MID-TERM EVALUATION

OF

HealthTech

Technologies for Child Health

Prepared for the
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MID-TERM EVALUATION

OF HEALTHTECH:

TECHNOLOGIES FOR CHILD HEALTH

Cooperative Agreement Number DPE 5968-A-00-7035-00

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LIST OF ACRONYMS AND ABBREVIATIONS

A.I.D.	Agency for International Development
ASTM	American Society of Testing and Materials (Philadelphia, PA)
BD	Becton, Dickinson and Company (Franklin Lakes, New Jersey)
CCCD	Combatting Communicable Childhood Diseases program at the Centers for Disease Control
CIDA	Canadian International Development Agency (Hull, Canada)
CSP	Child Survival Program
CSS	Child Survival Strategy
CTO	Cognizant Technical Officer, A.I.D.
DiaTech	Diagnostic Technology for Community Health (A.I.D.-funded project managed by PATH)
EPI	Expanded Programme on Immunization (WHO)
EPITECH	Evaluation Panel for Injection Technologies
GMP	Good manufacturing practices
HealthTech	Technologies for Child Health (A.I.D.-funded project managed by PATH)
HMPI	Horizon Medical Packaging, Inc., Santa Ana, CA
HPN	Health, Population and Nutrition
ICCIDD	International Council for the Control of Iodine Deficiency Disorders
IDD	Iodine deficiency disorder
IDRC	International Development Research Centre (Ottawa, Canada)
IEC	Information, education, and communication
ILF	International Loan Fund
LBW	Low birth weight
LDC	Less developed country
MBE	Management by Exception
MCH	Maternal and child health
MSH	Management Sciences for Health
NIH	National Institutes of Health
NGO	Nongovernmental organization
JHU/APL	The Johns Hopkins University/Applied Physics Laboratory (Laurel, MD)
OAS	Organization of African States
ORS	Oral rehydration salts
ORT	Oral rehydration therapy
PAHO	Pan American Health Organization (Washington, D.C.)
PATH	Program for Appropriate Technology in Health
PHC	Primary health care
PRE	Bureau for Private Enterprise, A.I.D.

PRITECH	Technologies for Primary Health Care (A.I.D.-funded program managed by MSH)
Project SUPPORT	Supply, Production, and Promotion of Oral Rehydration Salts in Developing Countries (A.I.D.-funded project managed by PATH)
PVO	Private voluntary organization
QA	Quality assurance
QC	Quality control
REACH	Resources for Child Health (A.I.D.-funded project managed by John Snow, Inc., Arlington, VA)
TAP	HealthTech Technology Assessment Panel
TBA	Traditional birth attendant
TBD	To Be Determined
UNDP	United Nations Development Program
UNFPA	United Nations Fund for Population Activities (New York, NY)
UNIPAC	United Nations Procurement and Assembly Centre (Copenhagen, Denmark)
USAID	United States Agency for International Development
WASH	Water and Sanitation for Health Project (A.I.D.-funded project)
3M	Minnesota Mining and Manufacturing Company (Minneapolis, MD)

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EXECUTIVE SUMMARY

An evaluation team was assembled under agreement between A.I.D. and OIH, PHS and charged with performing an interim evaluation of HealthTech, an A.I.D. funded cooperative agreement with the Program for Appropriate Technology in Health (PATH), a Seattle-based non-profit organization.

HealthTech is designed to develop a mechanism for promotion of the development, testing, introduction and where possible local manufacture of child survival technologies for use in less developed countries.

According to the scope of work (SOW) for the evaluation team, "The general purposes of this mid-term evaluation are to: 1) Assess the relevance of the project objectives to the Child Survival Program (CSP); 2) Review assumptions made in the initial project proposal and determine their continued validity; 3) Review the overall performance of the project in terms of technological achievements and outputs; 4) Assess the relative efficiency of the project's internal management and coordination systems; and 5) Prepare recommendations that may enhance the effectiveness and efficiency of the project." (See Annex 1.)

To accomplish its mandate from A.I.D. the team carried out extensive interviews with A.I.D. staff, members of the Technology Assessment Panel (TAP), and PATH/HealthTech officers and staff. (See Annex 2, List of Contacts.) Site visits were made to PATH offices in Seattle, Washington as well as to Becton, Dickinson and Company of Rutherford, New Jersey, and Horizon Medical Packaging, Inc./ACACIA of Santa Ana, California. (See Annexes 3 and 4.) Extensive review of A.I.D. and PATH/HealthTech documents was undertaken and information was requested from HealthTech for special analysis. (See Figure 6.)

The nature of the tasks to be performed by HealthTech is different from more traditional A.I.D. projects and the accomplishment of these tasks through relationships between collaborating public sector, non-profit and private/commercial entities is a unique approach. The evaluation consequently includes discussion of the philosophy and conceptualization of the project, realistic timeframes and other factors which appear necessary for sustainability of the mechanisms being developed through HealthTech.

The evaluation team examined the HealthTech project within the context of the Child Survival Program administered by A.I.D. While the Child Survival Program is only in its fourth year, it is a focused effort that has evolved out of more general A.I.D. goals.

HealthTech is clearly a new and innovative project; however, it is a logical next step in the evolution of A.I.D. strategies. The concept of evolving better technology to support A.I.D. program strategies is almost as old as the agency itself. The development of oral

rehydration salts is an excellent example. The incremental differences in the HealthTech project are to:

(1) Encourage private/public technology development for primary care;

(2) Accelerate the development and implementation of technology for primary care; and

(3) Establish a technology resource available to A.I.D. on a continuing basis.

The evaluation concentrated on these three innovations that make HealthTech unique.

HealthTech has made major strides in encouraging private/public sector collaborative development. The two best examples are "SyringeLOCK" with Becton, Dickinson, and Company and "SafeTject" with Horizon Medical Packaging. (See Annex 5, HealthTech Technologies, as well as Annexes 3 and 4, Site Visits.) While there is a great deal of rhetoric about private/public cooperation, the two cases cited above are concrete examples that this can work. If they continue at their current rate of progress, A.I.D. will receive a great deal of justly deserved credit for pioneering efforts in private/public cooperation.

The interface between private/public is a "no man's land" in which PATH and the HealthTech must operate. There will be a continuing struggle to maintain the trust of both sides due to major differences in motivation and language. The private sector will continue to have concerns about proprietary interests and secrecy as well as the uncertainty of public markets. The public sector will be suspicious of the motivation of the corporate partners, will be concerned about protecting the public interest, and will also be wary of PATH's intentions at the interface between the public and private sectors.

This project is unique for A.I.D.. Communications and trust are central to success. The innovative approach to building collaborative relationships requires careful attention to trust and communication issues that are less relevant in more conventional projects. Project management must be designed to make these collaborative trust-building activities an integral, explicit part of the project.

The team found PATH as an organization to be more public than private oriented. The team found no evidence of pursuing PATH-owned technologies when better alternatives existed. There are examples of PATH-owned technologies being dropped when better alternatives were found. (See Annex 6, PATH-Rejected Technologies.) PATH has procedures in place that provide for continuing re-evaluation of alternatives to technologies underdevelopment. It is critical to the continuance of the HealthTech project that PATH continually demonstrate to A.I.D. that protection of the public interest is an integral part of their management and operating principles. (See Annex 7 for PATH's Licensing Policy.)

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The second major evaluation question concerns HealthTech's ability to accelerate the development and implementation of new technologies. This involves a complex and largely subjective evaluation as illustrated in Figure 6. After weighing all of the evidence the team is convinced that the HealthTech project has been successful in moving these technologies through the various stages of development. This may not have been possible without the previous joint projects undertaken by PATH and A.I.D. Through the HealthTech and previous project(s) A.I.D. has established a continuing technology resource with an operating philosophy which mirrors A.I.D. goals (evaluation issue #3).

The evaluation team has identified certain key elements for the success of the project, one of which is continuity. Success to date has evolved over a long A.I.D./PATH working relationship. Because of the nature of technology development it is recommended that future contracts be made on a five-year basis. It is also recommended that transitions between CTO's be handled carefully.

The HealthTech personnel are well-organized, professional, enthusiastic and dedicated to the success of this project. The project makes very effective use of expertise in the private sector for product development and eventual manufacture, yet carefully ensures that public sector interests are protected in all cases. In several cases, this private sector involvement will actually make possible the availability of appropriate technology and hasten its introduction into the third world. The impact of the initial A.I.D. funding is being increased enormously by the coinvestment of time and expertise by PATH and the financial support and knowledge from the private sector.

HealthTech has developed effective management techniques for motivating personnel, overseeing and reviewing progress and controlling costs. PATH is well-managed, but will have to continually review its management and strategic goals as the organization evolves into a much larger enterprise. See Annex 8 for an organizational chart of HealthTech management.

The Technology Assessment Panel demonstrates the effective management use made by HealthTech of outside advisors for very modest cost compared to the wisdom supplied. HealthTech should review its needs and mechanisms for obtaining further outside advice in additional areas as various products evolve:

- Effectively using A.I.D. local missions;
- Effectively interfacing with UNICEF, WHO and other global and country-specific public health agencies;
- Effectively using the corporate sector both here and abroad; and
- Continuing to use effectively advice from the end-user at the early development stages of the product.

The credibility of the project has attracted significant outside players to the development team from public health care agencies here and abroad, and from the private sector.

The team finds that the innovative nature of the project may have created uncertainties leading to a tendency toward micro-management by A.I.D.. Analysis of PATH management of the HealthTech process indicates their capability to assume more responsibility. The team recommends that as much administrative responsibility as possible be delegated to PATH/HealthTech. It is also important that key approval processes be carried out as quickly as possible while allowing for appropriate A.I.D. input and direction. These recommendations focus on ways to enhance the effectiveness and efficiency of the project through more flexible management. The team believes that flexibility is essential if the full potential of this innovative approach is to be achieved.

HealthTech must be viewed as a three-year "window" in a number of parallel processes with much longer timeframes. Inventions may take a whole generation before being generally available throughout the industrialized world, much less in the rest of the world. HealthTech must work diligently to ensure that a multitude of players, including themselves, have a realistic set of expectations in terms of development time, costs and cultural impact. Progress must be judged on the basis of interim steps along these processes. Achievement of final goals is realistically attainable during the initial three-year period in only a limited number of sub-projects. The HealthTech project was authorized by A.I.D. at a level of $4.618 million, including buy-ins of up to $1 million by USAID missions. The team recommends that A.I.D./W make every attempt to fully fund this innovative project up to the presently authorized level. The team recommends that the project be extended now, for an additional three years with appropriate funding.

This report also details areas where additional incremental A.I.D. funding could be used effectively. The greatest concern of the team is for the future. The emphasis for certain products is changing to field evaluation and promotion of the technology and its availability. Since the ultimate goal is introduction into developing countries, A.I.D. is encouraged to develop innovative incentives to ensure wide distribution and proper use of the end product. Special funds could be one way to accelerate the process beyond the present approach which limits PATH to countries where they have other related activities underway. See Annex 10 for a listing of potential additional countries identified by PATH and Annex 11 for strategies for country involvement.

The evaluation team feels that the technology transfer is greatly enhanced by information dissemination. Several recommendations are made in Chapter VIII which would increase knowledge about HealthTech in A.I.D., international agencies, and developing countries. While costly and not necessarily showing immediate results, information dessemination should improve general receptivity to technology innovation.

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In conclusion, the evaluation team found the HealthTech project to be successful at the mid-point of its three-year term. Its continuing potential is closely entwined with A.I.D.'s goals for the Child Survival Program. A.I.D. should make information on this project widely available as a demonstration that private/public sector activities can be developed that work to everyone's benefit. A.I.D. is to be congratulated for supporting this unique project. An exceptionally good beginning has been made.

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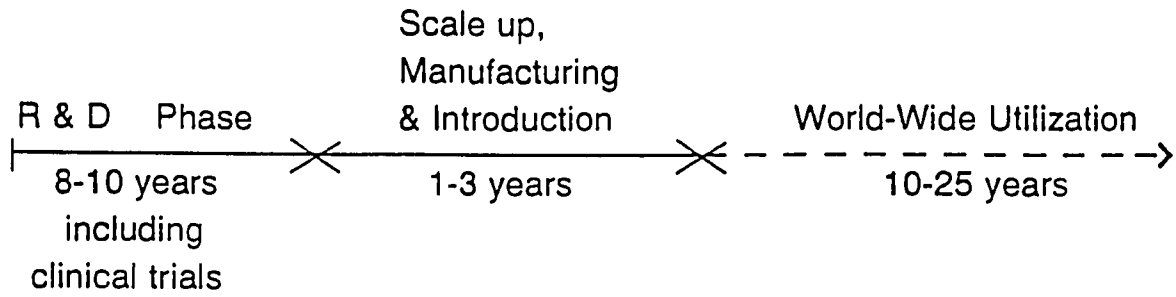
I. TECHNOLOGY DEVELOPMENT CONCEPTS

In the Western industrialized world, we have become accustomed to think of rapid technological change as a cultural imperative. The Wall Street Journal keeps us informed in great detail regarding such fast moving fields as the computer industry, where the life expectancy from market introduction to obsolescence is 18 months.

In reality, different technological fields evolve at different rates, even within, or perhaps especially within, the health care arena. The process by which an idea evolves from an academic setting to a marketed product in world-wide clinical use is a long and complex one. Experience with the FDA medical device program and the history of international health policy development suggests a general model for this process shown in Figure 1 below:

Figure 1. The Process of Technology Development and Dissemination



Even on a limited scale within the U.S. health care system, medical technology development is a process which cannot be rushed.

The flow chart in Figure 2 illustrates the evolution of a medical innovation. It is interesting to note that there are two alternate paths in the final steps from clinical trials to marketing which are dependent on whether the product is incremental to existing medical knowledge or is seen as completely innovative.

Section 510(k) of the Medical Device Amendments of 1976 permit a modified grandfather clause by which a medical device may be introduced to the market based on "substantial equivalence" to an existing product. Over 5000 products per year are marketed via premarket notification, often termed 510(k), based on review of data to establish

that they are 1) for the same intended use as an existing product, and 2) any technological changes do not raise different questions of safety and efficacy than those of the product to which it is being compared. By contrast, approximately 100 products a year are so innovative or the consequences of failure would be so catastrophic, that they are subject to complete review of all testing and clinical trial data for a formal risk/benefit analysis under the Pre-Market Approval (PMA) process.

Although there is a great deal of rhetoric about the burdens and delays of the PMA route, in the present context it should be emphasized that the regulatory requirements add perhaps one year to what is inherently a 10+ years sequence from concept to marketed product.

The team has evaluated HealthTech within the context of broader medical technology development as described above. The Program for Appropriate Technology in Health (PATH) has developed as an organization to address a specialized niche of medical technologies which they refer to as "social technologies". These are technologies designed and developed expressly for the purpose of meeting a public health need and range from simple products suitable for home or cottage industry to highly sophisticated technologies requiring state-of-the-art industrial processes and materials. All of these "social" technologies differ in one important respect from the technologies developed exclusively for business: they are produced to meet a perceived health need with little or no perceived potential for financial return rather than a measured market demand with a highly attractive financial return. Since need does not equate with ability to pay, the economic viability of social technologies is always in question.

Some social technologies have no evident significant private market potential (labelled "Type A" in PATH nomenclature); instead, they respond to an important perceived health need. For this type of technology, there are no opportunities for gaining industrial economies of scale or for covering the risks of the development and capital costs with profits from commercial-sector sales. The public health sector must bear the entire cost of these technologies by underwriting the development costs, purchasing the capital goods, and paying a price that covers the remaining cost as well as profit margins.

It follows that this type of technology should where possible involve simple materials and processes so that the risks are bearable and manufacturing can be carried out locally, on a small or medium scale, within the countries that need the product. It is helpful to be able to turn to small-scale industry or polytechnics and the technology departments of university for local manufacturing. Generally, it is useful to provide some business and marketing assistance to these manufacturing units, as well as quality assurance auditing, up to the point where production and sale of the product to public sector agencies are well established.

When a social technology has an identifiable commercial market potential ("Type B"), the strategies can be quite different depending upon the extent to which those private markets are marginal or exist

only in the developing world rather than the developed world. And finally, some technologies cannot be manufactured or distributed without the collaboration of a commercial manufacturer ("Type C").

The HealthTech Cooperative Agreement is designed to deal with strategies and processes for moving all three types of selected social technologies into the health care systems where they are needed through public-private sector collaboration. PATH has adopted a four-stage general model that is applicable to all social technologies. The stages are shown in Figure 3.

The effective strategies and the detailed processes associated with moving a specific product through these stages are widely variable, depending on:

- The nature of the product and its associated manufacturing technologies;
- Potential commercial market (A, B, or C technology);
- Cultural considerations in the manufacturing, distribution, or marketing environments; and
- The nature of interactions with, or operating styles of, collaborating entities.

Because of this variability, PATH does not assign time frames to the stages of their general model. HealthTech products/activities are characterized, however, by technology type and stage in the development process. (See Annex 5.) Based on this characterization, time frames and specific actions/milestones are developed for the project.

At the conceptual level, it is important that the reader of this evaluation report keep these three models in mind. They provide the context within which HealthTech is operating and serve as a basis for judgments regarding the appropriateness and effectiveness of the HealthTech project.

Figure 2. Medical Device Development and Introduction in The United States

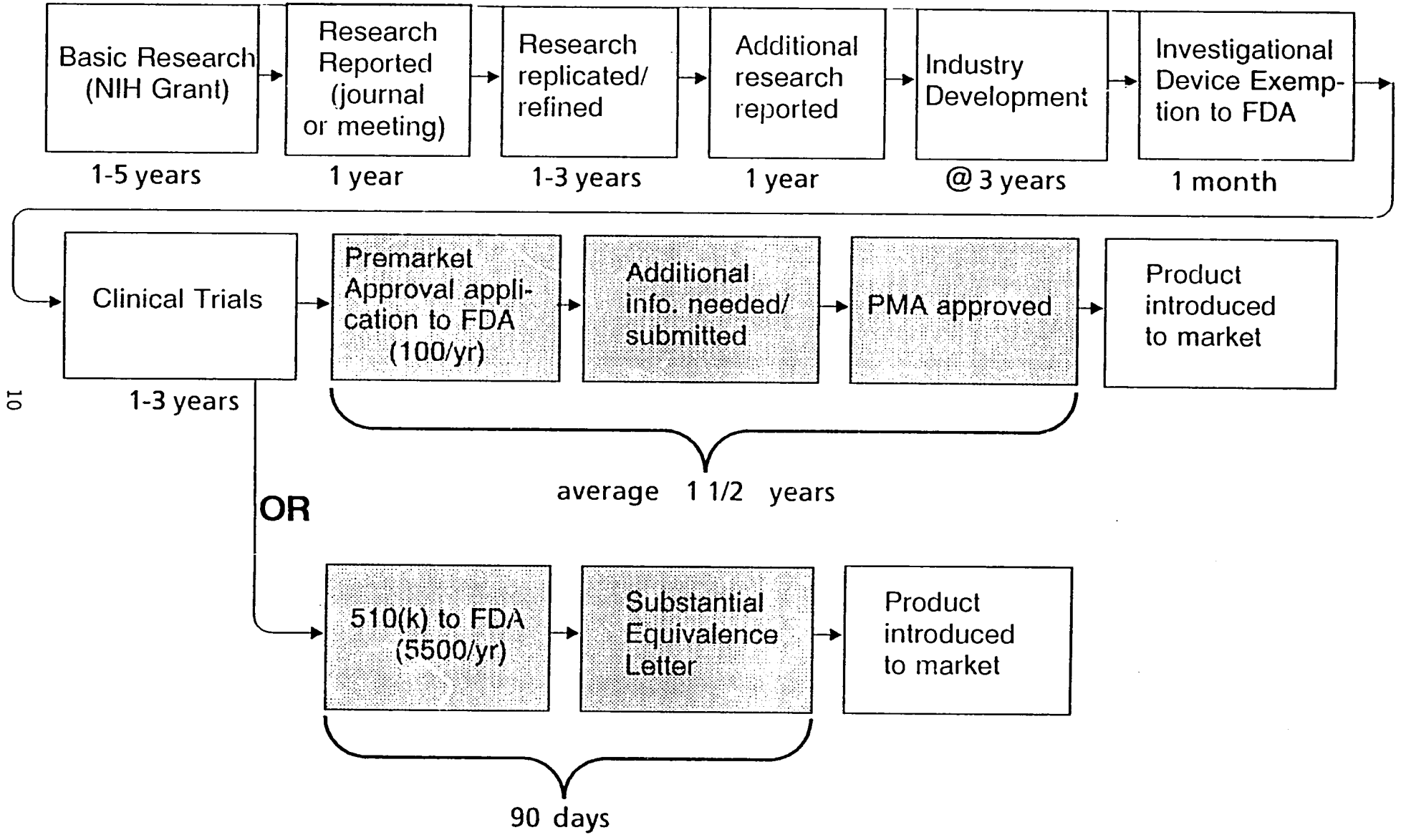
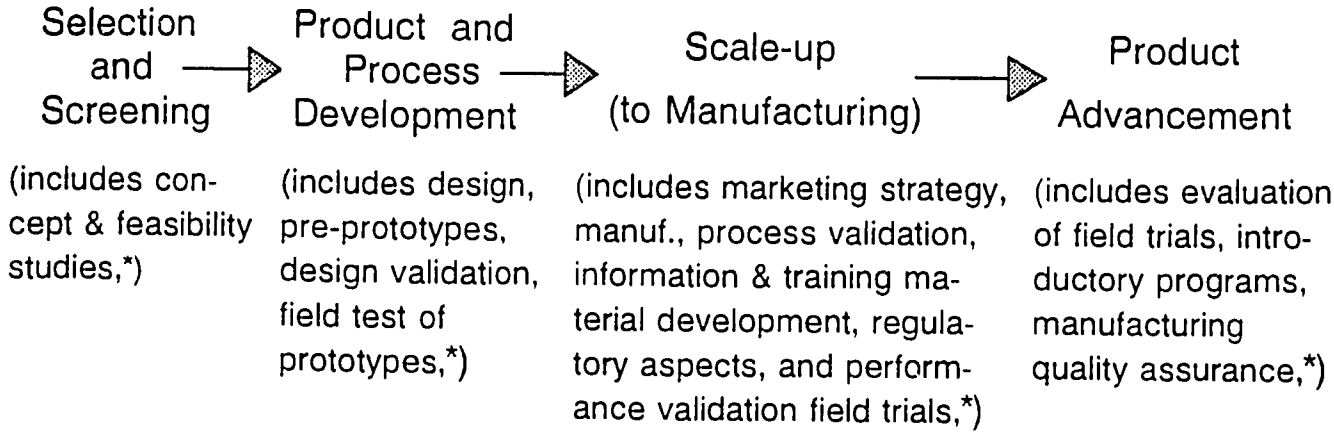


Figure 3. Model for Social Technology Transfer



* Involvement with private sector collaborator will be sought and can occur at any stage of the process.

II. TECHNOLOGY AND THE CHILD SURVIVAL PROGRAM

The stated purpose of the HealthTech cooperative agreement requires that an evaluation of the HealthTech project be relative to its ability to enhance A.I.D.'s broad objectives in the Child Survival Program. The project must demonstrate the ability to coordinate closely with and contribute to other major components of the Child Survival Program (CSP).

A. Global Crisis in Child Health and Survival

"A child dies every 3 seconds in the developing world".[1] Almost 15 million children a year die in less developed countries. Under conditions of poverty, overcrowding, and malnutrition they die from preventable diseases like measles and diarrhea. In the poorest countries 1/4 of all children do not live to see their fifth birthday. These figures do not include those millions who live, but whose growth is physically or mentally stunted.

The tragedy of these deaths and developmental arrestments is that most of them are preventable and at relatively low cost. Programs of immunization, diarrhea control, and nutrition could prevent most of the pathology. It is clearly an opportunity for more developed countries to act with compassion and a forward look to enhanced economic growth for less developed countries.

B. Congressional Mandate to A.I.D.

Responding to the unacceptable worldwide death toll of children in the poorest parts of the third world, the U.S. Congress established the child survival fund to begin in July of 1985. Based on this funding, A.I.D. has developed and administers the Child Survival Program. Consistent with the World Health Organization's goals of "Health for all by the year 2000" and "Universal Child Immunization" by 1990, this program has developed child survival goals. These goals relate to child spacing, nutritional promotion/breastfeeding, immunization, oral rehydration therapy, growth monitoring, water and sanitation, disease control, and prevention and treatment of malaria and acute respiratory infections.

C. Successes Achieved Through Service Delivery Programs

Working with A.I.D., UNICEF, WHO, and many private voluntary agencies (PVO's), much has been accomplished by developing countries in the area of child survival. Against the recognized minimum goal of 75 deaths per thousand live births, countries like Thailand, Botswana, and

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1 Child Survival: A Third Report to Congress on the USAID Program, U.S. Agency for International Development, Washington, DC 20523

Ecuador have made rapid strides reducing their infant mortality rates to 39, 67 and 63 deaths per 1,000 live births respectively. Sixty percent of children with diarrhea have access to oral rehydration therapy (ORT). WHO estimates that over 1.5 million lives have been saved with immunization and O.R.T.

The goal of A.I.D.'s health sector program is to increase life expectancy in less developed countries. Since infant and child deaths account for one half of all deaths in these countries, A.I.D. focuses on the reduction of infant and child morbidity and mortality.

A.I.D.'s specific objectives in the health sector are to assist developing countries to:

- o Reduce infant and early child mortality and morbidity;
- o Reduce maternal mortality and morbidity;
- o Build on child survival interventions to develop comprehensive health care systems;
- o Sustain gains in health and child survival; and
- o Develop and adapt technologies to promote child survival.

D. Impediments to Continued and Further Success

Despite these remarkable accomplishments in reducing infant mortality, much remains to be done in the child survival program:

- o Sustaining the gains made by developing the desire and ability of host governments to contirue and sustain what has been initiated.
- o Developing or adapting existing technology to meet child survival needs.
- o Planning for and preparing for the future.

E. Identification of Technology Associated Impediments

Specific technology associated impediments in carrying out the child survival program as identified by A.I.D. and others are as follows:

- o Loss of vaccine potency due to failure to maintain the cold chain;
- o Improper sterilization of needles and syringes;
- o Need for improved oral rehydration salts that reduce volume and duration of diarrhea;

- o Need for simple low birth weight identification and growth monitoring (hard and soft technology);
- o Need for specific nutritional supplements (e.g., slow-release iron);
- o Need for simple, inexpensive, child spacing technology;
- o Need for low cost technology for the prevention and treatment of vector borne diseases (e.g., malaria, schistosomiasis, and onchocerciasis); and
- o Need for inexpensive diagnostic tests for HIV and for blood bank monitoring.

The HealthTech project addresses nearly all of the above impediments.

F. Historical Experience with Technology

A.I.D. has extensive experience with technology development predating the Child Survival Program. One of the best examples of this has been the development of oral rehydration salts as a key factor in the oral rehydration therapy approach to diarrheal disease control. This successful technology development, starting with a major long-term investment by A.I.D. in the Dhaka-based Cholera Research Laboratory (now the International Center for Diarrheal Disease Research/ Bangladesh), also illustrates the multiple development strategies of A.I.D.. Specifically:

- o Development of a low cost technology to meet a specific health need;
- o Development of "soft technology" to support technology implementation;
- o Developing "ownership" by the host country to insure continuity of effort;
- o Developing host country ability to produce the technology;
- o Developing "private sector" distribution and marketing where appropriate; and
- o Continuing quest for an improved product.

The above example well illustrates A.I.D.'s continuous efforts to develop and adapt technologies to the needs of less developed countries. The HealthTech project appears to be a logical next step by A.I.D. in a well thought out evolutionary process. The next chapter will look specifically at "What's New with HealthTech"?

III. NEW APPROACHES TO CHILD SURVIVAL TECHNOLOGIES

A. Reasons for HealthTech

There has been a growing sense of urgency which led to establishment of the child survival strategy and this continues to accelerate. Much of this urgency can be traced to deteriorating economics in many less developed countries and increasing regional political tensions. While there has been tremendous progress in health services, there is a universal feeling that more can be done more quickly and that better technology will be a key factor in overall development and progress toward the Child Survival Program (CSP) goals. What initially appeared as one of the "givens" of health--availability of safe, effective, acceptable, appropriate technology--is now seen as largely ephemeral. It was determined that what was needed was the development of new technologies or the adaptation of existing products to meet the unique conditions of developing countries.

The international health community has responded aggressively to the need for adaptation and development of new technologies. Programs of research on new formulations of ORS are now well under way. While very inadequate in relation to need, there are international efforts to develop new and improved contraceptives. A.I.D. has funded the WASH project to work in water and sanitation. WHO has set up the Tropical Diseases Research program which, in part, is concerned with control of vector-borne diseases. A.I.D. sponsors the Diagnostic Technologies for Community Health (DiaTech) program to develop new diagnostic tools to be used in conjunction with immunization and other disease control programs. Also sponsored by A.I.D. is Project SUPPORT (Supply, Production, and Promotion of Oral Rehydration Salts in Developing Countries).

It is of interest to note that each of these programs has been set up with public sector funding. Industry did not see a business opportunity and did not step forward to invest the required developmental funds. This is understandable in light of the perception that sales of health products to the public sector in developing countries are of marginal profitability. On the other hand, industry has been a willing collaborator in these programs.

Furthermore, one tendency has been to view primary health care needs as a low-technology imperative; to a certain extent, this approach helps to emphasize the decentralized and self-sufficient aspects of primary health care. However, the impressive array of modern materials, electronic capabilities, pharmaceuticals packaging technologies, and mass manufacturing processes offers abundant possibilities for tools that meet the demanding criteria and fiscal constraints of community health care.

In early 1987, PATH submitted a proposal to A.I.D. which outlined an extensive program to address the needs for appropriate technology

development. This led to the current three-year Cooperative Agreement (DPE-5968-A-00-7035-00) between the A.I.D. Office of Health and PATH to carry out the HealthTech program.

HealthTech provides a flexible and efficient mechanism to deal with the "hardware" aspects of immunization and other child survival priorities. This program, which complements the activities of other A.I.D.-assisted projects, builds on PATH's capability to improve health in the developing world through the accelerated development, field assessment, and introduction of needed technologies.

Prior to HealthTech, PATH had screened, evaluated, or initiated the development process on 30 specialized products for primary health care in the developing world. In the process, PATH established contacts with technology sources and made a number of collaborative arrangements. Strategies whereby products can be developed in a reasonable time at minimum cost were identified. Thus, PATH has created an effective means of bridging the gap between advanced technologies and primary health care needs. This has been accomplished through effective participation in and control of the creative process, strong management of the flow of information and development, and use of a worldwide network for information gathering and dissemination.

The process of product development for developing world needs requires, among other things, knowledge of and sensitivity to different regions and population groups. Management of this process must be capable of orchestrating all the financial, technical, and legal inputs required to conceive, create, and reduce the technology to practice. Sponsoring organizations must be willing to manage the financial risk without the usual assurances of a return on the investment and to understand the many uncertainties in dealing with public sector agencies. International public agencies generally have not been able to move sufficiently quickly and with adequate flexibility to manage the vagaries of technology research and development. They can, however, provide valuable resources and inputs for assessing needs as well as networks for international field testing of technologies.

PATH, in general, and the HealthTech program in particular, is set up to manage this process, serving as the intermediary between international agencies on the one hand and private sector collaborators on the other, to increase the availability of appropriate health technologies in the developing world. This is the critical uniqueness of the HealthTech project.

The HealthTech Cooperative Agreement between A.I.D. and PATH was negotiated and started in the summer of 1987. During the first six months, management developed strategies, planned implementation procedures, and built the infrastructure of HealthTech, relying on previous experience and philosophies regarding health technologies for the developing world.

HealthTech was designed to provide a mechanism for promotion of the development, testing, introduction, and local manufacture of state-of-the-art child survival technologies. It was not intended that

private sector sponsors carry the entire burden of risk for these technologies, or that products arising from the project be available exclusively or even primarily through public sector programs. Rather, it was intended that the products be brought to a stage where they could be transferred to parties whose primary business is manufacturing and/or marketing, so that the products could become economically viable and therefore widely available.

The strategies by which this is accomplished differ for each technology. However, in every case a means is devised whereby public-sector interests are protected and not usurped by private market interests. In other words, the incentives for commercial-sector involvement must be balanced with the public-sector need for adapted, low-cost health products. A number of general strategies are described herein:

B. Incentives for Commercial Involvement

Technologies designed and developed expressly for the purpose of meeting a public health need range from simple products suitable for home or cottage industry to highly sophisticated technologies requiring state-of-the-art industrial processes and materials. All of these "social" technologies differ in one important respect from the technologies developed for business: they are produced to meet a perceived health need with little or no perceived opportunity for financial return rather than a measured market demand with a highly attractive financial return. Since need does not equate with ability to pay, the economic viability of social technologies is always in question. Because of this, the HealthTech project must pay attention to gaining commercial-sector interest in the products or finding substitute arrangements that assure availability, quality, and low cost.

The most important factor determining the strategy used to gain commercial sector interest is whether or not there exists a commercial market for the products. Some social technologies have no evident, significant private market potential (labelled "Type A" in PATH nomenclature) although they respond to important perceived health needs.

An example of such a technology among HealthTech products is the BIRTHweigh risk assessment weighing device for newborns. This simple technology, designed for use by nonliterate traditional birth attendants, has no obvious utility other than in developing world primary health care settings. Little or no commercial interest exists for this device at a price that can be borne by health programs or assistance agencies. For this type of technology, there are no opportunities for gaining industrial economies of scale or for covering the risks of the development and capital costs with profits from commercial sector sales. The public health sector must bear the entire cost of these technologies by underwriting the development costs, purchasing the capital goods, and paying a price that covers the remaining cost as well as profit margins.

It follows that this type of technology, where possible, should always involve simple materials and processes so that the risks are bearable and manufacturing can be carried out locally, on a small or medium scale, within the countries that need the product. It is helpful to be able to turn to small-scale industry or, as in the case of the BIRTHweigh, polytechnics and the technology departments of universities, for local manufacturing. Generally, it is useful to provide some business and marketing assistance to these manufacturing units, as well as quality assurance auditing, up to the point where production and sale of the product to public sector agencies are well established.

When a social technology has an identifiable commercial market potential (PATH-Type B), the strategies can be quite different, depending upon the extent to which those private markets are marginal or exist only in the developing world rather than the developed world. And finally, some technologies cannot be scaled up, manufactured, or distributed without the collaboration of a commercial manufacturer (PATH-Type C). It is often necessary in HealthTech to specify the nature and size of private markets in order to gain commercial sector interest. Other incentive-raising strategies include: demonstration of public sector commitment through grant funds for engineering or issuance of purchase orders; reduction of project risks by providing loans at favorable terms; or purchase of capital equipment using public sector funds.

It is necessary to preserve, insofar as possible, the proprietary nature of the technology through pursuit of patents, licenses, and confidentiality to encourage the commercial party to view the technology as protected and therefore of some value. By the same token, often it is necessary to offer exclusive rights to selected private markets, based on specific geographic regions or markets segments. Provided that the private markets are an economic reality or that public agencies are willing to make up-front commitments, a commercial collaborator can be identified, as has occurred with such HealthTech products as SyringeLOCK, SafeTject, and PATHWeigh. The next step is to implement other strategies to protect public sector interests in negotiations with the collaborator.

C. Protecting Public Sector Interests

It must be assumed that the commercial sector collaborator is not motivated by the public health objectives for which the technology was developed. Rather, this collaborator is interested in recovering as quickly as possible any costs incurred by being involved in the project. In addition, the collaborator demands a profit to justify the risks of the investment. Consequently, protecting the public sector interest, i.e., universal availability of the product, lowest possible cost, and responsiveness to local needs, becomes the full responsibility of HealthTech and other interested parties whose goals and objectives are aligned to the public sector interest, e.g., the public sector purchaser. The broad strategies that must be adopted include maintaining sufficient control of the product as it moves into

the commercial sector and achieving the greatest possible efficiencies and economies of scale.

Under the first strategy--maintain control--it is necessary to protect the technology at the outset with patents, licenses, copyrights, design registrations, or even trade-marks, so that title is clear and negotiations are not hampered by questions of ownership. Licensing strategies seek to avoid monopolies, maintaining as much as possible the nonexclusivity of public sector sales in order to promote price competition. If possible, price ceilings are maintained for public-sector sales. The emphasis, however, is on rewarding efficiency since reduction in costs can have a much greater impact than profit margins on the price of the product. Manufacturers in the developing world are employed whenever possible in order to encourage local development, reduce the length of the supply pipeline, and take advantage of lower costs.

Dual pricing is also encouraged so that the commercial sector can carry the burden of cost recovery and return on investment. Commercial manufacturers are encouraged to view public sector sales, not as a direct source of profit, but rather as a means to achieve an internal economy of scale, thereby reducing production costs and increasing the margins on commercial sector sales. Achieving economies of scale is the greatest single goal in bringing down the cost of social products to a level commensurate with public sector needs.

A combination of these strategies must be applied in a highly coordinated and flexible way which takes into account the commercial imperative of economic viability.

D. Strategies for Ongoing HealthTech Technologies

Three HealthTech technologies currently under implementation --PATHwatch/PATHmarker, SyringeLOCK, and SafeTject--illustrate the need for the distinct strategies outlined above.

PATHwatch/PATHmarker is a cold chain indicator based upon a proprietary technology licensed from Allied Corporation. There are no evident commercial markets for this technology. It is basically a printing technology, although the nature of the active material used makes it unsuitable for manufacture in a standard print shop. The production economies are such that sufficient units could be made to supply all the world's cold chains in a few weeks of operation of a single production operation. It also does not blend well with other product lines. PATHwatch/PATHmarker is, therefore, almost entirely a Type A social technology; yet it is one that does not lend itself to local or small-shop operations, either economically or technically.

The principal strategy, therefore, is to develop and promote the public sector use of this device and meet the demand by contracting out the production to a commercial manufacturer. No licensing is therefore involved. Since the development and validation testing of the device have been underwritten almost entirely by a variety of public sector donors (A.I.D.; Canadian International Development Agency;

International Development Research Centre; Clark Foundation), and since no special machinery other than the standard offset printing press is required, there are no project costs to recover. Otherwise, the price of the product would be prohibitive. At this time, the price need only reflect the costs involved in production and distribution to public sector, World Health Organization/Expanded Program on Immunization (EPI) programs. Some economies of scale are still possible, so the strategy is to extend the use of this device to as many EPI programs as possible through introduction trials, cooperation with international and national agencies and governments, and other promotional activities.

SyringeLOCK is a component which attaches to an ordinary disposable syringe and renders it capable of only a single filling and injection cycle. Since the developed world relies upon disposable syringes designed to be used only once, a technology that guarantees single use has both health and commercial value. The market for syringes in the U.S. and Europe does not yet demand this single-use guarantee, however. Unless syringe manufacturers anticipate a future demand or future legislative intervention in this regard, they do not have a strong incentive to become involved in developing this type of technology.

The strategy to gain commercial sector interest in SyringeLOCK was focused primarily upon demonstrating public sector commitment, and secondarily, upon pinpointing commercial sector markets in the developing world. In anticipation of the commercial sector view of the SyringeLOCK as a marginal business proposition, the technology is being protected with patents. Advanced development and engineering, including scale-up engineering, have been carried out under HealthTech. As a result, international syringe manufacturers have expressed interest in it and it has been licensed to one of them. PATH has been especially effective in gaining access to the commercial developer and bridging the private-public sector gap with the international public sector purchasers. Immediate future strategies include field trials to demonstrate the practicality and acceptance of the new technology in the EPI setting, and negotiations between a key public sector purchaser (UNICEF) and the licensed manufacturer in order to arrive at a price/quantity structure.

In the case of SafeTject, a new set of factors prevails. SafeTject is a prefilled, disposable, self-destruct injection system that has not previously been used in the commercial sector. It is based upon the Ezeject technology owned by Merck and licensed to PATH for adaptation to developing world situations. There is, however, a potential commercial market which should be exploited in order to achieve the economies of scale that would bring the public sector price of the technology down to an acceptable level. SafeTject is a Type C technology requiring participation by industry at many levels; this includes the production of custom machinery and components, the assembly and sterilization of SafeTject systems, the supply of the product to vaccine and medicament manufacturers and the filling and marketing of vaccines and medicaments packaged in this form. The key customers in this scenario are the medicament and vaccine

manufacturers who need to be persuaded of the economic value of this technology before they will be willing to make the large investments required in market development, regulatory clearance, and filling and sealing machinery.

Licensing the use of SafeTject entirely to a single commercial party in this case would defeat the objective of public sector interest. In a commercial investment setting, the large capital cost required for the production machinery would need to be recouped in two to three years, forcing the price of the devices to a level beyond the means of public sector programs. Since the machinery involved generally depreciates over very long periods (15 to 20 years), a system of financing could be offered that can be paid back over the long term, thus relieving the pressure on pricing. Strategies must then be adopted to expand the applications for SafeTject as quickly as possible, so that costs can be spread over the greatest number of markets.

Efforts to achieve economies of scale include working with manufacturers of injectable medicines and vaccines to assist in achieving regulatory approval, identification of new applications for the system, active promotion to the pharmaceutical industry, introductory field trials, and a number of other activities. Licensing strategies are aimed first at a commercial development partner and secondly at the medicament or vaccine manufacturers who will fill SafeTject with their various medicines or vaccines. These strategies will assure general public sector availability, high economies of scale, and dual pricing for primary health care injectables packaged in SafeTject.

The orchestration of these activities to lead to the introduction of a radically new product requires a high degree of coordination and a good deal of flexibility. Suitable checks and balances are already built into this program, including a fully paid-up, royalty-free, nonexclusive license to the U.S. government; independent evaluation and validation of the technology by each medicine or vaccine manufacturer and their regulatory agencies; independent field evaluation by WHO/EPI; and the availability of the device to any or all vaccine manufacturers for public sector use on a nonexclusive basis.

The information presented above provides examples of strategies for converting social technologies developed or identified by HealthTech into economically self-sustaining health products available for public sector health programs over the long term. The application of these strategies by nonprofit agencies dedicated to social objectives represents to some extent a pioneering effort. Another important step is the clear communication of HealthTech's intent, objectives, and strategies to international and national organizations. Such groups have traditionally viewed the public and commercial sector as separate and distinct entities operating in a spirit of mutual mistrust. The synergistic value of collaboration between public and private sector and the many useful ways that commercial entities can facilitate and participate in the process of making social technologies

available to the development world are messages that HealthTech and PATH seek to put forward at every opportunity.

IV. THE HEALTHTECH PROJECT

On August 31, 1987, A.I.D. informed PATH of three year funding for its proposal entitled "HEALTHTECH: Technologies for Child Care". A level of support of $4.618 million was committed through a cooperative agreement. One million of the total was provided for A.I.D. mission participation via "buy-ins" concerning field testing of new technologies and/or support for local manufacturing. Effectively, $3.6 million would be provided directly to PATH and relevant A.I.D. missions could realign their own budgets in support of HealthTech projects up to a total of $1 million.

A. Purposes and Objectives

HealthTech would provide, within A.I.D.'s Child Survival Program, a flexible and efficient mechanism to deal with the "hardware" aspects of immunization and other child survival priorities. This program which would complement the activities of other A.I.D.-assisted projects, and build on PATH's capability to improve health in the developing world through the accelerated development, field assessment, and introduction of needed technologies.

The purpose of the Cooperative Agreement is to provide support to the HealthTech project which is designed primarily to establish a mechanism for identifying, developing, field testing, and introducing technologies for child health that will address critical needs in product development for child survival technologies. The project is to adapt first world technologies for third world use or to create new, appropriate, products within the context of the Child Survival Program. Thus the products would be oriented to child survival interventions which are appropriate for field use in less developed countries.

HealthTech's philosophy is to provide a turnkey, holistic approach, i.e., develop the product, ensure a sufficient infrastructure in the target country to support the product, implement a program of introduction including communication, training, cooperation with relevant local authorities and health care providers and with global health care agencies, and to provide for follow on support after introduction to ensure sustainability of use.

Other key objectives of the Cooperative Agreement include:

- A.I.D. would be substantially involved in the project by actively participating in key activities;
- HealthTech would encourage private sector involvement in all aspects of the project including product development, investment, indigenous manufacturing and/or product distribution, etc;

- o HealthTech would develop a single use vaccine injector and other immunization-related technologies appropriate for field use in less developed countries;

- o HealthTech would seek technologies, adapt them and lead them through implementation by carrying out field trials, refinement activities, production engineering, packaging and the manufacturing activities;

- o HealthTech would ensure that manufacturing, distribution, technical assistance and financing would be provided through indigenous organizations in less developed countries; and

- o HealthTech would introduce products into public-sector health programs through information dissemination activities.

HealthTech can be viewed as a model mechanism to speed up the process by which new technologies are brought to the health area in the developing world.

B. Time Frames of HealthTech

A.I.D. is experienced in acquiring and distributing tried and true demonstrated technologies into developing countries. A.I.D. personnel are familiar with the multi-year time frame connected to this process. Because HealthTech is developing and testing new products prior to their distribution, the overall time frame is even longer. Thus overall expectations must be adjusted to this longer time frame and not viewed in the three year time frame of the initial A.I.D. support.

C. Relationship of Specific HealthTech Projects to the Child Survival Program

HealthTech interacts with the Child Survival Program in terms of mutual goals, common projects and use of common groups to implement projects This interaction is possible because A.I.D. focuses on the reduction of infant and child mortality in a number of different technical, geographical, and services areas under the umbrella of CSP.

A major area for HealthTech support is in immunization programs. Broader issues in immunization programs include:

- o Logistical complexities impacting on the effectiveness of immunization campaign;

- o Need for newer, better vaccines which require expensive research to develop and test;

- o Injection devices are needed that eliminate the risks of immunization-associated infection;

- o Local production as an approach to logistical and economic problems of immunization programs;

- o Alternative financing of programs to support sustainability of national immunization programs; and

- o National political environments impacting on programs.

HealthTech seeks to facilitate technologies addressing specific problems of logistics, e.g., vaccine cold chain, and immunization associated infection, with transfer to local production where feasible. This facilitating role includes taking advantage of established relationships between A.I.D., WHO, UNICEF, other U.S. agencies (both government and PVO), and private sector entities here and abroad.

HealthTech does not limit "facilitating" to aspects of technology or service delivery, but will, when necessary, address problems associated with conventional financial processes, or general economic and political policies. This was demonstrated in an activity supporting another major CSP area, maternal/child growth monitoring, when they tackled the problem of how to obtain stainless steel for local production in Malawi given currency and customs restrictions.

The CSS has five major intervention strategies: diarrheal disease control, immunization, child spacing, nutrition, and related interventions. HealthTech is only one mechanism by which A.I.D. develops technologies in support of CSS. For example, the DiaTech project is funded by A.I.D. to develop diagnostic technologies. There is also, for example, the program for introduction and adaptation of contraceptive technology (PIACT) sponsored by the Population Council. It is not within the scope of this evaluation to evaluate HealthTech products relative to the needs of the entire child survival strategy. To do so would require examining all existing primary care technology development programs for less developed countries as a whole. Because of PATH's unique role in many of these programs, HealthTech is in a good position to make these judgments, and it appears that they have done so in an effective way. A.I.D. should consider doing an evaluation of all primary care technologies developed relative to A.I.D.'s priorities within the child survival strategy.

Given those caveats mentioned above, the Evaluation Team arrayed the current HealthTech technologies under CSS strategies. (See Figure 4.) The HealthTech products were evaluated as to their relevance to CSS. There is an excellent synergy with the immunization strategy. The injection and cold chain technologies, when fully developed, can make a major contribution to this strategy.

The maternal/child growth monitoring and iodine deficiency diseases technologies can make substantial contributions to the nutrition strategy. Under related interventions, infection control technologies provide some potential solutions to specific situations of the general spread of infection. HealthTech has selected an array of technologies that support key aspects of the CSS. It appears that they do not duplicate complimentary CSS efforts funded through other mechanisms or with other sponsors.

Figure 4. A.I.D. Child Survival Strategies and HealthTech Technologies

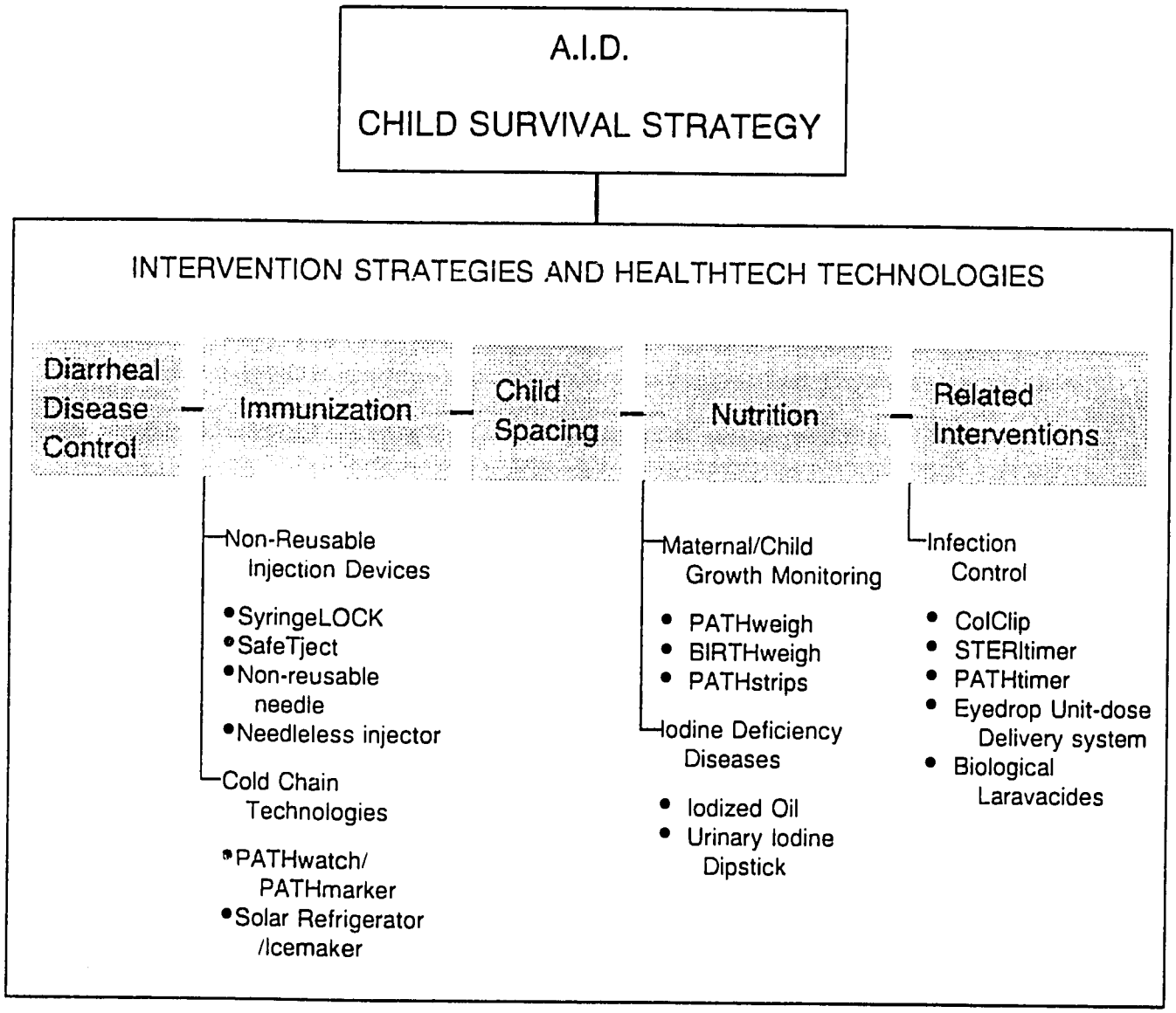

Figure 5 shows current levels of opportunity for technology application in various A.I.D. child survival emphasis countries.

D. Continued Efforts are Needed

Leaders in developing countries want help to improve their immunization programs, but they face many barriers.

- o Logistics systems for immunization are complicated and need continued A.I.D. assistance;
- o Research is needed to discover new and improved vaccines against malaria, cholera, measles, whooping cough, rotavirus, diarrheal diseases, typhoid fever, pneumococcal pneumonia, and Group B Streptococcus;
- o Nonreusable injection devices are an urgent priority to eliminate the risk of immunization-related infection;
- o Private sector pharmaceutical companies in developing countries could manufacture vaccines and other immunization commodities;
- o Developing countries cannot afford to sustain national immunization campaigns unless alternative financing systems are found; and
- o Immunization programs can be important to the political goals of leaders in developing countries.

E. Collaboration With Other Agencies

A.I.D. has become increasingly closely allied with multilateral agencies like WHO and UNICEF in seeking ways to alleviate the health problems of developing countries. UNICEF is most closely involved with the global immunization initiative. A.I.D. has contributed $54 million to UNICEF, WHO and UNDP over the last four years.

A.I.D. actively works with the private commercial sector:

- o With firms making oral rehydration salts;
- o With employers who are anxious about rising health costs; and
- o With potential manufacturers of vaccines and other health sector products.

The academic community is another resource that A.I.D. calls upon to assist with health programs.

Figure 5. Child Survival Program Emphasis Country Strategies

AFRICA	ASIA/ NEAR EAST	LATIN AMERICA/ CARIBBEAN
Kenya[1]	Bangladesh[2, 3, 4]	Bolivia
Malawi[2]	Egypt[3]	Ecuador[4]
Mali[4]	India	Guatemala[4]
Niger	Indonesia[1]	Haiti
Nigeria	Morocco	Honduras
Senegal	Nepal[4]	Peru
Sudan	Pakistan[3]	
Zaire	Yemen[2]	

1 PATH has existing infrastructure (2)

2 Other PATH programs exist (3)

3 Countries likely to have buy-in funds (3)

4 Other countries where application may be possible (5)

A.I.D. works with other government agencies:

- o Department of Health and Human Services:
  - Office of International Health
  - The National Institutes of Health
  - The Centers for Disease Control
- o The Peace Corps
- o Department of Commerce:
  - Bureau of the Census

F. Achievables Within the HealthTech Project 1987-1990

In spite of the long time frames involved from product development to actual daily use in the third world, progress can be measured in terms of interim steps toward the final goal of effective products widely distributed and properly used.

Health product development from definition of need to product approval is a process that normally takes from three to ten years in a commercial setting. Scaling up to manufacture the product, followed by introduction of the product to all identified markets, may take an additional one to three years. For social technologies, adapting the product for local use and effectively coupling the plans and actions of the buyer and the user groups can take much longer, as judged by experience with vaccines, oral rehydration salts, and other widely endorsed technologies developed for primary health care.

HealthTech must be viewed as a mechanism to speed up the process by which new technologies are brought to the health arena in the developing world. Progress in HealthTech can be measured at intervals of months with milestones that indicate real progress down the pipeline toward the final goal of effective products widely distributed and properly used.

The following was developed by the Evaluation Team with active HealthTech involvement and represents the milestones that can be reviewed to indicate progress down the pipeline:

1. Adaptation of PATH's system for development and advancement of social technologies to function efficiently and effectively under an A.I.D. Cooperative Agreement.

2. Continual screening of new technological opportunities: since relatively few products successfully arise from a larger number of candidates, it is important for HealthTech to maintain a vigorous technology screening activity.

3. Advancement of specific technologies from one development stage to the next; for example, from feasibility stage to product development, or proof of concept to design validation field trials.

4. Successful implementation of a risk sharing strategy; cost of a project shared in part or in whole with a third party (public or private) outside of A.I.D. or HealthTech.

5. Establishment of relationships and ongoing interactions with local A.I.D. missions in different countries; participation of missions in planning and implementation of field trials, introduction, and/or technology transfer of HealthTech technologies.

6. Securing, through written agreements, arrangements which serve to protect the public sector. Without the influence of HealthTech as an intermediary, these factors would not normally be considered in the best commercial interests of a private collaborator.

7. Effective introduction of a technology into a developing world setting; making sure the technology is locally suitable and acceptable, and that mechanisms are available for procurement and distribution.

8. Establishment in a developing country setting of a local production unit for social technologies that do not appear to have high initial commercial appeal.

9. Demonstration of effective collaboration between private and public sector parties in the development and advancement of social technologies for health; these interactions can become models for public health programs and convince private sector firms of the value of such collaboration.

10. Achievement of wide coordination and collaboration between national and international health agencies in the pursuit of meaningful social technologies for health.

Expectations for progress can only be realistic if it is remembered that there are a number of large organizations involved in the process, e.g., A.I.D., WHO, UNICEF, indigenous health ministries and government departments. While their involvement <u>is critical</u> to the success and sustainability of the end products, their involvement will ultimately lengthen the time necessary to achieve the final goal.

V. DESIGN AND MANAGEMENT OF THE HEALTHTECH PROJECT

A. General Management Issues

HealthTech was organized recognizing that it must work at the interface of a number of dissimilar organizations worldwide: public sector agencies, private sector corporations and universities are all involved both in the U.S., on a global basis and in particular less developed countries. In response to this recognition, specific individuals have been hired by PATH for HealthTech who appear to work well in such a fluid, interface environment.

HealthTech has adopted matrix management techniques where individuals are involved in a number of ongoing projects. This style of HealthTech management is effective and ensures that relevant expertise and enthusiasm are drawn upon within HealthTech and within PATH as needed to get the job done. This matrix of skills and people is very appropriate given the complexity of the product development and the differences in dealing with public agencies and private sector corporations. However, in each project, one person is designated project leader so that responsibility for the success of the project is clearly designated.

PATH Management meets in a Management Council once a month for a full day. HealthTech progress is routinely discussed. Shorter weekly meetings of the Management Council ensure constant surveillance and support. In addition, the collegial management style of HealthTech and PATH managers helps promote progress. Once a project is conceived, financing identified and a manager found, progress milestones are established and expressed in GANTT chart format. The available HealthTech GANTT charts tended to give detailed engineering milestones of product development. An additional chart including estimated budget allocations for each project extending over the entire project would prove useful to management.

The HealthTech project uses modern management tools and techniques that would be found in progressive companies in the private sector undertaking product development and marketing.

There has been a question whether HealthTech should focus on fewer technologies to get a smaller number of them into the field more quickly. The evaluation team believes the current method is the best, i.e., A.I.D. funds an array of technologies and approaches. This method is better suited to the uncertainty that any one technology will actually reach final implementation as well as the ability to divert to other technologies when work is slowed down or stopped by the process.

Questions have also been raised about PATH's potential conflict of interest with PATH-owned technologies or ones in which they had large time investments. The evaluation team found no evidence of this, in fact we find that PATH mirrors the public interest values of A.I.D..

B. Leveraging Projects with Ongoing Programs for Child Survival

HealthTech has effectively collaborated with ongoing projects of the Child Survival Program to lever its own scarce resources. HealthTech's technologies are developed with the assistance of individuals within the following A.I.D. supported programs: REACH, SafeBirth, SUPPORT, and EPI. This assistance ranges from inclusion of HealthTech technologies with ongoing field trials, to feedback for product design depending on specific developing country needs. In addition, USAID mission personnel suggested to HealthTech the name of an African manufacturer who is now very interested in manufacturing the PATHstrips.

C. Expanding Capability to Provide Internal Critical Mass to Support Progress

A.I.D.'s support is critically important as it provides funds to gather a critical mass inside PATH to concentrate on health care product development. The financial support allows PATH to focus activities in this area and provide the necessary human and financial resources that will improve the chances of success.

D. People Management

The Evaluation Team was constantly struck by the overall enthusiasm and dedication of HealthTech and PATH personnel to public health and child survival. While all individuals demonstrated high personal enthusiasm, the organization and management of the project formally pays attention to constantly renewing and enforcing this enthusiasm and dedication. Again, very modern and sophisticated management techniques are used by HealthTech.

Personnel support policies are used wisely and well to create an active project morale and a feeling of being part of the team. HealthTech has taken care to select individuals for the project where their experience, background, and personalities are well suited to make major contribution to the project. Both PATH and HealthTech appear to have effective affirmative action programs and sustain a very progressive social attitude

E. Intellectual Property Management

Because HealthTech and PATH operate on the interface between the public and private sectors, it is necessary for HealthTech to ensure that public sector interests are properly protected, thus ensuring that the results of this project are widely available, at the lowest cost. One mechanism of protection for such intellectual property is the use of such legal instruments as patents, trade marks and copyrights.

The Evaluation Team was specifically asked to "review and evaluate PATH/HealthTech invention disclosure process, as required by the Cooperative Agreement's Optional Standard Provision for Nongovernmental Grantees, Patent Rights (November 1985)".

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HealthTech personnel have a good knowledge of intellectual property management. PATH has recently added in-house legal counsel specializing in this area. PATH employee policy manuals contain copies of the relevant A.I.D. requirements and key HealthTech people are sensitive to this issue and actively work to comply with these regulations. Work projects are designed in such a way that there appear not to be any incentives not to actively comply with these government regulations. After a detailed review of this aspect of the HealthTech project, the Evaluation Team concluded that HealthTech has a mechanism in place to protect the public interest through protecting the intellectual property and furthermore, that the public interest is being protected in the legal licenses between HealthTech and the private sector. (See Annex 7.) This mechanism appears to be working well. The team believes there is active compliance with the government regulations and demonstrated success in HealthTech's ability to attract major corporate partners and protect the public interest.

F. Financial Management

The significant participation of A.I.D. ensures some degree of A.I.D. awareness and financial control of the expenditure of its funding through the HealthTech project. While the team did not perform a financial audit, some members did read the audited 1987 and draft 1988 financial reports for PATH. The statements were straightforward and no significant issues arose. The financial statements were audited by Ernst & Whinney in accordance with generally accepted auditing standards and the relevant Federal directives.

VI. PRODUCT BY PRODUCT DATA REVIEW

In order to provide a focused framework for the analysis of such varied products/projects, it was necessary to define some common data elements that are applicable "across the board". A review of the statement of work for the evaluation team provided an array of issues to be examined for each product development activity and for the project as a whole. The next step was to identify factual data elements that would serve as indicators to support judgments of success/progress in each area of interest.

The characteristics or criteria as developed requested ten specific pieces of information as follows:

1. Timelines showing major milestones were requested, showing

   a) the development process as originally envisioned; and

   b) the development process as it has played out to date, with any modifications of anticipated milestones.

2. Having reviewed PATH's general model of project management, the team requested "management-by-exception (MBE)" information on each activity, i.e., "What modifications or other adaptive processes have been required to manage this activity effectively?"

3. What private sector interfaces have developed in the course of this activity?

4. What selection and screening processes were used to focus on this particular product/technology as most suitable to pursue development under HealthTech?

5. What relationships has PATH developed with other organizations operating in the child survival programs arena which will contribute to progress or success of this activity?

6. What are the product development and technology transfer plans specific to this activity/product?

7. What relationships have been developed with USAID missions specific to this activity?

8. What provision is being made in transferring these products/activities to private sector entities to protect public sector interests as required to justify A.I.D. funding of these activities?

9. What is the disclosure status of any product/technology associated with this activity?

10. What are the promotion and dissemination plans for the product resulting from this activity?

Forms briefly addressing each of the ten items were filled out by PATH staff for sixteen products associated with the HealthTech project. In analyzing this data, it is important to remember that the HealthTech project essentially provides a three year "cut" or "window" in much longer development/dissemination life cycles. The discussion of models of these life cycles provided in the introductory section of this report was intended to provide a context for this analysis. Because HealthTech enters the process at different stages for each product development activity, the requests for uniform data elements result in very different, but appropriate and relevant, facts from activity to activity.

Review of the timelines emphasizes that product development is an iterative process, not a linear one. Six of the activities are approximately on schedule per their long-term timelines, although delays may have slipped milestones within the three-year HealthTech "window".

Two obvious categories of unanticipated delays are apparent from the review of the timelines and the MBE data. One more-or-less predictable category is associated with technical problems in the product development, manufacturing scale-up sequence. Five activities have experienced these types of problems. Three products experienced major design problems resulting in significant reconfiguration or a completely new approach to the technology. In the case of PATHweigh, which uses solar technology for weighing the existing technologies being evaluated by the HealthTech project were abandoned when a breakthrough technology became available. Two activities experienced less significant problems with design of either the product or of innovative manufacturing equipment. As explained by the President of Acacia Laboratories, "PATH had taken these technologies 90% of the way, but the last 10% included some tricky technical issues requiring solution before full production." In one final activity, technical problems with an individual manufacturing firm resulted in a search for an alternate source of the product.

The other problem category can roughly be described as "process" issues. Negotiations tend to get bogged down on minor points that no one expected to be problematic, e.g., Becton Dickinson's very conservative policy regarding disclosure agreements for external technologies, which affects two projects. Unpredictable quirks in relationships with individuals at early phases of activity may control process, e.g., ColClip inventor's representative is often unavailable due to other commitments; the subcontractor for the Urinary Iodine Dipstick is an entirely appropriate selection from a technical viewpoint, but seems to be determined to operate at his own pace and timeframe. At the introduction-dissemination end of the range, environmental/political factors may come into play, e.g., difficulties in obtaining stainless steel and/or hard currency allocations for production of BIRTHweigh in Malawi, or the problems in locating a less developed country manufacturer for PATHStrips.

Nine of the activities include concrete relationships with private sector entities which appear appropriate for the current phase of product development. Five activities include active searches for private sector collaborations. Two activities related to accessories/adaptation for existing technologies include more tenuous relationships with manufacturers of those products.

No one model for selection and screening of technologies dominates the PATH activities. When possible PATH builds on selection processes by existing organizations such as the WHO EPITECH panel, or NIH peer review panels. PATH may do such scanning as in-house activities, e.g., search of 687 patent abstracts of devices to prevent needle sticks, or it may be included as a phase of a subcontract. Flexibility and appropriate selection criteria relating to the end use of the product are key to this process.

PATH has a long history of involvement in contraceptive technology and maternal/child health programs. This is apparent from the wide range of relationships with other child survival program entities in support of each activity.

Seven products/activities have firm product development and/or technology transfer plans in place. In five of these the responsibility for this transition rests with the collaborating entity rather than with PATH. One product group, PATHwatch/PATHmarker, has been determined to be unsuitable for technology transfer. Three activities are in more preliminary stages, but plans are conceptually complete pending identification of a private sector collaborator. Three activities are at early phases and such plans would be premature. One product, STERItimer, is undergoing re-evaluation of this issue, due to technical problems in retrofitting the device to previously distributed sterilizers.

PATH is actively pursuing relationships with USAID missions, especially as activities move into field level phases, e.g., field design review, limited field trials. At this time, five activities actively involve the support of USAID Missions. In five other cases, USAID Missions are informed but not actively involved. Plans for three activities do not include field activities and probably will not involve individual USAID missions. Five activities are in early stages and appropriate roles/relationships/locations of USAID Missions have not been defined.

PATH policies and programs demonstrate a full commitment to the protection of public sector interests in the process of product developer. Within the HealthTech context, PATH often has no legal or economic power to impose these condition on private sector collaborators. Given these constraints, the fact that eleven operational agreements, in place or pending, include significant concessions to the public sector is remarkable. A twelfth collaborator is, in fact, a parastatal organization acting for the public sector. In only three cases is PATH's ability to act in the public interest restricted to informal influence and persuasion.

Only SafeTject is a subject invention subject to disclosure. There is a possibility that the activity to develop a Urinary Iodine Dipstick could result in something subject to disclosure, but all other activities have been reviewed and found not to be subject to disclosure at the time of the review.

Twelve of the activity plans address, at least in general terms, the promotion and dissemination of the product. Three of these place primary responsibility on the private sector collaborator; two are at an early enough stage that this is primarily a matter of timing, but marketing plans for the third are held confidential under the license agreement. The other nine plans focus entirely on traditional public sector/donor programs dissemination.

Figure 6 on the following pages presents a summary of HealthTech products.

Figure 6. HealthTech Product Summary

Product	Timelines	MBE	Private Sector Interface	Selection & Screening	Child Survival Program Interface	Product Development & Tech. Transfer Plan	USAID Relations	Public Interest	Disclosure Status	Promotion & Dissemination Plans
SyringeLOCK	Prolonged negotiations delayed license agreement @ 1 yr.	Iterative development process not anticipated	Becton-Dickinson	EPITECH panel	WHO/EPI UNICEF AID, REACH IDRC	Field trials by REACH; BD has rest of responsibility	USAID/Pakistan & Gov. of Pakistan agreeable to field trials using REACH project	BD license includes royalty free to public sector, intervention clause	None	AID programs, UNICEF, WHO/EPI
SafeJect	@ 6 mo.s behind; field trials rescheduled	Non-conventional product & manufacturing technologies; iterative development process	Acacia Laboratories	EPITECH panel	AID WHO/EPI	Acacia/PATH develop, Acacia markets	Plan to involve for field trials	Merck gave license with all public sector clauses	Subject Invention fully disclosed	Confidential to date
Non-reuseable Needle	On schedule	Prolonged negotiation with JHU/APL	JHU; ATC re: sterilization of polymers anticipated– BD or Terumo	Concept review at WHO & NIH; material selection screen at JHU/APL	AID WHO NIH	Phase I & II via HealthTech; plan to license from for remainder	N/A	Influence/persuasion only	None	TBD
Needleless Injector	1 yr. screening and evaluating available technologies not anticipated in original plan	End user study needed	Providing feedback to manufacturers of existing devices	In progress; will include EPI	AID UNICEF WHO/EPI CDC	PATH planning to assist manufacturer	N/A	Plan to include provisions in license	None	TBD
CelClip	5 mo.s manufacturing delays on prototypes; BD disclosure policies delaying negotiation phase	Inventor's representative often unavailable	2 potential firms identified	687 patent abstracts for same application	AID WHO/EPI	PATH assisting	Not yet	Public interest through WHO/EPI process	None	EPI trials; DIRECTIONS ?
PATHwatch/ PATHmarker	Negotiations, gaining WHO acceptance took 2 1/2 yrs.	Product team, Inc. Product Mgr. and Field Activities Mgr.	Indicator licensed from Allied; printing contractor; vaccine manufacturers	Continuous Monitoring of other cold chain technologies	AID WHO/EPI,HQ WHO/EPI, PAHO UNICEF nationalprograms	Not suitable for transfer	USAID/Thailand, Kenya, & Indonesia informed and supportive	License from Allied for public sector; goal to get donor to provide to vaccine manufacturers at low/no cost	None	AID programs; PATH developed info module for UNICEF and local EPI's; relevant conferences, DIRECTIONS ?
STERItimer	Redesign required	First model did not meet criteria; reconfiguration required	Sterilizer manufacturers	WHO/GPA; lab testing reconfiguration	AID WHO/GPA UNICEF/UNIPAC	?	N/A	License includes unrestricted public sector use	None	WHO/EPI; UNIPAC; PATH info sheet; DIRECTIONS
PATHtimer	HealthTech funds/time period cover validation, market introduction phase of product originally conceived in 1983	First manufacturer inadequate; search for alternate source	License from technology owner; searching for firm to manufacture	Materials screening	AID WHO/EPI UNICEF IDRC	US production; introduction via SafeBirth project; in 1990 UNIPAC catalogue	TBD	Price & availability clauses in license; QA monitoring for 1st yr.	None	AID programs; UNIPAC; WHO/EPI; DIRECTIONS
Solar Refrigerator	On schedule prior to workplan submission	AID funds for field assessment only	U.S. developer; Thai manufacturer	Conducted under HealthLink	AID Thai EPI,MOH	Technology transer under separate AID grant to US developer	USAID/Thailand fully informed	Conditions of license at discretion of US developer	None	Product promotion up to firm; PATH may help to spread to other programs; results of trials to AID programs, WHO

Figure 6. HealthTech Product Summary (Continued)

Product	Timelines	MBE	Private Sector Interface	Selection & Screening	Child Survival Program Interface	Product Development & Tech. Transfer Plan	USAID Relations	Public Interest	Disclosure Status	Promotion & Dissemination Plans
PATHweigh	Not available	Genuine technology breakthrough required	Kistler-Morse (Phase I); Masstech through "Sensor" joint venture	Existing technology evaluated/ developed by PATH; dropped in favor of breakthrough technology	AID UNICEF; WHO/MCH; IDRC; Aga Khan; OXFAM; Carneigie Corp.	Limited field trial-UNICEF acceptance-large field trials-major manufacturer of scales	USAID/Pakistan informed & supportive of field trials; USAID/ Malawi informed of trials	Sensor commitment to PATH on public sector provisions	None	AID programs, WHO/MCH Bulletin; marketing TBD
PATHstrips	Pilot plant mfg. 1987; search for LDC firm on-going since then	Problems finding LDC manufacturer	Private firm in Zimbabwe; parastatal in Indonesia	Standard technology	AID WHO/MCH IDRC	Product ready, problem is finding manufacturer in LDC	USAID/Zimbabwe assisting in search for manufacturer	License will include cost & QA provisions	None	Product info sheet; PATH will assist LCD firm in promotion & distribution; WHO/ MCH, UNICEF regional
BIRTHweigh	Expansion to new locales more complex than expected	Hard currency/ steel source problems in Malawi partially overcome	Manufacturer/ iinstitutions in Egypt, and/or Pakistan	Other spring scales reviewed-need for durability, illiterate users drove choice	AID WHO/MCH; UNICEF; IDRC; Carnegie Corp. Ford Foundation	Transferred to Malawi Polytechnic Institute for region; similar arrangements sought	USAID/Egypt, Malawi informed	License includes QA, public sector clauses, availability	None	Training for TBA programs; info sheet for UNICEF
Silver Nitrate Eye Dropper	First approach was dead-end; re-start required	Re-start	Inquiries to 30 firms	WHO/MCH; FDA master file	AID WHO/MCH	PATH training/ distribution package; WHO/ MCH trials; local production?	TBD	Lower cost than under current procurement contract	None	AID programs; International Eye Foundation; WHO; DIRECTIONS; SafeBirth Project
Urinary Iodine Dipstick	Subcontract took 5 months; subcontractor taking much slower approach than planned	Pace controlled by subcontractor	TBD	Addressed in subcontractor feasibility study in-progress	AID others TBD ICCIDD?	TBD	TBD	AID patent provisions in subcontract	Not yet	TBD
Iodized Oil	On schedule prior to workplan submission; site visit delayed pending AID approval	Pace controlled by Kimia Farma, Indonesia	Kimia Farma; refused by Merck, Guebert	Review of treatment modalities programs	AID ICCIDD; MOH Indonesia; WHO; UNICEF	Kimia Farma responsible	USAID/Indonesia supportive	Parastatal developer	None	Via ICCIDD
Biological Larvacides	Field trials pending AID approval of workplan; approval rec'd. 1/89	PATH facilitating between Abbott & MOH	Abbott Labs	Conducted under Health-Link	AID MOH Indonesia; MOH Thailand	US approvals obtained Abbott & local partner responsible	USAID informed but uninterested	Field trials to demonstrate public appropriateness; will compete with existing pesticides on safety profile	None	TBD

VII. LONG-TERM AND PHILOSOPHICAL ISSUES ASSOCIATED WITH HEALTHTECH

The A.I.D. Cooperative Agreement with PATH for HealthTech and the Scope of Work (SOW) for the evaluation team are both rather narrowly focused on the conventional project management aspects of the current three-year agreement. HealthTech is not a conventional project, however. The nature of the tasks to be performed and the innovative approach to relationships between collaborating public sector, non-profit, and private/commercial entities introduce much broader issues that are not specifically addressed by the formal documents for the project.

First and foremost, HealthTech takes A.I.D. into new roles and relationships. Traditionally, A.I.D.'s role has been in the procurement and distribution of conventional Western-style medical equipment for use in health care delivery systems in less developed countries. The intellectual recognition that this has not always been effective has driven the search for newer approaches to locating and providing more appropriate technologies. The lack of availability of such technologies in the market-driven Western industry has, in turn, driven A.I.D. to experiment with the actual development of such technologies via the HealthTech project.

The fact that this is a perfectly logical sequence of events does not obviate the fact that this is a new approach, a new way of doing business. This fundamental newness inherently creates a loss of comfort, a sense of risk, and a general sense of uncertainty regarding the project.

At a slightly less abstract level, HealthTech deals with a type of research and timeframes that A.I.D. is unaccustomed to dealing with. Within the health field, A.I.D. is used to providing grants to non-profit groups for model projects in social services delivery. A.I.D. is used to dealing with arms-length, buyer-seller, procurement relationships with private sector firms. HealthTech involves products, not services, and the cooperative agreement which mandates more "significant involvement" for A.I.D. staff in the project than is customary for either grants or procurement contracts. It creates entirely new roles in a complex three-way collaboration between entities from sectors driven by very different assumptions and values. These differences have a potential for creating significant miscommunications and a general level of anxiety around everyone associated with the project.

The evaluation team believes that it is important to deal with these less tangible issues associated with HealthTech explicitly. The ultimate contribution of these technologies to the Child Survival Program depends on the ability of all entities involved to:

- Stay-the-course through relatively prolonged timeframes;

- o Understand the process well enough to judge when relatively modest infusions of resources can catalyze critical points/progress; and,

- o Accept the risk associated with innovation.

Institutionally, A.I.D. understands the complex factors needed to provide "sustainability" to a development project. In order to meet the final goals of effective products widely distributed and properly used, HealthTech must have built-in sustainability in all of the sectors which it draws together.

The evaluation team believes that the collaborative approach and relationships being developed in the HealthTech project have a very high potential for making long range contributions to the Child Survival Program and perhaps ultimately to even broader aspects of international public health. In order to fulfill that potential it will be necessary to define the philosophical differences underlying each sector and make explicit the co-existing value that make collaboration possible. HealthTech can succeed only on the basis of "win-win" deals.

Acknowledging these fundamental, philosophical value-driven issues will permit the use of resources, especially people and travel, for the activities necessary to build the trust and communication levels essential to sustainability in this collaborative context.

In discussions during both of the site visits to commercial collaborators, it was apparent that HealthTech has been very sensitive to these issues of trust and communication in their activities to date. Despite very different organizations and values, both relationships were effective and productive. This sensitivity may very well reflect institutionalized humanistic values within the corporate culture of PATH.

If HealthTech is to serve as a model for other types of public-private sector collaborative projects, these intangible aspects of developing collaborative relationships for long-term effectiveness must be made an explicit part of both the HealthTech project and any generalized model growing out of it.

VIII. POLICY RECOMMENDATIONS

A.I.D., through this cooperative agreement, has recognized the importance that basic health technology can play in improving the delivery of child survival services. This foresight is applauded. There is concern that A.I.D. may not have adequately addressed the long-term nature of the technology development process. (The evaluation team recommends that A.I.D. review the time paths included in this evaluation report for each technology under development under HealthTech and make an early decision regarding the possible extension of this project.) A time path review taken well in advance of the terminal date of the agreement will allow the HealthTech project managers in PATH and in A.I.D. a better understanding of the framework within which health technology development is taking place. The evaluation team recommends the project be extended now for an additional three year with appropriate funding. Because of the long-term nature of the activity, the team recommends that future technology development agreements have, at a minimum, a five year basic cooperative agreement.

With technology development often having blind alleys, it is appropriate that the HealthTech project provides for exploration of a variety of products in the child survival field. A.I.D. should continue to follow this pattern for technology development and should not limit the research field to any one particular area (lest new technology be left out of the running for lack of funding) since there is a very real risk that significant new technology would be overlooked under such funding restraints.

Regarding the cooperative agreement with A.I.D., the agreement calls for a collaborative style. The Cognizant Technical Officer (CTO) at A.I.D. can greatly influence the success or failure of any project through timely project management. The team recognizes productive working relationship that has developed between the HealthTech staff and the A.I.D. CTO. This is an especially important management element for this innovative project. Normal A.I.D. personnel rotational policies do not lend themselves to the long-term nature of this project. The team recommends that transitions between CTOs be handled very carefully to avoid detrimental effects on the project.

Because time paths for technology development are often critical, we are concerned that the HealthTech work plans that must be submitted to A.I.D. for review and approval be approved by the Office of Health with all due speed. Attached to this evaluation is a brief table which sets forth the workplan submissions date(s) by HealthTech and the date(s) of approval by A.I.D. (See Annex 9, HealthTech/A.I.D. Work Plans Approval Process). It should be noted that approval of the workplan has in some cases taken as long as seven months. With new

technology development, **the team recommends** that the workplan submission and approval process be streamlined and shortened to the benefit of all concerned parties. **The team recommends** that as a part of this approval process that the HealthTech staff be clearly informed regarding the clearance process for each of the technologies.

In reviewing the terms of the cooperative agreement, the team questions whether A.I.D. is trying to micro-manage some aspects of the project. **The team recommends**, for example, that the approval for U.S. travel be left up to PATH/HealthTech. **The team recommends** that A.I.D. consider raising funding approval levels for procurement within general guidelines. Review might lead A.I.D. to identify these and other cooperative agreement conditions for the HealthTech agreement that could be eased to speed up project implementation.

Because PATH owns some of the technologies being developed under HealthTech and inherently PATH will tend to support technologies that it has invested time in, it is critical that PATH recognize these issues and continue to deal with them. Specifically PATH must continue its current technology review activities to insure that the most appropriate technology is being developed at every stage. At the same time PATH must insure that A.I.D. is aware of this process and PATH's continued commitment to protecting the public interest. The team is convinced of PATH's commitment to the public interest, but also understands A.I.D.'s need to ensure that there is no apparent or real conflict of interest in its stewardship of public funds.

While the team recognizes that the technology being developed under this agreement is for use in developing countries, A.I.D. should not assume that USAID Missions will be able to interest their host country counterparts in authorizing the use of bilateral funds for field tests of the technology itself as well as for demonstrating effectiveness under field conditions. **The team recommends** that A.I.D. provide adequate funds to finance field tests in important Child Survival Program countries in all regions where A.I.D. is financing programs. These field trials can then be used to demonstrate and publicize the new technology within the trial region.

The team believes there may be scope once again to stimulate the interest of the Private Enterprise Bureau in the HealthTech project. While it is recognized that the HealthTech project is a follow-on to the Health Link project funded by the Bureau for Private Enterprise (PRE), the team feels that communication with the PRE Bureau should be maintained and strengthened to ensure that the PRE Bureau is aware of the opportunities for the private sector in health technology. Along this line, the Office of Health should recognize that geographic bureaus also have private sector offices or divisions and these units should be made aware of possible sector development under this project.

It appears that at least one aspect of local private sector involvement in product development has been overlooked or de-emphasized in HealthTech. Since most of the products will be used primarily in the public sector, the focus for many of the products has been on availability at affordable public sector cost regardless of source.

This approach does not take into account practical experience with the linkage between industrial development and public procurement in many countries. In these situations the active involvement of a local private sector partner can often stimulate the adoption of the innovative technologies by programs that are funded or controlled at the national level. The team encourages HealthTech staff to review with A.I.D. their plans for supporting private sector involvement in developing countries. This may need more emphasis now that the project has several products at the testing stage. There may also be some opportunity to support the A.I.D. budget earmark of funds for private provision of social services.

The team believes that dissemination of information concerning technology tailored to the Child Survival Program is important and deserves more consideration. As one step in this process, the team recommends that the cooperative agreement include funds for publication and distribution of selected issues of PATH's newsletter entitled "health technology directions". With selected issues focusing on specific Child Survival Program needs and implementation problems, new technology could be identified and explained. These particular issues could also call for submission of new technology ideas to HealthTech for possible collaboration, solicit country interest in field trials, and identify opportunities for/or stimulate interest in private sector collaboration in developing countries. Funding for these newsletter issues should be sufficient to allow for translation and distribution in French-speaking Africa.

PATH/HealthTech publications are normally distributed to a carefully targeted audience. Opportunities to disseminate less detailed information about HealthTech activities to the broader community of development programs should be sought. Periodicals are distributed by a number of organizations, e.g., World Bank and OAS, which are concerned with less developed countries. Awareness of health technology activities could lead to more effective accessing of the "intersections" between the international health and development networks. PATH's history of leveraging resources by "piggy-backing" on other projects suggests that efforts spent to expand this network will be very cost-effective.

After a cursory review of the HealthTech project with A.I.D. HPN staff, it appears that a number of technical officers are not aware of the technology being developed under this agreement. It is appropriate to continue to use the HealthTech Technology Assessment Panel meeting to orient a limited number of A.I.D. bureau personnel. The team notes that the CTO invited bureau personnel to the February 1989 meeting. It is hoped that these invitations to other bureaus will continue. Because information on new technology is so important, we would also encourage the Office of Health to invite HealthTech representatives to provide a briefing on their activities during the HPN training course which is conducted in Washington each summer. The team would also encourage other bureaus to invite a HealthTech representative to provide a briefing on the project to field personnel when regional HPN meetings take place. Travel for these briefings should be built into the HealthTech project budget. HealthTech personnel should be

encouraged to be more aggressive regarding visits to USAID in the field to ensure that information on their project is being widely disseminated (See Annex 11, Strategies for Country Involvement).

With limited resources, HealthTech must take advantage of collaborating with others in order to act as a catalyst in achieving a multiplier effect. One example, the Technology Assessment Panel, demonstrates the effective use made by HealthTech of outside advisors for very modest cost compared to the wisdom supplied. Additionally, by taking advantage of WHO and UNICEF financed activities, HealthTech will be able to field test several products at a fraction of the cost of doing it alone. Also, the impact of the initial A.I.D. funding is being increased enormously by other collaborations such as the coinvestment of time and expertise by PATH and the financial support and knowledge from the private sector. For example, Becton Dickinson is a $1.7 billion dollar corporation. The expertise this world leader has built up over several generations to emerge as the world's foremost syringe manufacturer and marketer is being brought to bear on the "SyringeLOCK" development. This will greatly enhance the likelihood of HealthTech success in terms of wide availability and proper use. Without this massive backup, the project would be on much shakier grounds. Think also of massive leverage of the A.I.D. funding for this project due to the Becton Dickinson involvement. A.I.D. funding is allowing HealthTech to access generations of Becton Dickinson expertise and wisdom. Such collaborations also elicit commitment to HealthTech success by outsiders at a formative early stage.

All the above are examples of the HealthTech strategy to lever its resources in a synergistic, clever way. To ensure that this continues in the future and to ensure continued outside commitment to HealthTech projects at an early stage, the team recommends HealthTech review its needs and mechanisms for obtaining further outside collaboration as various products evolve. The team recommends that thought be given to the following areas:

- Effectively interfacing with and using A.I.D. and its local missions. This is referred to elsewhere in these recommendations; and

- Effectively interfacing with UNICEF, WHO and other global and country specific public health agencies. These agencies will be the main purchasers and distributors of products. Their early involvement will ensure that products will respond to their needs. Their early involvement will also ensure a level of knowledge, comfort and commitment on their part.

- Effectively using the corporate sector both here and abroad, PATH has shown how selected collaboration with the private sector both at home and abroad, speeds product development and greatly increases the probability of wide distribution of needed technologies. A separate advisory group composed of representatives from the corporate sector may also be worth considering.

- o Continuing to use effectively advice from the end-user at the early stages of the product.

To address the issues raised above, an Advisory Group including UNICEF, A.I.D. and WHO representatives among other may be one effective mechanism to put into place as various projects evolve and the emphasis changes from development to field testing, manufacturing and distribution. Care must be taken to enhance the wisdom gained from the groups and minimize the bureaucratic hassle inherent in meetings, reports, time delays, etc.

The evaluation team heard some disappointment about products not being available as originally stated. It is worth reemphasizing the long development times inherent in this activity, but more specifically, the team recommends that for each project, HealthTech prepare a GANTT chart that contains less technical detail, but extends over the entire project from the start to where the product is beginning to be broadly available and properly used (5 to 15 years). Such a chart should include cost estimates for the various steps. These would be of immense benefit in ensuring that both HealthTech personnel and outsiders have realistic expectations for the development and delivery of individual technologies.

The team considers the issues in Chapter VII.," Long Term and Philosophical Issues Associated with HealthTech" crucial to the success of the HealthTech project. The team recommends that HealthTech and A.I.D. reaffirm the importance of "staying the course"; "understanding the process"; and "accepting the risks inherent to innovation". The discussed issues of communication and trust are central to the success of this A.I.D. project.

Because the HealthTech project is not a typical A.I.D.-financed project, the team recommends that the Milestones developed by the team and presented in Chapter IV, Section F "Achievables" be used to judge progress of individual technologies and form the basis for evaluation of the HealthTech project.

Several references are made in the preceding chapter to the fact that HealthTech is involved in a number of different technologies. The team considers this to be good and necessary. A multitude of new ideas must continue to be screened to ensure that some will have an eventual impact in the world. The team recommends that HealthTech continue in this vein. The team is not currently worried about HealthTech diffusing its resources over too many projects. This is an issue that should continue to be closely monitored by HealthTech management.

Questions have been raised as to how long HealthTech should remain involved with a product as it evolves. This also ties in with the question of "too many activities?" It is recognized that each product will go through similar stages of development and introduction. However, HealthTech will be involved to a different extent in each stage, depending upon the product. In some cases HealthTech involvement will taper off rapidly because outside collaborators have been found who have demonstrated their effectiveness to HealthTech.

Thus HealthTech will "hand over" the product earlier than in other cases where HealthTech and A.I.D. acknowledge this "messiness" and continue to use flexibility and judicious judgment in determining where HealthTech involvement should taper off.

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THE EVALUATION TEAM

John A. Fraser, M.Sc., brings to this evaluation his hands-on entrepreneurial perspective and solid business acumen based on a Masters in Biochemistry from UC Berkeley; 8 years with NSERC, the Canadian equivalent of the NSF; Vice President, TDC, a Toronto-based venture capital company, and most recently, the 1988 sale of his technology transfer company, University Technology Corporation, which he cofounded and served as Executive Vice President. Mr. Fraser's unique experience with federal agencies, major corporations and universities allows him to successfully navigate the minefield of technology transfer. Clients include universities and small high tech companies where he advises on health care, biotechnology and marketing strategies.

Michael E. Samuels, Dr.P.H., Team Leader, is Chairman of the Department of Health Administration, School of Public Health, University of South Carolina. Formerly Principal Assistant to the Surgeon General, C. Everett Koop, he has been extensively involved in the issue of injection technologies relative to the spread of HIV. He has directed several national primary care programs and been involved in primary care in Tunisia, Portugal and Jordan. Dr. Samuels has also served as the Acting Director and Deputy Director of Health Evaluation for the U.S. Department of Health and Human Services.

Roberta L. Dresser, M.S., is a Commissioned Officer in the U.S. Public Health Service, currently serving as international affairs specialist with the Center for Devices and Radiological Health, FDA. Trained as a Medical Technologist and Medical Microbiologist at the University of Missouri-Columbia, Ms. Dresser had broad clinical experience at all levels of health care delivery when she joined FDA's medical device program prior to the enactment of the 1976 Medical Device Amendments. Since that time she has been responsible for a wide variety of technical and analytical functions within the medical device program. Ms. Dresser is also currently a doctoral candidate in the University of Southern California School of Public Administration, concentrating in intergovernmental relations and health policy.

Michael R. Jordan, RPh., M.P.H., is a Counselor in the Senior Foreign Service serving with A.I.D. He is currently Senior Advisor to the A.I.D. Afghan Task Force in Washington, D.C. He has held major A.I.D health and population posts in Washington and throughout the developing world, including Vietnam, India, Egypt, and Bangladesh. In India (1968) and Bangladesh (1974), Mr. Jordan helped to start the first social marketing programs in the world by linking the public and private sectors for the promotion of family planning and the sale of contraceptives. These programs have continued and expanded to this day and have been emulated in many other countries. Mr. Jordan will shortly take up a new position as Chief, Population, Health and Nutrition Division, Bureau for Asia and the Near East, A.I.D./Washington.

ANNEX 1

Scope of Work

ANNEX 1

Scope of Work

HEALTHTECH PROJECT INTERIM EVALUATION

1. Background

The project entitled HealthTech:Technologies for Child Health (Project No. DPE-5968-A-00-7035-00) is implemented through a Cooperative Agreement between the U.S. Agency for International Development and the Program for Appropriate Technology in Health (PATH), a Seattle-based non-profit corporation. It is a three year activity which commenced July 1, 1987 and is scheduled to continue through June 30, 1990. The total estimated cost of the project is $4,618,000. Within this amount, $1 million is planned for USAID mission participation in country specific activities concerning field testing of new technologies and/or support for local manufacturing.

The project was designed to serve as a mechanism through which new and available child survival technologies can be identified, adapted and introduced into less developed countries (LDCs), and as a vehicle to promote the development, testing and local manufacture of state-of-the-art technologies for child survival.

Under the terms of the Agreement (Schedule, Sect. E.3), an interim evaluation is to be conducted to provide a comprehensive review of the progress the project is making towards realizing its stated objectives, and to evaluate the management of the project.

2. Purpose of the Evaluation

The general purposes of this mid-term evaluation are to: 1) assess the relevance of the project objectives to the Child Survival program; 2) review assumptions made in the initial project proposal and determine their continued validity; 3) review the overall performance of the project in terms of technological achievements and outputs; 4) assess the relative efficiency of the project's internal management and coordination systems; and, 5) prepare recommendations that may enhance the effectiveness and efficiency of the project.

3. Evaluation Plan

(CONTRACTOR) will be requested to contract, coordinate and support all services, including typing, reproduction, and travel and accommodation arrangements for a four person team which will evaluate the HealthTech project.

It is anticipated that the four member team will possess multidisciplinary skills, and that one member will be selected from among AID/W staff. The team will consist of individuals with professional working experience in less developed countries, and technical proficiency in one or more of the following fields: primary health care, immunization programs, clinical products engineering, applied biomedicine, business administration, intellectual property administration, technology transfer and licensing management, investment brokerage, financial management, program management, and project evaluation. A descriptive profile of the team members' pertinent skills and experiences is included as Attachment 1 of this work. (CONTRACTOR) will identify candidates for the evaluation team, and will submit their names and specialties to the HealthTech project Cognizant Technical Officer (CTO) for his concurrence that the proposed individuals are suitable for the assigned task. In the event the prospective candidates are not selected or are otherwise unable to serve as members of the evaluation team, (CONTRACTOR) will then identify other alternative candidates.

The evaluation will be conducted in Rossyln, Virginia, Seattle, Washington, Santa Ana, California, Rutherford, New Jersey and Washington, D.C. during January 30 through March 1, 1989. During the third week of January, (CONTRACTOR) will provide team members with briefing materials consisting of Child Survival program reports, the HealthTech project proposal, the Cooperative Agreement, reports of the Technology Assessment Panel (TAP), project workplans, progress reports, and annual reports.

The team will meet at the offices of A.I.D. in Rosslyn, Virginia on January 30, 1989 for a project briefing by S&T/H personnel and to prepare an operations plan for conducting the evaluation. The team will reconvene on January 31 to continue the operations planning, review project literature and meet with pertinent A.I.D. personnel as required. These activities will be coordinated by (CONTRACTOR). On February 1, 1989 the evaluation team will attend and observe the proceedings of the HealthTech Project Technology Assessment Panel (TAP) meeting which is scheduled to be held at the Washington, D.C. offices of PATH. During the week of February 6-10, the team will make site visits to the PATH corporate offices in Seattle, Washington, and to the corporate offices of two of PATH's licensees, Horizon Medical Packaging, Inc., Santa Ana, California, and Becton-Dickinson, Rutherford, New Jersey. It is anticipated that the complete team will travel to Seattle, and will spend the days of February 6-8 meeting with PATH project staff who will provide the team with orientation briefings on project activities and a site visit of PATH/HealthTech project facilities. On February 9-10 two members of the evaluation team will travel to the corporate locations of Horizon Medical Packaging, Inc. and Becton-Dickinson and will meet with management personnel to review corporate perceptions regarding the licensing process used by PATH and other matters that may be pertinent to the project. These and other information gathering and evaluation activities will be coordinated by (CONTRACTOR). On February 13-15 the evaluation team will reconvene and meet at the office of Devres, Inc., Bethesda, Maryland to review project documentation, summarize their findings, and write the project report. The team will meet again at the office of Devres, Inc, Bethesda, Maryland on March 16, 1989 to complete the draft report and to organize a presentation of their findings. (CONTRACTOR) will coordinate these activities and will provide a secretary to assist with the typing and other administrative matters. The evaluation team will present their report and recommendations individually to A.I.D. and PATH HealthTech project staffs on March 17, 1989 at the offices of A.I.D. in Washington, D.C. This activity will be coordinated by (CONTRACTOR).

4. Scope of Work

As stated earlier in this work, the purposes of the proposed HealthTech project evaluation are to review the assumptions upon which the project was organized, determine its continued relevance to A.I.D.'s Child Survival program, review the overall performance of the project, and provide recommendations which may contribute towards improving the project. Within this context, the evaluation team will undertake the tasks which follow.

Project Design and Relevance -

The evaluation team will review the appropriateness of the HealthTech project in relation to the assumptions and goals under which it was first designed, and its role in support of A.I.D.'s Child Survival and health strategies.

Project Implementation, Management and Performance -

a. The evaluation team will compare and evaluate the project outputs and accomplishments to date in relation to the specific objectives that were identified in the project proposal and those which are described in the Cooperative Agreement.

b. The team will evaluate the overall effectiveness and efficiency of PATH's project management and coordination systems, including project administration, the product development process, management of production, and field operations.

c. The team will review and evaluate the strategies and plans which are proposed by PATH for involvement of the private sector in the project, and the appropriateness of such plans and activities in accomplishing the goals and objectives of the project.

d. The evaluators will review and assess the effectiveness and appropriateness of the methods utilized by PATH to assure that the project has full access to the broadest range of expertise and sources of technology, and that technologies are improved and promoted in a way that insures the lowest cost and the broadest, most rapid availability to LDC public health programs.

e. A review and evaluation will be made of PATH's invention disclosure process as required by the Cooperative Agreement's Optional Standard Provision for Nongovernmental Grantees, Patent Rights (November 1985).

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f. The evaluation team will identify and report upon any issues which may affect the adequacy and effectiveness of PATH's relations and efforts in coordinating with such agencies as WHO/EPI, UNICEF, PAHO, and with A.I.D. contractors such as REACH in futherance of project goals.

g. The team will evaluate PATH's strategies and plans for USAID mission involvement in the HealthTech project, the appropriateness of current plans for regional focus of project activites, and the actual and planned role for the recipient's regional offices in accomplishing the project's objectives.

h. The evaluation team will review and assess PATH's strategies and plans for the rapid dissemination of project related information to the scientific and development communities, and for articulating and communicating project goals and achievements to U.S. and international audiences.

i. The evaluators will give special attention and emphasis to the review and assessment of the strategies and plans which will be employed by PATH to accomplish product development goals, with particular consideration to the field trail process, and to tranfer and introduce new or improved technologies through the estimated completion date of the project.

j. The evaluation team will assess and recommend actions for the future direction of the project, including continuation funding and other follow-on activities which may further the goals and objectives of the project.

5. Evaluation Report

The (CONTRACTOR) will be responsible for coordinating the preparation, editing, and production of the evaluation report. These activites will be carried out in close collaboration with the project CTO.

The evaluation report will follow the standard A.I.D. format and will contain the following sections: Executive Summary; Table of Contents; Body of the Report; and, Appendices. The (CONTRACTOR) will prepare and include a draft A.I.D Project Evaluation Summary (P.E.S.) as part of the report.

A draft of the evaluation report will be prepared by (CONTRACTOR) and submitted to the CTO for his comments and approval prior to the publication of the report. Thirty-five copies of the completed evaluation report will be submitted to the CTO on or before April 10, 1989.

Drafter: S&T/H:CGonzmart:x54427:Wang #3738j:Revised 4/07/89

ATTACHMENT 1

Proposed Skills and Experiences of Evaluation Team Members

Member 1:	clinical products engineering applied biomedicine
Member 2:	business administration financial management investment brokerage intellectual property administration technology transfer and licensing management
Member 3:	primary health care immunization programs program administration project evaluation
Member 4:	AID/W staff person international health Child Survival program

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ANNEX 2

List of Contacts

ANNEX 2

LIST OF CONTACTS

A.I.D.

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David J. Sencer, M.D.
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PRITECH

14'

PATH

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Rebecca Fields
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Technology Assessment

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Technology Promotion

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Primary Health Technology

Regan Warner
Assistant Program Officer
Technology Promotion

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ANNEX 3

Site Visit
Horizon Medical Packaging, Inc./ACACIA

ANNEX 3

SITE VISIT
Horizon Medical Packaging, Inc./ACACIA
Santa Ana, California

Bobbi Dresser and John Fraser visited Horizon, Thursday, February 9, 1989, to assess the relationship to the HealthTech "SafeTject" project.

Realizing that a nonreusable, prefilled, unit-dose injection system for vaccines and other intramuscular injectables had enormous potential for commercial and public sector uses, HealthTech actively solicited proposals from potential private sector collaborators to assist with the project. Following a careful screening and visits to each of the four finalists, Horizon was selected because of the experience of Horizon's principals and their corporate and personal enthusiasm for the project. ACACIA Laboratories is a wholly owned subsidiary of Horizon, created for the SafeTject project.

Horizon is a young medical device company operating as a subcontractor for such giants as Smith Kline French and 3M. Sales by the end of 1989 will be $1.21 million with 17-19 employees.

Bill Goolsbee, President, has eleven years of extensive experience in medical device product development, new business creation and successful corporate management with the Cooper Vision family of companies eventually rising to president of the new division he created. Bill Goolsbee is SafeTject project manager and expects to see the SafeTject product ready for field tests in 1990. Horizon will help HealthTech design the product and will carry out studies to validate the design and process as well as assist with limited field trials. The corporate entrepreneurial culture of Horizon is very well suited for this particular project. The project has a strong internal champion in the person of Bill Goolsbee. In addition, there is a fine appreciation and understanding of the public health needs and cost constraints.

The legal agreement that exists is an option to an exclusive license for the technology. Careful review of the agreement and discussion with Horizon personnel lead to the conclusion that the agreements are standard business-like arrangements with normal terms. Public interest is properly protected in the view of the team.

The actual working relationships between HealthTech and Horizon are effective, cordial and trusting. This relationship will enhance the chances of success for this project and accelerate the introduction of a product.

There is enormous leverage for A.I.D. funds through HealthTech including the Horizon contribution. Horizon realizes that $1.5 million will have to be expended before product is released for field testing by mid 1990.

Horizon sees its own corporate interests being served by the success of the SafeTject project and by the favorable access to global health agencies.

As stated, Horizon has created its own credibility with organizations like Johnson and Johnson, Smith Kline French and 3M. The Horizon clean room has consistently passed FDA Good Manufacturing Practice inspections. HealthTech's own credibility is enhanced by a relationship with Horizon.

ANNEX 4

Site Visit
Becton, Dickinson and Co.

ANNEX 4

SITE VISIT
Becton, Dickinson and Company
Rutherford, N.J.

Bobbi Dresser and John Fraser visited Becton Dickinson Friday, February 10, 1989 to assess the relationship with the HealthTech "SyringeLOCK" project.

Realizing that a one-use disposable syringe would have enormous potential for commercial and public health uses, HealthTech actively solicited proposals for private sector collaboration from the three major U.S. corporations operating in this field.

HealthTech had to mount a major campaign to get in the door at Becton Dickinson because of their extremely conservative approach to external technology. HealthTech used its personal contacts very effectively to gain the attention of key Becton Dickinson employees. Becton Dickinson was selected because of its preeminent world position in syringes and its track record of supplying syringes for WHO and UNICEF.

Becton Dickinson is a mature health care manufacturer with a worldwide manufacturing, marketing and sales presence world-wide sales topped $1.7 billion in 1987. The project officer is Mr. Tony Kosinski, who has several years experience in product development and sales acquired at C.R. Bard and Becton Dickinson. Currently he is New Product Manager for Becton Dickinson's largest division.

Becton Dickinson is familiar with relevant product development as it is constantly improving its syringe product line. Kosinski expects to have sufficient product available for a scheduled field trial in Pakistan in summer 1989. The corporate culture of Becton Dickinson is very well suited for this particular product. The project also has a strong internal champion in the person of Tony Kosinski.

The legal arrangement that exists is an exclusive worldwide license for the technology. The public interest is well served by the appropriate royalty free use, fiv- -year duration arrangements. Careful review of the agreement and discussion with Becton Dickinson personnel led to the conclusion that the agreement is a standard business-like arrangement with normal terms.

The actual working relationships between HealthTech and Becton Dickinson are effective, cordial and trusting. Becton Dickinson is prepared to expend $50,000 - $75,000 of direct material costs prior to the field trial and is well aware of the multimillion dollar expenditures required for a manufacturing line in the future.

This project is now a budgeted project for Becton Dickinson with its own momentum in addition to the enthusiasm and interest of the Becton Dickinson staff. Becton Dickinson sees its corporate interests being well served by the success of this project both for commercial and private sector markets. There is a significant Becton Dickinson interest in this project.

HealthTech is fortunate to have captured the commitment of Becton Dickinson for this project. This will enhance the chances of success for this project.

ANNEX 5

HealthTech Technologies

ANNEX 5

HealthTech Technologies

Reference Chart

	Type of Product	Stage of Development: At Inception of A.I.D. funding	Stage of Development: At Present
Injection Technologies			
• SyringeLOCK™	C	2	5
• SafeTject™	C	2	4
• Nonreusable Hypodermic Needle	C	1	2
• Needleless Injector	C	1	1
• ColClip Antistick Device	C	1	1
Adjunct Technologies to Immunization/Vaccination			
• STERItimer™	C	2	2
• PATHtimer®	B	4	5
• PATHwatch™/PATHmarker™	A	3	4
• Solar Refrigerator/Ice Maker	B	2	3
Maternal Care Technologies			
• PATHweigh®	C	2	3
• PATHstrips™	B	3	4
• Noninvasive Hematocrit Instrument	C	1	1
• Labor Timer	A	1	1
Newborn Care Technologies			
• BIRTHweigh™	A	4	5
• Eyedrop Unit-dose Delivery System	B	2	2
• Umbilical Cord Safety Clamp	B	1	1
Other Primary Health Care Technologies			
• Urinary Iodine Dipstick	C	1	2
• Iodized Oil	C	4	5
• Biological Larvicides	C	4	5

Type of Product:

A = no commercial market potential
B = commercial partner optional
C = commercial partner required

Stage of Development:

1 = selection and screening
2 = product development
3 = field trials
4 = product advancement
5 = transfer of risk and responsibility to third party collaborator

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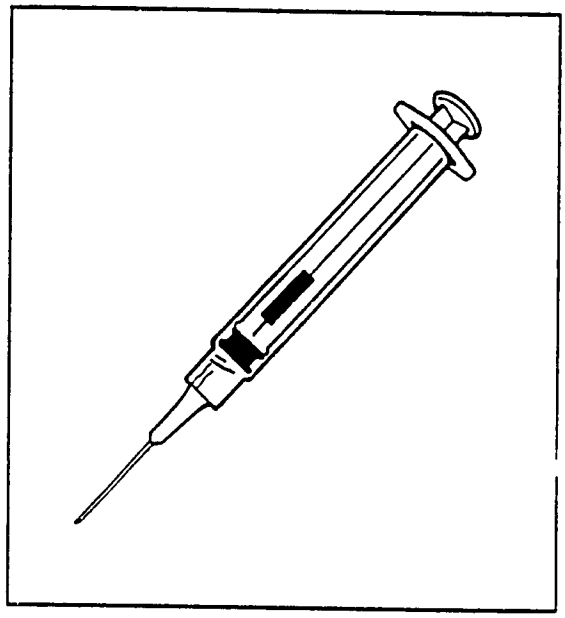
Type: C ; Stage: 4
Budget: Year 1 $ 150,215
Year 2 $ 54,335

SyringeLOCK™

An autodestruct system for standard disposable plastic syringes

Product Description

SyringeLOCK is a component that fits into a standard disposable plastic syringe and allows only one filling and emptying cycle. After the injection is given, SyringeLOCK permanently locks the plunger at the base of the syringe, thereby prohibiting reuse. SyringeLOCK is assembled into standard disposable syringes at the factory and does not alter the normal handling and operation of the syringe.



Stage of Product at Inception of A.I.D. Funding

Prior to the start of HealthTech, several embodiments of the SyringeLOCK principle were reduced to practice at PATH.

Current Status

The SyringeLOCK technology was demonstrated to WHO/EPI through the EPITECH panel in July 1987. EPITECH judged SyringeLOCK to be promising as an autodestruct technology which could be used in support of the EPI program. Under HealthTech, an intensive program was initiated to optimize the SyringeLOCK technology as quickly as possible. Late-stage development of SyringeLOCK, including engineering for large-scale manufacture, was carried out under HealthTech from July 1987 to November 1988.

SyringeLOCK was licensed to Becton, Dickinson and Company (BD), the leading manufacturer of syringes in the U.S., in July 1988. The exclusive license provided for royalty-free supply of the technology to the public sector as well as continued surveillance and intervention in the event of failure to perform. SyringeLOCK received regulatory approval from the USFDA in November 1988, based on a 510(k) application, and is therefore cleared for international field trials under the auspices of U.S. government agencies. Preliminary approval has recently been received from WHO/EPI and the process of formal approval by that agency has begun. Two hundred SyringeLOCKs are being prepared and will be sent to Geneva at the end of January for EPITECH panel review as well as laboratory testing at a WHO/EPI-designated laboratory. A field trial of the device is planned for June 1988 in Pakistan, to be conducted by the REACH program funded by A.I.D. Training and instructional materials on the use of SyringeLOCK are being prepared under HealthTech.

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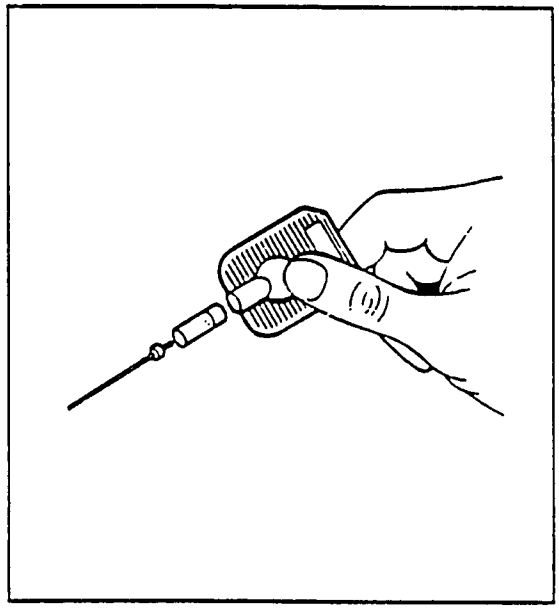
Type: C ; Stage: 2
Budget: Year 1 $ 226,774
Year 2 $ 151,090

SafeTject™

Prefilled, unit-dose injection system for vaccines and other intramuscular injectables

Product Description

SafeTject is a combination package and injection device for delivery of vaccines and other intramuscular injectables. The reservoir with an integral needle assembly is manufactured on high-speed equipment and subsequently sterilized. The reservoirs are then provided to producers of pharmaceutical and biological injectables for filling with vaccine or medicine under aseptic conditions using high-speed equipment designed specifically for this application.



Stage of Product at Inception of A.I.D. Funding

The concept for this product originated under a National Institutes of Health (Fogarty Center) program in 1986. The project was also funded by A.I.D. prior to HealthTech as part of the Bureau for Private Enterprise Health Link program.

Current Status

SafeTject has advanced through several design iterations and is ready for scale-up. Production and filling machinery have been designed. One filling and sealing machine has been built for preparation of field trial prototypes. A contract for co-development leading to an option for the manufacture and distribution of SafeTject has been signed by Acacia Laboratories, Santa Ana, California. Terms of the agreement call for HealthTech to support remaining development activities, while Acacia is obligated to fulfill regulatory approval tasks as well as identify and establish agreements with producers of vaccines and other injectables.

The remaining technical development tasks include studies of storage stability of SafeTject and engineering support of initial manufacturing.

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Nonreusable Hypodermic Needle

A small device added to disposable needles which renders them unusable after one filling and injection cycle.

Product Description

A small plastic insert is added to a modified standard needle hub or syringe nozzle assembly. The insert swells after contact with aqueous solutions, blocking the fluid pathway. Once swollen, the insert remains swollen and cannot be reshrunk, so reuse of the needle or a one-piece needle/syringe is impossible.

-- Proprietary --

Stage of Product at Inception of A.I.D. Funding

The Johns Hopkins University Applied Physics Laboratory (JHU/APL) applied for a patent for this device in February 1987. Hand-fabricated prototypes of the device were demonstrated to the National Institute of Drug Abuse and the World Health Organization in 1987. A subgrant was signed with JHU/APL in August 1988. Under this agreement, JHU/APL will carry out the development, scale-up, and preliminary licensing activities for this product.

Current Status

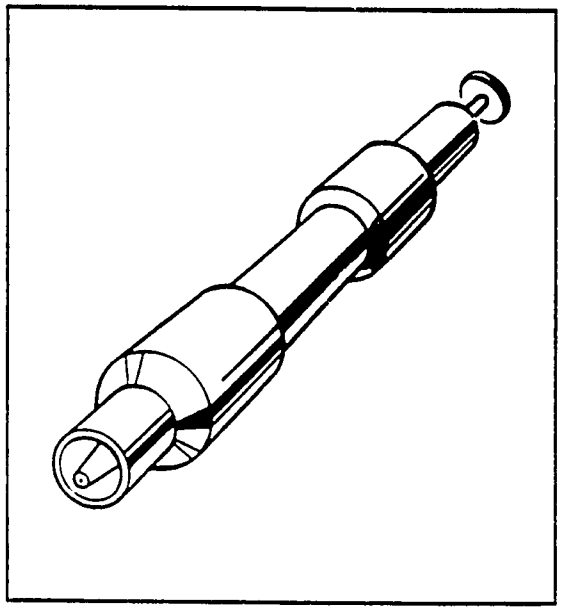
Appropriate materials have been identified and preparations are under way for production of the first prototypes to be manufactured rather than hand fabricated. These advanced prototypes will be available by the end of February 1989. A limited number of hand-fabricated prototypes are now available for demonstration. Research on alternate materials, production techniques, use requirements, and product configuration is ongoing.

Needleless Injector With Disposable Nozzle

Hand-held needleless injector for vaccines using prefilled, single-use reservoir and disposable nozzle

Product Description

The needleless injector is a self-contained, hand-held device in which a disposable plastic capsule filled with vaccine acts as both single-dose reservoir and disposable nozzle. The process of releasing the contents under high pressure to accomplish injection results in the destruction of the nozzle, thereby prohibiting reuse and the potential for cross-contamination that has occurred with existing jet injectors.



Stage of Product at Inception of A.I.D. Funding

Prototypes of two different designs had been engineered by at least three private companies. PATH has been in contact with VCI in the U.S. and Vitajet in Brazil. A third company, Bioject, based in Canada, has also developed a prototype with features similar to those of the Vitajet injector.

Current Status

This project is currently a selection and screening activity, although a work plan has recently been approved. PATH has signed secrecy agreements with two companies to allow for review of prototypes of the two designs. Reviews of prototypes have indicated that both designs possess desirable attributes but neither is ideal in its current configuration. The VCI design ensures trauma-free injection, eliminating the possibility of skin tears or contusions; however, it requires the use of carbon dioxide canisters as a source of power, a requirement that contributes to both a higher price and the difficulty of ensuring a reliable supply of components. The Vitajet model, while a fully self-contained unit requiring no external energy source, currently employs an unwieldy winding mechanism for cocking the spring, and is easier to misuse. This implies a higher training burden for health workers who administer vaccines.

ColClip Antistick Device

This technology is covered by a confidentiality agreement. The report on the technology can be reviewed after a confidentiality agreement has been signed.

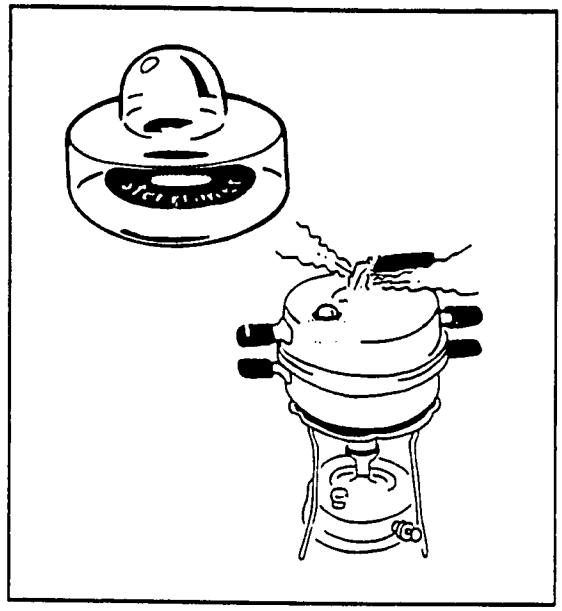
Type: C ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 53,807

STERItimer™

Heat-exposure monitor for steam sterilizers that indicates adequate sterilization by a color change

Product Description

STERItimer is a plastic, shallow, inverted mushroom-shaped device that is approximately 7.5 cm in diameter and 2 cm deep. It is affixed inside a steam sterilizer on the underside of the lid. A viewing lens penetrates the lid to allow monitoring. A disk of heat-sensitive material is embedded in the monitor and is black when the steriiizer is being heated. The disk changes to green after 20 minutes of steam release from the sterilizer, in response to heat conducted through the plastic body of the STERItimer over time.



Stage of Product at Inception of A.I.D. Funding

The technology for time/heat color indicators was licensed to PATH in June 1985 based on a 1979 patent from Robert Parker Developments, Inc., Alamo, California. At the inception of HealthTech funding, numerous prototypes had been constructed and evaluated by PATH personnel. Key prototypes were documented by drawings and engineering notes in April 1986 and again in March 1987.

Current Status

Under HealthTech, PATH is now laboratory testing six prototypes, with a single feature varied in each. After several repeats, data will be evaluated to determine the next prototype configuration.

Current prototypes are relatively easy to read and consistent in performance. The color of the monitor changes from black to "full" green an average of 21 minutes from the time of steady steam release from the relief valve, as per WHO specifications.

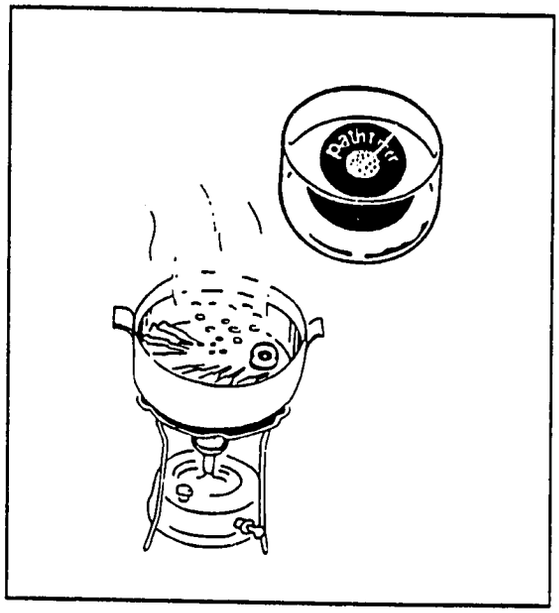
Type: B ; Stage: 4
Budget: Year 1 $ 0
Year 2 $ 23,616

PATHtimer®

A reusable plastic sensor that indicates when water has boiled sufficiently to disinfect medical instruments

Product Description

PATHtimer is a plastic device embedded with a disk of heat-sensitive material. This disk is black at room temperature and changes to green after 20 minutes in boiling water. When placed with instruments in boiling water, PATHtimer indicates when instruments have been boiled long enough to ensure proper disinfection. PATHtimer is lightweight and reusable, with an expected life span of 600 cycles.



Stage of Product at Inception of A.I.D. Funding

Several advanced prototypes have been constructed and dimensional specifications have been defined, addressing the issue of heat dispersion during the manufacturing and curing process.

Current Status

PATHtimer is now in the scale-up phase of development. Two manufacturers for production of PATHtimer have been identified. Coordination and fine-tuning of the production is occurring and production-type units are available for field evaluation or introductory activities. Units have been procured by UNICEF and WHO/EPI. One of the manufacturers has made several hundred production-type units that have undergone laboratory and quality assurance testing. The other potential manufacturer is experimenting with manufacturing processes before production-type units are made.

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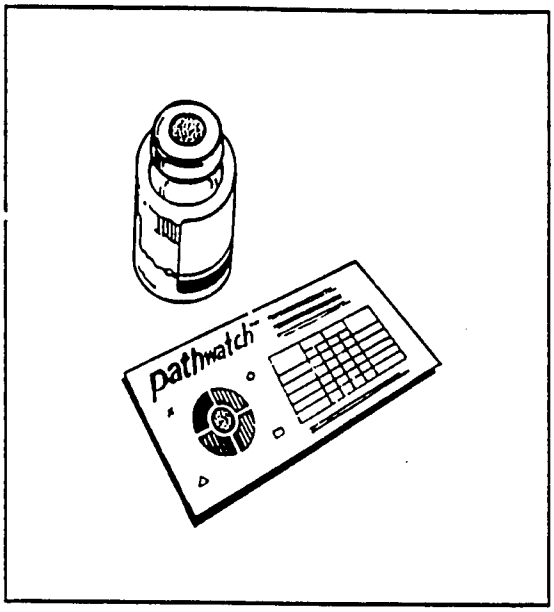
Type: A ; Stage: 3
Budget: Year 1 $ 44,380
Year 2 $ 57,692

PATHwatch™/PATHmarker™ Cold Chain Monitors

Irreversible, color-coded indicators of cumulative heat exposure of vaccines

Product Description

PATHwatch, a label attached to the outside of vaccine boxes, consists of the indicator (a small dot of heat-sensitive ink surrounded by a color reference ring) and a record-keeping table. PATHmarkers are small adhesive dots that are applied to each vaccine vial or ampule at the vaccine manufacturer or the national vaccine storage facility. PATHwatch and PATHmarker contain heat-sensitive ink that changes color from pink to purple to black, becoming black after cumulative heat exposure equivalent to 8 days at 37°C.



Stage of Product at Inception of A.I.D. Funding

Development of PATHmarker began in 1979 using a technology initially developed by Allied Corporation (New Jersey). With support from WHO/EPI, field trials were carried out in ten countries in 1982-84. Based on the results of the field trials, the PATHmarker was refined and the PATHwatch label was developed. After a positive evaluation of the technology by WHO/EPI in 1987, introductory trials in Zambia were initiated with Canadian International Development Agency funding. HealthTech funding covered additional field trial sites and training materials development.

Current Status

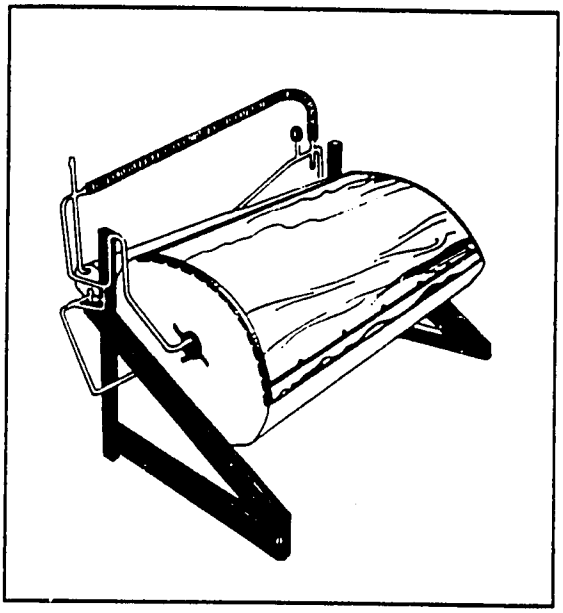
Introductory trials are under way in Thailand, and plans have been made to launch a trial in Kenya in January 1989. Preliminary discussions have been held to investigate field trial possibilities and work with a local vaccine manufacturer in Indonesia.

Solar Refrigerator/Ice Maker

Solar-powered refrigerator and ice maker

Product Description

The Intermittent Solar Ammonia Absorption Cycle ice maker developed by Energy Concepts Company combines the dependability of the ammonia absorption cycle with other proven and highly reliable solar collector technology. The result is a design that incorporates simplicity, reliability, and affordability. This product is designed to be used in remote areas of developing countries where electricity is unavailable or unreliable.



Stage of Product at Inception of A.I.D. Funding

Under Health Link, PATH identified a company in Thailand (Pan Siam Engineering) interested in collaborating with Energy Concepts Company (ECC) of Annapolis, Maryland, on the field testing and local production of the solar ice maker. The two companies have signed an agreement and are collaborating on the design of two units to be used in a field trial.

Current Status

Work on this project has been carried out as a selection and screening activity. In January 1989 a work plan for this project was approved by A.I.D. A prototype unit will be shipped from Annapolis to Thailand in February or March 1989. The first stage of field testing will be carried out by Pan Siam and will assess the technical performance. The second stage of field testing will be organized by PATH and will involve the Thai Government EPI. A solar ice maker will be tested for acceptability in a rural field health center.

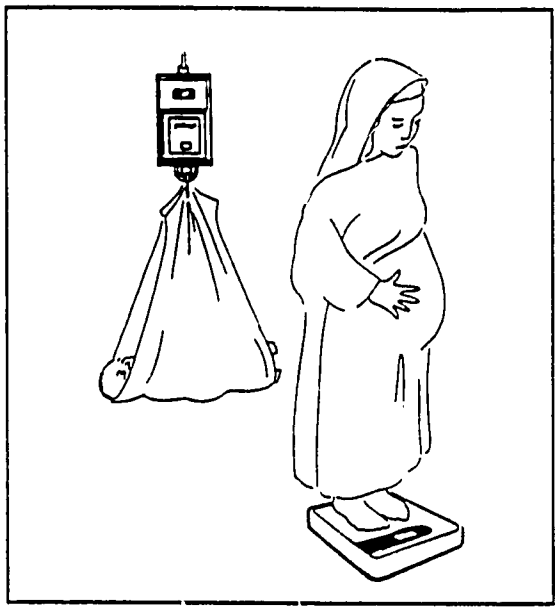
Type: C ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 28,864

PATHweigh[R]

Solar-powered electronic scale for growth monitoring of infants, children, and pregnant women

Product Description

The solar-powered PATHweigh scale was developed by Masstech of Australia in both hanging and stand-on versions. A mother or health care worker can stand on the scale and receive the infant in her arms for weighing, as the display can easily be reset to zero after placing a load of any size up to 150 kg on the scale. The digital display, which calibrates the weight in 100-gram increments, averages the weight of a moving load and is easy to read. The case is weatherproofed and sturdy for rugged use.



Stage of Product at Inception of A.I.D. Funding

The principle of this technology was devised by Peter Goodier of Masstech Proprietary Ltd., Oxley Cove, Australia, at the instigation of UNICEF Australia. A development company, Sensor International, Inc., was formed jointly by PATH and Masstech in 1987 in order to obtain financing and oversee the development of the scale. Both WHO and UNICEF provided funding for proof of concept and early development of the sensor.

Current Status

Twenty-six prototype hanging scales and 26 stand-on scales are nearing completion. Although the outside appearance of the case differs from the proposed final design, the inside components are close to the final manufacturing configuration. Thirty of the new prototypes will be made available directly to UNICEF under a separate agreement. The remaining 22 units will be available to HealthTech for laboratory and field evaluation. Direct HealthTech involvement will commence with the purchase of these prototypes.

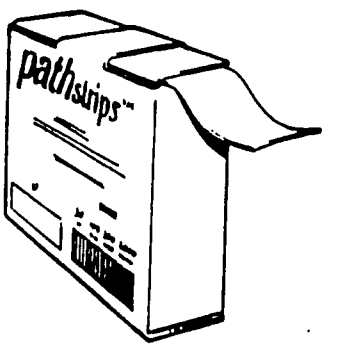
Type: B ; Stage: 4
Budget: Year 1 $ 0
Year 2 $ 40,415

PATHstrips™

A low-cost, color-coded test strip for detecting protein in urine

Product Description

PATHstrips are low-cost, ready-to-use dipstrip indicators of proteinuria. They are packaged in a convenient tear-off form which eliminates the need to prepare chemical reagents. To use PATHstrips, a health care worker tears a strip from the box and dips it into a urine sample; then the worker determines protein amounts by comparing the strip color to a color reference chart on the box. The presence of protein in urine (proteinuria) may indicate preeclampsia during pregnancy, urinary schistosomiasis, urinary tract infections, or kidney disease.



Stage of Product at Inception of A.I.D. Funding

PATHstrips were at the manufacturing and introductory stages of development at the inception of the HealthTech project. Prior to HealthTech, concept, feasibility, and development of the simple dipstrips, and laboratory and shelf life studies had been conducted. Preliminary manufacturing procedures were in place. Field testing by traditional birth attendants (TBAs) in Malawi, North Yemen, and Zambia, including use of training and instructional materials developed for PATHstrips, had been completed under other funding sources.

Current Status

The majority of current work on the PATHstrips project is directed towards transfer of the technology for producing the dipstrips. Field testing showed that PATHstrips were generally well understood and able to withstand tropical environmental conditions. However, since diagnostics for proteinuria are not always available to both referral centers and TBAs, efforts are under way to identify manufacturers of PATHstrips in developing countries. Preference will be given to a pharmaceutical facility in an African country with a TBA training program and/or a strong system of antenatal care.

Noninvasive Hematocrit Instrument

This technology is covered by a confidentiality agreement. The report on the technology can be reviewed after a confidentiality agreement has been signed.

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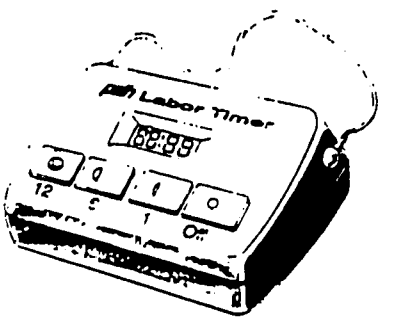
Labor Timer

A simple electronic timer that provides a signal at the end of each stage of labor

Product Description

The Labor Timer is a small electronic "countdown" timer that is used for monitoring the stages of labor. It can be easily set by depressing one of its picture-coded buttons which sets off an audible and visible signal indicating prolonged labor or retained placenta. This signal provides a cue for intervention, referral, or the need for transportation to a clinic setting during the first, second, and third stages of labor.



Stage of Product at Inception of A.I.D. Funding

Concept and performance criteria for the Labor Timer were developed under the Safe Birth Program, a PATH needs assessment and technology introduction program involving focus groups of traditional birth attendants in Malawi, North Yemen, and Zambia.

Current Status

The Labor Timer is undergoing review and feasibility assessment outlined by PATH's selection and screening procedures. Similar devices that could be adapted for use as a Labor Timer are available for demonstration.

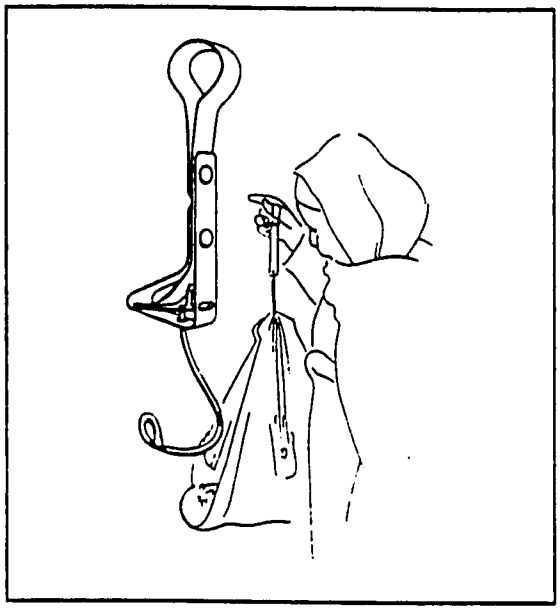
Type: A ; Stage: 4
Budget: Year 1 $ 0
Year 2 $ 51,393

BIRTHweigh™

A hand-held, color-coded scale for identifying low birth weight newborns

Product Description

BIRTHweigh is a portable, color-coded spring scale made from a band of stainless steel. A viewing window on the handle reveals a simple yes/no color indicator. The newborn baby is placed in a cloth sling suspended from the scale; any yellow color in the window indicates weight of less than 2,500 grams and the need for special care, while solid blue indicates the baby's weight is normal. BIRTHweigh gives traditional birth attendants and health care workers a simple and accurate way to assess the newborn's weight in the home or at a health center.



Stage of Product at Inception of A.I.D. Funding

BIRTHweigh prototypes were extensively laboratory tested and refined prior to the inception of HealthTech. Initial prototypes were assessed in a large nutritional project in Egypt and refined prototypes were field tested in Malawi, North Yemen, and Zambia. The manufacturing technology was transferred to Malawi. At the inception of HealthTech funding, BIRTHweigh was in the manufacturing and introduction stages of development.

Current Status

BIRTHweigh is currently manufactured in Malawi and is available to countries interested in field testing and introducing the scales into national health programs. Quality assurance and technical assistance for the Malawi manufacturing site is ongoing. For policy and decision makers in countries interested in introducing the BIRTHweigh scale into antenatal health programs, information packets describing BIRTHweigh and the impact of the scales on a country's policies and programs are being prepared and distributed.

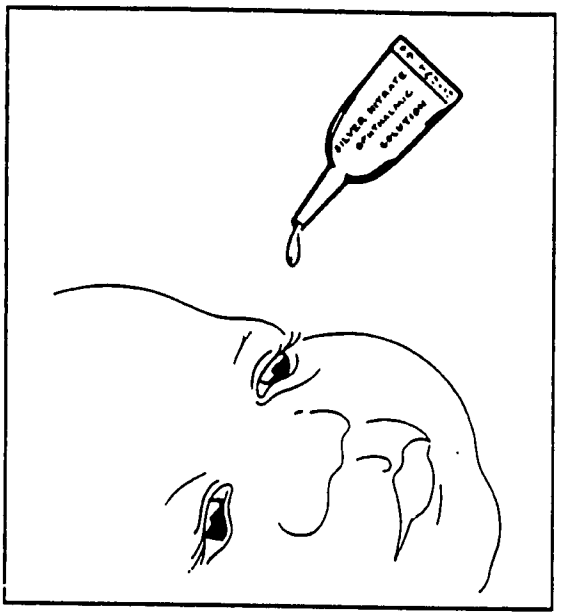
Type: B ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 15,536

Eyedrop Unit-dose Delivery System

Unit-dose package with dispensing capabilities for eyedrops

Product Description

This system is a single-use dispenser for silver nitrate or tetracycline ophthalmic solutions especially for dispensing eyedrops into newborns. It provides long shelf life and stability, well-controlled fluid delivery, and protection against cross-contamination. The current configuration is a polypropylene cone-shaped tube with a twist-off stopper. An individual foil overwrap is tamper resistant and provides a vapor barrier. The plastic vial and overwrap are printed with instructions.



Stage of Product at Inception of A.I.D. Funding

This product, in various forms, has been in trial studies within WHO/MCH since before October 1986. The package configurations currently under consideration have been in production and use by the contract packaging firm of CP Packaging (Jamesburg, New Jersey) for delivery of other fluids for the past six years.

Current Status

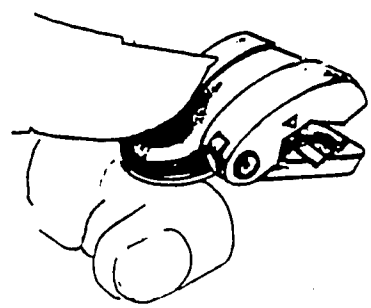
Numerous candidate packages currently available from packaging contractors have been identified. The best candidate so far is available at a low cost of below US$0.04 per unit. The contractor has USFDA Class II designation and previous experience with silver nitrate packaging. Final checks are under way to determine which tests of the best configuration are required by USFDA. Samples of the candidate package are available.

Umbilical Cord Safety Clamp

A small device which in one motion cuts and clamps the umbilical cord in a clean, safe manner

Product Description

This hand-held clamp cuts and clamps the umbilical cord in one motion. The user simply depresses opposing thumb rests and clamps the device over the umbilical cord. When in the clamped position, the device protects the cut end of the umbilical cord from infection. After use, the knife is embedded in plastic and both it and the unused clamp are disposed of. The applicator may be retained for reuse.



Stage of Product at Inception of A.I.D. Funding

The concept and performance criteria were developed under the Safe Birth Program, a PATH needs assessment and technology introduction program involving focus groups of traditional birth attendants in Malawi, North Yemen, and Zambia.

Current Status

Feasibility studies are under way, based upon concept drawings and descriptions. No prototypes have been produced.

Type: C ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 10,000

Urinary Iodine Dipstick

A simple field test to measure urinary iodine

Product Description

Urinary iodine assessment is the main indicator used for identification and evaluation of iodine deficiency disorders. Until now, this test has required laboratory facilities and trained personnel. The product under development will allow low-level personnel to do rapid field assessment of urinary iodine levels.

-- Drawing unavailable --

Stage of Product at Inception of A.I.D. Funding

Initial research was carried out by Dr. John Dunn at the University of Virginia at Charlottesville. The major technical issues remaining to be resolved are the effect of impurities in the urine, characterization of the color change, and stability of the final product under tropical conditions.

Current Status

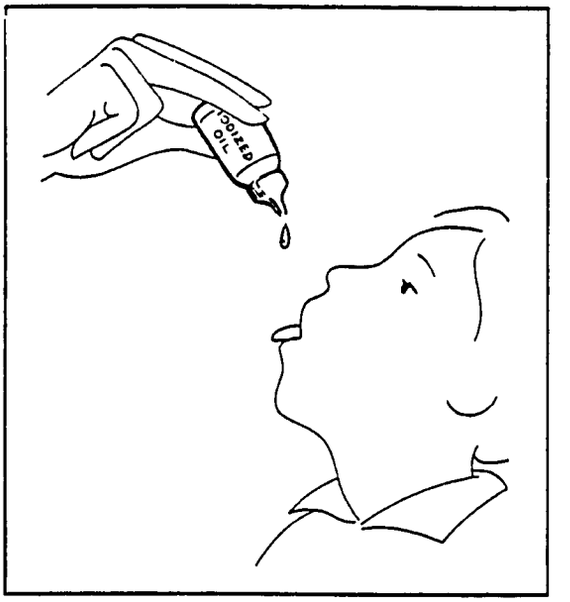
The project has been approved by A.I.D. and work has begun on development of a prototype. Dr. Dunn is conducting a feasibility study of the concept under a subcontract with PATH.

Iodized Oil

Iodized oil is given either orally or by injection to prevent or treat iodine deficiency disorders

Product Description

Iodized oil is a prophylactic or treatment for iodine deficiency. It can be administered as an intramuscular injection or given orally. Oral administration is preferred in most settings and a single oral dose will provide sufficient iodine for up to two years. Iodized oil is the intervention of choice in areas where iodinated salt is not available.



Stage of Product at Inception of A.I.D. Funding

Injectable-grade iodized oil is currently being produced by facilities in France and the People's Republic of China. The government of Indonesia (GOI) is interested in local production of less expensive orally administered oil to decrease the cost of providing oil for Indonesian health programs; the GOI has asked PATH for assistance. PATH has worked with P.T. Kimia Farma, a pharmaceutical firm owned by the GOI, to develop the initial laboratory-scale process for production.

Current Status

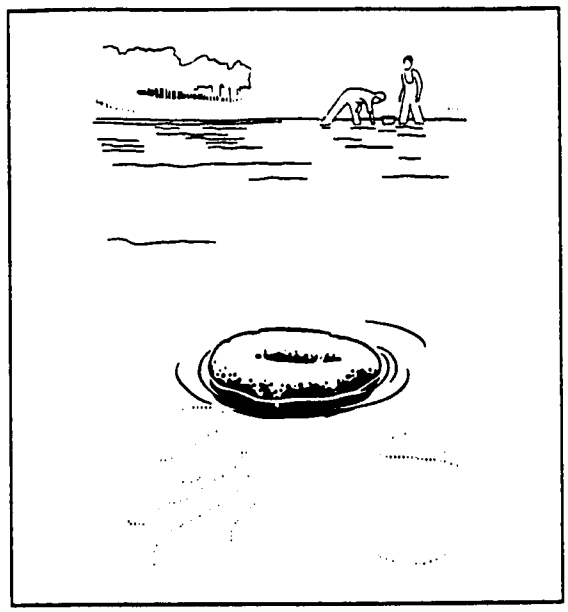
Some HealthTech funding has been used to evaluated the feasibility of this product under Selection and Screening Activities. The work plan for the iodized oil project has recently been approved by A.I.D.; work will begin in February 1989.

Biological Larvicides

Biological larvicides for use in vector control programs for dengue fever and malaria

Product Description

Bacillus thuringiensis serotype H-14 is a biological larvicide traded under the name VECTOBAC and produced by Abbott Laboratories. VECTOBAC is available in several formulations, including aqueous solutions, granules, and powder. VECTOBAC appears to have strong potential against *aedes aegypti*, the vector of dengue fever. *Bacillus sphaericus*, although not yet commercially available, is a new generation of this product which holds promise for control of the anopheline mosquito, the vector of malaria.



Stage of Product at Inception of A.I.D. Funding

In 1985, PATH undertook a market feasibility study of VECTOBAC in Indonesia and Thailand and determined that a significant urban market existed for using VECTOBAC in the integrated control program for dengue fever. Numerous contacts were made with key figures in both the private and public sectors in order to develop this study.

Current Status

PATH, working with Abbott Laboratories and the Indonesia Ministry of Health, developed protocols for testing the product efficacy of VECTOBAC in two separate laboratories in Indonesia. The tests, which were paid for by Abbot and completed in November 1988, were conducted to support the registration of the product. The outcome of these laboratory evaluations was very positive, showing that VECTOBAC was able to kill the selected mosquito vectors and thus might be applicable in the national vector control program. In January 1989 the work plan was approved. The work to date has been completed as a selection and screening activity.

ANNEX 6

PATH-Rejected Technologies

ANNEX 6

PATH Rejected Technologies

Technology	Identified Need	Reason for Rejection	Dates	RPM
Incubator for Newborns	Child Health	Prototypes built; temporarily shelved due to lack of interest from field	1985	MJF
Electronic Scale (PATHweigh[R] I)	Maternal and Child Health	Field trials revealed battery and software problems	85-87	MJF
ORS With Amino Acids "Super PATHtab"	Child Health	Clinical research on appropriate formulas inconclusive	1986	RF
Weighing Chair for Use With Scales	Child Health	Prototypes built; concern with child comfort; local chairs/slings better suited	1986	MJF
Baby Scale Based on Hydraulics	Child Health	Testing showed scale difficult to use	1986	MJF
Umbilical Cord Tie Soaked with Iodine	Child Health	Difficult to manufacture	1986	VT/MJF
Screening Test/Device for Bacteriuria	Maternal and Child Health	Complicated technology; need is low	1986	MJF
Dipstrips for Detection of Glucose in Urine	Maternal and Child Health	Shelf-life studies showed poor stability	86-87	MJF
Swaddler for Low Birth Weight Infants to Prevent Hypothermia	Child Health	Inadequate data as to whether the material (aluminized mylar) can prevent and control hypothermia	86-88	VT
PATHtimer[R] Manufacture by Extrusion Instead of Casting	Immunization	Method requires use of expensive adhesives prone to failure	1987	KFM
Length Board for Measuring Babies (plastic)	Child Health (Growth Monitoring)	Too expensive	1987	MF/KFM
Length Measurer (Modification of a Tape Measure)	Maternal and Child Health	Health workers not interested when demonstrated in field	1987	KFM
Water Bag Labor Timer-- low cost "hour glass" timer for identifying prolonged/ obstructed labor	Maternal and Child Health	Variability with different water; no audible signal; too difficult to use/reset; rejected in field design review	87-88 88-89	KFM GDA

Plastic Bag Silver Nitrate Package	Child Health Newborn Eye Prophylaxis to Prevent Vapor Loss and Over-Concentration	Leaked in field trials; drop delivery unacceptable	87-88	KFM GDA
Water Quality Test for Fecal Contamination	Maternal and Child Health	Field testing showing poor sensitivity to E. coli detection	1988	KFM
Anti-Stick Device for Needles	Immunization	Temporarily shelved due to the existence of several other available technologies	1988	MJF
Delivery Surface Made of Plastic and Fabric	Maternal and Child Health	Expensive; only gives qualitative information if woman is hemorrhaging	1988	DR/KFM
Labor Timer Based on Separation Techniques (liquid/oil)	Maternal and Child Health	Not appropriate; device would be very large	1988	KFM
Custom Electronic Labor Timer	Maternal and Child Health	Minimum quantity to meet cost target > 100,000; no commitment from agencies for that quantity; rejected in selection and screening	1988	GDA
Rachet Syringe Controller Single-Use Device	Immunization	Too complex to integrate with existing manufacturers; rejected in selection and screening	1988	MJF/GDA
Optical Refractor	Child Health (vision)	Inadequate mission and health ministry demand; now coordinating with International Eye Foundation	1988	GDA

ANNEX 7

PATH Licensing Policy

ANNEX 7

PATH Licensing Policy

The goal of PATH's licensing policy is to maintain proprietary control over appropriate products for the benefit of the public sector.

PATH recognizes that different products and potential licensees require varying licensing strategies to achieve the above stated goal. Even so, many of the same licensing strategies can be used to help ensure low-cost availability of the licensed products to the public sector of developing countries.

In general, PATH's policies are:

1. PATH attempts to distinguish between public and private sectors and between developing and developed countries when negotiating licensing agreements.

2. PATH's policy is to forego any royalties or fees for sales of products to the public sector of developing countries.

3. Where practical, PATH will forego any royalties or fees for sales to the public sector of developed countries.

4. PATH will attempt to collect a reasonable and competitive royalty or fee on all sales to the private sector of both developing and developed countries.

5. All royalties and fees collected by PATH are deposited in a special account established by the PATH Board of Directors entitled "Fund for Health Technologies." This account is auditable and available for public inspection. The funds in this account are used for the development and introduction of appropriate technologies in health.

6. Where possible, PATH attempts to control the licensed product's price for sales to the public sector either through an absolute price quantification or a formula based on cost plus. The underlying principle is that price shall be set at a minimum amount necessary to ensure the economic viability of the product in the public sector of developing countries.

7. PATH requires licensees to adhere to Good Manufacturing Practices. Such standards will reflect the specifications of appropriate international agencies and authorities.

8. PATH attempts to grant exclu ve licenses for defined markets, where possible, in order to provi e incentive necessary for a company to participate in manufactur and distributing products to the public sector with minimal co sation. To prevent monopolistic abuses, such exclusive licenses may include performance clauses with enforcement provisions requiring the company to meet reasonably anticipated public sector demands and pricing agreements. Enforcement provisions may include the threat of losing the license.

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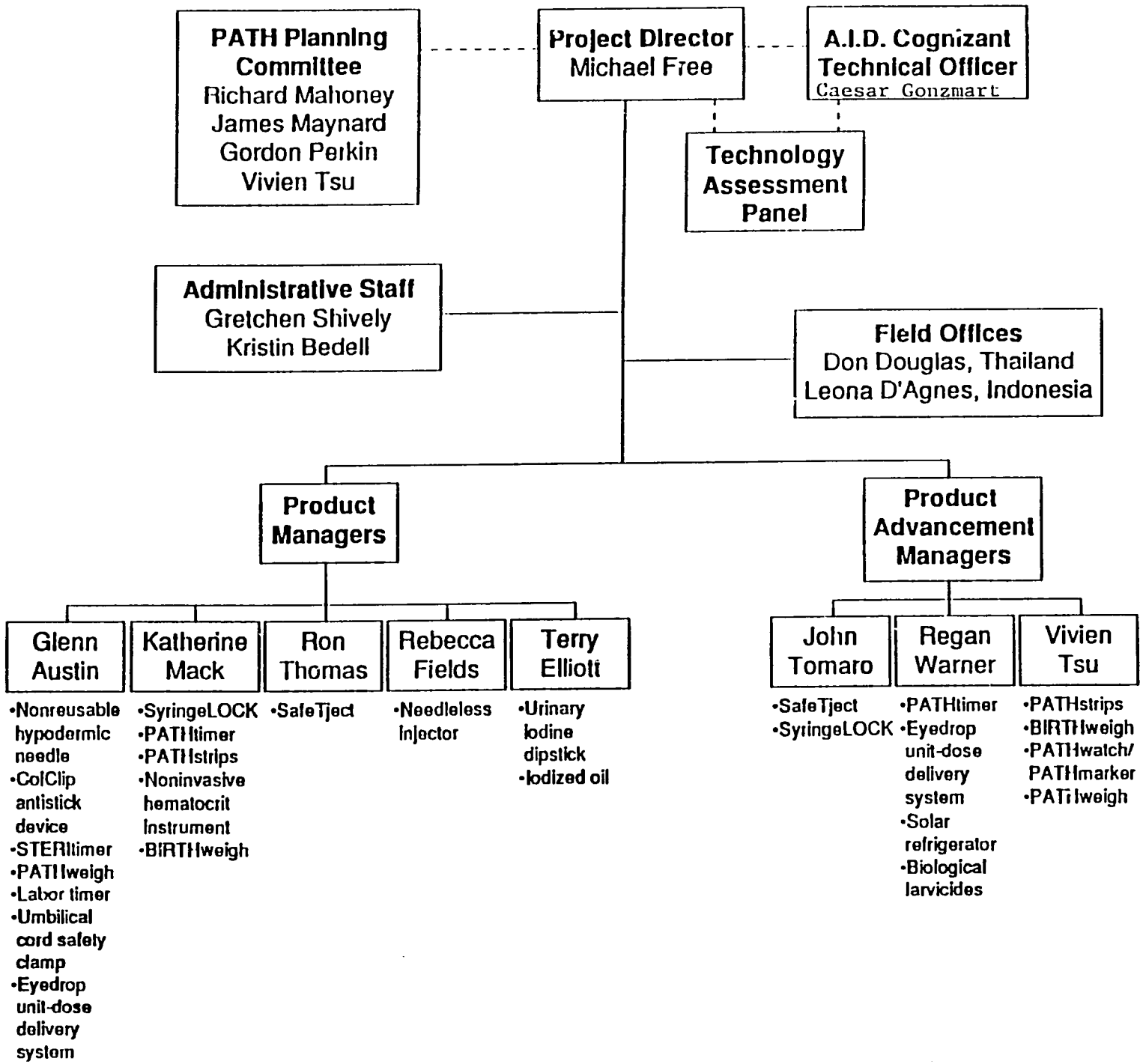
9. As a nonprofit organization with public sector funding, PATH seeks to obtain "Hold Harmless clauses" from all of its licensees. PATH also reviews the liability insurance and assets belonging to a potential licensee to insure that PATH's risk of liability is minimized.

March 14, 1989

ANNEX 8

HealthTech Management

HealthTech Management



January 1, 1989

ANNEX 9

HealthTech/A.I.D. Work Plans Approval Process

ANNEX 9

HealthTech/A.I.D. Work Plans
Approval Process

Technology	Submission Date	Resubmission Date	Approval by Letter	Work Plan Approval Date
SyringeLOCK™	09/24/87 (I) 08/17/88 (II)	04/04/88 (I)	05/09/88	not signed 11/01/88 01/10/89
SafeTject™	09/18/87 (I) 08/17/88 (II)	09/24/87 (I) 04/04/88 (I)	05/09/88	not signed not signed 11/01/88 01/16/89
Nonreusable Hypodermic Needle	04/04/88		05/09/88	11/01/88
Needleless Injector with Disposable Nozzle	05/12/88			01/16/89
STERItimer™	09/24/87	04/04/88	05/09/88	not signed 11/01/88
PATHtimer®	09/24/87	04/04/88	05/09/88	not signed 11/01/88
PATHwatch™/PATHmarker™	09/18/87 (I) 08/17/88 (II)	09/24/87 (I) 04/04/88 (I)	05/09/88	not signed not signed 11/01/88 01/10/89
Solar Refrigerator/ Ice Maker	09/24/87	05/12/88 08/17/88		not signed not signed 01/10/89
PATHweigh®	09/24/87	04/04/88	05/09/88	not signed 11/01/88

Technology	Submission Date	Resubmission Date	Approval by Letter	Approval Date
PATHstrips™	04/04/88		05/09/88	11/01/88
BIRTHweigh™	09/24/87	04/04/88	05/09/88	not signed 11/01/88
Eyedrop Unit-dose Delivery System	04/04/88		05/09/88	11/01/88
Urinary Iodine Dipstick	09/24/87	08/17/88	05/09/88	not signed 01/10/89
Iodized Oil	09/18/87	09/24/87 08/17/88	06/15/88	not signed not signed 01/10/89
Biological Larvicides	09/24/87	08/17/88	05/09/88	not signed 01/10/89
Iodized Salt Test	09/24/87			not signed
Mosquito Repellent Bar	09/24/87			not signed
Hepatitis B Vaccine	09/18/87	09/24/87		not signed not signed

MS00959V

ANNEX 10

Possible Additional Countries for HealthTech Work

ANNEX 10

Possible Additional Countries for HealthTech Work

Latin America/Caribbean

1. Guatemala	relatively good infrastructure; INCAP as potential collaborator; typical of ethnic and environmental diversity of Central America; strategic country; other PATH activities there
2. Ecuador	diversity of Andean and tropical environments; ethnic diversity; stable political environment; other USAID projects there for collaboration

Francophone Africa

3. Mali	typical Sahelian environment; some health infrastructure; relatively stable politically; other NGO projects; highly motivated staff despite difficult conditions
4. Cameroon	multi-cultural; strong public health community; potential for local manufacture of products; other PATH activities there; relatively stable politically

Anglophone Africa

5. Ghana	focus on primary health care/maternal and child health; good governmental staff; relatively stable economically and politically; typical of West Africa culture and environment; big enough (15 mil) to be significant; other PATH activities there; priority Child Survival country
6. Zimbabwe	effective health infrastructure; potential for local manufacture of products; typical of southern Africa culture; stable; PATH staff based there; other projects there

Asia

7. Bangladesh	typical of South Asia conditions; NGO as well as governmental infrastructure; other PATH activities there; other USAID projects there; priority Child Survival country
8. Nepal	diversity of environments; other PATH activities there and several Nepali speakers on staff; other USAID health projects

9. Philippines — potential for local manufacture; other PATH activities there; good governmental and NGO infrastructure; diversity of environments; strategically important

NOTE: We would not expect all of these to work out, nor would we want to be spread so thin, but the option of working in any of these places would be very useful given the diversity of technologies we work with.

ANNEX 11

Strategies for Country Involvement

ANNEX 11

Strategies for Country Involvement

A three-tiered system for selecting sites for field trials, be they design-stage, validation, or introduction, was agreed upon by A.I.D. and PATH.

The first level is countries most likely to have funds for buy-ins to support local activities. These countries include Egypt, Bangladesh, and Pakistan. Some Latin American countries might be included at this level.

The second level includes countries where PATH already has an infrastructure that could efficiently manage these field activities. These countries include Thailand and Indonesia, and may eventually include Kenya.

The third level includes countries where PATH programs funded by other sponsors already exist. This includes the Safe Birth countries: Bangladesh, Malawi, Sierra Leone, Yemen, Zambia, and Zimbabwe.

Action: PATH will supply to the CTO a list of current technologies with field activities and their distribution among these countries.

Source: Minutes of Meeting with Pamela Johnson and Caesar Gonzmart regarding HealthTech Project, Washington, D.C., Nov.1, 1988.