he was considered sufficiently disinterested in the vaccine goals of BRI's program to preclude any conflict of interest. The researcher later likened the experience to "walking a tightrope. It required us to constantly balance the amount of information which was presented to make the point against giving away data in which the reviewers have a vested interest."

AID also rejected objections raised by the researcher at Agouron Institute that a proposed reviewer was perceived to be hostile and had lacked objectivity in dealing with his work in the past. This reviewer had just submitted a proposal to AID for funding, and approval of his proposal depended on the availability of funds in a very restricted budget environment. The MIVR project officer wrote the researcher that objective review was mandated and the team would be able to fairly assess and provide positive feedback on Agouron's performance; also, the researcher was reminded that he could respond to the team's comments and final report, if he disagreed.

Guidance Needed to Clarify Conflicts of Interest

AIBS requires external reviewers to individually determine whether they have conflicts of interest but does not define or give examples of conflicts of interest. Since August 1987, AIBS has required external reviewers to sign an AIBS form certifying that they are unaware of any matter which might reduce their ability to render unbiased evaluations or place them in a position of conflict between their responsibilities as a reviewer and any other interest. Reviewers must also agree to (1) treat information reviewed or collected as proprietary and confidential, (2) use no information obtained without the prior permission of the applicant or researcher being reviewed, and (3) review no proposals submitted by researchers from their own institutions. The current AIBS project director told us that the form was designed to focus on intellectual rather than financial conflicts.

We heard a wide range of opinions as to what constitutes a conflict. For example, an AID ethics officer told us that financial interest in the outcome of a decision was generally accepted as constituting a conflict of interest. The MIVR project officer has determined that using network members to review each other's work presents a conflict of interest. One researcher believed that reviewers conducting related research would have conflicts of interest. Another believed that anyone from a specific competing laboratory would be biased. An AID ethics officer told us AID has not issued guidance to help its employees identify situations creating real or apparent conflicts of interest but believed that such guidance would be worthwhile.

Onsite Reviews May Be Scheduled Less Often

The current MIVR project officer told us that onsite reviews will be scheduled at greater intervals than in the past. The external team evaluating the AIBS subproject in early 1989 advised AID to make this change, pointing to the cost of reviews and the difficulty of identifying enough qualified reviewers with appropriate qualifications and with no apparent conflicts of interest.

Progress Reports May Assume Greater Role in Monitoring Process

If onsite reviews are scheduled less frequently, semiannual progress reports will become the primary monitoring tool. However, progress reports cannot become an effective monitoring tool until AID (1) resolves the researchers' fears about premature release of proprietary information, (2) ensures that the reports receive adequate review, and (3) provides useful and timely feedback on the reports to network members.

In mid-1988, AIBS drafted a new format for network members to use in preparing semiannual progress reports, which required greater attention to administrative matters, such as equipment and animal inventories. In June 1989, the MIVR project officer told us that he was considering a change which would require researchers to divide their research data into confidential and non-confidential sections to help resolve researchers' complaints about premature disclosure of their research data. AID would not circulate the confidential data but would disseminate the other information in a newsletter.

At present, subproject performance is subject to detailed external scrutiny through periodic onsite reviews. If progress reports substantially replace these reviews, the technical and/or scientific progress of individual subprojects will not be subject to comprehensive external scrutiny for extended periods. It is important, therefore, that the project's semiannual progress reports receive adequate review to note any problems or deficiencies as soon as possible. The MIVR project officer told us that AID has no plans to submit progress reports to external experts for critical review. At present it appears that the project officer has sufficient technical expertise available to review these reports without external assistance. However, if the staffing pattern should change, it may be necessary to seek external advice. In selecting these reviewers, AID would again have to balance its need to monitor performance with the researchers' need to protect confidential data.

Expanded External Review

In recognition of its need for external advice on a variety of complex technical issues, AID established the Scientific Consultants Group for Malaria Vaccine Field Trials and Scientific Consultants Group for Malaria Vaccine Research and Development.

AID also re-established the primate use committee, which had fallen into disuse by 1987. The Office of Health formed a new 3-member committee, which held its first meeting in August 1988. The committee is primarily responsible for reviewing requests to use AID's research monkeys in malaria vaccine research studies. In June 1989, the MIVR project officer told us that he planned to add two members with malaria research expertise to the committee so that it could evaluate not only the ethical considerations of using animals in a proposed study but also the scientific merit. The committee may also be asked to provide advice on primate acquisition and management issues. The committee makes its recommendations to AID through AIBS.

The Scientific Consultants Group for Malaria Vaccine Field Trials held its first meeting in October 1988 and the Scientific Consultants Group for Malaria Vaccine Research and Development held its first meeting in March 1989. There is some overlap in membership of these groups to ensure consistency in the MIVR and field trials projects. According to AID, the responsibilities of the research and development advisory group include

- formation and updating of a strategic plan for research, support, and evaluation activities;
- review of technical and scientific progress within the network, with recommendations for AID actions;
- review of proposed subproject funding decisions; and
- identification of capable scientists as consultants or additions to the network.

Members of both consultants groups were appointed by the Senior Assistant Administrator for Science and Technology. AID developed the agenda for and participated in both meetings. Both groups issued summary reports and recommendations at the conclusion of their first meetings. Members of these groups were also asked to sign the standard AIBS conflict of interest forms and were expected to absent themselves from discussions or decisions which might represent potential conflicts of interest. Neither of these meetings was open to the public and network members participated only if invited.

Advisory Groups Need to Adhere to Applicable Federal Statutes

Regulations implementing the Federal Advisory Committee Act state that advisory groups covered by the Act must be chartered in accordance with the regulations before they may meet or operate. In addition, meetings of advisory groups established or used by any agency official as a preferred source of advice or recommendations on issues or policies within the scope of his/her responsibilities should be open to the public. Reports issued by these groups should be available to the public. Groups which are convened for the purpose of obtaining the advice of individual members rather than consensus opinions are excluded from the Act. However, the Act's requirements for public access to meetings and reports apply when an agency accepts the groups' deliberations as a source of consensus advice or recommendations.

We believe that the Scientific Consultants Groups for Malaria Vaccine Research and Development and Malaria Vaccine Field Trials are covered

by the Act because AID is accepting their consensus reports and recommendations. The groups should be chartered as advisory committees according to regulations implementing the Act. In addition, their meetings and reports should be open and available to the public to the extent possible. Part or all of an advisory group's meeting can be closed if justified in accordance with criteria and instructions in the Government in the Sunshine Act and notice is published in the Federal Register. For example, meetings can be closed if proprietary information is likely to be disclosed.

Additional Financial Audits Necessary

The OIG gave us copies of all audit reports in its files for institutions in the MIVR network. The reports covered four former and six current network members, including AIBS and the Universities of Hawaii and Illinois. The audits were conducted by either the OIG, the Defense Contract Audit Agency, or the Department of Health and Human Services. Audits prior to 1988 focused primarily on indirect costs and overhead rates rather than direct project expenses. Except for the OIG's audit of KT&R Laboratories in late 1987, the reports identified few questionable costs and uncovered no major financial management weaknesses, misuse of government funds, or indications of fraud.

Post-1987 Audits Disclose Questionable Costs Billed to AID

In a memorandum dated May 1988, the Office of Health requested the AID OIG to audit the records of specific network members, including AIBS, and provided funds to pay for these audits. In response, the OIG audited the records of the terminated Scripps Clinic and Research Foundation subproject and ongoing subprojects at New York University, Battelle-Northwest, and the University of Hawaii. The OIG questioned or suspended almost $450,000 paid to these four network institutions, including the following.

- Almost $28,500 paid to the University of Hawaii for unauthorized salary and leave payments to the principal researcher and a staff researcher; the University had also billed AID about $61,000 for the per diem costs of non-AID monkeys maintained by the Department of Tropical Medicine and for the purchase of monkeys not authorized by AID.
- About $102,000 paid to New York University for excess salaries and related fringe benefits and overhead; in addition, auditors were unable to account for equipment costing about $52,000.

Although the Office of Health made funds available for an audit of AIBS, an OIG official told us that the OIG delayed initiating a comprehensive

audit because AIBS' financial records were being used in ongoing criminal investigations of the AID project officer and three researchers. The Deputy Director of the Office of Health told us that she has asked the OIG to expedite its review of AIBS and that she plans to request and make funds available for audits of the remaining network institutions to take place in fiscal years 1990 and 1991.

AIBS Reimbursed for Questionable and Excessive Costs

AID has reimbursed AIBS for questionable and/or excessive expenses. Two examples are discussed below.

- In August 1988, we told officials in the Office of Health that AIBS was charging AID excessive salaries for two employees. The current AID-AIBS contract limits contractor salaries to the FS-1 salary level, unless higher rates are approved by the Office of Procurement. The maximum allowable rate in 1988 was about $71,300 per year, or about $274 per day. AIBS charged AID about $98,000 in 1988 for the salary of the project director and $337.50 per day for the executive director. In August 1989, the Office of Health, with approval of AID's Office of General Counsel, decided to ask the Office of Procurement to retroactively waive the salary limitation for the project director and approve his current salary of $104,100 per year.
- In 1985, AIBS arranged a conference for the MIVR project in Ft. Lauderdale, Florida, and paid the transportation, room, meal and supplemental costs for about 50 conference participants. AIBS also paid some transportation, lodging, and meals costs for two AID employees. We found that the daily cost for lodging and meals for conference participants was as much as $222 per participant. We also noted that AIBS billed AID more than $1,400 for alcoholic beverages, $225 for a harpist, and $1,050 for a band. This appears to violate AID regulations which state that luxury items, including liquor, are not allowable expenses. These questionable costs would not have been readily apparent, because the vouchers submitted to AID did not identify individual expenses but rather summarized costs in broad budget categories, such as salaries, travel, or subcontracts. AIBS included these conference costs in its summary total for subcontracts.

Project Design and Evaluation

The MIVR project's goal of developing one or more vaccines against malaria was for many years routinely accepted by AID as relevant and appropriate to its mission and health strategies. However, AID obligated millions of dollars to support malaria vaccine research and to initiate

field trials activities in Papua New Guinea without updating or preparing standard agency design and project planning documents. There is now considerable controversy within AID whether it should continue to fund malaria vaccine research activities.

The Office of Health designed a project to succeed the MIVR project without adequately evaluating or reassessing the

- design, research strategies, or management problems of the MIVR project;
- current state of malaria vaccine research, both within and outside the network;
- relative merit of supporting research as opposed to other malaria control options; or
- current division of effort among U.S. agencies currently funding malaria vaccine research and the most effective role for AID.

Design Documents Not Prepared

AID's primary project design documents are the (1) project identification document and (2) project paper. According to AID regulations, the project identification document is the first formal document in the process which leads to the approval of a specific project. The project paper provides the basis for approval of the project and records the rationale for the project, description of project elements, analyses supporting the proposed design, and initial project implementation and monitoring plans.

A project paper for the MIVR project had been prepared in 1975 but was never updated. In September 1987, AID broke off a segment of the MIVR project to form a separate Malaria Vaccine Field Trials Project, which envisioned field trial sites in Asia, Africa, and Latin America at a total cost of $23 million during a 5-year period. AID authorized the first phase of the project and obligated $2 million for project activities in Papua New Guinea. This was done without preparing either a project identification document or a project paper. AID obligated another $1.838 million in fiscal year 1988 and $661,616 in fiscal year 1989 for this site, still without these design documents. MIVR project staff began drafting a project paper in February 1988. During the review process, the scope of the project was changed, the name was changed to the Malaria Vaccine Epidemiology and Evaluation Project, and the budget decreased to $15 million. This project had not been approved by AID management as of September 1989.

In March 1988, the Senior Assistant Administrator for Science and Technology authorized the Office of Health to design a 5-year project to succeed the MIVR project, and he waived the preparation of a project identification document for the proposed project.

The absence of design documents does not appear to be an unusual characteristic of the Office of Health project portfolio. An April 1988 management review showed that, of the then-current portfolio, only 14 of 32 projects had project papers and research projects were particularly apt not to have design documents. The Bureau for Science and Technology's 1988 internal controls assessment also indicated that the lack of project design was a Bureau-wide weakness. The Bureau proposed to correct the deficiencies by developing Bureau-specific design guidance to supplement existing agency regulations, creating a project design officer position, and assessing its current processes for project design review, which it stated tended to be weak and "pro forma." In September 1989, we were told by an AID official that the Bureau hired both a design officer and an evaluation officer but other corrective actions were still in process.

Poor design processes may have contributed to another Bureau-wide weakness. The 1988 internal assessment points out that "[p]roject evaluations are often hindered by inadequate project design which does not provide a base against which progress can be measured".

Continued Support for Vaccine Research Proposed Without External Evaluation of Past Activities

AID policy requires that projects reaching completion be evaluated if follow-on projects are anticipated. AID requires that evaluations be designed to answer the following questions.

- Are the problems the project was originally designed to address still germane to AID's development strategies?
- Is the project achieving satisfactory progress toward its stated objectives?
- Are project costs acceptable compared to alternative approaches to accomplishing the same objectives?
- What positive and negative impacts are resulting from the project?

MIVR project staff drafted a project paper for the proposed $45-million, follow-on, malaria vaccine research and development project without arranging for a comprehensive, external evaluation of the terminating MIVR project as required by AID regulations.

Office of Health and Bureau for Science and Technology officials told us that they believed that the series of onsite reviews of MIVR subprojects which took place in 1987 and 1988, the meetings of the project's three advisory committees, and a review of the Office research portfolio by AID's Research Advisory Committee comprised the equivalent of a standard end-of-project evaluation. In our opinion, however, these reviews and studies were useful tools for monitoring and overseeing the implementation of project objectives but did not validate those objectives or answer the other broad questions listed above.

Future Support for Vaccine Research Debated

During the past year, AID officials outside the Bureau for Science of Technology have questioned whether (1) AID should fund research which is also funded elsewhere, (2) malaria vaccine research should retain its high funding priority, (3) AID has the mandate or capacity to carry out such large-scale biomedical research, and (4) the approach proposed by the Bureau for future malaria vaccine research efforts was being adequately reviewed.

An external team appointed by the AID Deputy Administrator assessed the Office of Health in early 1988 in response to a congressional request for a review of several AID offices. The team reported that it had encountered strong opinions, both pro and con, regarding the malaria vaccine research project and that the project

> "introduces the question as to whether AID should ever again attempt to undertake long term basic research of this nature. Most members of the Team would opt for not undertaking long term basic research again. One member believed that AID should engage in supporting basic research on major (less developed country) problems, but should find ways to reduce the direct management burden of such involvement."

Among the reasons to continue funding were the severity of problems caused by malaria and a perception that other U.S. agencies would not share AID's interest in a non-U.S. health problem. Reasons to discontinue support included a perception that AID lacked qualified personnel to manage basic research and the indefinite time frame and funding required. The team recommended that any decision to continue research be accompanied by a commitment to periodic, intensive reviews and maximum coordination among all malaria vaccine research donors.

An onsite team, reviewing AIBS' performance in early 1989, noted a need

"for substantial change in network management. Because of personnel limitations AID can no longer provide the needed level of day-to-day supervision. We therefore recommend that a competitively bid contract or cooperative agreement delegating broad management responsibilities and authority for directing vaccine development replace the AIBS contract on expiry.... Serious consideration should also be given to what separate mechanisms will be needed to supervise overseas field trials."

Proposed Evaluation Could Resolve Internal Dispute

According to the Deputy Director of the Office of Health, the Institute of Medicine of the National Academy of Sciences has agreed to a request from the Office of Health to evaluate global malaria control efforts and current malaria control options, including vaccine research. Although the agreement has not been signed, the evaluation was expected to begin in September 1989 and cost about $608,000. The Deputy Director of the Office of Health told us that the evaluation could take as long as 2 years to complete. In the meantime, AID must resolve its internal debate and decide whether it will continue to fund malaria vaccine research activities and, if the decision is affirmative, whether to approve interim funding to maintain project activities until the Institute of Medicine has completed its evaluation or make longer term commitments for malaria vaccine research and field trials activities.

Conclusions

Although AID has consistently supported the goals of the MIVR project, it did not exert sufficient supervisory control to ensure that MIVR project activities were efficient or effective or that government funds were controlled. As awareness of the deficiencies in the MIVR project grew, AID began to take steps to improve the quality, consistency, and objectivity of external review; improve subproject selection and monitoring processes; and expand audit coverage. However, we believe that a number of additional actions should be taken to improve AID's management of its malaria vaccine research activities.

AID has taken steps to ensure that project decisions are based on external advice by establishing advisory committees for specific project activities. However, the advisory process is closed and not subject to scrutiny by interested parties. We believe that openness would benefit the program and AID should continue to use these committees but ensure that they are chartered in accordance with the Federal Advisory Committee Act. We recognize that there may be a need to close part or all of some meetings, but applicable federal regulations provide mechanisms for doing so.

AID could further ensure objective and open external review by developing guidance and a new procedure for selecting reviewers. Given the lack of consensus as to what constitutes a conflict of interest, we believe that AID should not rely on consultants to make self-assessments as to whether their participation creates a conflict. Instead, AID should identify those financial, personal, or scientific interests that should be disclosed by potential consultants and that would permit selecting officials or an AID ethics officer to make independent tests for conflicts of interest. In determining whether a particular selection poses an actual or apparent conflict, the reviewing official should consider both the nature of the official responsibilities to be given to the external reviewer and the information disclosed.

Progress reports have had limited usefulness as a management tool because AID used them primarily as a means to share general information within the network and not to monitor performance. The reports, as currently designed, cannot be effectively used for both purposes. If AID does not make a change to safeguard confidential data, researchers can be expected to continue to exclude confidential and unpublished information from their reports. Progress reports could be a valuable monitoring tool for AID management if they are redesigned to protect confidential data, receive adequate review, and are used to provide timely feedback on any noted performance deficiencies.

AID should have evaluated the MIVR project and its strategies and objectives before authorizing field trials activities in Papua New Guinea or designing the proposed follow-on Malaria Vaccine Research and Development and Malaria Vaccine Epidemiology and Evaluation Projects. AID has recognized the need for an assessment and has taken steps to fund a comprehensive evaluation by the Institute of Medicine. The evaluation could affirm the high value AID has placed on such research. On the other hand, the reviewers could also recommend a change in strategies or validate the growing concern expressed by some AID officials that AID should not fund any basic research activities, including malaria vaccine research. We believe that if AID decides to support malaria vaccine research activities it should not make long-term funding commitments until the evaluation results are analyzed and the management deficiencies identified in this report are corrected.

OIG audits and investigations during the past year uncovered evidence of fraud and questionable costs in several subprojects. We identified numerous examples of questionable costs under two contracts between AID and AIBS. Because of past problems, we believe that the records of all

remaining network members should be audited. The Office of Health has indicated that funds have been reserved to cover the cost of auditing the remaining subprojects, and the OIG should prepare a schedule for conducting these audits.

Recommendations

To resolve outstanding MIVR project management deficiencies, we recommend that the Administrator of the Agency for International Development take the following actions.

- Develop descriptive guidance for the disclosure of scientific and financial interests, which would enable reviewing officials to identify and resolve real or apparent conflicts of interest in the selection of external consultants.
- Redesign the project's semiannual progress reports to improve their usefulness as performance monitoring tools and ensure that confidential information is safeguarded, the reports receive adequate review, and the researchers receive timely feedback on their performance.
- Ensure that the scientific consultants groups established for research and development and field trials activities are chartered in accordance with the Federal Advisory Committee Act.
- Await the results of the Institute of Medicine evaluation before authorizing long-term funding commitments for malaria vaccine research activities.

We also recommend that AID's Inspector General schedule and audit those MIVR subprojects which were not audited by the Office of the Inspector General during the past year.

AID's Management of Research Monkeys

Between fiscal years 1984 and 1988, approximately $6.7 million of MIVR project funds was obligated to acquire, house, and maintain monkeys for malaria vaccine research. AID has developed no comprehensive action plan for acquiring, housing, and caring for its monkeys. The lack of an integrated plan resulted in AID's

- purchasing monkeys with limited use for malaria research;
- delaying the sale, trade, or transfer of any of its surplus monkeys;
- providing inadequate housing for its rapidly expanding inventory of monkeys; and
- maintaining demographic and biomedical databases on its research monkeys that had limited use for researchers and did not provide complete census information for inventory accountability purposes.

A procurement of monkeys from Bolivia is under investigation by the OIG for possible fraud.

Why Monkeys Are Needed

Aotus and Saimiri monkeys from Peru, Bolivia, and Colombia are used to test the safety and efficacy of malaria vaccines prior to tests in humans. Safety trials measure a vaccine's toxicity and possible harmful effects. Efficacy trials seek to determine a vaccine's protective value against malaria. Safety and efficacy trials are conducted on a small scale by researchers in their laboratories and on a large scale by the Centers for Disease Control in Chamblee, Georgia. Monkeys are also used in immunology studies and to produce parasite-infected mosquitoes and immunogenic material for use by researchers.

According to the MIVR project staff member responsible for monkey-related issues, the research community generally agrees that safety trials are useful and appropriate, but there is a significant difference of opinion over whether available monkey-parasite models adequately measure vaccine efficacy.

AID justified a rapid increase in its inventory of research monkeys between 1984 and 1987 on several factors, including its belief that a large number of vaccines would be ready for testing. In addition, there was an assumption that the Food and Drug Administration (FDA) would not approve human clinical trials for a vaccine until its efficacy had been demonstrated in monkeys. However, an FDA official told us that the FDA does not require efficacy trials in monkeys. The official added, however, that such studies are expected if an adequate monkey-parasite model exists.

The current MIVR project officer told us that AID now realizes that the FDA does not currently expect efficacy trials in monkeys prior to authorizing human trials. However, he stressed that AID will continue to conduct large scale efficacy trials in monkeys because the information from such trials will be useful to AID management in deciding whether a candidate vaccine should be tested in humans.

Questionable Procurement Actions

AID purchased most of its monkeys during the years 1984 through 1987. The largest number of monkeys were obtained through an interagency agreement between AID and the National Institutes of Health. NIH had an agreement with the Pan American Health Organization (PAHO) to support a primate conservation and breeding program in Peru and AID essentially replaced NIH as the primary project supporter. Three major procurement actions, each with questionable aspects, are discussed below.

- AID's first large procurement began in February 1984, when it sought to establish a stable source of monkeys from the Peruvian Primatological Project (PPP). AID agreed to provide the PPP with an estimated $1.1 million, through NIH and PAHO, for conservation activities and identification of surplus monkeys which could exported. At the same time, AID requested the PPP to send 83 monkeys in 1984, 100 in 1985, and 200 in both 1986 and 1987 and paid a per capita transfer fee for each monkey delivered. Although AID documents indicate that it wanted the PPP to send karyotype V Peruvian Aotus,[1] the interagency agreement specified only that monkeys of the "appropriate karyotype" be supplied. AID's failure to clarify its requirements and willingness to accept less desirable monkeys allowed the PPP to send more easily captured but less desirable karyotype I Peruvian Aotus. An AID official stated that this was a mistake that must be avoided in future acquisitions from the PPP.
- In April 1985, AID decided to purchase up to 600 Bolivian monkeys, using unexpended funds from the suspended AIBS subcontract with the Colombian National Institute of Health. AIBS ordered the monkeys from a firm called Gerrick International, which bought them from another company, Worldwide Primates. In January 1986, 341 Bolivian Saimiri and 20 Bolivian Aotus arrived in the United States. The Bolivian press then reported that the monkeys were being sent to U.S. zoos and pet stores.

[1] Aotus subspecies are differentiated by their chromosomal patterns and are identified as karyotype I, karyotype II, karyotype III, etc. Saimiri subspecies, on the other hand, are identified by their country of origin—Peruvian Saimiri, Colombian Saimiri, etc.

The adverse public reaction caused Bolivian officials to rescind Worldwide Primate's export waiver before it could ship the remaining monkeys.

It appears that Gerrick International made a substantial profit from this arrangement by charging AIBS $54,250 more than the $191,625 it paid Worldwide Primates. The AID OIG is investigating this matter because the AIBS consultant who arranged the procurement was also a principal officer in Gerrick International.

- In November 1986, the MIVR project officer asked the PPP to provide 500 Peruvian Aotus and 500 Peruvian Saimiri to meet AID's "critical need for animals for use in the conduct of required pre-human use trials." The estimated cost of this procurement was $523,190. At an August 1986 meeting of network and other primate experts, Peruvian Saimiri had been rated fourth among available species for testing blood stage vaccines. According to an AID official, AID sent the initial shipment of about 30 Peruvian Saimiri to CDC for evaluation after CDC questioned their suitability for malaria vaccine testing. In December 1987, CDC reported that the Peruvian Saimiri subspecies was not suitable; nevertheless AID decided not to cancel its order because of the up-front commitments the PPP had made to fill AID's large order. AID, however, did arrange for the transshipment of 150 Saimiris to other government agencies, who paid NIH directly for the transferred monkeys. AID eventually accepted the remaining 350 Saimiris at a cost of about $183,000.

Estimating Requirements for Monkeys Is Difficult

It has proven difficult for AID to estimate the number of monkeys it should keep onhand to provide network researchers with sufficient numbers of suitable monkeys for malaria vaccine research. AID's inventory management problems have been caused by (1) difficulties in estimating the number of vaccines to be tested within a given time frame, (2) the fact that the subspecies deemed most suitable for malaria vaccine research are in short supply, while marginally suitable subspecies are relatively easy to obtain, and (3) the fact that continued availability of monkeys from South America cannot be guaranteed.

Although AID owned 1,452 monkeys in March 1989, it was not certain that either the size or composition of its inventory was appropriate. The MIVR project officer told us that he intended to sell 1,000 monkeys to interested researchers. Approximately 550 monkeys would be sold because they were considered unsuitable for malaria vaccine research or because they had been used in prior malaria vaccine trials. The project

officer expected to identify 450 more monkeys, including both suitable and marginally suitable species, for sale because he considered them to be excess to projected needs. He believed that AID needed to keep only a minimal number of monkeys onhand because suitable monkeys could be obtained from Peru to replace monkeys used in trials.

In August 1989, AID officials acknowledged that AID had purchased more monkeys than it needed but blamed the excess on inaccurate estimates of the number of vaccines to be tested submitted by network researchers. In August 1989, AID asked researchers to submit updated estimates and they indicated a need for 1,734 monkeys during fiscal years 1990 through 1992. This number far exceeds the number of suitable monkeys in AID's current inventory. The MIVR project officer wrote that these "projections may be somewhat inflated, but premature inventory reduction could be detrimental to progress if they are accurate". In addition to continuing uncertainty as to the number of monkeys needed, AID has new doubts about the continued availability of monkeys from Peru because of concerns expressed by PAHO officials.

In August 1989, AID officials told us that they now believe that only 440 monkeys should be sold. These are monkeys presently considered to be poor models or which have been used in vaccine trials. The remaining inventory will be retained and some subspecies placed in breeding programs. AID officials acknowledge that maintaining a large inventory will be expensive.

Peru, Colombia, and Bolivia have embargoes on monkey exports. As discussed above, Bolivia granted a waiver to its export ban in 1985 and, although Peru permits limited export of monkeys for research, many of the monkeys AID obtained from the PPP are considered marginally suitable for malaria vaccine research. AID is negotiating a 2-year, $600,000 grant with PAHO to support conservation and primate census activities in Colombia and Peru. AID hopes that these activities will permit the identification of surplus monkeys which could be imported for malaria vaccine research.

Subspecies Suitability and AID's Inventory

The suitability of monkeys for human malaria research is measured by their susceptibility to human malaria. Suitable monkeys, when exposed to human malaria, will develop a high level of infection and demonstrate no significant genetic protection against the human malaria being tested. CDC has conducted a number of screening trials which have identified a

limited number of subspecies which meet, to a greater or lesser extent, the susceptibility-to-infection criteria.

Table 4.1 presents AID's inventory of monkeys by subspecies as of March 1989 and by ranking of suitability for sporozoite or blood stage research on the two malaria species most dangerous to man. In April 1989, we asked CDC's leading expert on the use of monkeys in malaria vaccine testing to review this table and he indicated that it accurately reflected his views on the relative order of subspecies suitability. This table illustrates a number of points.

- AID's inventory included 508 Colombian Aotus and Bolivian Saimiri, the two subspecies considered to be most valuable for malaria vaccine research.
- AID had 526 karyotype I Peruvian Aotus, which have only a marginal suitability ranking. One AID official pointed out that while the ranking for these animals is relatively low, it could improve if a better parasite-monkey combination is discovered. She added that even a marginal parasite-monkey combination has value if the number of monkeys used is large enough and the variable response rates are understood and interpreted properly.
- AID's primate inventory included 237 Peruvian Saimiri, which are presently considered to be unsuitable for malaria vaccine research because they usually have high levels of infection with monkey malaria and other parasitic diseases when captured. These monkeys are among the group that will be sold.

Table 4.1: AID's Inventory of Monkeys, by Subspecies and Suitability Ranking, as of March 1, 1989.

Subspecies	Number of Monkeys	Percent of Total	Suitability Ranking[a]			
			P. falciparum vaccine		P. vivax vaccine	
			Sporozoite[b]	Blood Stage	Sporozoite[c]	Blood Stage
Colombian Aotus (K-II, III, IV)	160	11	•	(1)	•	(2)
Bolivian Saimiri	348	24	•	(2)	(1)	(1)
Peruvian Aotus (K-V, X, XI)	2	•	•	(3)	•	(3)
Peruvian Aotus (K-I)	526	36	•	(4)	•	(5)
Bolivian Aotus (K-VI)	23	2	•	(5)	•	(4)
Peruvian Saimiri	237	16	•	•	•	•
Other Saimiri	94	6	•	•	•	•
Unknown Aotus	60	4	•	•	•	•
Mixed Aotus	2	•	•	•	•	•
Total	**1,452**	**99**				

[a](1) represents the highest suitability ranking.

[b]No acceptable subspecies has been identified.

[c]Only Bolivian Saimiri subspecies deemed appropriate for testing P. vivax, anti-sporozoite vaccines.
Source: CDC documents and interviews

The acquisition of a large number of monkeys with marginal utility for malaria vaccine research and the difficulties in arranging for the disposition of monkeys after their use in vaccine trials might have been prevented if the Office of Health had developed a plan for managing AID's growing inventory of research monkeys, including a mechanism for periodically estimating needs and schedules for the acquisition and disposition of monkeys.

In a memorandum dated May 19, 1987, addressed to the Senior Assistant Administrator for Science and Technology, the Director of the Office of Health agreed to develop such a plan, stating that the Office of Health

"will develop a 5-year plan which outlines the needs (how many and when needed) for non-human primates in the malaria program and the expected sources.... Each year [the Office of Health] will prepare a plan outlining the number of animals to be procured, the source of the procurement (i.e., captive or semi-captive bred or wild population and the country and/or organization) and their destinations."

Such a plan had not been developed as of the end of our review. MIVR staff told us they had not been able to devote any time to this effort.

Delay in Disposing of Surplus Monkeys Costly

In July 1987, MIVR project officials began discussing with AID's Office of Procurement and Office of General Counsel the feasibility of establishing a mechanism for selling AID's large inventory of unsuitable and previously tested monkeys to interested researchers. The AID official responsible for coordinating this activity with the General Services Administration told us that competing work priorities had not allowed her to spend a great deal of time on this project and the mechanism was not finalized.

In April 1989, Battelle-Northwest proposed that it sell or otherwise dispose of these monkeys for AID. The MIVR project officer told us that the Office of the General Counsel has approved selling the monkeys through Battelle-Northwest, but the arrangement is awaiting a contract amendment. The project officer said that AID will require Battelle-Northwest to ascertain whether other government laboratories need any of the excess monkeys before it solicits offers from the private sector.

AID's delay in implementing a mechanism to dispose of surplus monkeys has been costly. At least $217,000 was spent to house the Peruvian Saimiri that AID began receiving in late 1987, and which were shortly thereafter deemed unsuitable for malaria vaccine research. This does not include the cost of housing monkeys used in vaccine trials and which could not be used for further studies.

Oversight of Animal Housing and Care Inadequate

AID awarded a 5-year, $9.5-million contract, effective October 1986, to Battelle-Northwest to establish a central housing facility for the care and breeding of AID-owned research monkeys. Some renovation was required to enable Battelle-Northwest to provide separate facilities for Aotus and Saimiri monkeys, which cannot be housed together. As a result, AID had to make other arrangements to house some monkeys arriving from South America.

In May 1987, AIBS arranged for the Perrine Center, an NIH facility operated under contract by the University of Miami, to temporarily house the monkeys it could not send to Battelle-Northwest. AIBS used a monthly purchase order arrangement to pay the Perrine Center based on a fixed daily fee for each monkey at the Center.

By March 1988, Battelle-Northwest had finished the renovation of its facilities and was able to house Saimiri monkeys. However, according to a MIVR project staff member, AID decided to leave a large number of monkeys at the Perrine Center because of its lower housing fees.

AID's decision to continue to house a large number of monkeys at the Perrine Center was not immediately formalized. AIBS did not sign a subcontract with the Center until April 1989, even though it had spent more than $210,000 to house an average of 400 monkeys between March 1988 and March 1989. The subcontract, which runs through September 30, 1990, has not been approved by the AID Office of Procurement, even though advance approval of subcontracts is required by AIBS' contract with AID. According to the contract officer, without an approved subcontract, AID does not have assurance that the terms and conditions of its contract with AIBS flow to the subcontractor and AIBS runs a risk that costs associated with the unapproved subcontract will be questioned and disallowed during an audit.

Perrine Center Does Not Meet NIH Guidelines

AID expects all network institutions housing AID monkeys to comply, at a minimum, with U.S. Department of Agriculture and NIH guidelines for the care and use of laboratory animals. AID monitors the quality of care provided to monkeys primarily through onsite visits by a team that includes a veterinarian who sees that inspection certificates are current, the animal care facility is adequate, and the monkeys appear to be in good health. Although the AIBS/Perrine Center subcontract requires the Perrine Center to follow NIH care and maintenance guidelines, the director of the Center told us that the Center does not meet NIH standards, primarily because of deficiencies in a building housing sick monkeys and monkeys in transit. A team composed of an AIBS official, MIVR staff member, and expert on animal welfare issues hired by AIBS visited the Center in July 1988. The consultant's report to AIBS after this visit noted the inadequate indoor facilities, stating that "[e]ach of the rooms is in dire need of renovation, as neither will meet the minimum standards for maintenance of laboratory primates." He also reported that "the facilities at the Center are limited, and are substandard, except for the 12 cribs" (cribs are outdoor facilities used to house Saimiri monkeys). The University of Miami's Animal Use Committee also reported in December 1988 that the facility did not meet NIH guidelines. In June 1989, the Director of the Center told us that many of these deficiencies had been corrected but that several planned actions had not yet been taken.

Monkey Databases of Limited Use

AID decided that centralized databases would benefit animal husbandry and breeding, disease diagnosis and treatment, and evaluation of malaria pathology and candidate malaria vaccines. However, databases developed with AID funding to provide inventory control and biomedical information on AID monkeys do not contain census information on all monkeys and had apparent limited use for researchers.

AID entered into a $750,000 cooperative agreement with Battelle-Northwest, effective September 1984, to develop, monitor, and coordinate demographic and biomedical databases for all AID-owned monkeys. However, external reviewers in 1986 and 1988 noted that network researchers had not submitted the data requested by Battelle-Northwest. The 1986 review report noted that the failure of some researchers to provide information had limited the quantity of information in the database. The 1988 review team noted that "the utility of the database is not immediately clear" and that network compliance with AID's data submission requirements ranged from total to minimal. They suggested that researchers might be more willing to provide information if the data were easily accessible and the researchers could interact with the databases.

Battelle-Northwest's proposal for a new cooperative agreement to begin in late 1989 was reviewed by AID's pre-award review panel in February 1989. The panel noted that little effort had been placed on assuring the integrity of information in the databases. It concluded that lack of information on controls reduces the credibility of any statistics derived from the databases. AID rejected Battelle-Northwest's proposal but approved a short extension for the data management subproject to allow AID and Battelle-Northwest time to reassess AID's data management needs. Battelle-Northwest has indicated that it intends to submit a new proposal when these needs have been clarified.

Incomplete Demographic and Census Information Reduces Accountability for Monkey Inventory

AID established a policy that each of its monkeys would be tattooed with an individual identification number so that it could account for and keep individual health and research records on monkeys in its inventory. Battelle-Northwest has been unable to collect demographic information on all AID-owned monkeys because (1) those monkeys at the Perrine Center are not tattooed with identification numbers and the Center does not collect information on individual monkeys and (2) network researchers have not submitted accurate inventory records.

Many monkeys housed at the Perrine Center have not been tattooed with AID identification numbers and the April 1989 subcontract between the Center and AIBS does not require tattooing. The AIBS project director told us that AID had not asked the Center to tattoo these monkeys because those selected for research would be tattooed by the receiving network facility and there was no need to tattoo monkeys or collect information on the remaining monkeys which AID had decided to sell.

OIG auditors found that the University of Hawaii had purchased monkeys with AID funds and had not disclosed that fact to AID. They also determined that the inventory submitted by New York University omitted eight AID-owned monkeys. The manager of the Battelle-Northwest database told AID in April 1989 that some researchers have "chosen to hide animals in their colony by not defining them in the data base." He told us he believed that researchers did this to avoid comprehensive review by AID's Primate Use Committee and to keep their work as confidential as possible.

Conclusions

AID's poor planning and management of the acquisition and care of its large inventory of research monkeys resulted in the waste of project funds. For example, we found that AID

- acquired monkeys of limited use to malaria vaccine research;
- purchased more than 300 monkeys under questionable circumstances;
- wasted funds to house surplus and unsuitable monkeys;
- had not determined the number and mix of monkeys it should retain for network research purposes;
- did not develop an adequate acquisition and disposal schedule or mechanism to dispose of surplus monkeys; and
- maintained primate databases with little apparent use to network researchers and which did not provide complete census information for inventory accountability purposes.

A comprehensive, inventory management plan, developed and updated with advice from AID's Primate Use Committee might have prevented many of the costly errors we identified.

Recommendations

We recommend that the AID Administrator develop a comprehensive management plan to be periodically reviewed by AID's external scientific advisors and updated to reflect new information and scientific developments; the plan should include

- an assessment of the suitability of specific Aotus and Saimiri species for malaria vaccine research;
- an assessment of future needs and a corresponding plan for acquiring suitable primate species;
- an evaluation of the usefulness of efficacy trials in monkeys and how AID will use data from such trials in deciding to approve and support human clinical trials; and
- plans for disposing of unsuitable and surplus monkeys.

We also recommend that the AID Administrator

- ensure that research monkeys receive appropriate care and are housed only in facilities meeting NIH standards;
- ensure that all AID-owned monkeys are individually tattooed and included in AID's centralized inventory system; and
- reexamine the MIVR project's primate databases and (1) stop collecting unnecessary information, (2) ensure the integrity of any information collected, and (3) ensure that information is easily accessible to network researchers.

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