



U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

MEMORANDUM

TO: DA/AID, Carol Lancaster

FROM: AA/G, Sally Shelton *SS*

SUBJECT: Report of the External Review of the Office of Health and Nutrition Research

It is my pleasure to provide you with the final report, "External Review Meeting Summary: Office of Health and Nutrition Research Portfolio."

The panel of experts invited to the Review, found the HN research portfolio to be balanced, targeted and results-oriented. They cited several examples of research activities which made critical contributions to sustainable development including: input into setting worldwide health priorities, research to change health practices and health-seeking behavior, technologies such as Oral Rehydration Salts, and key elements of nutrition interventions. The Review Panel recommended that the Agency develop a vision for research capacity building which encourages existing and new models for institution building. Other recommendations focused on gleaning lessons learned from USAID's field experiences, providing flexible funding for research, and allowing for some risk-taking and failures.

Overall, the expressed feeling from OHN has been that the review process initiated by your office has been a successful as well as a useful endeavor. The OHN staff and I are available at any time to discuss any item in the Report or plans being made to follow up on some of the recommendations. Your continued guidance and support for this activity are much appreciated.

cc:
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Clearance:

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EXTERNAL REVIEW MEETING SUMMARY OFFICE OF HEALTH AND NUTRITION RESEARCH PORTFOLIO

INTRODUCTION

An external review meeting on USAID's Health and Nutrition's (HN) research portfolio took place on May 10, 1995 in Rosslyn, Virginia. Six experts were convened to provide advice on the overall performance and direction of HN's research efforts, and to answer specific questions posed by the Agency Research Council (ARC) to all sectors. Invited experts included:

Dr. Lincoln Chen
Chairman, Department of Population and International Health
Center for Population and Development Studies
Harvard University

Dr. Dennis Foote
President, Applied Communications Technology

Mr. Davidson R. Gwatkin
Director, International Health Policy Program

Dr. Robin Powell
Chairman, Scientific Consultants Group
USAID's Malaria Vaccine Development Program

Dr. Beatrice Selwyn
Associate Professor of Epidemiology
School of Public Health
University of Texas at Houston

Dr. Daniel Tarantola
Director, International AIDS Program
François-Xavier Bagnoud Center for Health and Human Rights
Harvard University

BACKGROUND

The Agency Research Council (ARC) conducted reviews of the current USAID research portfolio in order to advise senior management on the short- and long-term research investment needs within the Agency. As part of this process, an external review of the Agency's health and nutrition research portfolio was convened to assess:

1. Strengths of the portfolio
2. The unique role of USAID in HN research
3. Critical gaps in the portfolio
4. Emerging issues that will require the Agency's attention
5. Appropriateness of the portfolio composition given diminishing resources
6. Adequacy of the peer review process and coverage of ethical biosafety issues.

Six professionals representing a broad range of expertise were invited to participate in the May 10, 1995 meeting. The expert reviewers were provided with background materials on HN research within USAID, an agenda (Annex A), and a set of questions (Annex B) prepared by USAID's Bureau of Policy and Program Coordination (PPC). These questions addressed three major topics of concern to the ARC: 1) Research Balance; 2) Capacity Building; and 3) Research Management.

SUMMARY

The one-day experts' review meeting was opened by Duff Gillespie, Deputy Assistant Administrator, Center for Population Health and Nutrition, Bureau for Global Programs, Field Support and Research (Global Bureau), and by Fran Carr, Senior Science Advisor, PPC. Both highlighted the importance of HN research to meeting the Agency's objectives and underlined the importance of planning ahead to ensure that the substantial investments and gains from important HN research initiatives are not compromised as USAID continues to face ever decreasing budgets.

Staff from the Office of Health and Nutrition (OHN) in the Global Bureau provided the reviewers with a summary of USAID's HN research portfolio and highlighted priorities, types of research, management of research and major areas of activity (Annex C). The morning's proceedings included specific summaries and discussions in the following topical areas: Child Health, Malaria Vaccine Development, Maternal and Reproductive Health, HIV-AIDS, and Health Systems and Policy Reform. The reviewers were given time to comment and raise questions.

The group had a working lunch with Senior Deputy Assistant Administrator, Global Bureau, Ann VanDusen. Robert Clay, Deputy Director, OHN then led the formal discussion of the PPC questions surrounding portfolio balance, capacity building and research management.

The expert reviewers carefully noted the constraints under which they were operating. One day was too short a time for them to comprehensively answer the questions that were raised, especially those with strategic implications. As such, the group did not make recommendations, but rather, offered observations based on their experience and the day's presentations and discussions.

The HN research portfolio was judged to be balanced, important and well respected. It was felt that budget cuts have hurt the Agency in terms of research content and leadership, and the narrow definition of research used by the Agency to account for what it does, may hurt as well.

Suggestions focused on concentrating research on gleaning the lessons learned from USAID's field experience, providing flexible funding for research, and allowing for some risk-taking and failures. USAID is urged to develop a vision for research capacity building which encourages existing and new models for institution building, and for sustaining the gains in capacity building. The management of USAID research is well-respected, though at times inflexible. More attention needs to be paid to some of the sample sizes of field surveys and operational research with a view to being more cost effective. And, finally, USAID should reach out to U.S. foundations as possible partners for the future.

Results of the day's discussions were presented to Deputy Administrator, Carol Lancaster, who reiterated the Agency's interest in continuing to support research. She particularly expressed interest in exploring the ideas of large, field-based research on USAID interventions, and flexible funding and quick response mechanisms. Ms. Lancaster expressed her thanks and gratitude to the members of the external review group.

Following is a brief summary of points made by the group.

SESSION SUMMARIES: OBSERVATIONS OF THE EXPERT GROUP

The Balance of Research

Portfolio is balanced and important. A strong consensus was voiced that the HN portfolio is balanced and well respected. The topics in the present portfolio are of worldwide importance, and historical evidence exists that USAID has been at the helm of various technological and behavioral research breakthroughs. Input into setting worldwide health priorities, research to change health practices and health seeking behavior, technologies such as Oral Rehydration Salts, and key elements of nutrition interventions were all cited as critical contributions to sustainable development and improvements in health at the global level. None of the reviewers suggested cutting out particular areas of research, and many questioned whether there was a way USAID couldn't protect research budgets. USAID was advised to examine the findings of a multi-donor review now underway on priorities for health research in the next century. (OHN staff have and will continue to follow the review.)

Budget cuts hurt. USAID has been a leader in research but by reducing resources and cutting back on its technical capabilities, its leadership position has eroded. The effect of this is especially felt by those who were receiving funding. Overall leadership, as in setting priorities and encouraging others to assume responsibility, has also suffered. (No mention was made of narrowing research priorities.)

A narrow definition of research could hurt. The ARC definition for research was included in the materials sent to the reviewers prior to the meeting, and the issue of having a set definition across the entire Agency became an issue for discussion. The definition reads as follows:

The systematic investigation of a well defined problem. USAID supports research that is intended to produce knowledge that will offer solutions to specific development challenges. This includes the spectrum of research that is required to foster marketable technology. The research process incorporates a well-defined hypothesis, a defined methodology for the gathering of information, analysis of data, and for interpretation of the data to formulate conclusions. This definition includes research, experimentation and product development in all fields.

This definition excludes routine product testing, quality control, geographic mapping, collection of general purpose statistics, experimental production, and routine monitoring and evaluation of an operational program. Research for the sole purpose of training scientific and technical personnel is not included.

While no one criticized the definition itself, two concerns were raised about setting up artificial constraints on how to define and prioritize USAID's research portfolio:

First, USAID was warned against being too rigid. If a multi-year research effort requires a minimal amount of discovery research or survey research, it should be considered on a case-by-case basis. The point made was that any "definition" needs to be accompanied by good judgment.

Second, while the Agency narrowly defines its research portfolio (representing approximately 10% of the entire HN budget, and approximately 30% of the OHN budget), most of the remaining activities the Agency does could, in fact, be considered as a large operational research laboratory to test approaches to sustained development, population stabilization, and improving human health. USAID's field presence and U.S. research capabilities join to provide this Agency with a comparative advantage for national-level findings. (This recommendation will be considered as plans proceed for a new PHN evaluation project next fall.)

While various aspects of the issue were discussed, considerable conversation focused on the importance of research methodologies to improve the quality of data within survey instruments. Sample size, for example, could be addressed to improve the quality of operations research, i.e., extrapolations and conclusions of success are often made from too small a sample, or too large a sample is used to reach a conclusion that could have been reached with a smaller sample, thereby saving money and time.

Research should focus on USAID's lessons learned. A corollary to the point made above is that USAID has a comparative advantage in behavioral research but has not had the resources to look across projects for lessons learned, or generalizable results. In project evaluations there is no common language used that allows cross comparisons. In many cases, evaluators are collecting information that justifies future funding. While individual evaluations may be done well, the evaluation of different kinds of behavioral approaches have not been effective.

Provide flexible funding. USAID needs to think about having available some "flexible funds" (5-10%) to encourage groups, individual researchers, institutions, foundations, and universities, to think with the Agency about emerging issues, issues of interdependency not captured in particular programs, and the impact or relevance of disease outbreaks (e.g. Ebola virus in Zaire) to USAID's program. An enormous unrealized opportunity is being ignored considering the enormous value of USAID's field programs as operational research, the lack of flexible funds across sectors and organizational units within USAID, and entrée to use field programs as laboratories. This is aside from a few cases where considerable coordination is exercised on the part of the Global Bureau, field missions, regional bureaus, and host country institutions.

Make room for failure. Good research should anticipate and plan for what is not known. Some research should fail, or appropriate risks are not being taken. USAID's current system is not flexible enough to accept failure. Of necessity, the Agency is instead oriented towards immediate results and success stories. However, there needs to be recognition of the requirement for long-term investment and the potential for failure in order to progress. USAID's investment in ORT was presented as an example of risk taking that would not happen under a "results oriented" approach to development. USAID's flexibility has diminished over time and without flexible funding and contracting mechanisms, research that advances the state-of-the art cannot be accomplished. Certainly fast-track research into emerging issues is severely limited without flexibility.

Research Capacity Building

Agency vision needed. The current focus for USAID's program is results-oriented, with capacity building as an ancillary benefit. If the Agency is serious about capacity building, they need to invest more resources (money and time) into it. The group pointed out the necessity of the Agency being clear about its goals for research capacity building. It was estimated that to train a good scientist costs about \$225,000. Further, it was noted that two- and three-week training courses don't create a good researcher nor do they sustain the newly acquired skills of the researcher. The group asked USAID to reflect on its vision of its mandate regarding capacity building, and to develop capacity building strategies that can overcome some of the obstacles posed by current programming. This could include such items as how to undertake capacity building during times of political turmoil and instability in host countries.

Encourage models for institution building . While it was mentioned that American universities represent an enormous untapped resource, it was pointed out that there has tended to be a bias in investing in national research institutions. Models for capacity building were discussed in cases where general agreement exists that host country institutions should be involved in research or better empowered to take on a particular research agenda. One model suggested putting money into in-country research institutions and asking them to put out bids for collaboration with U.S. institutions. Another suggested an approach already found to work: the encouragement of long-term sister relationships between institutions.

Work to sustain positive changes. The important role of in-country institutions in supporting the continuing development of a researcher was pointed out, i.e., in many cases, the structures that are in place don't support the capacity that has been created. It was also pointed out that there is often no career ladder for the researcher and that good researchers are often pulled out of the public sector into the private sector. The group also discussed how many of the best institutions and researchers are oversubscribed precisely because they house the best researchers and everyone knows how difficult it is to train new ones. It was agreed that capacity building implies long-term institutional support and that USAID's current focus on results does not allow for this kind of long-term investment, though various Mission level programs do continue to contribute to human capacity building more directly through bilateral programs.

Research Management

Add some flexibility to a solid approach. The group looked favorably on management of the OHN portfolio. Both the peer review process and the use of human subjects appear to follow generally accepted practices. USAID has set up and is adhering to peer review procedures that are admirable but in some circumstances, may be overdone. With regard to peer review and evaluation of proposals, for example, it was noted that in some cases, such as the early work done on HIV/AIDS behavior change, USAID's review process was perhaps too strict and slow. The suggestion was made that USAID experiment with fast tracking some types of research, especially for research relating to emerging diseases.

Review sample plans. Regarding internal efficiency, it was noted that often in research studies, samples are too small or too large, and much of what is described as research is not. Studying the effects of projects without an adequate design, is not really research. More care needs to be given to planning field activities when research results are expected as an outcome.

Improve research dissemination. Though publishing articles in scientific journals is one way to get information out to the public, in many cases, developing countries have neither the luxury of journal subscriptions nor are they in an environment that encourages habitual reading. USAID needs to encourage researchers to be sensitive to the dissemination issue. On the other hand, one of the Agency's strengths has been to promote the application of research results to policy, but the Agency has had more opportunities for leadership than it has taken. One suggestion was to issue an RFP soliciting opinions on how to best disseminate research, thus encouraging and supporting innovative ideas.

Review partnerships with U.S. foundations. While various opportunities for donor coordination are apparent in the HN portfolio, and some direct relationships among donors have been set up within particular research areas of study (e.g. Malaria; WHO programs), most partnerships are limited to organizations that receive funding from USAID. Given the budgetary pressures to have a wider impact with less funding, USAID should concentrate on possibilities for partnerships with

U.S. foundations. Initiating and renewing such partnerships is important, but will not be easy as many foundations have, in the spirit of cultural appropriateness, directed much of their attention to developing country institutions.

OHN Presentations

Constance Carrino, Chief of the Health Policy and Sector Reform Division (HPSR), summarized the February 22, 1995 presentation to the Agency Research Council (ARC) on Health and Nutrition Research. Ms. Carrino noted budgetary trends, areas of concentration, issues surrounding research quality and future directions. Since that review, the Office of Health and Nutrition estimates that between 35% and 39% of its entire FY 1995 and FY 1996 budget will be directed to the various research topics covered below. Research as a percentage of the HN portfolio worldwide is expected to remain between 10% and 12%.

Caryn Miller, Manager for Child Health Research, presented the OHN research activities in child health and nutrition. Issues discussed included funding, causes of death, global burden of disease, and the effects of malnutrition on infectious diseases. Research priorities within child health and nutrition are driven by the magnitude and severity of the problems.

Steve Landry, Manager for the Malaria Vaccine Development Program (MVDP) discussed the program. Following substantial budgetary cuts over the last several years, the MVDP has successfully leveraged the resources of others (NIH, WRAIR, TDR) to accomplish their goals. The program is also collaborating with the EC and with individual countries to work out agreements to test promising vaccine candidates. The MVDP may well represent a model for other collaborative research initiatives.

Beth Plowman, a Strategic Objective team leader for the OHN, discussed research in reproductive health, a relatively new initiative within the Agency. The priorities within the program are family planning services, safe pregnancy, nutrition and promotion of breastfeeding, and the prevention and management of HIV-STDs. USAID's field work in developing country settings continues to be at the forefront of understanding the risk factors contributing to maternal deaths.

Barbara de Zalduondo, co-team leader for the HIV/AIDS Strategic Objective team, discussed research within the HIV/AIDS portfolio. Research priorities within HIV/AIDS are to improve HIV/STD risk behavior change interventions, identify and evaluate female-controlled barrier methods, and identify and evaluate STD diagnostic and management tools for low-resource settings.

Constance Carrino presented the Health Sector Policy Reform research agenda. The two major paths of USAID research in this field are: 1) finance and management within the reform process; and 2) quality assurance. USAID has taken a leadership role in research on how to improve the priority setting and cost effectiveness of health programs, the development of successful models of public/private partnership for health, and on how to improve client provider interactions and scale up programs to a national level.

Agenda For
the External Review of USAID's Health and Nutrition Research Program
May 10, 1995
Room 1104, 1601 N. Kent, Arlington, VA (SA-18)

MODERATOR: *Constance Carrino, Acting Deputy Director, Office of Health and Nutrition*

- 8⁴⁵ - 9 Introduction - Remarks (include mandate for group)
Duff Gillespie, Deputy Assistant Administrator for Population, Health and Nutrition
- 9 - 9²⁰ Background - ARC, Agency Policy on Research, Agency Organization and Role vis a vis Research, Budgeting Process
Francis Carr, Senior Science Advisor
- 9²⁰ - 9⁴⁵ Overview of H/N Research within USAID, including USAID's comparative advantage
Constance Carrino
- 9⁴⁵ - 12³⁰ Portfolio review (highlighting priorities, types of research, research management, and major projects):
1) Child Health (*Caryn Miller*)
2) Malaria and Emerging Diseases (*Steven Landry*)

--ten minute break--

- 3) Maternal and Reproductive Health (*Beth Ann Plowman*)
4) HIV/AIDS (*Brazey DeZalduondo*)
5) Health Systems and Policy Reform and other cross-cutting areas
(*Constance Carrino*)
(Fifteen to thirty minutes for each of the five areas, including a presentation by an Office staff member for each and follow-up discussion)
- 12³⁰ - 1³⁰ Lunch

MODERATOR: *Robert Clay, Acting Director, Office of Health and Nutrition*

- 1³⁰ - 1⁴⁵ *Nils Daulaire, Senior Policy Advisor for Population, Health and Development, PPC*
USAID Investments in Health and Nutrition: Goals, Strategies and Priorities
- 1⁴⁵ - 2³⁰ Balance of Research
Identifying research gaps and assessing the level of effort
Discussant: *Lincoln Chen*
Facilitator: *James Heiby*
- Open discussion

2³⁰ - 3³⁰ **Research Capacity Building**
Improving the effectiveness of, and support for, research capacity building
Discussant: *Davidson Gwatkin*
Facilitator: *Constance Carrino*

Open discussion

--ten minute break--

3⁴⁰ - 4¹⁵ **Research Management**
Assessing peer review, monitoring, coordination, leveraging, and dissemination efforts. Identifying other elements and models for research management
Discussant: *Daniel Tarantola*
Facilitator: *Caryn Miller*
Open discussion

4¹⁵ - 5 **Oral Report to Carol Lancaster, Deputy Administrator**

Summary and Conclusions: *Dawn Liberi, Associate Assistant Administrator for Population, Health, and Nutrition, and Robert Clay*

Discussion and clarifications: *Members of the ERG*

Closing Remarks: *Carol Lancaster*

April 17, 1995

**Discussion Questions for
the External Review of USAID's Health and Nutrition Research Program**

1. **Balance of Research**
 - a. Are there research areas neglected by others that would address the major problems of developing countries and conform to USAID's mandate and priorities?
 - b. Given USAID's strategic objectives in the health and nutrition sector, are there important research needs that are not being addressed?

2. **Research Capacity Building**
 - a. How does the research portfolio contribute to building developing country research capacity, and how could USAID make its efforts more effective?
 - b. What are the advantages and disadvantages of strengthening international research centers versus national research institutions?
 - c. How can USAID best argue the importance of building research capacity?
 - d. What is the most appropriate role for U.S.-based research institutions in building research capacity in developing countries? What mechanisms would the committee recommend for developing this role?

3. **Research Management**
 - a. Comment on USAID's use of peer review and selection and monitoring of research. Comment on the level of coordination and leveraging. What other elements might improve the management of the research program?
 - b. How well does USAID disseminate and use the results of HN research studies?
 - c. How effective was USAID's Research Advisory Committee (RAC)? Are there lessons learned from that arrangement?
 - d. Are there good alternative models for the management of research that USAID might adopt (eg. IDRC, SAREC)?

Health and Nutrition Research Portfolio Review

Agency Research Council
February 22, 1995

- I. Population, Health, and Nutrition at USAID
 - A. Why population, health, and nutrition at USAID?
 - B. Why research in population, health, and nutrition at USAID?
- II. The Health and Nutrition Research Portfolio
 - A. Priority Areas for Health and Nutrition and Their Relationship to Agency Goals
 - B. Guiding Principles for Selecting Research Priorities
 - C. Research Portfolio Summary
 - 1. Child Health Research
 - 2. Maternal Health Research
 - 3. HIV/AIDS Research
 - 4. Health Systems and Policy Reform Research
 - D. Research Trends and Allocations
 - E. Quality Assurance
 - F. Donor Collaboration
 - G. Issues
- III. Appendices
 - A. Summaries of Health and Nutrition Research Projects Supported by USAID's Global Bureau.
 - B. Summaries of Health and Nutrition Research Projects Supported by USAID's Regional Bureaus.
 - C. Summaries of Health and Nutrition Research Projects Supported by USAID Missions.

I. Population, Health, and Nutrition Research at USAID

A. Why Population, Health, and Nutrition at USAID?

Investments in population, health, and nutrition (PHN) aim to reduce the burdens of overpopulation, high mortality, and high morbidity that seriously hamper sustainable development. Better health and nutrition and lower fertility are crucial to broad-based economic growth and human development because they increase productivity, improve enrollment and performance of children in school, free resources that would otherwise have been used to treat illness, and ensure greater opportunities for those most handicapped by ill health, namely, women, children, and the poor. PHN investments in developing countries also benefit donor countries, including the United States. Healthy, stable populations abroad mean healthier citizens at home who can live in confidence that their children's children will be able to enjoy the same basic human rights they have now. Healthy, stable populations abroad also mean improved U.S. national security because disease and overpopulation increase the risk of armed conflict and the need for expensive humanitarian assistance.

B. Why Research in Population, Health, and Nutrition at USAID?

Research in PHN is needed if USAID is to achieve its strategic goals in the population, health, and nutrition sectors and if better health and lower fertility are to be sustained. The World Bank's *1993 World Development Report* calculates the enormous payoff for research investments targeted at the major health problems in developing countries. Research provides new and more cost-effective interventions and ensures that existing interventions are implemented more effectively. It empowers developing country decision makers, from the household level to the national level, by providing them with more accurate information and new options. Finally, when research is conducted in developing countries, it not only fosters a problem-solving culture but also builds indigenous capacity for responding to rapidly changing health problems. Thus, investments in PHN research reap diverse, rich rewards that include, but are not limited to, the improvement of health.

Among U.S. government agencies, USAID has the mandate and the perspective for supporting research pertinent to the unique problems of developing countries. Because of its field presence, USAID is uniquely positioned to define local problems, specify the research agenda accordingly, and implement the results of the research. Population, health, and nutrition research focused on field needs and priority global issues is an historic strength of USAID. USAID has played a leadership role in applied research that is unparalleled by other donors. This research has benefitted many countries because of its global relevance, thus compounding USAID's investments. Policy and program improvements stemming from USAID-supported research have been crucial to the remarkable reductions in population growth and childhood mortality.

II. The Health and Nutrition Research Portfolio

A. Priority Areas for Health and Nutrition Research and Their Relationship to Agency Goals

Stabilizing population growth and protecting human health are fundamental strategies for achieving USAID's goal of sustainable development. Priority areas for USAID's health and nutrition (HN) research program are:

- o Infant and child health,
- o Maternal health,
- o HIV/AIDS, and
- o Health systems and policy reform.

HN research in these areas is necessary for achieving the subgoals of USAID's PHN program, which are:

- o A reduction in maternal mortality by one half before the year 2000,
- o A reduction in child mortality rates by one third before the year 2000,
- o A decrease in the rate of new HIV infections by 15 percent before the year 2000, and
- o A total world population of between eight and nine billion by the year 2025, and of less than 10 billion by the year 2050.

The HN research program also contributes to USAID's other sustainable development strategies by (1) building human capacity, (2) identifying and evaluating environmental interventions which impact on health, (3) addressing emerging and re-emerging health threats, (4) improving health care services across the socio-economic spectrum, and (5) empowering women.

HN research advances the achievement of these goals and strategies by 1) identifying, developing and evaluating new and improved interventions, 2) developing indigenous capacity for addressing research priorities through institution and human resource development, and c) addressing health policy and sector reform related to the priority areas.

B. Guiding Principles for Selecting Research Priorities

The HN research program¹ adheres to the following guiding principles when selecting its research priorities. The research should:

- o Contribute to the achievement of USAID goals and strategies,
- o Build indigenous capacity to design and implement research for addressing current and future health issues,
- o Be a priority for developing country and international decision-makers,
- o Be likely to produce useful knowledge within a specified period of time at a reasonable cost,
- o Provide new cost-effective interventions and ensure that existing interventions are implemented more effectively,
- o Aim to overcome key constraints to successful program implementation,
- o Address questions unlikely to be adequately addressed by others,
- o Serve a catalytic effect (eg. leverage resources from other sources),
- o Take advantage of targets of opportunity, and
- o Be conducted in accordance with U.S. government standards for ethical conduct and scientific responsibility.

The criteria for selecting research priority areas are outlined more explicitly in USAID's Research Policy document. USAID staff receive the advice of external technical advisory and ad hoc consultative groups for the identification of global research priorities. Country level input is provided by USAID missions and national policy makers and implementors. Priority areas are redefined during the course of project implementation. Mid-project external evaluations are a primary method for redefinition.

¹Unless otherwise noted, research discussed in this report conforms to USAID's definition of research, which is:

The systematic investigation of well-defined problem. USAID supports research that is intended to produce knowledge that will offer solutions to specific development challenges. This includes the spectrum of research that is required to foster marketable technology. The research process incorporates a well-defined hypothesis, a defined methodology for the gathering of information, analysis of data, and for interpretation of the data to formulate conclusions. This definition includes research, experimentation and product development in all fields.

This definition excludes routine product testing, quality control, geographic mapping, collection of general purpose statistics, experimental production, and routine monitoring and evaluation of an operational program. Research for the sole purpose of training scientific and technical personnel is not included.

C. Research Portfolio Summary

1. Child Health Research

a. Problem: Child survival programs have achieved dramatic decreases in mortality among children under five years of age. Nevertheless, 12.2 million children under five still die each year in the developing world. The World Health Organization estimates that 34% of these deaths are due to acute respiratory infections, 25% to diarrhea, 20% to perinatal causes, and 6% to malaria. An estimated 29% of all childhood deaths are associated with malnutrition. The World Bank's *1993 World Development Report* has ranked diseases according to their contribution to premature death and disability. The top contributors to this burden of disease and the percent of total disability-adjusted life years (DALYs) lost to each disease are: respiratory infections (9), diarrhea (7.3), perinatal causes (7.3), neuropsychiatric disease (6.8), cancer (5.8), and vaccine-preventable childhood infections (5.0).

The key constraints hampering sustainable child health improvements and reductions in the number of child include:

- i. Lack of feasible cost-effective interventions for preventing pneumonia, diarrhea and malaria;
- ii. Lack of more cost-effective interventions for treating illness in malnourished children and infants less than two months of age;
- iii. Lack of more effective treatment interventions for persistent diarrhea and drug-resistant shigella, malaria and pneumonia;
- iv. Inability of health workers to diagnosis and treat overlapping conditions;
- v. Poor nutritional status, especially that resulting from inappropriate breastfeeding and weaning practices;
- vi. Limited indigenous capacity for performing high quality health research to guide policy and implementation;
- vii. Uninformed policy makers and implementors, and lack of national commitment to child health;
- viii. Inappropriate treatment by health care providers and inappropriate care-seeking behaviors and compliance by care givers.

b. Research priorities: Emphasis is placed on the major causes of mortality and morbidity in children under five and on the key constraints to sustainable improvements in child health.

Research in prevention focuses on the development and evaluation of:

- i. Integrated prevention packages, including cost-effectiveness analyses where needed;
- ii. Vaccines for ARI, diarrhea, and malaria;
- iii. Behavioral and environmental interventions especially at the household and community levels (ARI, diarrhea, nutritional deficiencies, and malaria);
- iv. New approaches for improvement of nutritional status (especially during the weaning period) through complementary feeding, supplementation, fortification, and improved processing, preservation, and safety of foods;
- v. Ways to address the cycle of nutrient deficiencies, impaired growth and development, and disease.

Research in case management focuses on the development and evaluation of:

- i. Integrated approaches for improving child health (eg. treatment algorithms and training materials evaluated in a variety of settings);
- ii. Improved formulations of oral rehydration solution (ORS), as well as behavioral interventions to improve correct use of ORT;
- iii. Nutritional approaches to case management and rehabilitation;
- iv. Simple, inexpensive, and readily available diagnostics for anemia, malaria, and pneumonia;
- v. Improved ways to train health care providers and communicate with mothers to assure correct diagnosis, referral and treatment;
- vi. New drug regimens for the treatment of ARI, diarrheal diseases, and malaria and methodologies for monitoring drug resistance;
- vii. Effective treatment of invasive and persistent diarrhea;
- viii. Targeted interventions to prevent illness in the young infant.

Research in child health and nutrition is also aimed at developing indigenous capacity to identify and solve local health problems. This research focuses on:

- i. Implementation of high quality epidemiological, clinical, social science, and laboratory research by developing country researchers;
- ii. Limited institutional strengthening;
- iii. Documentation, analysis, and dissemination of the processes by which research results are most effectively translated into policy and programs;

- iv. Development of methodologies for program monitoring and evaluation, including indicators for institutional and human resource capacity building;
- v. Facilitation of south-to-south collaborations and technical assistance.
- vi. Improved dissemination of health and nutrition research results to policy makers and implementors.

Improvements in case management of ARI, diarrheal disease, nutritional deficiencies, and malaria are most likely to result in decreases in under-five mortality over the short-term. However, over the long term socio-economic improvements, preventive strategies, and integrated approaches to treatment and delivery of services will decrease morbidity as well as mortality and may prove to be more cost-effective and sustainable.

c. Selected research achievements: USAID has played the leading international role in support for applied health and nutrition research. Both short term and long term research have shown impact on country programs and child mortality. A list of achievements for current projects are listed in the appendices. Selected achievements include:

The development and evaluation of new interventions

Seminal research on the development of oral rehydration solutions (ORS), and clinical trials demonstrating efficacy of oral glucose saline solutions, which is the cornerstone of diarrheal disease control programs.

Development of a vaccine vial monitor (heatmarker) to reduce vaccine wastage and increase immunization effectiveness. WHO/UNICEF has revised their open vial policy and approved use of the monitors for selected vaccines.

Development and evaluation of a dietary treatment algorithm for the management of persistent diarrhea, which is estimated to cause 30 % of all deaths from diarrhea in children under 5, was developed and evaluated in a multicenter trial. The overall success rate of the algorithm was 90% and has been recently incorporated into WHO guidelines.

Research on the etiology and epidemiology of acute respiratory infections in children in the early 1980's laid the groundwork for the case management strategy developed by WHO. The research also guided the development of a vaccine for pneumococcal pneumonia which would be appropriate for use in developing countries.

Education and managerial intervention studies in a Mexican Social Security clinic significantly reduced the proportion of children who received antibiotics and antidiarrheals, increased ORS use, and improved patient compliance. The methodology was extended to 17 clinics, with medication costs decreasing by 36% and medication wastage decreasing by 51%. A new strategy for diarrhea case management is being implemented in 12 Mexican states.

Development of an integrated treatment algorithm and training materials to address the major causes of childhood illness: The materials will facilitate treatment of multiple conditions by the healthworker, address missed opportunities for immunization and provide nutritional counseling.

Handwashing using mud or ash was found to be nearly as effective as soap in reducing bacterial contamination of hands after defecation. This provides an effective preventive intervention where soap is not available.

Discovery of a tissue culture system growing liver-stage parasites in the laboratory. This methodology provided access to parasite materials that were previously unavailable for study. It also provided a means for laboratory testing of sporozoite vaccine candidates.

Application of the technique of immunoelectron microscopy to the localization of malarial parasite antigens. This technique has proved to be extremely important as a means of screening potential antigens as possible vaccine candidates.

A diarrhea morbidity and treatment study in Bangladesh reported higher levels of ORS use in more severe diarrhea but low levels in young infants, resulting in changes in the social marketing for ORS.

The high titer E-Z measles vaccine was found to lead to increased delayed mortality in girls and, as a result, policy stipulated that the vaccine would not be used.

Demonstration that candidate malaria vaccines are safe and immunogenic in humans. In addition, these studies have established a mechanism for experimentally challenging study subjects using virulent strains of human malaria in insectary-reared mosquitos.

Research showed the important relationship between measles, blindness, and Vitamin A status. Vitamin A supplementation is now part of the WHO protocol for treatment of measles and has reduced mortality by 50% in areas where Vitamin A deficiency is a public health problem.

The enhancement and evaluation of existing interventions

Demonstration of the limitations of the old injectable cholera vaccine in the control of epidemics and the prevention of transmission. Research to identify safe and effective vaccines against cholera and other diarrheal disease continues.

Thirty years of demographic studies in Matlab, Bangladesh are having a worldwide impact in advancing appreciation and understanding of the dynamics of impoverished populations and rural populations and form the basis for the targeting of health and family planning programs across the globe.

Low osmolarity ORS solutions were shown to reduce stool output and treatment failure in comparison with standard ORS when used in children with acute non-cholera diarrhea. A new formulation will undergo large scale testing and analysis will provide data for potential changes in formulation world-wide.

In Pakistan, research carried out by a medical college In Lahore showed the dangerous side effects of antidiarrheal drugs, a treatment commonly used for children's diarrhea. The government responded by prohibiting the use of these drugs. Sixteen other developing countries have followed suit.

Vitamin A supplementation was found to be associated with a reduction in the incidence and duration of severe diarrhea episodes, thus supporting the promotion of Vitamin A-rich foods and Vitamin A supplementation in children greater than 6 months of age.

In Pakistan, facility and community-based trials of cotrimoxazole, the drug of choice for outpatient treatment for pneumonia, showed that the drug was effective in 91% of cases despite laboratory data showing high levels of drug resistance. At a savings of \$1.85/episode compared to the alternative drug, the Pakistan ARI program will continue to use cotrimoxazole, thus saving millions of dollars.

Child mortality decreases of at least 23% in Vitamin A-sufficient populations were verified through meta-analysis of research trial results. Vitamin A supplementation programs are underway in over 100 countries.

Low birth weight infants cared for with the Kangaroo Mother Method (infant kept upright in skin-to-skin contact with the mother's breast) had significantly lower rates of serious illness. Their mothers made more unscheduled visits to the clinic but the infants had fewer readmissions to the hospital so costs were lower.

The development of indigenous research capacity

Since 1978 the Centre for Health and Population Research (ICDDR/B) has trained nearly 15,000 health care professionals now operating in field sites in the five continents. The Centre has trained many of the leading experts in public health and enteric diseases.

Hundreds of developing country researchers have been successfully trained to perform high quality applied research in diarrheal, respiratory and tropical diseases as shown by their international presentations, publications in peer review journals, and ability to compete for international funds.

It is worth noting that these achievements have also generated substantial reforms in international and national health care policies. Furthermore, many of these achievements have improved the health and safety of U.S. citizens, as well as saved money, improved strategy, and expanded knowledge.

d. FY94 investments in research:

Title	Description	FY94 Total Research (\$000)	Implementors
Child Survival Action Program (CSAP-JHU)	Evaluates program effectiveness and impact and the efficacy and feasibility of child health interventions	910	Johns Hopkins U./IIP
Diarrheal and Respiratory Disease Research and Coordination (DRDRC)	Identifies and evaluates new interventions (including integrated approaches) for improving case management and prevention of pneumonia, malnutrition, and diarrheal diseases.	5,550	WHO/CDR, ICDDR/B, Harvard U./ADDR
Malaria Vaccine Development Program (MVDP)	Conducts vaccine development research, produces and tests candidate vaccines	3,400	Various U.S. universities
Opportunities for Micronutrient Interventions (OMNI)	Supports research in developing countries regarding ways to combat micronutrient malnutrition	2,640	ILSI
Technologies for Child Health (HealthTech)	Develops and introduces health technologies (such as diagnostics and vaccine delivery hardware)	1,000	PATH

Tropical Disease Research II (TDR II)	Seeks more economical methods for diagnosis, treatment, and prevention of six tropical diseases	1,200	WHO/TDR
Vitamin A for Health (Vitamin A)	Supports research on the role of Vitamin A deficiency in childhood mortality	800	Johns Hopkins U.

The following projects contributed smaller amounts of funding for child health research: Breastfeeding, Maternal and Neonatal Health (BMNH); Data for Decision Making (DDM), Environmental Health (EHP), Health and Human Resources Analysis for Africa (HHRAA), Program in Science and Technology Cooperation (PSTC), Schistosomiasis Research and Child Survival Projects (USAID/Egypt), University Linkages Project (ULP) and Women and Infants' Nutrition: A Family Focus (WIN).

e. Quality assurance:

Global Bureau

Major activities are subject to external peer review. Studies involving humans or animals are reviewed by institutional review boards (IRBs) in developed and developing countries in compliance with U.S. government regulations.

Projects that manage rather than conduct research programs (WHO, ADDR/Harvard, MVDP) use a multi-level system for review. This system includes initial screening of proposed research activities for relevance, feasibility, and potential contribution, followed by external peer review.

These projects are also subject to the guidance of technical advisory groups and ad hoc external consultative groups, who review research agendas and priorities. Projects that conduct their own research (eg. Vitamin A for Health/JHU and CSAP/JHU) conduct in-house reviews and external reviews as needed.

Intervention trials are monitored by external safety and technical committees. USAID-commissioned, external evaluations of projects take place at each project's midterm and end.

The majority of project officers that monitor centrally-funded research have Ph.D.'s in a health-related field. Fellows and consultants provide additional technical support.

See appendix for project-specific information.

Missions and Regional Bureaus

Methods for review and monitoring health and nutrition research vary enormously (as reported in a survey of mission and bureau research activities.) Conformity with U.S. regulations regarding scientific standards for research also varied. Some missions conduct a formal external review for individual research studies. Mid-project and end-of-project evaluations are conducted

regularly, but it is not clear from survey responses how the research component is evaluated.

See appendices for project-specific information.

f. Future directions:

In response to budget cuts in FY93 and FY94 and to shifting needs and priorities over the past several years, the following adjustments in the research portfolio have been made.

- i. Research in prevention is emphasized over research in case management.
- ii. Disease-specific research in case management has been shifted to research in integrated case management (eg. appropriate provision of care, young infant, anemia).
- iii. Remaining disease-specific research in case management focuses on testing new ORS formulations, clinical drug trials for shigella, and community-based treatment of persistent diarrhea.
- iv. More funds have been committed for studying acute respiratory infections.
- v. The Malaria Vaccine Development Program is focused on the major bottleneck in vaccine development; "scale-up" and pilot lot production of investigational vaccines and the testing of those vaccines in humans. Support for laboratory-based "fundamental" research was eliminated and support for non-human primate trials and field trials was markedly reduced.
- vi. Capacity building efforts have been broadened beyond implementation of research to include dissemination of research results to decision makers, measurement of capacity building, etc.

Given increased levels of funding, the following areas might be initiated or expanded.

- i. Emerging health threats, such as drug-resistant microorganisms causing diarrheal diseases, malaria, and pneumonia
- ii. Pneumonia prevention, including vaccine testing in developing countries and reductions in indoor air pollution
- iii. Diarrhea prevention, including vaccine testing and improvements in household hygiene
- iv. Expanded field testing and monitoring of integrated case management and prevention packages
- v. Role of micronutrients other than Vitamin A and iron in improving child health

- vi. Development of methodologies for improving measurement of cause-specific mortality and morbidity
- vii. Development of ways to use day-care centers and schools to deliver health and nutrition interventions

2. Maternal Health

a. Problem: The maternal mortality ratio (MMR) is one of the social indicators with the greatest disparity between the developed and the developing world. In developed countries it averages 30/100,000 live births, while in the developing countries it averages 450/100,00 live births. The risk of a death related to pregnancy in sub-Saharan Africa is as much as 200 times the risk in developed countries. WHO estimates that there are 500,000 maternal deaths worldwide each year. For every maternal death, there are 14 stillbirths and neonatal deaths; most are attributable to the health status and care of women before and during pregnancy. In addition, there are an estimated 100 serious maternal morbidities for every maternal mortality.

Maternal undernutrition is an important contributing factor to maternal mortality. The extent and consequences of undernutrition among women in developing countries is dramatic but has received inadequate attention. Conservative estimates suggest that 500 million women are anemic, almost 500 million stunted as a result of childhood protein-energy malnutrition, about 250 million suffered a range of consequences of severe iodine deficiency, and about 2 million are blind due to Vitamin A deficiency. The human welfare losses associated with women's malnutrition are wide-ranging and severe, including reduced quality of life for women themselves, impaired ability to bear and nurture children, and diminished capacity for domestic and income-generating work. Women's undernutrition can also be carried to the next generation through low birth weight infants, 24 million of whom are born each year.

Sexually transmitted diseases (STDs) contribute disproportionately to adverse effects on fertility and maternal and infant morbidity and mortality. Non HIV-STDs facilitate the transmission of HIV. Up to 10% of all reproductive age adults are infected with an STD each year.

The key constraints that hamper maternal health improvements and reduction of maternal mortality include:

- i. Poor nutritional status of adolescent girls and women, especially resulting from inadequate diets;
- ii. Inadequate knowledge at the community level about ways to reduce chance of illness and death from pregnancy and birth;

- iii. Insufficient resources at the community level to secure transport to health services or to purchase life-saving drugs;
- iv. Underdeveloped problem-solving approaches of mid-level health workers in the face of life-threatening complications;
- v. Restrictive policies and legislation which do not allow mid-level providers to practice life-saving skills in an emergency;
- vi. Poor deployment of trained medical personnel to meet emergency needs of women on a 24 hour basis;
- vii. Dilapidated facilities lacking in essential equipment, supplies, and drugs;
- viii. Limited indigenous capacity for using available data to monitor activities and identify problems;
- ix. Uninformed and unsupportive policy makers, managers, and supervisors.

b. Research priorities: Research focuses on the prevention, diagnosis and treatment of the principle causes of severe lifelong disabilities and death resulting from women's poor health and nutrition. Research is also aimed at sustaining beneficial health and nutrition practices.

Priority areas include the development of improved low-cost diagnostics for the detection of STDs, improvement of cost-effective systems to combat iron deficiency anemia, testing of IEC/marketing approaches to benefit women's health and nutrition status, study of adolescent beliefs and practices and reproductive sexual behavior, and testing the cost-effectiveness of packages of antenatal, postpartum, and delivery services.

Pregnancy Complications/Safer Deliveries

- i. Impact of a new antenatal care model on improved maternal and neonatal outcomes.
- ii. Feasibility of training non-physician providers to improve post abortion care.
- iii. Evaluation of cost-effectiveness of varied approaches to life-saving skills training of physicians and midwives.
- iv. Evaluation of the cost-effectiveness of various communications strategies to increase demand for facility-based obstetric care.
- v. Impact of treatment protocols on case-fatality rates.

Maternal Nutrition

- i. Effect of improved women's (and adolescent's) nutritional status before and during pregnancy on complications during pregnancy, delivery and postpartum.

- ii. Effect of community-based dietary intervention using IEC/social marketing on women's dietary intake, nutritional status, weight gain and perceived health.
- iii. Effect of a supplement package (such as iron folate, antihelminths and antimalarials) to target causes of anemia (including parasites, malaria).
- iv. Development and field testing of new or improved iron fortification delivery systems.
- v. Development of new, cost-effective field instruments for diagnosing anemia.
- vi. Impact of low dose Vitamin A supplementation at time of delivery on prematurity and maternal and neonatal infections.

Sexually Transmitted Diseases

- i. Evaluation of clinical algorithms to determine etiology of STD infection in symptomatic women and to detect STD infection in asymptomatic women.
- ii. Effect of creative approaches in STD prevention and treatment programs in reaching adolescents.
- iii. Effect of sensitive, efficient and cost effective models for partner notification and referral.
- iv. Feasibility of integrating STD services into MCH/FP programs.
- v. Impact of mass treatment for syphilis on pregnancy outcomes.

c. Selected research achievements:

Making iron folate available to pregnant women in the community through distribution by traditional birth attendants (TBAs) significantly increased the availability, coverage, and consumption of iron folate. An IEC campaign to increase use of services and iron folate tablets did not significantly increase coverage and compliance above and beyond the effect of community distribution. However, an IEC campaign in the control area (without TBA distribution) significantly increased coverage and compliance after the campaign.

Development of iron-EDTA as a new, effective iron fortificant.

Development and testing of a new slow-release iron capsule which shows greater efficacy and fewer side effects than conventional iron supplements.

Development of better iron status assessment techniques that are more accurate, less time consuming, less costly, and require fewer drops of blood than previous assessment methodologies.

Development of methods to measure new parameters of Iron status, such as the transferrin receptor, which permits a measure of iron deficiency not limited to anemia.

A community-based maternal care program that included IEC, birthing huts, alarm and transport system, and provider training increased referrals to appropriate facilities for antenatal and delivery services for women with complications and decreased the perinatal mortality rate in Indonesia.

An integrated antenatal-syphilis screening and treatment program aimed at preventing congenital syphilis in Kenya showed an increase in new prenatal attenders screened for syphilis (60 vs. 100%), treated if found seropositive (9 vs. 85%), and partners notified and treated (15 vs. 52%).

Perinatal mortality was significantly decreased after women's groups in isolated mountain communities of Bolivia developed increased understanding of maternal and newborn complications through the "autodiagnosis" technique.

Development of UNIJECT, a pre-filled single-dose autodestruct injection system that enabling peripheral health workers to give safe injections and facilitating new outreach strategies for the delivery of vaccines, especially tetanus toxoid for pregnant women.

d. FY94 projects and their funding for research:

Title	Description	FY94 Research (\$000)	Implementors
Breastfeeding and Maternal and Neonatal Health (BMNH)	Promotes breastfeeding and demonstrates the feasibility of providing a package of effective appropriate maternal and neonatal health and nutrition services to women and their infants in developing countries	440	John Snow, Wellstart
Opportunities for Micronutrient Interventions (OMNI)	Supports research in developing countries regarding ways to combat micronutrient malnutrition	2,640*	ILSI

The following projects contributed smaller amounts of funding for maternal health research: Diarrheal and Respiratory Disease Research and Coordination (DRDRC), Technologies for Child Health (HealthTech), and Women and Infants' Nutrition: A Family Focus (WIN).

* Also listed under child health section

e. Quality assurance: Technical advisory groups are convened to discuss research priorities. Research proposals are subject to external peer review as well as USAID/W review.

f. Future directions: With increased funding, the following directions are anticipated.

- i. Cost-effectiveness of various packages of services (prenatal, labor and delivery and postpartum) will be emphasized.
- ii. Cost-effectiveness of different training approaches will be identified.
- iii. Impact of mass media communication on use of essential obstetric services will be addressed.
- iv. Cost-effectiveness of national IEC campaigns to improve women's nutritional status.
- v. Feasibility of "scaling-up" maternal health pilot projects to national level programs will be studied.
- vi. Capacity building efforts in host countries will be expanded.

3. HIV/AIDS Research

a. Problem: The World Health Organization estimates that 19 million men, women and children are infected with HIV worldwide. Two-thirds or more of all HIV infections to date have been the result of heterosexual transmission; and this proportion will increase to 75% or 80% by the year 2000. By mid-1994 about half of all HIV infections in the world had been acquired in adolescence and young adulthood. Approximately one out of three children born to an HIV-infected woman is HIV-infected and dies of AIDS, usually by the age of five years; the remainder of uninfected children eventually become orphans when their mothers or both parents die of AIDS. As of mid-1994, about one million infected children had been born and over half of them have already died of AIDS. Most of these children are in Sub-Saharan Africa. The vast majority of HIV infections is in the developing world where the epidemic puts new markets and fledgling democracies at risk. Conservatively, WHO estimates that by the year 2000, at least 30 to 40 million people will have been infected with HIV since the beginning of the pandemic. While Sub-Saharan Africa was affected earliest and hardest, if current conditions persist the majority of new cases of HIV in the next decade will be in South Asia. The key constraints to slowing and eventually controlling this pandemic are:

- i. Difficulty of changing high risk behaviors across a broad range of populations;
- ii. Absence of effective and acceptable barrier methods, especially female-controlled, to block the transmission of HIV and other STDs;

- iii. Insufficient public and private/NGO infrastructure to facilitate the effective and efficient delivery of health and mitigation services, including condoms, to those in most need;
- iv. Policy environments that inhibit, through denial or other more bureaucratic obstacles, the design and successful implementation of HIV prevention interventions;
- v. The absence of an efficacious vaccine; and
- vi. The presence of parallel epidemics such as TB.

b. Research priorities: Given the diversity of social and economic contexts for HIV risk behavior, formative intervention and operations research and evaluation are the bulk of HIV/AIDS programming. Research to build new scientific knowledge is only a fraction of the HIV/AIDS portfolio. This research focuses on a better understanding of the social and behavioral factors/context that place individuals at risk, the bio-medical impediments to effective STD and HIV control and the economic, bureaucratic and logistical obstacles that impede national responses to HIV/AIDS.

The major research foci are:

- i. Identification and testing of new behavior change interventions, such as counseling and education in combination with HIV testing;
- ii. Development of effective HIV/STD prevention and diagnostic tools that are rapid, simple, and inexpensive;
- iii. Development of female-controlled barrier methods against STDs including HIV;
- iv. Improved policy dialogue and reform technologies inclusive of the development of simulation computer modeling for the HIV pandemic and more sensitive methodologies for assessing socio-economic impact;
- v. Assistance in the field testing of vaccines including limited laboratory, epidemiologic, and cohort sampling support for vaccine field trials; and
- vi. Research on more rapid and effective treatment of individuals infected with both HIV and Tuberculosis.

c. Selected research achievements:

Development of an in vitro assay which is a model of HIV and Chlamydia infection of vaginal epithelial cells. The assay is being used to screen candidate microbicidal compounds.

Identification and phase one testing of candidate microbicides leading to the development of an effective female-controlled barrier method for STD and HIV prevention.

Development and technology transfer of the HIV dipstick in five countries, setting a precedent for local manufacturing of needed immunodiagnosics. The dipsticks cost 30-70% less than commercial tests, and millions of these tests have been made available.

A study of the economic losses associated with high consumer prices for condoms was used successfully by local advocates to convince the Brazilian government to abolish taxes on condoms.

Development and field evaluation of a diagnostic algorithm flow chart for STDs to greatly expand the local capacity for the diagnosis and treatment of STDs.

Data collection and analysis of the economic and sociocultural factors contributing to women's vulnerability to HIV infection from 17 research sites in developing countries resulted in the development of nine pilot HIV interventions focusing on women.

The identification of various behavioral factors impinging upon normative change in risk behaviors in a number of developing countries.

d. FY94 projects and their funding for research:

Title	Description	FY94 Research (\$000)	Implementors
AIDS Technical Support	Supports research aimed at understanding the social and behavioral factors which place individuals at risk for HIV infection, as well as developing HIV/STD intervention programs, assessing in-country policy environments, and developing microbicides.	3,088	FHI, Pop Council, NIAID
Global Program on AIDS (WHO/GPA)	Provides funds to WHO/GPA for development and implementation of effective AIDS control strategies	5,700	WHO/GPA

Health and Human Resources Analysis for Africa (HHRAA)	Increases the use of research, analysis, and information in support of improved health and nutrition in Africa	2,605	multiple
Technologies for Child Health (HealthTech)	Develops and introduces new technologies	1,000*	PATH

*Also listed under child health section

e. Quality assurance: Major activities are subject to external peer review. Studies involving humans or animals are reviewed by institutional review boards (IRBs) in developed and developing countries. Projects that manage rather than conduct research programs use a multi-level system for review, including initial screening of research proposals and peer review for technical soundness. Research is subject to the guidance of technical advisory groups. External USAID-commissioned project evaluations, both mid and end-of-project, are part of all projects inclusive of research.

f. Future directions: Given current funding levels behavioral and biomedical research will not expand. Ongoing research in factors contributing to the rapid increases in HIV infection among women and the growing TB co-epidemic are two areas which, funds permitting, research would expand. HIV/AIDS mitigation at the community level is another research topic of interest to USAID and of importance to the epidemic and developing countries as they cope with growing numbers of AIDS deaths and orphans and increasing demands upon fragile economic and social infrastructures.

4. Health Systems and Policy Reform Research

a. Problem: All too often, scarce government resources are not used efficiently, health care is inaccessible, services are of poor quality, and drugs are neither affordable or available.

Health sector research addresses the impact of health policies, examines options for reform, explores the use of information for decision making, and develops methodologies for improving health care. The focus of this research is on the functioning of the health sector -- those public and private institutions concerned with the provision of health care.

b. Research priorities: In order to ensure the sustainability of health and nutrition interventions (and in some cases to obtain decreases in mortality directly), emphasis will be placed on (1) methods for improving the use of health information for better decision-making by caregivers, health care

providers, and policymakers and (2) methods for improving the allocation and use of resources within the health sector.

Cost Recovery

- i. Exploration of the degree to which quality improvements must be made in government health services for consumers to be willing to pay more for them, and of the effectiveness of cost recovery in financing quality improvements
- ii. Analysis of different methods to identify and protect the poor under cost recovery systems
- iii. Evaluation of bypass charges, pharmaceutical fees, and insurance deductibles as alternative approaches to queues and referrals for influencing consumer behavior in choosing whether and where to seek health care

Productive Efficiency

- i. The effects of alternative approaches for improving the efficiency of health sector operations. These alternative approaches include new employee incentives, contracting out to the private sector, and understanding the value, potential, and feasibility of mimicking private sector performance incentives.
- ii. Examination of the productivity and efficiency gains to be obtained from reallocation of current government spending on health. This research will include potential and actual gains from reallocations among primary, secondary, and tertiary care and between personnel, drugs, and supplies, as well as institutional barriers to such reallocations

Social Financing

- i. Examination of the feasibility of greater reliance on private and public social financing from the consumer, provider, employer, and insurer standpoints
- ii. Study of the advantages and disadvantages for developing countries of adopting delivery through the private sector while retaining financing through government or social security

Private Sector

- i. Determination of the factors involved in the development of private markets for delivery of health services, including the

- role of competition and regulation, availability of health personnel, and presence of insurance markets
- ii. Determination of the magnitude of efficiency differences among public, private, and social security providers of health services, and identification of factors influencing the differences
- iii. Examinations of the effects of permitting government physicians to practice medicine privately and the effects of private wards in public hospitals, and also determination of which health care services or inputs may be appropriate for delegation to the private sector

Policy Development

- i. Identification of the requirements, both in terms of human skills and data, necessary to improve health financing policy development. In addition, the research will develop information to help donors choose between project and non-project assistance in the health sector. It will also seek to identify the major issues that lie ahead in health financing.

Quality Assurance

- i. Development of approaches for institutionalizing quality assurance in developing country health systems. These approaches will address the quality of clinical care, the management of support systems, and the efficiency of services.

c. Selected research achievements:

Based on research, a nationwide system of fees in government health facilities has been put in place in Kenya. The system has not discouraged health-care seeking behavior. Revenue is retained at the local level for health facilities.

Quality assessment instruments developed, refined, and adapted for use by program managers, with more than 5000 sets distributed.

Patient counseling principles successfully validated in three developing countries.

First empirical comparison of the cost effectiveness of alternative techniques for assessing quality of care. This study provided policy makers with a model for examining the productivity of routine supervisory interventions, a costly element of health systems that has remained largely unaccountable.

Research framework developed for examining the empirical relationships among cost of services, their quality, and the cost of quality assurance activities.

Tools developed for institutionalizing the use of data for policy formulation, private sector assessments, tracking budgets, and presentations. These tools have been applied in a number of countries and have resulted in rational decision making for decentralizing or shifting public sector service burdens to the private sector and reallocating resources.

NIS morbidity and mortality assessment greatly aided USAID's understanding of health trends in the region.

Testing of alternative methods for cost recovery showed that improvements in the quality of health services will offset additional costs and improve use. Based on these results, the governments of Niger and the Central African Republic have announced plans to initiate cost recovery nation-wide.

d. FY94 research investments:

Title	Description	FY94 Research (\$000)	Implementors
Applied Research in Child Survival Services (ARCSS)	Develops, refines, and institutionalizes approaches to assure the quality of care in developing country health programs	290	Center for Human Services
Data for Decision Making (DDM)	Provides assistance to developing countries seeking to make better use of data for decision and policy making	3,500	Harvard U., CDC, NAS
Health Financing and Sustainability (HFS)	Improves the allocation and use of resources within the health sector	1,450	Abt. Assoc., WHO, John Snow, Mgt. Sci. for Health, USPCI

These projects address policy and sector reform related to the priority areas of child health, maternal health, and HIV/AIDS. Conversely, a number of projects that are primarily engaged in the development and evaluation of new interventions for the priority areas are also engaged in developing new methods for improving the use of health information and health resources (eg. DRDRC, OMNI, AIDSTSP).

e. Quality assurance: A variety of mechanisms are used for monitoring and evaluation, including project research committees, external peer review, external technical advisory groups and evaluations, and USAID review.

f. Future directions: Many countries are grappling with how to pay for health care. More work needs to be done to test the applicability of health care financing models in different settings. More research is needed to understand impediments and opportunities for health care reform. Research is also needed to address how the private sector can serve as a vehicle for meeting public health goals.

D. Research Trends and Allocations

USAID contributed \$646 million to health and nutrition research during the period 1985-1994. This amount was 14% of USAID's \$4 billion budget for health and nutrition during that time. In 1994, health and nutrition research constituted 6.8% of total USAID obligations in health. The Global Bureau implemented 80% of the research, while the Africa and Asia/Near East Bureaus implemented much of the remainder (HHRAA and Egypt Schistosomiasis projects respectively). Research was conducted in over 30 developing countries. FY93 obligations for health and nutrition research by major activity were as follows: HIV/AIDS (32%), Child Survival (22%), Tropical Diseases (21%), Health Systems Development (17%), Women's Health and Nutrition (4%), and Other Areas (4%). Beneficiaries included (1) developing country scientists, institutions, NGOs, field staff, and families, who secured better health and training; (2) women, who constituted 40% of trainees; and (3) U.S. citizens, who were protected from emerging health threats and received public health training and new low cost technologies. Partners included U.S. and local universities, research institutes, government agencies, PVOs/NGOs and bilateral/multilateral donors. Developing country scientists conducted the vast majority of the research in developing countries.

USAID's funding for health and nutrition research grew steadily from FY87 through FY92, primarily due to increases in support for HIV/AIDS. However, health and nutrition research funding dropped significantly in FY93 and FY94, essentially due to decreases in support for child survival and HIV/AIDS research (Note that at least some of the research reduction can be accounted for by significant budget cuts to the Global Bureau's Office of Health and Nutrition, which funds much of the research). These reductions have forced USAID to narrow the focus of its research activities. The most dramatic decreases in research occurred in vaccine development for malaria, diarrheal diseases, and acute respiratory infections. Additional decreases anticipated in FY 95 will result in the termination of a significant number of ongoing research studies in developing countries. Multicenter trials with critical policy implications (such as the EPI-linked Vitamin A supplementation trial) will be jeopardized. A decrease in research funding will also preclude meaningful contribution to addressing emerging health threats (such as drug resistance) and research in perinatal and maternal health and prevention of childhood illness.

E. Quality Assurance of Research

Quality of HN research is assured by a variety of methods.

- o Research management by qualified institutions
- o External peer review of research proposals
- o Guidance by TAGS and external consultative groups
- o Application of ethical standards for human and animal use
- o Mid-project and end-of-project external evaluations

- o Safety, data monitoring, and technical steering committees for intervention trials
- o Project monitoring by qualified USAID staff

For project-specific information, see appendices.

F. Donor Collaboration

Donor collaborations are described for each project or subproject in the appendices. Collaborators include multilateral donors (mainly WHO, FAO, the World Bank, and UNICEF), bilateral donors (mainly SIDA/SAREC, CIDA/IDRC, ODA and AIDAB), foundations (eg. Rockefeller, Thrasher, Edna McConnell Clark, ILSE/Nutrition and Ford foundations). USAID's HN research program also collaborates with other U.S. government agencies including NIH, CDC and DOD. Collaboration takes many forms, including co-funding of research and dissemination activities, provision of technical assistance for research activities, co-sponsoring of meetings and workshops, participation on TAG and steering committees, collaboration in inter-agency activities (such as the development of a National Vaccine Plan and an Emerging Diseases Strategy), and collaboration in technical development activities (such as research capacity building indicators.)

G. Issues

1. Need for stable multi-year funding (eg. for intervention trials and product development)
2. Demand for short term results and impact (eg. the shift from prevention to case management research)
3. Inability to address emerging issues and new initiatives (eg. HIV/TB, antimicrobial drug resistance) as a result of declining budget and internal/external earmarks
4. Limited direct hire, technical staff