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Program for
Appropriate Technology
in Health

HealthTech: Technologies for Child Health

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

Final Report

path

HealthTech:
Technologies for Child Health

Final Report

July 1, 1987 - July 31, 1990

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

Submitted to

United States Agency for International Development
(USAID)

By

Program for Appropriate Technology in Health
(PATH)
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The following report for the HealthTech: Technologies for Child Health project (USAID Cooperative Agreement DPE-5968-A-00-7035-00) covers the period July 1, 1987, through July 31, 1990, and is divided into five sections: Summary of Program Achievements; Program Management; Meetings/ Conferences; Add-ons to Cooperative Agreement; and Summary of Progress by Technology.

Summary of Program Achievements

During the past three years, the HealthTech program has made significant progress toward its goal of improving the health status of developing country populations. A summary of program achievements follows:

- The infrastructure for HealthTech was established at PATH during the first year of the program. Since its inception, over 100 PATH employees have contributed to the HealthTech effort. A team approach to technology development has been successfully designed and implemented.

- Over 30 technologies have been examined and screened for possible inclusion in the program. Currently, an additional 35 technologies are under review. (Examples include blood pressure equipment, a simple fetascope, a pelvic training model, a simple birthing kit, technologies for detecting membrane rupture, gloves for midwives, reusable heat-reactivated syringe, cold box, vaccination record, and autodestruct needles.)

- Sixty unsolicited product ideas have been received and logged into a database for technology ideas. These include nonreusable syringe devices and anti-stick needle devices.

- Work plans for 24 different technologies have been prepared and submitted to USAID for approval. Twenty of these projects have been approved, and work is ongoing.

- The approved projects include four injection technologies (SafeTject, SyringeLOCK/SoloShot, Needleless Injector, JHU Auto-destruct Syringe), five adjunct technologies for immunization/vaccination (VaccineMarker, STERItimer, PATHtimer, Solar Refrigerator/Ice Maker, PolioMarker), five maternal care technologies (PATHweigh, PATHstrips for protein, PATHstrips for hematuria, Labor Timer, Noninvasive Instrument for Detecting Anemia), three newborn care technologies (BIRTHweigh, Eyedrop Unit-Dose Delivery System, Umbilical Cord Safety Clamp), and three primary health care technologies (Urinary Iodine Dipstick, Iodized Oil, Biological Larvicides).

- Product development phases have been completed for six technologies (SyringeLOCK/SoloShot, BIRTHweigh, PATHstrips for protein, JHU Auto-destruct Syringe, PATHtimer, and PATHweigh). Laboratory testing of almost all of these products has been conducted at the PATH laboratory.

- Design-stage field trials in developing countries have been conducted for seven technologies (PATHstrips for protein in three countries; BIRTHweigh in six countries; VaccineMarker and PolioMarker in five countries; and in one country each, JHU Auto-destruct Syringe, Needleless Injector, SafeTject, and PATHtimer).

- Validation field trials of four technologies have been conducted in ten countries (SyringeLOCK/SoloShot in Pakistan, PATHstrips for protein in three countries, and BIRTHweigh in six countries).

- Introductory field trials of three different technologies are occurring in five countries (PATHwatch/PATHmarker in Indonesia, Kenya, and Thailand; Solar Ice maker in Thailand; and PATHtimer in Sierra Leone) and have been completed for PATHwatch/PATHmarker in Zambia and Sierra Leone.

- Complete technology transfer of production capability has been accomplished for one technology in two countries (BIRTHweigh in Egypt and Malawi) and is nearly complete in one country for another technology (PATHstrips for protein in Zimbabwe).

- HealthTech currently has activities ranging from information dissemination to field trials to technology transfer in over 50 developing countries.

- Collaborations with 12 private sector organizations have been established. Seven agreements have been reached that range from co-development agreements to contracted services. Private sector collaborators include:

Acacia Laboratories Los Angeles, California	Licensee and co-developer of SafeTject
Becton-Dickinson and Company Rutherford, New Jersey	Licensee of SyringeLOCK and developer of SoloShot
Lifelines Technology, Inc. Morris Plains, New Jersey	Developer and manufacturer of PolioMarker/VaccineMarker core technology
Polymer Technology International Issaquah, Washington	Developer of core technology for PATHstrips hematuria
Minnesota Mining & Manufacturing Company (3M) Minneapolis, Minnesota	Licensee of University of Washington technology and collaborator for development of the Noninvasive Instrument for Detecting Anemia
Vitajet Company Rio de Janeiro, Brazil	Developer and manufacturer for adaptation of needleless injector technology

Masstech International (Sensor International) Victoria, Australia	Inventor and partner in development of PATHweigh
SECA Germany	Potential PATHweigh manufacturer
CAPS Holdings Harare, Zimbabwe	Licensee and in-country producer of PATHstrips for Protein
Polytechnic Institute Blantyre, Malawi	In-country producer of BIRTHweigh
SOFTECS Cairo, Egypt	In-country producer of BIRTHweigh
Pan Siam Engineering Thailand	Evaluator and potential local manufacturer of solar icemaker technology
Kongsak X-ray Medical Industry Company, Ltd. Thailand	Potential licensee and prototype producer of PATHtimer

- HealthTech has provided licenses for four technologies to private sector manufacturers and co-developers (SyringeLOCK/SoloShot to Becton-Dickinson, SafeTject to Acacia Laboratories, BIRTHweigh to SOFTECS, and PATHstrips for protein to CAPS Holdings). PATH has been awarded licenses on three other products on behalf of HealthTech (PATHtimer and STERItimer from Robert Parker, PATHwatch/PATHmarker from Allied Chemicals, and SafeTject from Merck).

- PATH has applied for and has been awarded a patent on one HealthTech subject invention (SafeTject). The 3M Company has applied for a HealthTech subject invention patent for aspects of the Noninvasive Instrument for Detecting Anemia. Five of PATH's private sector collaborators hold prior-design patents on HealthTech technologies (JHU Auto-destruct Syringe, STERItimer, PATHtimer, PATHwatch/PATHmarker, PATHweigh).

- Collaborations and working relationships have been established with the major international public health agencies including WHO and UNICEF as well as other public sector PVOs (REACH, AMREF, The Johns Hopkins University).

- WHO has issued product information sheets on one HealthTech technology (PATHtimer) and has approved the SoloShot device for possible purchase by UNICEF.

- UNICEF has agreed to list another HealthTech product in the UNIPAC catalog (BIRTHweigh), is arranging for another technology to be included in every UNICEF-distributed midwifery packet (PATHstrips for protein), and has ordered a number of other prototypes for evaluation.

- Two USAID missions have implemented programs as add-ons to the HealthTech Cooperative Agreement (Egypt and Indonesia).

- An issue of *Health Technology DIRECTIONS* on the subject of immunization was researched and funded under HealthTech and mailed to over 6,000 recipients in the developing world.

- Over 1,000 brochures on HealthTech have been distributed including a mailing to all the USAID missions in the developing world.

- Publicity about the HealthTech program has included a presentation to the National Academy of Science/USAID luncheon, presentations at NCIH conferences, a box on technology development in USAID Report to Congress, and a press release and announcement by the A.I.D. administrator regarding SoloShot.

Program Management (January 1 - July 31, 1990)

An unsolicited proposal entitled "HealthTech: An Expanded Scope of Work" was submitted to the Office of Health on March 25, 1990. Negotiations and discussions regarding the renewal of the HealthTech program and the establishment and award of a new cooperative agreement have taken place during this period. On July 25, 1990, Cooperative Agreement No. DPE-5968-A-00-0025-00, a five-year continuation of the program, was awarded to PATH.

A level of effort report for the six-month period is provided as Attachment 1. A financial report showing spending on the various technologies during the period is provided as Attachment 2. The total unspent balance for approved work plans of $505,273 represents the final obligation of funds not received under the first cooperative agreement. Explanations of the variations in spending vs. work plan budgets are included in a separate letter to the CTO.

Inquiries for information on HealthTech and technologies continue to be received from the field. An update of the country activities database is provided as Attachment 3 and demonstrates the current extent of HealthTech activity geographically.

Meetings/Conferences (January 1 - July 31, 1990)

Two Technology Introduction Panel (TIP) meetings took place during this period. On January 30, 1990, a meeting was held at UNICEF/NY which Drs. Michael Free and Gordon Perkin attended. PATH technologies discussed for the first time included PATHpak, the noninvasive hemoglobinometer, and STERItimer. The final report for this meeting is

included as Attachment 4. Dr. Free also attended the TIP meeting held on June 27, 1990, at the USAID Office of Health and presented four additional HealthTech technologies. The official minutes are being written by UNICEF.

Dr. Free attended a TECHNET meeting on cold chain technologies and issues which was held in Nicosia, Cyprus, March 12-16, 1990, and presented information on the development of VaccineMarker and PolioMarker. Specific impressions which apply to HealthTech technologies are described in Attachment 5.

The annual NCIH meetings held June 17-20, 1990, in Washington, D.C., were attended by Dr. Free and Ms. Debra Kristensen. Dr. Free gave a presentation on public/private sector collaborations as depicted by several HealthTech projects. Ms. Kristensen presented a poster on technology transfer and promotional activities for PATHstrips for the detection of proteinuria. The NCIH meeting also provided an opportunity for USAID to formally publicize SoloShot to the international health community.

PATH is collaborating with health professional associations in an effort to exchange information, provide expertise where appropriate, and develop partnerships to advance programs of mutual interest. In June, HealthTech and DiaTech management met with the International Relations Committee of the College of American Pathologists (CAP) in Seattle. This committee is attempting to facilitate the development of appropriate laboratory practices in foreign countries. Project management strategized with CAP on how to improve technical education and how best to transfer appropriate technologies to developing countries.

The annual meeting of the Association of University Technology Managers was held July 8-9, 1990, in Vancouver, B.C. Dr. Free and Ms. Shively gave a presentation entitled "The Developing World: Another Market for Health Technologies." Contacts were made with university technology transfer managers who will regularly provide information on licensable technologies. An abstract of the presentation and selected handouts are provided as Attachment 6.

Add-ons to Cooperative Agreement

During this period the USAID Mission in Cairo provided funding in the amount of $29,017 as an add-on for a feasibility study of technology transfer of Hepatitis B vaccine production to Egypt.

The scope of work included visits by several PATH experts in technology transfer to Egypt and to Merck Sharp & Dohme in Pennsylvania, and a written analysis. The study has been sent under separate cover to the HealthTech CTO.

A report on the current state of the Indonesian buy-in to field test PATHwatch/PATHmarker is included as Attachment 7.

During the period, HealthTech received a request from the Jordan USAID Mission for a feasibility study of the potential technology transfer of SafeTject, PATHstrips, and ORS production. A team of PATH experts in technology transfer and marketing were to have gone to Jordan for two weeks. Several discussions with the HPN officer in Jordan and with representatives of the ANE Bureau were held. It was determined that the project should be postponed until the new HPN officer could evaluate it as an appropriate program.

Summary of Progress by Technology

Biological Larvicides

HealthTech funding for biological larvicides was provided to enable the Ministry of Health in Indonesia to determine whether VECTOBAC, a biological larvicide produced by Abbott Laboratories, was suitable for use in village vector control programs. VECTOBAC was tested in laboratory settings to determine whether it was effective against *Aedes aegypti*, the vector of dengue fever. In addition, another biological larvicide, *Bacillus sphaericus*, is being tested as a possible product to control the anopheline mosquito, the vector of malaria.

Laboratory tests completed in November 1988 showed that VECTOBAC was able to kill the selected mosquito vectors and thus might be applicable in the national vector control program. VECTOBAC is available in several formulations, including aqueous solutions, granules, and powder. Originally, the Ministry of Health planned to conduct village-level field trials of VECTOBAC with the support of HealthTech. It has now suspended plans for a field trial after it was decided that Abbott's product was too costly and required frequent reapplications.

BIRTHweigh

A licensing agreement was signed by SOFTECS, the local consulting firm in Cairo, Egypt, for production of BIRTHweigh. A visit was made to SOFTECS by a PATH consultant in February 1990 to set up the production equipment and to start the initial production runs. UNICEF has placed an initial order with SOFTECS for 15,000 scales for the UNIPAC catalogue. New sources of stainless steel have been identified. SOFTECS can now order its raw materials directly from the suppliers. New procedures and equipment for attaching the hook have been developed which will make the production process smoother.

The Malawi Polytechnic Institute continues to produce small numbers of scales. The local UNICEF office has offered to facilitate the shipment of these scales.

UNICEF has become actively involved in promoting the use of the scale and in facilitating shipment of the initial batches. The scale will be listed in the Fall 1992 UNIPAC catalogue. PATH is preparing pictorial instructions for scale use. Each picture will also have written instructions in English, French, Spanish, and Arabic. These draft

instructions will be sent to UNICEF for inclusion with the scales ordered from UNIPAC. UNICEF is still considering several designs for the sling that will be used with the scale.

Letters of interest in the BIRTHweigh scale continue to be received. Agencies are referred to UNICEF for purchase of the scale. PATH will continue to be involved in scale-up and introduction activities on request.

Eye-drop Unit-dose Delivery System

Several hybrid packaging materials have been evaluated. A new genre of laminated "cold-formable" plastic/foil materials is being considered at this time. The cost target (without medicament) of $0.04 is difficult to achieve. This project is currently proceeding on a low priority basis.

Iodine Dipstick for Urine

A feasibility study of a simplified urinary iodine measurement was recently completed by Dr. John Dunn of the University of Virginia Department of Medicine. Inquiries continue to be received from the field that indicate this would be a valuable and important product for primary health care programs. Should PATH or USAID choose to further research this product, Dr. Dunn has indicated that he is willing to provide advice to collaborators or commercial companies. A report of the study is provided as Attachment 8.

JHU Auto-destruct Syringe

Storage stability tests were recently completed on units stored over six months in developing country environments. Tests showed little effect on performance of syringe or self-disabling time of storage at high humidity and over 30°C storage temperatures. JHU has received numerous inquiries regarding this technology but has not yet signed a formal license agreement. PATH has offered to assist JHU in representing the technology to major syringe manufacturers.

Labor Timer

Labor Timer has been reassigned to selection and screening status until adequate technological response to the need has been identified. A variety of approaches to inexpensively measure 1-, 6-, and 12-hour time periods have been tested. These include sedimentation and/or separation of dissimilar materials, burning lamp oil, spring-wound clocks, and electronic timing devices. However, none of these approaches currently appears to meet criteria of easy human interface, performance, accuracy, and low cost.

Needleless Injector

PATH's most significant achievement with the needleless injector over the past six months has been completion of the first stage of product adaptation. Working from an initial list of short-term and longer-term changes that would be desirable in converting an insulin injector into an EPI injector, Vitajet, Inc. and PATH have achieved a device with the following new features:

- lighter-weight body
- removable, sterilizable head assembly
- changeable pressure settings for adult and child injections
- revised dosage markings (in milliliters rather than insulin units)
- near-zero residue piston/chamber design
- improved ergonomics (easier to wind and activate)

The device was demonstrated to health workers and supervisors in Bolivia in June 1990. Comments received on this trip are provided as Attachment 9. Plans are now being made for an independent laboratory assessment of the potential for disease transmission with the device and for an in-house human subjects trial of the device.

Noninvasive Instrument for Detecting Anemia

A meeting between representatives from 3M and PATH took place in Seattle in January. During the last six months, 3M has achieved technical advances with the core technology that could be applied to the research and development efforts of a noninvasive instrument for detecting anemia. However, organizational reprioritization at 3M is currently preventing 3M from entering into an agreement with PATH to pursue the next phase of research on this device. Discussions with 3M are ongoing.

Efforts to obtain feedback from potential end users of this product continue. Responses from a recent survey of hematologists are included as Attachment 10.

ORS Dilution Meter

Due to other priorities for staffing, further research and development of this product have been postponed.

PATHstrips for Hematuria

Product development is ongoing at Polymer Technology International. A report is expected from the manufacturer by mid-September. Two potential field evaluation sites, one in Egypt and one in Tanzania, have been identified. (Note: the bulk of product development was supported by the Edna McConnell Clark Foundation.) Photographs are attached as Attachment 11.

PATHstrips for Protein

The licensing agreement between PATH and CAPS Holdings in Harare, Zimbabwe, has been signed. Technology transfer of the PATHstrips production capability is planned to take place in October.

A potential site has been identified in Indonesia for the production of PATHstrips and is currently being assessed.

PATHtimer

In June, WHO/EPI completed a series of tests on PATHtimer. WHO will forward the results of the tests to PATH as soon as they are available. Preliminary discussions indicate the results were favorable (see Attachment 12 for trip report of meeting at British Standards Institute where testing took place).

Issues regarding the effects of altitude, barometric pressure, and ambient temperature on boiling temperature are considered training issues and need to be explored in field trials. Sierra Leone has been selected for a trial involving 100-200 PATHtimers. No timeframe has yet been set for this trial.

PATH continues to evaluate casting materials that can withstand the constant heating and cooling cycles required of PATHtimer. Several materials under consideration could increase the durability of PATHtimer three-fold. Any materials selected for production that do not already have FDA clearance will undergo leachability studies to confirm that no particles that could adhere to the medical instruments are released during boiling.

PATHwatch/PATHmarker

The field trial in Kenya was completed in June. The final report is being reviewed by the Kenyan EPI before release, hopefully in September. The field trial in Indonesia is scheduled to be completed in September. Preliminary analysis of data from the Thai field trial has begun. A wrap-up visit to Thailand is scheduled in October.

Future work on a cold chain monitor for EPI vaccines is being continued as VaccineMarker (see summary below).

PATHweigh

Sensor International has produced seven advanced prototype hanging scales to be used in introductory field trials sometime in the fall. CARE in Bolivia has expressed interest in being the implementing agency for these trials. The current interest in some countries is for hanging scales since they are proven and familiar. In addition, they are simpler, pocket-sized, and, therefore, less expensive and more adaptable than stand-on scales for outreach workers to use.

Several updated stand-on scales will also be evaluated to ascertain the effectiveness of modifications requested after UNICEF field trials. Operator interface and environmental effects have been addressed.

Inquiries have also been made by the Demographic Health Survey project in doing a similar field project as part of their maternal assessment program.

PolioMarker/VaccineMarker

Design-stage field trials of PolioMarker have been conducted in Bangladesh, Bolivia, Cameroon, Kenya, and Sierra Leone. The results thus far have confirmed that the yellow to green color progression of these heat exposure indicators is culturally acceptable and easy to recognize and interpret. Valuable information was also collected on the format and content of potential training materials and programs.

Product development is ongoing. In accordance with instructions from WHO/EPI, priority has been given to PolioMarker development because oral poliovirus vaccine (OPV) is the least heat stable of the EPI vaccines. WHO/EPI has approved the time/temperature response curve for PolioMarker. Approval for the VaccineMarker response curve is forthcoming.

WHO/EPI plans to include these heat exposure indicators on all vials of oral poliovirus, measles, DPT, and BCG vaccine procured for the EPI from January 1992 onward. To date, representatives from PATH, WHO/EPI, and UNICEF have met with six European vaccine manufacturers to discuss the integration of these indicators into the packaging and labelling processes for all EPI vaccine vials. Trip reports of the meetings with European vaccine manufacturers which took place in June and July 1990, as well as a disclosure document for manufacturers of OPV, are provided as Attachment 13.

SafeTject

The manufacturing license with Acacia Laboratories has been executed. Acacia has finalized plans for offering two filling systems for SafeTject: (1) a small system oriented toward sample preparation, start-up, and small volume production runs that will fill, seal, and shape up to 1,200 units per hour; and (2) a full-scale production unit which will fill and seal 15,000 units per hour. Acacia has contracted with a major manufacturer of high-speed aseptic processing equipment to build the production equipment and to provide service through its global service network.

In conjunction with an international research institute, the first sterile fill of SafeTject with a medicament was completed (supported by a small Hewlett Foundation grant). Storage and stability trials are underway with possible field trials to follow. Basic stability and characterization studies have shown SafeTject to be an excellent candidate for a wide variety of medicaments.

Discussions have taken place with a number of vaccine and medicament manufacturers considering filling and marketing their products in SafeTject. Pasteur Vaccins (France), Merck Sharp & Dohme (United States), Evans Biomedical Ltd. (United Kingdom), Merieux Institute (France), Connaught Laboratories (Canada), The Upjohn Company (United States), SmithKline Beecham (United States), and Korea Green Cross Corporation (Korea) have all expressed interest in the device. Pasteur Vaccins, The Upjohn Company, and Korea Green Cross Corporation (KGCC) have committed to filling and testing SafeTject with their products.

The draft protocol for the Kenya design-stage field trial of SafeTject filled with tetanus toxoid (TT) has been revised and is now being reviewed by AMREF and Kenya EPI staff in Nairobi. Storage stability and shelf-life tests are scheduled to begin in September 1990 when 20,000 SafeTjects will be filled with Pasteur Merieux TT vaccine to be used in the Kenya trial. It is expected that filled SafeTjects will be available for use in the Kenya trial in the spring of 1991.

During the past six months PATH has followed up with the following groups who have expressed an interest in SafeTject field trials: UNICEF/Kathmandu, the USAID mission in Jordan, and representatives of Procosi, an NGO consortium in Bolivia. Partial funding was approved in May 1990 from the USAID Office of Private and Voluntary Cooperation for a SafeTject TT design-stage field trial in Lombok, Indonesia, to begin in September 1991. Plans are also under way for the filling of 1,500 SafeTjects with hepatitis B vaccine provided by KGCC for the fall of 1990.

PATH's Institutional Review Board will review all SafeTject field trial protocols to ensure the rights and welfare of individuals involved are protected. The end-user study of SafeTject by a market research firm has been completed. A summary report of the findings are provided in Attachment 14.

PATH has assembled a technical team to investigate enhancements to SafeTject's nonreusability feature. Several aspects of the current SafeTject device were tested, and based on this testing, criteria have been established for a nonreusable design. In addition, Acacia Laboratories will be investigating a Mark II design that will allow SafeTject to be filled with doses larger than 0.5 ml.

A drawing of SafeTject and summary of SafeTject activities which were prepared for the June TIP meeting are provided as Attachments 15 and 16.

Solar Ice Maker

A new field site has been selected for field trials of the solar ice maker. The inventor has now validated a smaller, more efficient unit that will be set up at the new field site. Two of the smaller units, called Mini-ISAAC's, are now being shipped to Thailand for assembly. One will remain at Pan Siam Engineering for testing.

The new Mini-ISAAC design has a new cold box design for storing vaccines at constant temperature and has a separate compartment for ice. The cost of the smaller unit is currently estimated at below $3,000.

The Mini-ISAAC will be moved to the field site in September of 1990. The site will be in the Mae Hong Sorn Province in the far north of Thailand near the provincial capital. The larger unit will also be set up in the field, in an adjacent district to facilitate field trial monitoring and demonstration visits. WHO, UNICEF, and a number of international NGOs are interested in seeing the units in operation. A variety of site visits are planned. Plans are also under way to send the Mini-ISAAC to WHO for evaluation. Two journal articles describing the Mini-ISAAC are provided as Attachment 17.

The solar ice maker project was funded under HealthTech on a "wind down" basis. It will not appear in subsequent HealthTech project updates.

STERItimer

A functional STERItimer prototype has been developed for the Prestige steam sterilizer. Tests conducted on this prototype using a simulated 8 mph wind show that the effects of wind on conversion time have been reduced to a four-minute increase. A sample prototype was delivered to Prestige in June for their evaluation. Kelomat has also requested a prototype for their evaluation; however, the current configuration of STERItimer does not have similar conversion times for both Kelomat and Prestige sterilizers. This is because the Prestige sterilizer is made of aluminum and the Kelomat sterilizer is made of stainless steel. Research is underway to qualify the differences between the two models in order to develop a single prototype that functions properly on both manufacturers' sterilizers.

PATH is working with the manufacturer of the lead material candidate for STERItimer to resolve regulatory issues; leachability studies will be performed if necessary to confirm the safety of this material.

SyringeLOCK/SCLOSHOT

PATH is awaiting the official release by the Pakistan government of the REACH report on the field trial of SyringeLOCK which took place in November 1989. Following a review of this report, WHO and UNICEF have indicated that they would welcome the product as part of their 1991 procurement program.

Becton Dickinson is proceeding on the development of nonreusable products using the basic syringe design.

Umbilical Cord Safety Clamp

No progress has been made since the last report. This product was moved to lower-priority status due to higher priorities within the HealthTech program.

Other Technologies

Anti-stick Needle Designs

Several anti-stick syringe and needle designs have been reviewed, and promising designs were presented to syringe and medical manufacturers including Becton-Dickinson. Manufacturers have found sales of first generation anti-stick products to be disappointing and are not receptive to more innovative designs at this time. Legal and policy issues from government and unions may change manufacturer attitudes. PATH will continue to review and evaluate new designs.

Genie Generator

The Genie human-powered generator continues under slow but active design development. Manufacturers of hand-powered generators have been located in Hong Kong and Taipei who may be able to supply a more powerful model for Genie. Much stronger armature magnets have been obtained for test configurations of a foot-powered Genie. One goal is a generator powerful enough to supply current to a laparoscope, and, to that end, more efficient lamps are being researched.

Potential New Products

A neonatal resuscitator prototype is being assembled for evaluation. An in-house evaluation of a membrane rupture detection test strip is underway. Feasibility studies of sterilizable examination gloves and a multi-fuel sterilizer stove have been initiated.

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Attachment 1

Level of Effort Report
January 1 - July 31, 1990

Name	Level of Effort (> 25%)
ELIZABETH ABU-HAYDAR* Product Advancement Manager	86%
GLENN AUSTIN Product Development Manager	61%
AMIE BISHOP Product Advancement Manager	25%
MICHAEL FREE Project Director	34%
SUZANNE JANZEN Product Advancement Manager	36%
DEBRA KRISTENSEN Product Development Manager	85%
CARIB NELSON Product Development Manager	26%
RUSSELL PAUL* Product Development Manager	52%
GRETCHEN SHIVELY Administrative Officer	37%
RON THOMAS Product Development Manager	77%
VIVIEN TSU* Product Advancement Manager	39%
REGAN WARNER Product Advancement Manager	27%

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* Part-time staff.

Attachment 2

HEALTHTECH TECHNOLOGIES FINANCIAL REPORT

As of July 31, 1990

APPROVED TECHNOLOGIES	APPROVED WORK PLAN BUDGETS	EXPENDITURES THRU 7/31/90 (DIRECT COSTS)	WORK PLAN BUDGET BALANCE	PERCENT OF BUDGET REMAINING
SafeTject	$733,002	$797,454	($64,452)	-9%
SyringeLOCK	144,962	141,077	3,885	3%
PATHwatch/PATHmarker	198,711	121,344	77,367	39%
JHU Autodestruct Syringe	133,234	116,786	16,448	12%
BIRTHweigh	135,632	155,139	(19,507)	-14%
PATHstrips-protein	69,932	86,566	(16,634)	-24%
PATHtimer	44,698	57,954	(13,256)	-30%
PATHweigh	104,572	27,543	77,029	74%
Eyedrop Unit-Dose Delivery System	15,536	14,425	1,111	7%
STERItimer	116,274	97,216	19,058	16%
Solar Refrigerator/Ice-maker	15,043	7,273	7,770	52%
Needleless Injector*	77,828	18,154	59,674	77%
Biological Larvicides	18,960	4,052	14,908	79%
Iodine Dipstick/Urine	10,000	4,292	5,708	57%
Iodized Oil	22,647	9,581	13,066	58%
Noninvasive device for detecting anemia	160,879	11,350	149,529	93%
Polio Marker	93,844	39,620	77,385	82%
ORS Dilution Meter	45,673	8,344	37,615	82%
PATHstrips-hematuria	20,000	1,689	19,992	100%
Labor Timer	39,763	2,874	38,578	97%
TOTALS	$2,201,190	$1,722,734	$505,273	23%

*First work plan budget approved = $98,169. Only $25,000 needed.

Attachment 3

PATH
Product Development
Country Activities Database
(HT indicates HealthTech)

COUNTRY	TECHNOLOGY	LEAD PRODUCT MANAGER	ACTIVITY	PRIMARY/SUPPLE-MENTARY FUNDING	COUNTRY EXPERTS/PATH	KEY CONTACTS	COMMENTS/STATUS
Afghanistan	PATHtimer	R. Warner	testing	HT/UNICEF	L. Krieger	M. Omar, UNICEF	Informal testing of timers in Kabul in 1988.
Bangladesh	BIRTHweigh	E. Abu-Haydar	potential sale	HT		A. Lynam Goddard, CARE Intnl.	Inquiry re: cost and availability from CARE Bangladesh.
	SyringeLOCK	J. Green	possible field trial	HT/?	D. Robinett B. Crook S. Wittet M. Zimmerman L. Krieger	Maxine Whittaker, Int'l Ctr for Diarrheal Disease Research (ICDDRB)	Inquiries about SafeTject (6/22/89). Interested in seeking funding for field trials of SyringeLOCK and PATHstrips (DD).
Bolivia	BIRTHweigh	E. Abu-Haydar	possible introduction	HT	S. Tifft S. Janzen G. Burdman	Paul Hartenburger, A.I.D. Joel Kuritsky, CSP Chris Roesel, CARE	Strong inquiry from mission (EAH responded 3/90). Interest in introduction; packet sent.
	HT Products		possible testing	HT/?		Betsy Alexander, R.N., UNC-Chapel Hill	Inquiry (11/89) about birth technologies. Interest in serving as test site.
	Needleless Injector	S. Janzen	Demonstrated model; possible field trial	HT		David Rogers (SCF)	Awaiting prototypes. Possible trials in 1990 (SJ).
	PATHweigh	E. Abu-Haydar	possible field trial	HT/CARE		Chris Roesel, CARE	Inquiry received from bureau cable (EAH responded 3/90). Protocol, field trial, budget sent. SJ visited 6/90.
	PATHweigh	E. Abu-Haydar	assessment	HT/CCH project		Joel Kuritsky, Technical Advisor in Child Survival Rita Fairbanks	Mission considering assessing the usefulness of PATHweigh. Request for additional information (4/90).
	PolioMarker	E. Abu-Haydar	assessment	HT/Mission		Paul Hartenburger, A.I.D.	
	SafeTject	J. Green	possible field trial	HT		Procosi (NGO Consortium)	Discussion held with Procosi and Mission 6/90 visit (SJ).
Brazil	Needleless Injector	S. Janzen	prototype development	HT	H. Zardo L. Bruce	Sergio Landau, Vitajet	Contract for development of prototypes.
Burma	BIRTHweigh	E. Abu-Haydar	introduction	HT	D. Douglas S. Wittet	Dr. Po, head of Burmese Nutrition Department	Expressed strong interest in collaboration (contact - LDA)
Cameroon	SafeTject	J. Green	field trial/hep B	HT/McDonnell		Peter Ndumbe, CUSS, University of Yaounde	Discussions in progress w/Peter Ndumbe.

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Product Development
Country Activities Database
(HT indicates HealthTech)

COUNTRY	TECHNOLOGY	LEAD PRODUCT MANAGER	ACTIVITY	PRIMARY/SUPPLEMENTARY FUNDING	COUNTRY EXPERTS/PATH	KEY CONTACTS	COMMENTS/STATUS
Egypt	BIRTHweigh	E. Abu-Haydar	intro local production	HT/Atlanta University/CSP	E. Abu-Haydar M. Zimmerman L. Krieger P. Morrow D. Robinett	Karen Hilliard, USAID Child Survival Project Dr. Eleiche, SOFTECS Dr. Basily, TECMAD Nancy Terreri, UNICEF	Atlanta U. requested proposal for intro activity; possibly ordering 1000 units. Transfer of production technology to SOFTECS in March 1990. Contact w/TBA UNICEF Program for intro. UNICEF orders 15,000 units for UNIPAC stock annually (EAH).
	VaccineMarker	D. Kristensen	introduction	HT/?		Nancy Terreri, UNICEF	Interested in availability
	PolioMarker	D. Kristensen	possible field trials	HT		Nancy Terreri, UNICEF	Very interested in project. Keep informed of progress.
Gambia	Malaria Serum Assay	B. Schaeffler	field trial	HT		Gerald McLaughlin, UI DiaTech sub-grantee Brian Greenwood, MRC Labs	Trial planned for Oct.-Nov. 1990.
Ghana	HT Products	R. Fields			F. Catron B. Crook L. Krieger	Dan Blumehagen, USAID	Expressed interest in HT products.
Guatemala	BIRTHweigh	E. Abu-Haydar	introduction	HT	B. Crook C. Margard F. Catron	Dr. Delgado/Dr. Boy, INCAP Jane Lyons, USAID Lilana Ayalde, USAID Miriam De Figueroa, UNICEF Al Bartlett, INCAP	Pilot intro. w/INCAP. Possible intro. w/ Project Hope and other NGO's. Hope to contact MOH in next months. Working w/UNICEF to introduce in their TBA Program. UNICEF may fund scales for other interested NGO's.
	Nonreusable Hypodermic Needle	G. Austin	design stage trial	HT		Lilana Ayalde/USAID Dr. Erick Boy, INCAP Dr. Edgar De Leon, Univ. de San Carlos	Trials inappropriate at this time. (SJ)
	PATHtimer	R. Warner	field trial	HT			Possible field trial in mid-1990.
	PATHweigh	E. Abu-Haydar	possible field trial	HT		Sergio Mack, Cuerpo de Paz	Received inquiry on possibility of collaboration in field trials (10/23).
	SafeTject	J. Green	design feedback study	HT		Dr. Arroyo, MOH	Design feedback study completed by BC in April '89.
Haiti	BIRTHweigh	E. Abu-Haydar	introduction activities	HT	J. Haffey L. Morales	Dr. Reginald Boulos, USAID	Mission requested scale & introduction packet in Spring '89.

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COUNTRY	TECHNOLOGY	LEAD PRODUCT MANAGER	ACTIVITY	PRIMARY/SUPPLE-MENTARY FUNDING	COUNTRY EXPERTS/PATH	KEY CONTACTS	COMMENTS/STATUS
Honduras	Various	M. Free	Mission request	HT/Mission?		USAID/Tegucigalpa	Mission requested more information on BW, PW/PM, HIV dipstick, Solar Ice Maker, and ARI technologies (response sent 4/90).
India	BIRTHweigh	E. Abu-Haydar	pcssible intro/ tech tsfr	HT/mission?	L. D'Agnes M. Zimmerman	Dr. Samaresh Sengupta, USAID Dr. Abraham Joseph, Christian Medical College	Dr. Samaresh requested 500 scales through JSI for use in pilot introduction - order cancelled due to end of project w/JSI. Looking for mission to fund order. Interest in local production (EAH).
	HIV dipstick	M. Tam	tech transfer	mission?		Dr. John T. Farrar, USAID	USAID considering potential 12/90.
Indonesia	PATHstrips - Protein	D. Robinett	potential tech transfer	HT/mission		Mr. Bill Carter, VHP Office USAID	Potential tech transfer tc Yayasan Hati Sehat (Lombok) under evaluation.
	PATHwatch/ PATHmarker	L. D'Agnes	intro trial	HT/mission add-on		Joy Riggs-Perla, USAID	Field trial launched 9/89 and progressing.
	HT Products		field trials and/ or intro trial	mission		Dr. Michael Linnan, CS Consultant, USAID	Potential funding from USAID Child Survival in Transition Project Studies Fund.
Jamaica	Hemoglo-binometer	B. Schaeffler	field trial	HT		Dr. A. W. Patterson, CFNI Dr. Simmons, CFNI	Field trial planned for January 1991.
Jordan	BIRTHweigh	E. Abu-Haydar	introduction	HT/possible mission	E. Abu-Haydar L. Krieger M. Britton B. Crook	William Jansen, USAID	Jansen exploring possibility w/MOH. LK visited Jordan in 9/89. PATH team to visit.
	PATHstrips - Protein?	D. Robinett	local production	HT/possible mission		William Jansen, USAID	Jansen will contact local firms.
	VaccineMarker	D. Kristensen	intro trial - proposed	HT/?		William Jansen, USAID	Inquiries received from USAID mission.
	SafeTject	J. Green	intro trial - proposed	HT/possible mission		William Jansen, USAID Dr. Ala Toukan, USAID	Both Jansen and Dr. Toukan interested in Hep B vaccine clinical trial. Jansen pushing production ASAP.
Kenya	PATHwatch/ PATHmarker	D. Kristensen	intro trial	HT	K. Sebastian J. Green B. Crook V. Tsu	Molly Gingerich, A.I.D.	Completed June 1990 (VT).

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Kenya	SafeTject	J. Green	field trial - proposed/T.T.	HT		Dr. Paget Stanfield, AMREF Dr. Panna Erasmus, AMREF Dr. Sang, KEPI	AMREF to conduct field trials w/TT. revised (AMREF) and reviewed (WHO/EPI, Pasteur). NM/VT/JM met with AMREF 7/89. Design feedback obtained. 7,000 samples for trial. Propose meeting w/Pasteur.
Korea	SafeTject	J. Green	field trial proposed	HT/AIDAB	R. Mahoney J. Maynard	Mr. Nam-Sup Huh, KGCC	Offer to KGCC to participate in Hep B field trial.
Malawi	BIRTHweigh	E. Abu-Haydar	local production	HT	V. Tsu D. Robinett G. Austin J. Haffey	Dr. Mhango, Polytechnic Institute Mr. Shrestha, UNICEF Dr. John Chiphangwi, Director, Medical School Project	Production in process. Updating of equipment & supply of raw materials. Production analysis and site evaluation done in Nov. '89 (EAH). UNICEF office involved in shipping scale.
Mali	Biological Larvicides	R. Warner		HT	?	Neil Woodruff, USAID	Expressed strong interest. RW responded (9/89).
Mexico	PATHstrips	D. Kristensen	purchase	HT	E. Younger N. Newton	Dr. Armando Ruiz Quintanilla Municipal De Salud Acapulco, Mexico	100 boxes PATHstrips sent 8/90 (DK).
Mozambique	Various	B. Schaeffler		HT		Carol Lidsker, USAID, Mozambique	Request for info. on hemoglobinometer and ELISA test that detects malarial antigen in serum (BAS responded 3/90).
Nepal	SafeTject	J. Green	possible field trial	HT/?	M. Britton S. Cluett S. Janzen S. Wittet	Dr. Suniti Acharaya, EPI/HMG Dr. Marta Levitt, Redd Barna Mr. Yuki Shiroishi, UNICEF/EPI	Informal discussions about possible trials (SJ). UNICEF K'du very interested in TT field trial. Response sent by NM 2/90
Pakistan	BIRTHweigh	E. Abu-Haydar	introduction	HT/CIDA/UNICEF	B. Crook J. Haffey	Dr. Heather Goldman, USAID Zubeida Khatoon, UNICEF Dr. Rushna Rivji, USAID Dr. Mushtag Khan, Pakistan Institute of Medical Sciences Dr. Pirkko Heinonen, UNICEF	UNICEF to conduct pilot intro funded by CIDA in June '90. Ordered 600 scales and slings (1/90). Intro activities w/Save the Children Fund and Int'l Resource Committee possible. Mission buy-in declined (EAH).
	PATHstrips	D. Robinett	introduction	HT/UNICEF?		Dr. Pirkko Heinonen, UNICEF	Interested in distributing in 3 areas during 1990-91 (25% of population in these areas).

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Pakistan	PATHweigh	E. Abu-Haydar	design trial	HT/mission?	B. Crook	Dr. Heather Goldman, USAID Dr. Mushtag Khan, Pakistan Institute of Medical Sciences Colonel Akram Khan, NIH	Field trials postponed. Proposal for buy-in put on hold until advanced prototypes available (EAH).
	SafeTject	J. Green	possible intro	HT		John Bennett, The Carter Center Dr. Hector Traverso, Global 2000	Inquiry from the Task Force on Child Survival re: collaboration. Use w/TBA delivery of tetanus toxoid. (JM)
	SyringeLOCK	J. Green	field trial	HT/REACH		Robert Steinglass, REACH	Trials completed in November 1989.
	S. pneumoniae diagnostic	M. Tam	possible field trial	HT		Dr. Abdul Ghafoor, NIH	Potential field trial collaborator (BAS-2/90)
Peru	Shigella diagnostic	M. Tam	field trial	HT	N. Newton L. Bruce E. Younger	Dr. Richard Oberhelman, JHU	DT subgrantee conducting trial of his nucleic acid probe for Shigella at Universidad Peruana Cayetano Heredia.
	PATHtimer	R. Warner	infcrmal testing	HT		J. Isidro Gallardo Mosquera, Profesional Tecnico de Medicina Servicios de Asistencia Medica	Interested in serving as testing site (RW responded - 3/90)
	Various	M. Free	mission request	HT/Mission?		Charles Mantione, USAID/Lima	Request for information about several HT technologies (response sent 3/90).
Thailand	Birthweigh	E. Abu-Haydar	introduction sling production	HT	R. Fields D. Douglas J. Green B. Crook S. Wittet	Ray Peterson, Plan Int'l Supanani?, The Fatima Ctr.	Peterson requested info. and sample scale to investigate possibility of intro Slings being locally produced by Fatima Ctr. Ordered 300 last spring. New order of 600 slings for PAKISTAN (EAH-1/90).
	diagnostic	M. Tam	research & development	HT		Henry Wilde, QSMI Dr. Savanat Tharavanij, Mahidol University	Development of inhibition ELISA for P. falciparum by Dr. Savanat.
	diagnostic	M. Tam	research & development	HT		Henry Wilde, QSMI Dr. Suttipant Sarasombath, Mahidol University	Development of an ELISA method & agglutination test for Salmonella Vi antigen by Dr. Suttipant.
	Hemoglo-binometer	B. Schaeffler	field trial	HT		Henry Wilde, QSMI	Phase 1 prototype evaluated at Surin in April 1989.

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Thailand	Nonreusable Hypodermic Needle	G. Austin	field trial	HT/JHU		PATH/BKK	Trials completed in 11/89. Coordinated and conducted by SJ.
	PATHtimer	R. Warner	possible field trial	HT		Catholic Relief Services World Vision Tom Dooley Heritage	Don. D. has identified 3 NGO's interested in field testing. Awaiting results of WHO testing.
	PATHwatch/ PATHmarker	D. Kristensen	field trial	HT		PATH/BKK Dr. Vason, MOPH	Field trial approaching completion, expected by September 1990 (RF).
Thailand	SafeTject	J. Green	design feedback	HT			Design feedback study carried out by SJ in November 1989.
	Solar Fridge	R. Warner	field trial and tech tsfr	HT		Don Erickson, Energy Concepts Boonrieb Sri-on, Pan Siam	Prototype shipped to Thailand. Lab testing in Bangkok continues. MOH is selecting site for field testing.
Uganda	PATHtimer	R. Warner	testing acceptability	HT/?	B. Crook F. Catron	Bob Davis, UNICEF	Mr. Davis expressed interest. Doubtful at this time (lack of funds). Waiting for WHO tests to be done.
Uruguay	RSV & S. pneumoniae diagnostics	M. Tam	possible field trial	HT		Dr. Maria Hortal de Peluffo Ministry of Public Health	Potential field trial collaborator (BAS-2/90)
Zaire	PATHtimer	R. Warner	field trial	HT/?	L. Cogswell S. Schneider L. Morales	Dr. Duale, SANRU Franklin Baer	Soins de Sante Primaires en Milieu Rural interested in testing - Funded by AID. Interest in PATHstrips and BW also. L. Morales to work in Zaire this fall.
Zimbabwe	PATHstrips - Protein	D. Robinett	tech tsfr	HT	V. Tsu N. Newton P. Bartlet	Joseph Manwa, CAPS Dr. Bevan Warambwa, CAPS	Licensing agreement signed. Production to begin in October 1990. DK to oversee transfer. CAPS will supply PATHstrips for UNIPAC catalogue.

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Attachment 4

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TECHNOLOGY INTRODUCTION PANEL

Record of Second Meeting at UNICEF House, New York
Tuesday 30 January 1990

Purpose of Meeting

1. In September 1989, following an agreement between the Executive Director of UNICEF and the Agency Director for Health, USAID, a Technology Introduction Panel was formed to introduce and promote newly developed technologies. Terms of Reference were established at the initial meeting of this Panel, and are appended to this meeting record as Appendix III. It was agreed at the initial meeting that the Panel would meet biannually. The Agenda and List of Participants are attached as Appendices I and II respectively.

Agenda Item I: Welcome and Introductions

2. The meeting was opened by the Chairman, Mr Jean Wasselin. Mr John Lloyd, Technical Officer, EPI, WHO, regretted that he was unable to attend due to illness. Dr Mark Belsey, Chief MCH, WHO and Dr Graeme Clugston, NUT, WHO, had conflicting commitments.

Agenda Item II: Follow-up of technologies discussed at first meeting

3. PATHtimer - Time/temperature monitor for disinfection by boiling. This device integrates time and temperature changes, but if the temperature of the boiling water does not exceed 90 degrees, the colour of the indicator will not change. Further testing has revealed that the indicator colour may not change completely at elevations above 1,000 metres, for example. (The combination of ambient temperatures and pressure can change boiling points at varying altitudes.) If the indicator disk does not change colour, water temperature has not reached 90 degrees and sterilisation has not taken place. In this way, the boiling indicator may serve as a negative indicator, helping health workers to realise that their "sterilising" practices are not effective.

4. The Panel recommended that the results of the laboratory trials being commissioned by EPI, WHO, should be awaited before introducing this technology. It was also recommended that a joint sterilisation policy from MCH and EPI should be considered, promoting the use of steam sterilisation in preference to boiling "sterilisation".

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5. Birthweigh - Low birth weight indicator, for use by TBAs.
A PATH technician will visit Cairo in March, transferring the technology and an initial stock of raw materials to a group called Softecs, and training workers in manufacture of the Birthweigh. Once manufactured, the device will be included in the UNICEF warehouse in Copenhagen. It has been listed in the new UNICEF Guide to PHC Equipment. A new grade of stainless steel is being used which is cheaper and more readily available, but will result in a smaller number of accurate weighings (3,000) as the tensile strength is less. The Birthweigh is already being made in Malawi, and the facility there has been up-graded.

6. PATHstrips - Reagent strip for detection of proteinuria.
Negotiations are almost completed for establishing production of this technology in Zimbabwe. One final Ministry approval is required. The strips are expected to be in production by the time of the next T.I.P. meeting. This technology will also be included in the UNICEF warehouse in Copenhagen, and included in kits supplied to midwives and health clinics where ante-natal work is done.

7. PATHwatch - Heat exposure indicator for measles vaccine.
WHO is reviewing field trial methodology used by PATH for this indicator. As agreed at the previous meeting, distribution of the technology is currently being delayed pending the development and introduction of an indicator for polio vaccine.

8. The representatives of PATH also gave a brief update on their development of a polio indicator. Several colour possibilities were displayed for the indicator. A yellow to green colour change was felt to the best option, though it was noted that the prevalence of green/red colour blindness (the most common type) among EPI workers should be studied in field trials or other surveys. The general consensus of opinion was that, if possible, the indicator should be placed on top of the vial of vaccine.

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Agenda Item III: MCH/Growth Monitoring Technologies

(a) TALC Direct Recording Scale

8. This scale has been developed over a period of several years by Professor David Morley, in association with technicians. It is already in use in several countries, mostly in Africa. It has been designed to operate in a way that will allow the mother to be in control of the weighing process. She is able to see how the principle of weighing works, and her awareness of the importance of weight is increased, by watching the spring stretching. She stands next to her child, who is suspended in the mother's own cloth - both factors that help to calm the child. The scale must be used with a specially sized growth chart, with the child's weight being entered directly on to the chart. The scale does not indicate weight in kilos or pounds.

9. It was noted that in using the scale the reading could be inaccurate if the scale is held on a slant, and if the chart moves up slightly with the pressure of making a mark on the chart. However, this had not been found a problem in field conditions. Both potential problems could be readily modified. A very positive report was given on local use of the scale in Togo.

10. T.I.P. Action

The consensus of the meeting was that the scale has potential for use in growth monitoring programmes, and that the Programme Division of UNICEF, in co-operation with the Senior Nutrition Adviser, should arrange for a full-scale field trial to be done, to assess how the scale could fit into UNICEF-assisted programmes involving growth monitoring and how it would fit into the range of other scales being provided by UNICEF.

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(b) PHC Kit Container

11. The container resembles a briefcase, is made of polyethylene by the box blow-molding method, and includes three oblong covered containers which can be fitted into slots inside the bag in various configurations. It can be carried by its handle, or a shoulder strap. Field trials have been conducted, resulting in refinements to the design. A model of the bag was demonstrated. The expected cost, including the three inner containers, is $18.

12. Discussion of this technology raised several questions on its size (it was considered too big for Asia) and how it would fit in with the bags already being supplied by UNICEF. The Panel was not convinced that such a relatively sophisticated, though fairly inexpensive, container was required for PHC/MCH, instead recommending that simple bags should be used, with local production being encouraged.

13. T.I.P. Action

PATH was recommended to review the potential of the case as a container for midwifery kits.

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(c) Non-invasive Haemoglobinometer

14. This potential product was presented as a concept for consideration by the Panel. It does not yet exist, though the core technology that would be used has been demonstrated to PATH. The Hbmeter would have a sensor which, when clipped to a finger or ear lobe, would give an immediate Hb reading. The sensor could be rather delicate, and thus susceptible to breakage. The instrument would operate electronically, with low power requirements. It could be solar-powered with battery storage, or use a hand-powered generator. Its effectiveness on different skin colours would be studied during development. The final cost of the instrument is estimated to be $300-800. Cost per test would be a few cents.

15. The Panel noted that the need for an instrument to test haemoglobin accurately and easily is great. This technology would be a major breakthrough. However, even if the final cost was $300, it could only be provided at district hospital level. This means that, at least for UNICEF-supported programmes, the technology would be effectively unusable.

16. T.I.P. Action

Further development of the technology for reasonably widespread use at health centre level was felt to be possible only if the final cost of the instrument was less than $50.

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Agenda Item IV: Micro-Nutrient Technologies

(a) Dispenser for Liquid Vitamin A

17. The difficulties of dispensing Vitamin A to young children were described, and the disadvantages of the current packaging in gelatin capsules. Currently, the capsules have to be cut, and the required number of drops placed in the child's mouth. An overdose of high potency Vitamin A may have toxic side effects. The dosage for a child can not easily be encapsulated, as that may result in confusion between the high dose and low dose capsules. Moreover, a young child would still not be able to swallow the capsule. The encapsulation of Vitamin A is considered to add about 50% to its price, and there are only three manufacturers making this preparation. Safe disposal of expired capsules can also be a problem.

18. These factors gave rise to an effort to develop a pump for the administration of oral Vitamin A to children below 23 months of age. A pump which is already commercially available was eventually selected. It administers horizontally an 0.5 ml dose of 100,000 units of Vitamin A, and is used upside down because there is no feeder tube inside the container. The container holds 60ml. It is primed once before use, then remains primed thereafter. The question of what type of cap to put over the spout is not resolved. The manufacturer uses a push-in plug, but this is not considered satisfactory.

19. A quantity of 200,000 pumps would cost about $1.50 each. The pump is reusable. Vitamin E will be added as an anti-oxidant for the Vitamin A. The solution in the pump will have a two month shelf life after the pump has been opened. Unopened, the Vitamin A in the pump has a two year shelf life. The pump will not replace capsules, but will be used in conjunction with them.

20. Various ways to minimise oxidation of the Vitamin A once the pump is opened were discussed, and the shelf-life of the product. Two years is too short for pharmaceuticals kept in the UNICEF warehouse, three years being preferred. It was also noted that the technical development needs to be done in co-operation with UNICEF, so that the market can be surveyed and as wide a range of potential suppliers found as possible.

21. The development of this technology was approved in principle. Some further technical work is required. Field trials and stability tests will be done. The protocols are already prepared. A WHO/UNICEF field trial is proposed, possibly in Bangladesh and Indonesia. WHO will request the assistance of UNICEF in arranging the purchase of pumps for the field trial. It was also noted that USAID is funding field trials on the relation between Vitamin A and morbidity/mortality in young children.

22. T.I.P. Action

WHO will take the lead in co-ordinating with UNICEF and USAID on further action, including field trials and finalising the development.

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(b) Water Iodisation System

23. The Rhone Poulenc Sante Foundation has developed a system whereby sodium iodide can be released through silicone polymer capsules, with the capsules placed in a plastic container inside a borehole, to provide sufficient iodine for one year for a target village population of 1,000 persons. The cost, for 1,000 persons per year, is approximately $125. For larger populations, the number of capsules can be increased. The system has been designed so that the capsules can be replaced annually, at the same time the water pump is removed for servicing.

24. The water iodisation system has been extensively field tested in Mali. Tests of the water and the population, during the year of the field trial, showed that the system provided sufficient levels of iodine. A comparison study of a group of 200,000 persons who received iodised oil capsules, and 200,000 who received iodised water, indicated that the overall cost is less with iodised water than with iodised oil.

25. The Panel in general felt that this system appears to have great potential. It was felt that for countries with large numbers of hand pumps, it may be difficult for the Ministry of Health to bear the recurrent costs involved. The technology for manufacture of the silicone polymers is complex, and cannot be made locally.

26. The consensus of opinion was that this is a technology deserving of further examination, and exploration of ways to combine the operation of Water and Environmental Sanitation projects with Nutrition projects. The representative of Rhone Poulenc was invited to meet with the WES group of USAID. Projects are being planned with the World Bank also.

27. T.I.P. Action

UNICEF and WHO groups for WES and Nutrition should explore the possibility of initiating pilot projects utilising this technology. Technical assistance would be provided by the Rhone Poulenc Sante Foundation.

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Agenda Item V: EPI Technologies

(a) STERITIMER

28. This device uses technology similar to the PATHtimer, but the STERItimer is for use in a steam sterilizer. A small plastic device is affixed to a steam sterilizer lid, with a viewing lens penetrating the lid. A disk of heat sensitive material in the plastic device changes colour from black to green after 20 minutes of full steam pressure.

29. It was noted that current demand for steam sterilizers for UNICEF-assisted projects is very low. It will not be possible to retro-fit sterilizers already supplied to projects as several thousands have been widely distributed in many countries. Retrofitting would be a logistical impossibility.

30. One manufacturer of the steam sterilizer was not willing to install the STERItimer, when approached by PATH a few years ago. There are now two approved manufacturers of steam sterilizers for use in the EPI.

31. T.I.P. Action

PATH was recommended to approach both manufacturers of the steam sterilizers to ask them if they would be willing to install the device, pending approval of WHO for this technology.

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Agenda Item VI: Conclusion

32. It was agreed that the next meeting would be hosted by USAID in their Washington D.C. offices. Friday 15 June 1990 was suggested as a suitable date, to be confirmed. Since the EPI, WHO representative was absent from this meeting due to illness, it is expected that several EPI technologies will be considered at the next meeting. It was also suggested that participants at the next meeting should attempt to identify technological needs to promote the goal of prevention of neo-natal tetanus.

cc: Participants
UNICEF Copenhagen
Mr J. Lloyd, EPI, WHO
Dr M. Belsey, MCH, WHO
Dr G. Clugston, NUT, WHO
Dr U. Jonsson, Senior Adviser, Nutrition
Dr T. Hill, Senior Adviser, Health/E.P.I.
Ms K. Cravero, Senior Programme Officer, ORT/CDD/ARI
Mr J. Bish, Deputy Director, Supply Division
Ms M. Mauras, Chief, Africa Section
The Representative, UNICEF Bamako
The Representative, UNICEF Bangui

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Fonds des Nations Unies pour l'enfance
Fondo de las Naciones Unidas para la Infancia

UNICEF HOUSE
Three United Nations Plaza
New York, New York 10017
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APPENDIX I

TIP/2-90/1

A G E N D A

I. 9.30 a.m.
Welcome and introductions.

II. 9.45 a.m.
Follow-up of technologies discussed at first meeting:
PATHtimer - PATH, WHO;
Birthweigh - PATH, UNICEF;
PATHstrip - PATH, UNICEF;
PATHwatch - PATH, WHO.

10.30 - 10.45 a.m.
Coffee Break

III. 10.45 a.m.
MCH/Growth Monitoring Technologies

a. TALC Direct Recording Scale - Hanging spring scale, records directly on to specially sized growth chart. (TALC, U.K.)

b. PHC Kit Container - Carrying case designed for use by PHC workers. (PATH, U.S.A.)

c. Non-invasive Haemoglobinometer - Proposal to design and manufacture an instrument for this purpose. (PATH, U.S.A.)

1.00 p.m. - 2.00 p.m.
Lunch

IV. 2.00 p.m.
Micro-Nutrient Technologies

a. Dispenser for Liquid Vitamin A - for administration of high-potency Vit. A, possibly also iodised oil. (WHO)

b. Water Iodisation System - "Capsule" containing iodine, to be placed in intake pipe of water pump. (RHONE POULENC SANTE, France)

V. 3.30 p.m.
EPI Technologies

a. STERItimer - indicates completed sterilization cycle, for use with steam sterilizers. (PATH, U.S.A.)

VI. 5.00 p.m.
Conclusion - directions for future action - timing of next meeting

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APPENDIX II

TIP/2 - 90/1

List of Participants

USAID:

Ms P. Johnson, Acting Co-ordinator, Division of Applied Research
Mr C. Gonzmart, Cognizant Technical Officer, Office of Health

UNICEF:

Dr Nyi Nyi, Director, Programme Division
Mr J. Wasselin, Deputy Director, Supply Division
Dr A. Paganini, Manager, Bamako Initiative Management Unit
Mr P. Greaves, Senior Adviser, Nutrition, Programme Division
Dr R. Atapattu, Senior Adviser, Primary Health Care, Programme Division
Mr P. Delahaye, Programme Officer, Programme Division
Mr K. de Rooy, Programme Officer, Water & Sanitation, Programme Division
Mr V. Srdanovic, Group Leader - Medical Procurement, Supply Division (Copenhagen)
Mr J. Gilmartin, Procurement Officer, Supply Division
Mr B. Van Gool, Procurement Officer, Supply Division
Ms N. Cain, Procurement Officer, Supply Division

WHO:

Dr M. Sathianathan, WHO Adviser to UNICEF, NYHQ
Dr N. Cohen, Consultant, EPI, Geneva

PATH:

Dr G. Perkin, President
Dr M. Free, Vice-President

RHONE POULENC SANTE FOUNDATION, FRANCE:

Dr Robert Sebbag

REACH:

Dr R. Steinglass, Senior Technical Officer

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Appendix III

TIP/2 - 90/1

TECHNOLOGY INTRODUCTION PANEL

TERMS OF REFERENCE

Purpose:	To make the best technology available to PHC programmes at a cost that can be afforded and sustained.
Current Panel Members:	USAID, UNICEF, WHO
Current Associate Members:	PATH, REACH, and other groups active in technology development, as appropriate.
Meetings:	To be convened every six months, or as necessary.

Principal Activities:

1. Identify technological needs, priorities and opportunities to support the health goals of WHO, UNICEF and USAID in developing countries, and determine the feasibility (technical, cultural and economic,) and optimal means of promoting the development of such technologies.

2. Promote the development process by reviewing progress and strategies at each stage:
   (a) Definition of technology;
   (b) Performance specifications;
   (c) Prototype production and testing;
   (d) Training development;
   (e) Limited production for field trial;
   (f) Mass production, promotion and distribution;
   (g) Long term monitoring and adaptation;
   to ensure continuing technical and economic viability.

Attachment 5

TECHNET MEETING, CYPRUS
March 12 - 16, 1990

The official (draft) minutes of this WHO/EPI consultation are attached. I also have on my shelf the following list of documents to use as reference materials:

- Cold Chain Information Series: Improving the Cold Chain (November 1989)
- EPI Technical Series: The Cold Chain Product Information Sheets (1989/90)
- EPI Technical Series: Standard Equipment) Specifications and Test Procedures (1988)
- EPI Technical Series: Standard Equipment Specifications and Test Procedures (Draft 1, 1990 Revision)
- EPI Technical Series: EPI Training Information Sheets (1986-87)
- Planning Smart and Buying Smart: Sustaining the Cold Chain in the 1990s
- Supplies Under National Immunization Mission: Item Detail, (Published by the Government of India, Ministry of Health and Family Welfare)
- Solar Photovoltaic Products: A Guide for Development Workers (1989)
- EPI Mid-Level Management Course: Manage the Cold Chain (Draft, February 1990)
- EPI Cold Chain Bibliography (November 1989)

Product managers with EPI-related technologies should review, in particular, the 1989-90 product information sheets and the 1988 and Draft 1990 revision of the Standard Equipment Specifications and Test Procedures. Note that in the latter, detailed test procedures are given

for auto-destruct syringes. Since these are still in draft form, there may be a possibility for inputs.

Note that the Technet network can be used for getting quick answers to questions on cold chain or for carrying out surveys. These inquiries can be sent out by fax or, to most members, by E-mail. Contact information is attached.

During the meeting, participants were asked to make lists of new tools they considered to be important or high priority for EPI in the 1990s. The following list was generated:

- Solar equipment
- Solar steam sterilization
- Modification kits for domestic refrigerators
- Vacuum packed insulation to replace polyurethane
- New kerosene refrigerator to replace RCW 42
- Low cost, reliable voltage stabilizers
- Local production of EPI equipment
- Heat stable vaccine
- Increased OPV titer (to increase shelf life)
- Reduce vial size to 10 cc for BCG, DPT, and Polio, and to five doses for measles
- Simple cold chain monitors and point-of-use indicators, including one for polio
- Simplified cold chain monitoring tools

One technology need that appeared to be particularly important is an improved method of delivering BCG vaccine. Currently, it is estimated that the amount of vaccine wasted is three times the amount actually given. This wastage occurs in the syringe. Additionally, lymphatinitis has been found to be a problem with BCG due to a tendency to overdose, i.e., to give 0.1 cc or more instead of 0.05 cc.

Another technology need identified was an improved, sterilizable plastic syringe. The current versions are not living up to their 200 injection promise, particularly in areas with hard water. Another opportunity is a much cheaper and more effective hard water pad. These pads are

currently stainless steel mesh and are used to decrease the amount of deposits on the sterilizable plastic syringe seals. Another technology need is for a drum that fits inside a steam sterilizer and completely encloses the syringes. This can then be lifted out and carried to the site or stored until needed. Currently, stainless steel drums are being made available at a very high price. This might be a perfect application for some thermal-stable plastic materials, resulting in a very substantial reduction in cost. Another technology requirement is for a very low cost, simple but precise hypodermic needle sharpener. This was suggested several years ago by Kathleen Elliot in England and was re-iterated with respect to the sterilizable needles used with the plastic reusable syringes.

An interesting criticism was that the WHO training modules produce theoretical knowledge but do not result in practical skills, improved supervision, or ultimately, an improved cold chain. These materials, therefore, need much more careful design and testing.

There was a general feeling that more operational research is required on EPI and cold chain issues in order to demonstrate a professional approach and to prove points that can be persuasive for health authorities.

MF:pr
Attachments
MF01732M

Attachment 6

Association of University Technology Managers
Summer 1990 Meeting

Workshop--The Developing World: Another Market for Health Technologies

American universities already make a significant contribution to health in the developing world through training, research, and consultation in such areas as tropical diseases, family planning, and nutrition. Another arena for contribution should be considered--design and development of preventive and primary health care products for the developing world. Some technologies presently being processed and marketed by university technology transfer offices might be easily applicable or adaptable to developing world health needs. Other technologies, considered unpatentable or of no interest to domestic commercial firms, might be very relevant to developing world health care. Furthermore, some university inventors might find particular satisfaction in directly addressing health care technology needs that cannot be served through commercial channels.

University technology transfer managers could play a major role in promoting this activity by:

- identifying technological opportunities which meet developing world health care needs;
- alerting licensees of potential additional applications and public-sector markets for these technologies;
- establishing channels and networks for promoting and advancing social technologies for developing world health care;
- informing university staff and students about developing world needs, opportunities to contribute, and steps required to properly define performance criteria and product specifications;
- developing strategies to license technologies in the public interest, balancing economic viability against the need for adapted, durable, affordable, and widely available, publicly supported products; and
- enlarging the roster of potential licensees to include developing world health industry firms or technology-based, nonprofit broker organizations with the objective of promoting developing world manufacturing capabilities.

In addition to the humanitarian advantages of these activities, universities could gain direct benefits as well. Legislation allowing inventors and universities to own intellectual property arising from government-funded research has proven to be an effective means of stimulating invention and ensuring that publicly supported research benefits the community. Nevertheless, these activities may be open to criticism if they result only in strictly commercial technologies or high-priced products with narrow application. Since most university research is publicly funded, universities have some obligation to respond to public-sector concerns. Public and social obligations can be discharged in part through "social technology" programs aimed at the developing world sector.
In cases where technologies have both domestic commercial and developing world public applications, e.g., auto-destruct syringes; anti-stick needle protection; HIV and hepatitis B rapid diagnostics; male or female contraceptives; new weighing technologies; noninvasive blood tests; tests for potable water, technology transfer staff can increase the value of their property by pointing out to potential licensees the scope and value of potential public-sector markets. These markets, often involving public donor or government agencies, are low margin but very high volume markets providing manufacturers with internal economies of scale and increased visibility with little or no marketing costs.

University technology transfer offices can also offer alternative, creative research outlets for faculty by coordinating and promoting problem solving, development, testing, knowledge transfer, and other activities focused on the needs of the developing world.

We propose to conduct a workshop that will explore technologies for health in the developing world as an additional objective for university technology transfer offices. Speakers and handouts will address the following concerns:

- the consensus about technology needs of developing world health programs;
- the human and institutional resources available for meeting needs;
- case studies of directed development of technologies for maternal and child health;
- strategies for licensing in the public interest; and
- problems, pitfalls, and benefits of technology transfer to the developing world.

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From the point of view of university technology transfer administrators, speakers will address:

- the opportunities and constraints of considering developing world markets;
- strategies for marketing "subject inventions"; and
- methods of motivating, involving, and guiding inventors.

GS00761F
September 14, 1990

path
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PATH'S GUIDELINES FOR LICENSING OF SOCIAL TECHNOLOGIES

PATH is concerned about protecting both the availability and affordability of suitable health technologies in developing countries. It is generally the goal of the licensee to achieve a reasonable return on an investment. There are ways in which a licensor can allow for private sector profits while ensuring an affordable product for the public sector.

Most public sector agencies are concerned about having a quality product that is adapted for public sector use and affordable. Large public sector agencies, such as the World Health Organization and UNICEF, are willing and able to purchase needed products in large quantities if the price is right and the terms are fair. These agencies typically have considerable experience in dealing with private sector manufacturers worldwide. If public sector funds are used to develop a product, it is often expected and always appreciated that the licensor include public sector protection provisions in a license.

Most comprehensive licenses designed to protect the availability of the product to the public sector will include, to the greatest extent possible, the following provisions:

- public sector pricing protection (affordability); and
- public sector supply protection (availability).

I. Assuring Affordability

Four different approaches have been used for price protection:

A) Set out a predetermined maximum public sector price, e.g., $2.00 per unit. This price is based on the cost to produce the product, the competitive public sector price of the product, or the amount the public sector can afford to pay. Required for this approach is sound information about production costs and comparative public sector costs. Even if this approach is not viable for the long term, it can be used for the first 12 months of the agreement when possible.

B) Permit the licensee to sell the product to the public sector under a "cost plus" formula. Generally, "allowable costs" are defined and the profit margin is set at 10% to 15%. Some license agreements use "allowable costs," "production costs," "ex-factory price," "manufactured costs," or less formal definitions of costs. This method of controlling the public sector cost of the product is easily initiated, i.e., quickly written by an attorney, but usually more difficult and costly to enforce than the other methods.

C) Require the licensee to sell the product to the public sector for the lowest unit price (irrespective of quantity) that was paid by a private sector customer in the preceding 12 calendar months, less

royalty and less 10%. This formula can be modified for products in which profit margins are low and profits are made from bulk sales by making the public sector price the same as the private sector bulk price less royalty.

D) Create a competitive environment where several technologies vie to meet a need when the public sector is the major market and price control is not feasible or practical (as when the true costs cannot be assessed at the licensing stage). In this case, the experienced public sector agencies with strong buying power can be used to negotiate price structure in the licensing or post-licensing phase.

A combination of the above strategies is useful when licensing a dual private/public sector product. The best scenario would be to include all four provisions. Public sector purchasing agents can then have a framework to negotiate the lowest possible price that is reasonable under the circumstances.

In all cases, PATH's policies favor agreements which are royalty free for the developing world public sector. Where bilateral public funds have been used in the development, this waiver of royalties is generally extended to the public sector of the supporting country.

II. Assuring Adequate Supply

Where a licensee is manufacturing the product for both private sector and public sector sales, it is important to include protection provisions in the license agreement to assure that an adequate supply of the product reaches the public sector. If demand for a product in the private sector is high, and the licensee makes greater profit from sales to the private sector than from those made to the public sector, there will be little incentive for the licensee to continue to supply the product to the public sector absent a prearranged agreement. Many public sector agencies will hesitate to contribute to a product's development without such an agreement in advance.

There are many ways to ensure that public sector demand for a product will be met:

A) Require the licensee to guarantee to deliver against future orders not less than a minimum number of units of the product for the public sector. It is necessary for the licensor or representative of the licensor to get a realistic estimate of potential demand for the product in the public sector.

B) Require the licensee to manufacture as many units of the product for the public sector as are ultimately requested. Most licensees will hesitate to agree to this without some restrictions.

C) Require the licensee to reserve production of a specified number of units of the product for the public sector. It is necessary for the licensor or representative of the licensor to obtain advance commitments from public sector agencies for this amount.

All of the above provisions require companion enforcement provisions. For instance, if the licensee fails to meet public sector demand, the license should be subject to revocation. Alternatively, the exclusivity of the license or the exclusivity of the license on sales to the public sector should be revoked. If the exclusivity of the license is revoked or the license terminated as a result of failure to meet public sector demand, the know-how that has been developed by the licensee subsequent to execution of the license should also transfer back to the licensor.

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SOCIAL TECHNOLOGIES FOR COMMUNITY HEALTH

Finding Commercial Collaborators

Incentives for Commercial Involvement

Technologies designed and developed expressly for the purpose of meeting a public health need in the developing world 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 rather than a measured market demand. Since need does not equate with ability to pay, the economic viability of social technologies is always in question. Because of this, PATH 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 significant private market potential (labelled "Type A" in PATH nomenclature).

An example of such a technology among PATH 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 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 margins.

It follows that this type of technology must 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 necessary 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 responsible 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. Some technologies cannot be scaled up, manufactured, or distributed without the collaboration of a commercial

manufacturer ("Type C"). It is often necessary 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 always necessary to preserve, as much 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 market 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 PATH products as the nonreusable syringe and a solar-powered weighing scale. The next step is to implement other strategies to protect public-sector interests in negotiations with the collaborator.

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 its 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 PATH 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--maintaining control--it is necessary to protect the technology at the outset with patents, licenses, copyrights, design registrations, or even trademarks, 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.

Attachment 7

SUMMARY OF ACTIVITIES, 1990
for PATHwatch™/PATHmarker™ Field
Trial taking place in Indonesia
January - July 1990

1. PATH markers and PATH watches application on DPT and Measles vaccine and shipment to 4 provinces:

Continuously performed by Biofarma. Last lot of the 10,000 target vials was shipped in June 1990.

2. Procurement and distribution of anti-blurred ballpoints

January 15, 1990. Distribution of anti-blurred ballpoints to 4 provinces.

3. Procurement of hard disc for Biofarma

June 20, 1990: Procurement of hard disc and training:

- Authorization for Biofarma to purchase the 40 MB hard disc NEC at Rp 1.025.000.
- Authorization for Biofarma's staff to get a Lotus (Symphony) training.

4. Visit to Biofarma, Bandung

A. February 4-6, 1990 by Daniel Ajamiseba. Purpose of visit:

1) to check the marked vials distribution schedule at Biofarma
2) to monitor the condition of unattached markers and working procedure to look for possible cause(s) for color difference between the PATHwatches and the PATHmarkers
3) to monitor the returned forms and labels from the field
4) to check Biofarma's computer type

B. July 19-20, 1990:

Dr. Anton Widjaya (PATH) and Ms. Erry Sakti SKM (MOH) purpose:

- to check vaccine shipment by Biofarma
- to check condition of left over PW/PM indicators
- to check data forms and PW labels already received
- to discuss data tabulation and evaluation strategy
- to discuss tentative agenda for last supervisory visit and evaluation meeting

5. Supervisory visit to provinces by Biofarma

Biofarma's staff, Drh. Thamrin Poeloengan to Kupang/NTT, Denpasar/Bali and Medan/Sumut and Drs R. H. Flokstra to Palu/Sulteng.

Main purpose:

1) to check supply management of marked vaccine at various levels in the province
2) to check physical condition of the markers at various health units.

6. Supervisory visit to provinces, districts and HCS by MOH/PATH.

Main purpose:

- to observe marked vaccine condition and stock management at various levels
- to monitor complotion of labels and data forms PM-1 and PM-4
- to monitor cold chain breakage and problem solving
- to monitor health provider's acceptability and other implementation issues

Province	Supervisory Personnel	Time
Denpasar/Bali	- Leona D'Agnes (PATH) - Erry Sakti SKM (MOH)	June 10 - 12, 1990
Medan/North Sumatra	- Dr. A. Widjaya(PATH) - Erry Sakti SKM (MOH) - Dr. A. Widjaya(PATH)	June 17 - 21, 1990 August 21 - 23, 1990
Kupang/NTT	- Dr. A. Widjaya(PATH) - H. Sukry (MOH)	April 8 - 12, 1990
Palu/Central Sulawesi	- Dr. A. Widjaya(PATH) - Erry Sakti SKM (MOH) - Leona D'Agnes (PATH) - Brad Otto (PATH) - Erry Sakti SKM (MOH)	January 21 - 25, 1990 April 8 - 13, 1990

Attachment 8

SUMMARY

Simplified urinary iodine measurement

Objective - To develop a field method for assessing urinary iodine in areas of iodine deficiency.

Background - Most iodine leaves the body via the urine. The urinary iodine levels are a reliable indicator of iodine ingestion. Thus, in areas of iodine deficiency urinary iodines will be low. The actual level correlates well with the severity of iodine deficiency, and has been used as a yardstick for gauging the likelihood of its various consequences including goiter, hypothyroidism, and cretinism.

Currently the only practical measurements for urinary iodine are by chemical reduction techniques. The most widely used is the reduction of ceric sulfate (a yellow color) to cerous sulfate (colorless) in the presence of arsenious acid. Iodide is a catalyst for this reaction. With proper reaction conditions, the speed of disappearance of the yellow color will be proportional to the amount of iodide present. It can be performed by manual, automated, or semi-automated technique.

This assay is available in only a few central laboratories in the world. It is frequently technically difficult to set up, for a variety of reasons. Transport of samples to other laboratories is usually difficult and expensive. Central laboratories in Europe and the US charge an average of about $5-12 per sample.

The current project is based on the concept that a simplified semi-quantitative method that could be easily applied in the field would greatly simplify assessment of iodine deficiency.

Progress so far - We adapted a test tube method that was quite satisfactory when applied to iodide in water. This method basically depended on disappearance of

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ceric sulfate in arsenious acid. To perform it, we mix ceric sulfate, arsenious acid, and a redox indicator (ferroine). We then add a sample containing iodide and measure with a stopwatch the time for change of color of the indicator (the conditions can be set to make this time a convenient one, such as one minute). The time to the color change is proportional to the amount of iodide in the sample. A standard curve is constructed for each run from known amounts of KI or KIO_3, usually from 5-100 ng, and the iodine content of unknown samples are read from it. The reaction can be further simplified to give a qualitative level of iodine content; e.g., above or below a particular level, such as 50 ng/ml iodine; this might be adequate for many screening situations. Appendix 1 gives specific conditions for the reaction and a standard curve.

This part of the work would fulfil the criteria for an acceptable field test. It requires no electricity, no heat, and all of the materials are easily contained in a portable kit. However, we have not been able to apply this successfully to urine yet. Pursuit of causes for this difficulty, and of possible solutions, has led us to look closely at the ceric sulfate reduction technique and particularly its application to urine. This review process is still continuing. At present we have the following observations:

1. Careful scrutiny of published methods for urinary iodines show wide variation in technique. All successful methods first employ a digestion step, to remove interfering substances. The nature of these interfering substances is not clear. They also appear to apply in some population groups but not others. Traditional teaching is that at least 90% of the iodine in the urine is in the chemical form of iodide. This concept is probably correct in areas with iodine sufficiency, where the thyroid does not take up a large fraction, but may not be true in areas of iodine deficiency. This observation may explain why a dialysis technique is satisfactory in areas where there

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is iodine sufficiency, but not in all with iodine deficiency. If the chemical form of iodine is not iodide, what is it, and what needs to be done to convert it into a measurable form? We are actively pursuing these questions.

2. For the present, we accept the need for digestion of urine before applying the ceric sulfate reduction method. Methods that are currently in use elsewhere include wet digestion, with chloric acid at different temperatures, and alkaline ashing, in a muffle furnace. While it is a retreat from our objective of having a test in the field with no standing laboratory facilities, we still believe it may be feasible to have a method that would require no more than a simple heating step. The techniques we are currently evaluating use heat in a sand bath or aluminum block at temperatures ranging from 100-170° C. This would require minimal laboratory facilities, and would be feasible at a local level such as a hospital or health post laboratory, but could not be applied at a more peripheral level. We are optimistic that a simple digestion step can be carried out and still have the overall technique simple enough for application at the local laboratory level.

3. We are keeping an open mind about other ways of assessing iodine. One would be use of saliva instead of urine, since this is readily obtainable and contains iodine. Other possible approaches are simple resin exchange methods, possibly isotope dilution, or possibly adaptation of the starch iodine reaction. In looking at any of these approaches, we focus constantly on a simple, cheap method that can be reliably executed in a basic laboratory.

Further plans - We are currently evaluating several techniques for urinary iodines in preparation of a manual for laboratory techniques to be used in developing countries. In the process we are testing several different methods and plan to provide

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detailed recipes for one of several methods and have this published in the ICCIDD practical manuals program. In the process we will also apply these different techniques to the semi-quantitative method described above. We hope that the combination of a simplified digestion method and our semi-quantitative colorimetric method described above may yield a satisfactory technique somewhat simpler than those currently available.

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URINARY IODINE ESTIMATIONS

REAGENTS

- Ferroine (O-Phenanthroline Ferrous Sulfate Complex) redox indicator Fluka #46270

- 20% Sodium Chloride

- 60% Sulfuric Acid

- Arsenious Acid
  10g arsenic trioxide
  50g NaCl
  400ml 5N H_2SO_4
  1liter H_2O
  Heat until dissolved then make to total volume of 2L.

- Ceric Ammonium Sulfate 16g in 1L H_2SO_4

PROCEDURE

In 12x75 tubes add:
a) 0.05ml ferroine
b) 0.1ml 20% NaCl
c) 0.05ml 60% H_2SO_4
d) 0.05ml As_2O_3
e) 0.1ml $Ce(NH_4)_4(SO_4)_4*2H_2O$

Vortex. Add 0.7ml sample.mix and time the color reaction

Attachment 9

Needleless Injector Feedback from Bolivia
June 1990

The most recent injector model, which we received from Sergio shortly before this trip, was demonstrated in two different group settings and with several individuals. The attached list of questions that Glenn Austin and I developed before the trip was helpful but not entirely useful in those settings. Primarily, it was not feasible to get involved in the head removal mechanism. I was able to take photos of the device in people's hands, and when the pictures are developed, I will add them to the file.

The technology itself intrigued people, although not many could suggest immediately where it might be useful. There are several confusing things about the overall appearance of the injector. They include the following:

1. The division in the middle of the body makes it appear the device should be twisted open there. **(Suggest: eliminate break in surface on body.)**

2. The arrow on the handle points to the right, which is correct for the first twisting motion inwards, which compresses the spring. For the outward or untwisting, though, there is no indication of action. **(Suggest: emphasize in training; other notation on surface?)**

3. Several people did not think they needed to twist all the way to the top of the column, only to a point <u>near</u> the top, but not completely at the top. **(Suggest: some visual, aural, or other mechanism that informs people that they've reached the top.)**

4. Once the person begins to untwist the handle to fill the injector, the first thing seen is "ml." Several people thought they should stop there, as it seemed they had filled it "one ml" at that point. **(Suggest: remove "ml" from top of column and instead place it after 0.1, 0.2, etc., e.g., "0.1 m." and "0.2 ml.")**

5. Others who were untwisting the injector stopped at the heavy red line that appears at .4 ml, which actually is the line to which the handle is returned as a last step to increase the pressure on the spring for an adult injection. **(Suggest: Heavy red line at 0.5 ml**

and dotted uncolored line or other marcation at a point not corresponding to an amount of vaccine. Perhaps add the word "adult" along the dotted line, too. Perhaps a circled "3," indicating the third step, would work, if circled "1" were on the handle and circled "2" were somewhere else to indicate first two steps. Numerous possibilities.)

In terms of the technology/user interface, virtually everyone "instinctually" gripped the injector as they would have a needle and syringe, i.e., using the right hand to "guide" the injector into place against the skin, the left hand to balance it against the skin, and the right hand thumb to push the button with the right hand fingers supporting the injector. Once demonstrated, however, the men had an easy time of holding it in one hand and pushing the button with the thumb of that hand, while women felt it was less comfortable/more awkward. No one had problems placing the device against the skin at the correct angle, once demonstrated.

Many people felt the vibration and noise at firing were major disadvantages of the technology. While some of this is an issue of familiarity, it seems that in settings were several children are lined up waiting for injections, the noise may cause those waiting to grow apprehensive (not to mention scaring the beans out of those receiving the injection). Does this version in fact make more noise and have more of a "recoil" feeling than the earlier version?

Finally, there are several "big issues" remaining to be resolved with the design of the injector, and most of them were raised by the participants. The most serious concerns are the sterilization requirements and protection from contamination for the head and the plastic "collar" for the vaccine vial. These will need to be addressed in later stages of product development.

NEEDLELESS INJECTOR QUESTIONS

I. User group characteristics

A. Occupation
B. Sex
C. Age
D. Static or mobile services (% of each)
E. Hand size
F. Avg. number of injections per month
G. Education
H. Experience with complex mechanisms

II. Tech/User interface

A. Gripping for filling and injecting (instinctual way of holding, balance in hand, thumb on trigger)
B. Filling (putting on vial, screwing in/out, setting adult/child)
C. Placement against skin (correct angle?)
D. Firing (ease of triggering, chock in hand, head movement)
E. Changing heads (unscrewing, removing piston)
F. Cleaning and sterilizing (how would they do it)

III. Training aids

A. Functions/tasks which are difficult to understand
B. Simple picture card with 1/2/3 steps adequate?
C. Suggestions for graphics on the unit itself that would facilitate correct use?

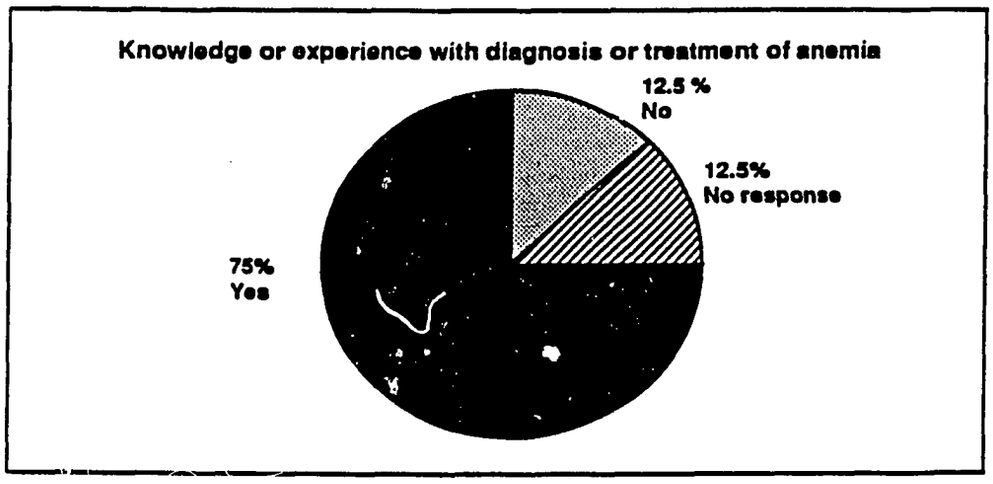
Attachment 10

Noninvasive Instrument for Detection of Anemia

Results of Survey of Hematologists
June 1990

In November 1989 a group of hematologists attending a meeting in Geneva, Switzerland, were asked by PATH to comment on a new "Product Concept," the Noninvasive Instrument for Detection of Anemia. All respondents who participated had background in public health and experience working in developing countries. A copy of the questionnaire is included as an appendix. Eight completed questionnaires were received by May 1990. The results are as follows:

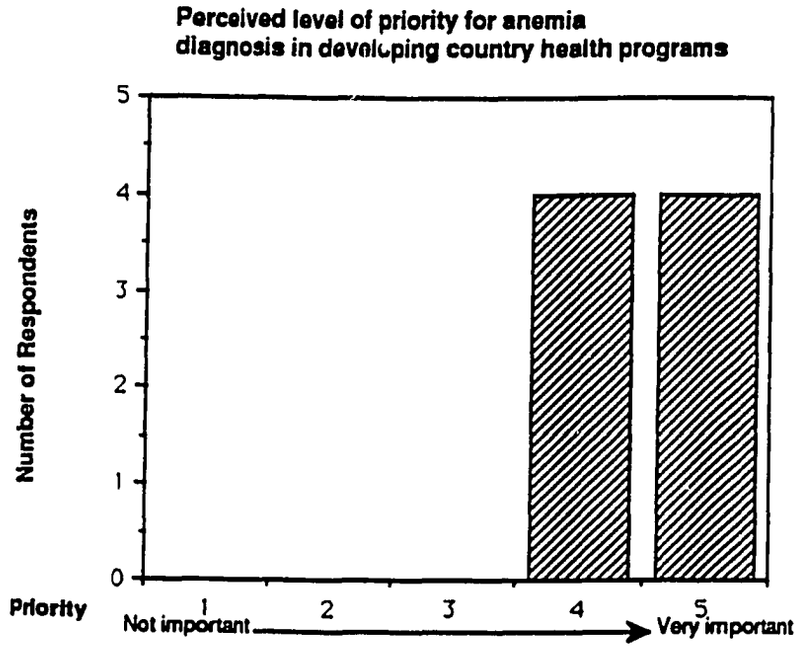
A majority of the respondents had some knowledge or experience relating directly or indirectly to the diagnosis, assessment of incidence, and/or treatment of iron deficiency anemia in developing countries.



Many of the respondents were familiar with or had used a variety of anemia diagnostics. They also described the advantages and disadvantages of each.

Method	Advantages	Disadvantages	# of respondents
Sahli Method	Low cost	Inaccurate, requires reagents	5
Talquist	Low cost	Inaccurate, invasive, needs pipettes	4
Lovibond Comparator	---------	Low reliability	3
Copper Sulphate	Low cost, easy to use	Screening only	3
BMS Hemoglobinometer	Accurate	Expensive	2
A.O.Spenser Hemoglobinometer	Accurate	Tedious	1
Delphi Hemoglobinometer	Accurate, easy to use	No longer available	1
Photometer	---------	---------	1
Gray Wedge	---------	---------	1
Colormetric Methods	Good	Limited by electrical supply	1
BMS Cyanox I	---------	Battery operated	1
HiCN	Fairly reliable	Some dilution required	1

All the hematologists rated anemia diagnosis as either a very high priority or a high priortiy for developing country health programs.

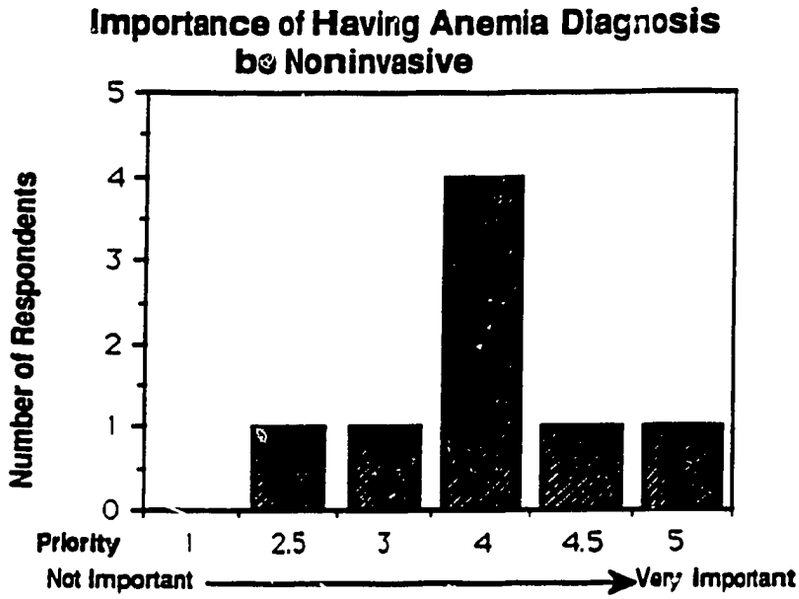


Over one-third of the respondents indicated that anemia diagnosis was most often performed at the primary health care level. All of them saw a need for anemia diagnosis at other levels as well. Many respondents reiterated the need for diagnosis at all levels with special emphasis at the primary health care level.

Health Care Level Where Anemia Diagnosis Is Most Often Performed

Level	%
Primary Health Care	37.5
Hospital	25
When Labs are available	12.5
All levels	12.5
No response	12.5

Many of the hematologists indicated that having an anemia diagnostic that was noninvasive was an important priority.



Very few of the hematologists commented on what they thought a health care system could afford to pay for a single hematocrit test. Only three people commented on potential cost. Their responses ranged from a high of 25 cents per test to a low of 1 cent per test. The other respondents thought it would depend a great deal on location.

When asked what up-front costs a health care system could afford for an instrument that could perform an infinite number of tests noninvasively, most of the group had no comment, but three participants suggested that the cost of the instrument should be within the range of $200 to $500.

path
Program for Appropriate Technology in Health

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Preliminary Product Survey
Prepared by the Program for Appropriate Technology in Health (PATH)

PATH is in the process of evaluating a new product concept. Your comments on the brief survey below will assist PATH in determining whether the proposed product would be useful in developing country health programs. Thank you.

A. Respondent's Name: _____ **(optional section)**

Title: _____

Organization: _____

Address: _____

_____

B. Product Description: Noninvasive Instrument for Detecting Anemia

We have identified a possible way of developing an instrument to measure hematocrit noninvasively. Very little training would be required to use the instrument. The health worker would simply place a probe on the finger or earlobe of the patient, activate the instrument, and read the digitally displayed hematocrit level. Accuracy is expected to be equal or superior to existing hematocrit measurement methods. The device will be portable (0.2 to 0.7 kg), durable, will require no calibration or maintenance, and can be used on patients of all age groups. The technology would facilitate widespread screening for the detection and treatment of anemia and eliminate the need to draw blood for hematocrit determination.

The estimated cost to public sector agencies is between U.S.$300 to 800 per instrument. However, the real price could vary substantially from this range, since the technology is currently in the very early stages of development. While the initial investment by the health system is significant, the cost per test could be as low as U.S.$0.01 depending on frequency of use, since the minimum product life is expected to be ten years.

WHO Collaborating Center on AIDS WHO Collaborating Center for Hepatitis B Vaccination
WHO Collaborating Center for Research in Human Reproduction

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C. Survey

1. Do you have any knowledge or experience relating directly or indirectly to the diagnosis, assessment of incidence, and/or treatment of iron deficiency anemia in developing countries?

Yes____ No____

If yes, please explain briefly.

_____

_____

If no, please use the space above to describe other experiences related to anemia.

2. Are you familiar with methods currently available in developing countries for detecting anemia?

Yes___ No____

If yes, please list methods.

_____

_____

3. What are the advantages and disadvantages of these methods?

_____

_____

_____

_____

4. How high a priority is anemia diagnosis in developing country health programs? (Circle the number that best represents your rating.)

0-------1-------2-------3-------4-------5

Very low priority Very high priority

5. a) At what health care level is anemia diagnosis most often performed?

_____

_____

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b) Is there a need for anemia diagnosis at other health care levels as well? Which levels?

_____

_____

6. How important is it that new methods for anemia detection be noninvasive? (Circle the number that best represents your rating.)

0-------1-------2-------3-------4-------5
Not important Very important

7. a) What is the most that a health care system can afford to pay for a single hematocrit test?

b) What is the most that a health care system can afford to pay for an instrument that can perform an infinite number of hematocrit tests noninvasively?

8. Are you interested in learning more about this device?

Yes _____ Not at this time _____

Other comments:

_____

_____

_____

_____

If you know of any individuals or organizations with applicable technical expertise, involvement in diagnosing or treating anemia, or field experience who you think would be interested in helping PATH to evaluate this technology, please list their names and where they can be contacted below.

_____

_____

_____

_____

Thank you.

OK00032V
October 20, 1989

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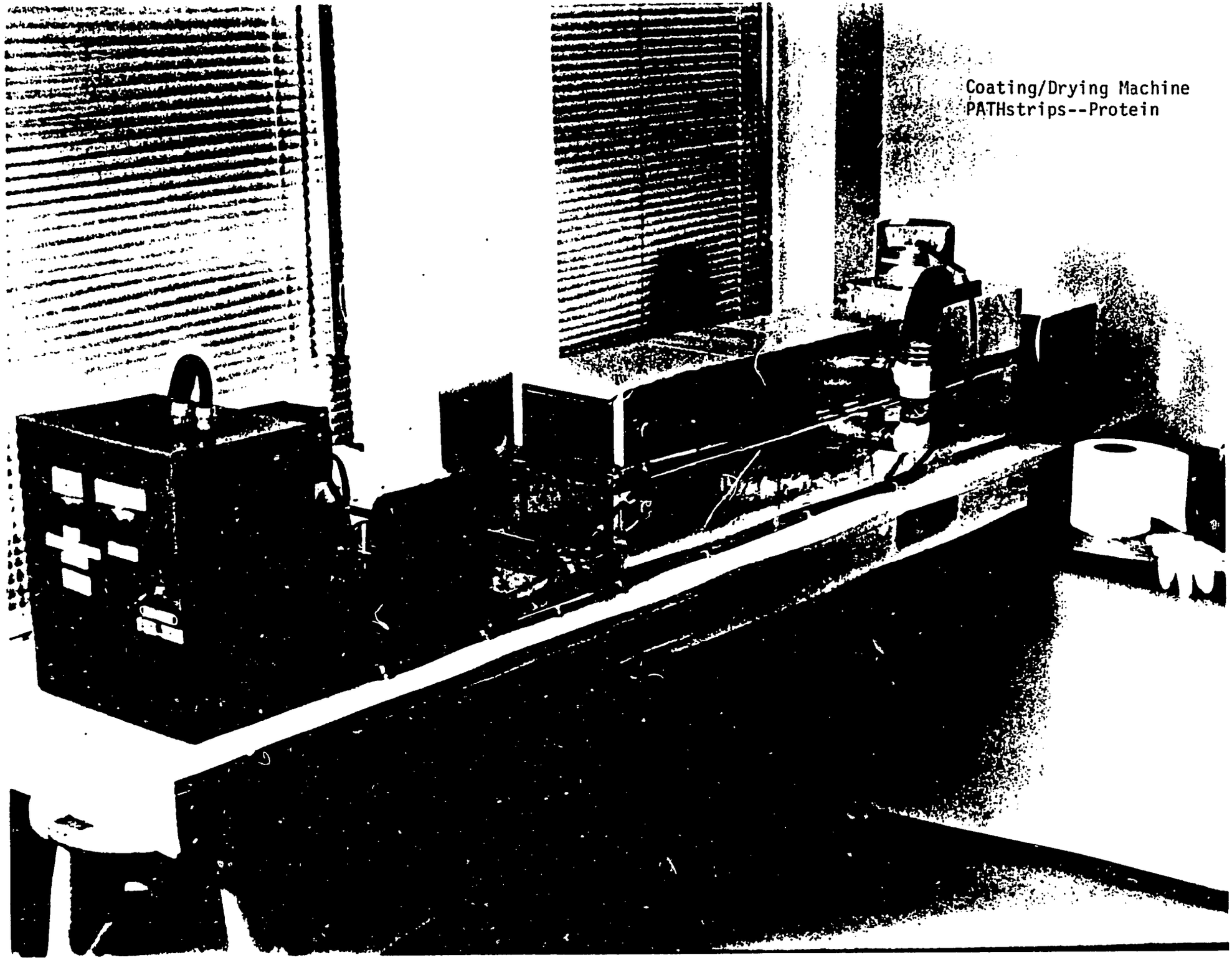
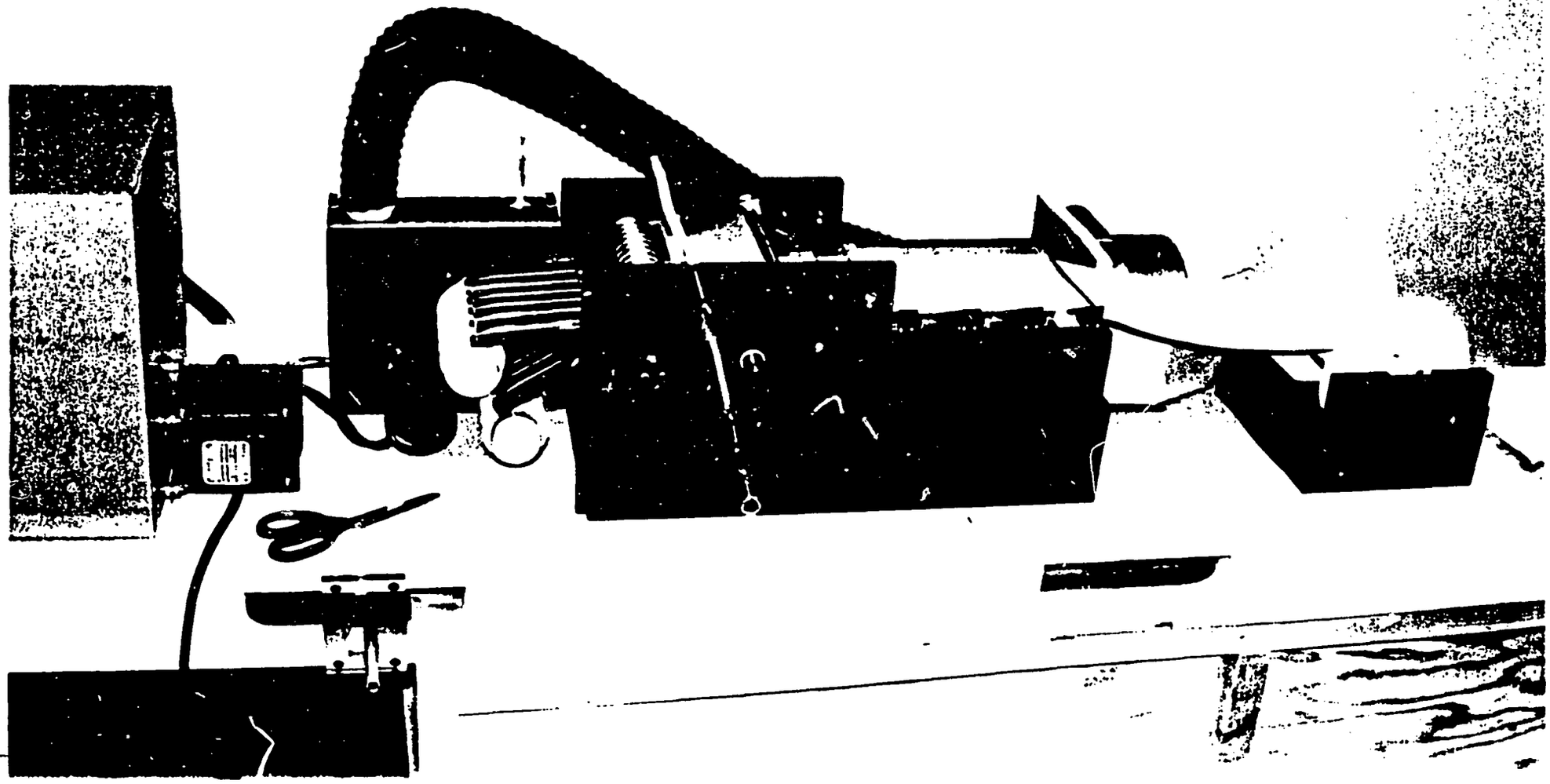
Attachment 11



Coating/Drying Machine
PATHstrips--Protein

Slitting Machine
PATHstrips--Protein



Attachment 12

Meeting with Ian Chamberlain of British Standards Institute (BSI)
and Peter Evans of WHO/EPI
to discuss PATHtimer™ test results
June 12, 1990

Observations at BSI

BSI has completed a draft of the PATHtimer test results. Peter Evans agreed to forward copies of the final test results and the test protocol to Glenn Austin at PATH as soon as they are available. Because WHO/EPI is working exclusively with PATH on this product, i.e., no competitors exist, Peter is willing to openly share information.

The PATHtimer that BSI used for this series of tests was a one piece timer, with a small, dome-shaped indentation in the middle of the bottom surface. Peter identified it as one of the 200 prototypes sent by PATH to WHO/EPI. (Because Peter was unaware of the limited durability of these prototypes, he also sent a number of them into the field for evaluation.) The PATHtimer had turned uniformly brown during testing but remained perfectly transparent. The coloration did not affect one's ability to read the crystal. The crystal was white on the edge and had approximately ten minute, white spots distributed on its surface. These white surface aberrations also did not affect one's ability to read the rest of the crystal. The bottom third of the timer, beneath the crystal layer, had cracked when the PATHtimer was boiled dry. These cracks were larger and further apart than those I have observed on other PATHtimers. No materials had seeped through the cracks, so the crystal could still be viewed from either side of the timer.

Peter delivered three of the latest PATHtimer prototypes to Ian at BSI. These were from the batch of 15 that PATH recently sent to WHO/EPI. Peter will not direct Ian to test them, however, until the results from the first test have been reviewed and thoroughly discussed with Glenn.

We observed one cycle of testing of these three new prototypes and the old prototype in boiling water. The official BSI tests at sub-boiling temperatures took place in a water bath with accuracy of ±1°C. The facility has large windows, so all testing occurred with only natural lighting. For this trial test, we used a pot of boiling water on an electric burner. The sides of the pot were approximately eight inches high, and the water level was about two to three inches above the PATHtimers. A stop watch was started when the PATHtimers were placed in

boiling water. All four of the PATHtimers converted appropriately; however, they had to be removed from the water in order to properly distinguish the color changes.

Peter is optimistic about the performance of the PATHtimers. He believes that in some areas, e.g., maximum boiling cycles, the device exceeds WHO/EPI requirements. WHO/EPI would be satisfied with a PATHtimer that only lasted a few hundred cycles, if that specification is clearly conveyed to end-users. I questioned Peter about his view on the size of the PATHtimers. He thinks that the size is fine and mentioned that if it was too small, it could more easily be lost. We also discussed the 20 minute boiling requirement. Peter estimates that a two- to three-year effort will be necessary to officially decrease this requirement.

Peter believes that the main issues to be resolved are training issues. For example, the colors of the PATHtimer crystal depicted in the instruction sheet are those of a PATHtimer viewed out of water. When observing a PATHtimer beneath the surface of boiling water, the color changes are muted. Under the conditions at BSI, after 20 minutes in boiling water, the timers appeared to be gray when submerged but were really blue-green when removed. If possible, the colors on the instruction sheet should more accurately reflect the muted colors observed through a layer of water. Alternatively, the instructions could identify a way to remove the timers from the water periodically for observation. Peter believed that the chain attached to the early timers was a good idea.

While I have not reviewed any reports from BSI, I was impressed with Ian Chamberlain's cooperative attitude, knowledge, and common-sense approach. I believe that he will be a good contact for PATH, should WHO/EPI continue to use BSI to test PATH products.

Peter Evans' PATHtimer philosophy: PATHtimer positively reinforces good disinfection practices. "There are many bad habits out there." The introduction of PATHtimer will provide opportunities for training.

Peter Evans' STERItimer™ philosophy: STERItimer is "o.k.," if it is technically and logistically easy to add to sterilizers. However, he believes that retrofitting would be difficult. There are 500,000 sterilizers currently spread throughout the developing world. They have long lives and rarely break down. Nearly all health workers use stop watches to monitor sterilization with good success--with the exception that the stop watches are stolen on occasion.

Prestige Sterilizers: Glenn, Peter agreed to initially retrofitting only one or two of the Prestige sterilizers with STERItimers.

:wr
DK00098M

Attachment 13

Visits to European Vaccine Manufacturers
July 1990

Discussions with Manufacturers

1. Swiss Serum--(Dr. Grünenfelder). Dr. Grünenfelder was the only person who met us at Swiss Serum. We never left the main office even though the factory was adjacent. Dr. Grünenfelder was clearly unenthusiastic about this new technology. His major question was, "Why is there a need for this monitor?" He was concerned about additional cost and the unknown but, in his mind, tangible engineering issues. It should be noted that Dr. Grünenfelder is on the marketing side of the business. We learned very little about Swiss Serum's process except that vaccine vials are filled and then stored without labeling for several days to several weeks. This acts as a strategic reserve which can be used for fast filling of orders. Labels are placed on the vials just prior to dispatch. It was not clear whether controls were done at this time.

Action: Send Dr. Grünenfelder a reel of 5,000 markers

2. Pasteur Mérieux--(Dr. Paturel). Summary of the Pasteur/Mérieux merger: In 1985 Pasteur Vaccine became a subsidiary of Mérieux. This year they merged and became one company with the name of Pasteur Mérieux, headquartered in Lyon. Currently, they are located at three sites: Lyon, which is the biggest production plant employing nearly 1,000 people and producing most of the bulk vaccine; Val De Reuil, a manufacturing site since 1973 which now has 400 staff and produces some vaccines and, in future, will package and distribute all Pasteur Mérieux vaccine; Marnes-La-Coquette near Paris is the clinical department as well as marketing and regulatory affairs. Pasteur Mérieux is quite distinct from the Institute Pasteur which is the original research institute situated in the center of Paris. However, Pasteur Mérieux has first refusal on the vaccine

developments of the Institute Pasteur. Pasteur Mérieux has also recently acquired Connaught in Canada. Pasteur Diagnostics is another independent company. Our meeting was at Val De Reuil in Normandy. Specifically, at Val De Reuil, they produce BCG and hepatitis B (both plasma derived and recombinant), flu and yellow fever vaccines, and have a large filling plant for bulk vaccines received from Lyon. There is expansion of the facilities mainly in the direction of filling, storage, and shipping capabilities. I have taken some photographs of part of the processing plant. In general, bulk polio vaccine is held at 4°C, then pumped into the filling area which is at approximately 21°C. The filling takes place in a sterile environment and the palleted, filled vials are passed out to a -30°C storage room. Here they are sampled for titer and held until required for shipping. Just prior to shipping they pass out into a 4°C room for 8 to 24 hours for conditioning (mainly to make sure the condensation is minimized in order to ensure that no moisture is present during labeling). They then pass into a 20 to 27°C (depending on season) labeling room. From this point they are directly packed into cartons and placed in the shipping boxes with ice packs. Thus, the vaccine is exposed to some period of time at 4°C and at 20-27°C after titering is done. After labeling, and presumably after the time the Polio Marker will be put in place, the vials will have some dwell time at 20-27°C and additional dwell time at the packing and shipping temperature, i.e., under 8°.

Pasteur estimated the production of polio vaccine at 2 million vials per month which would require about 400 rolls of markers per month.

Currently, Pasteur used both ampoules, vials with conventional caps, and vials with plastic caps. Ampoules are apparently historical and demanded by traditional markets but have no cost advantage because of the difficulty of sealing them under vacuum. Plastic flip caps are only used by Pasteur Mérieux on single dose vials. They do not yet have machines installed for ten dose vials (plastic flip caps). They intend to move in this direction in the future. Dr. Paturel will send samples of various Pasteur vials including DPT, Measles, and BCG.

Pasteur Mérieux estimates that the price of all components including the vaccine, vial, stopper and cap come to about 10% of the price of the product. Therefore, the cost of the markers will almost double the cost of the components.

Overall, Pasteur Mérieux believes that adding the markers was technically feasible but that the costs would have to be assessed. There is some concern about the placement of the marker since, in

order to put the marker on the bottom of the vial, the vial is going to have to be turned over on the labeling line and a new label attachment system put in place. They did not indicate awareness of any machinery to carry out this inversion of the vials, though I'm sure some systems must exist. Perhaps we should look into this aspect of the production machinery. In order to achieve the alternative placement on the side, the vials will have to be oriented in a very specific way so the marker is not placed over the current label but rather in the space between the edges of the label.

Action: Send Dr. Paturel one reel of 5,000 units. He may subsequently request more.

3. Interexport--(Mr. Lazic). Interexport does international trade for a variety of health, pharmaceutical, chemical, and other industries in Yugoslavia. It is the exclusive distributor for the Institute of Immunology and Biology Torlak. Torlak business has grown rapidly in the last several years. They still have a relatively unautomated process. All labelling is done by hand. Torlak declined our request to visit their laboratory or their plant. Furthermore, they reneged on an arrangement by Dr. Nastek of Interexport for a dinner meeting with their technical and engineering personnel. They have a capacity for around 60 to 70 million doses of polio per year. They have, apparently, some difficulty in obtaining capital, since the government milks off a considerable amount of their earnings. It seems likely they will find a way to place markers on if it becomes a requirement of WHO/EPI. Mr. Lazic stated he will work diligently to get them to assess the costs carrying out this procedure.

Action: Send one roll, 5,000 units to Mr. Lazic.

4. Sclavo--(Dr. Morini). Sclavo felt the technical problems of mounting the marker could be resolved and the only issues were economical. They believe they would need to purchase a new machine to attach labels and to orientate the vials. They also brought up the issue of dwell time after labeling. Apparently, the vaccine is filled into vials and stored without individual labeling until close to the shipping date. Prior to labeling, the vials are conditioned at 22^{0}C for 8-10 hours. After labeling they may remain for a maximum of 5 hours, at 22^{0}C. This constitutes about 2% of the life of the marker and probably would not bring about a perceptible change in the color. The labeled vaccine vials are placed at -22^{0}C until shipping or might go directly into shipping boxes. Sclavo provides the polio vaccine in unique plastic containers. The information is either embossed on the body of the container or ink jet printed on the flat extended portion of the container which also doubles as the cap of the plastic vial. There is only one clear option for the placement of the markers and that is over the extended portion over the tubular cap. It seems likely that Sclavo could be the most cooperative of the

manufacturers, although they too are caught up in a buy-out situation. Apparently, the relationship they had for some time with DuPont has now ended and they have been purchased by another Italian company. Currently, they are undergoing fairly massive layoffs of their research and development staff. Therefore, there are some uncertainties about their ability to deal with this situation in the near future. However, we should proceed as if they will be full participants.

General Issues

1. It is anticipated the next UNICEF order in 1991 for 1992 will request 1/3 of the order be supplied in 10-dose rather than 20-dose vials for polio and DPT. This proportion of 10 dose vials is eventually expected to go up to about 50%.

2. The price range for vials of vaccine is attached.

3. Peter Evans will write a confirmation of the specifications for OPV and measles markers. Measles is likely to be 8 days at 37^0, 6 months at 8^0, as per PATHmarker.

4. All components of vaccines (that includes the vaccine itself, glass vial, the rubber stopper, and the metal cap) amount to approximately 10% of the price of the product. This means the cost of purchase and attachment of the marker double the cost of components. Clearly, we should strive for a more economical outcome, perhaps no more than a penny a marker.

5. It will be necessary to place a clear batch code on each reel of 5,000 markers. Some manufacturers would also like to know the batch size of markers. Obviously, this information is so that the manufacturers can control the quality of their incoming markers without having to test each reel.

6. There needs to be some study of the effect of finger heat on the vial or directly on the marker. This would be an issue if the vials are handled, i.e., during transfer to carrying box or during the period in which the vial is actually being used and stored part empty.

7. It seems likely there will be a general trend toward using the combined plastic/metal caps on vaccine vials. These are currently used for caps that have to be removed, i.e., for oral polio, and are much more user-friendly than the nail-breaking metal disk on the standard cap. It should be noted that these caps and the standard metal caps are not sterile seals, i.e., they do not protect the outside of the rubber septum from contamination. They merely provide evidence of tampering or previous use.

8. Note that Pasteur had in their possession, a Lifelines brochure and indicated they had some contact with Lifelines. This should be investigated since it is a source of potential conflict.

9. Freeze-dry cycles are said by the manufacturers to be detrimental to vaccines, including polio. However, EPI has done tests for several hundred cycles and finds no effect of freeze-dry cycles on polio.

MF:aw
Attachments
MF01798M
P04.24.02

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Price (In 1989 U.S. $) of EPI Vaccines

Vaccine	Supplier	10 Dose Vial	20 Dose Vial
Oral Polio	Mérieux	0.45	0.85
	SmithKline	0.48	0.85
DT	Interexport	0.35	0.42
TT	Connaught	0.24	0.38
	Mérieux	0.27	0.42
DPT	Mérieux	0.52	0.76
	Connaught	0.50	0.84

Disclosure Document for Manufacturers of Oral Polio Vaccine

Polio Marker

An indicator of cumulative heat-exposure for attachment to oral polio vaccine vials and tubes

Prepared by:

The Program for Appropriate Technology in Health
(PATH)
4 Nickerson Street
Seattle, Washington 98109
USA

June 1990

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PRODUCT DESCRIPTION

Appearance and Function

Polio Marker is a small, adhesive-backed label that can be affixed to oral polio vaccine (OPV) vials and tubes (See Figure 1). The label is circular in shape (1.0 cm diameter*) and contains an inner square which consists of a heat sensitive compound. The compound in the square changes color irreversibly with cumulative exposure to heat. By comparing the color of the square to the background color (reference ring), a health worker can determine the heat-exposure history of the vaccine. The square is initially a light yellow-green and the reference ring is a medium green. When the square matches or is darker than the reference ring, the vaccine has been exposed to an excessive amount of heat and should not be used. Figure 2 contains the proposed indicator response curve for Polio Marker. Polio Marker will reach its endpoint, i.e., the square will match the reference ring, after 1 day at 37°C and 180 days at 8°C. (PATH is also developing a slower indicator for measles, DPT, and BCG vaccines.)

Expected Accuracy

The accuracy of the indicator response is expected to be ±5 percent at any given temperature. The primary source of variation is user subjectivity in color interpretation.

Durability

Polio Markers are laminated with a layer of clear polyester and are leach proof.

Stage of Development

Hand-made prototypes of Polio Marker are currently being produced and tested. The first automated printing of 10,000 labels will take place in July of 1990. Functional and mechanical integrity testing will continue through the fall of 1990. The product is expected to be available by year end 1990.

Design stage field trials have been conducted in Sierra Leone and Cameroon. These field trials consisted of focus group discussions with product end-users, health workers involved with the Expanded Programme on Immunization (EPI) cold chain. Product mock-ups were used to obtain feedback on the design and color change characteristics of the labels, as well as the accompanying instructional materials. Further focus groups will be held during the summer of 1990 in Bangladesh, Kenya, and Thailand.

Toxicology Study Results

Systematic toxicological testing has been performed on two representative compounds from the family of compounds used in Polio Marker. These tests did not identify any area for concern with regard to potential for adverse health effects. The available toxicity information indicated very little or no potential concern due to acute toxic effects, genetic effects, or irritation

*A 1.0 cm size is the size of choice. We are currently conducting trial printing runs to determine if this will be feasible. If it is not, a 1.35 cm diameter label will be used.

(ocular or dermal). In addition, toxicity information on several structurally related compounds suggested low intrinsic toxicity for such compounds. Furthermore, estimated exposures to the material in the finished products are expected to be low due to the extremely low solubility of these materials and the small quantities involved in individual labels. Therefore, no unreasonable risk is expected to occur due to the production and use of the compounds. The review period for the premanufacture notifications (PMNs) of the compounds ended in January 1984, allowing for their commercial introduction.

SHIPPING INFORMATION

A freight company has been identified that will deliver Polio Marker labels to your facility within 72 hours of shipment from the United States. The labels will be shipped on dry ice (-78.6°C). The freight company will assume responsibility for customs clearance.

STORAGE INFORMATION

The indicators should be stored at -20°C or colder.

METHOD OF ATTACHMENT

The indicators are produced in rolls of pressure sensitive labels. If automated attachment equipment is used to apply the labels, "tamp-blow" pressure-sensitive applicator equipment may be necessary to achieve the accuracy required for the small label and container size. The label manufacturer has suggested Label-Aire as a source of this type of equipment.

Specifications for the rolls are as follows:

Core size: 7.6 centimeters

Width: Label width + 0.32 cm (0.16 cm on each side of label)
For 1.00 cm label, width = 1.32 cm
For 1.35 cm label, width = 1.67 cm

Label quantity per roll: 5,000

Release liner material: 50 lb., 3 ml., densified craft paper

Adhesive: TF330, Standard freezer grade adhesive, all temperature emulsion acrylic, manufactured by Technicote

Indicator backing material: Polyester

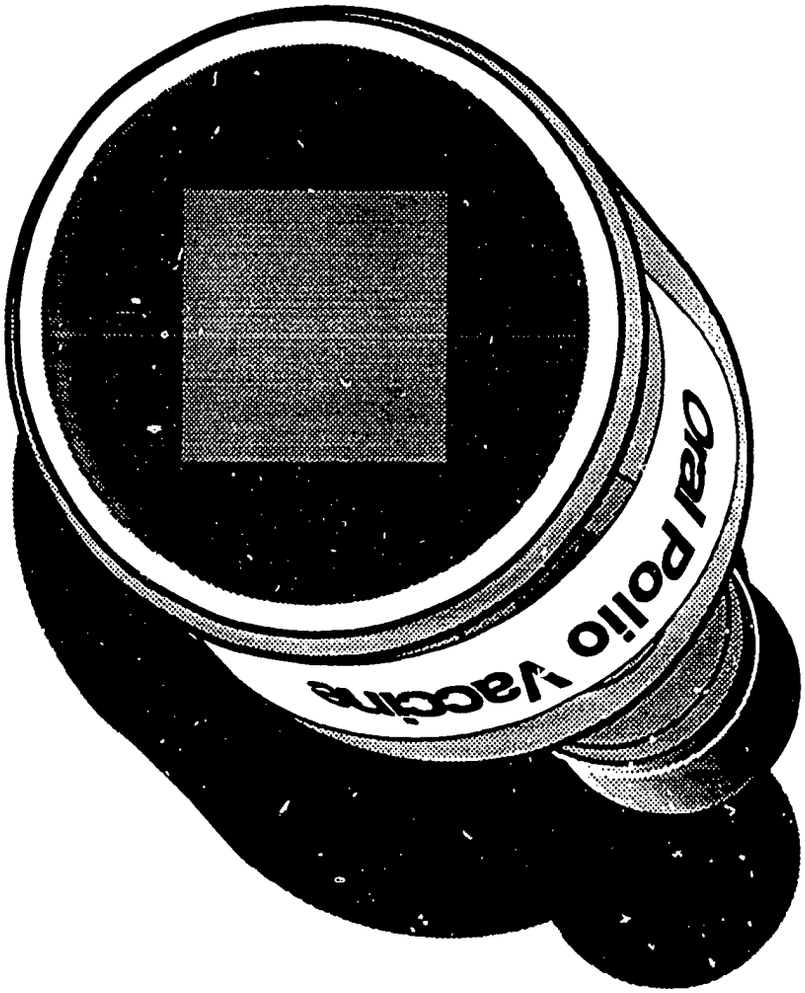

Figure 1

Indicator Response Curve for
OPV

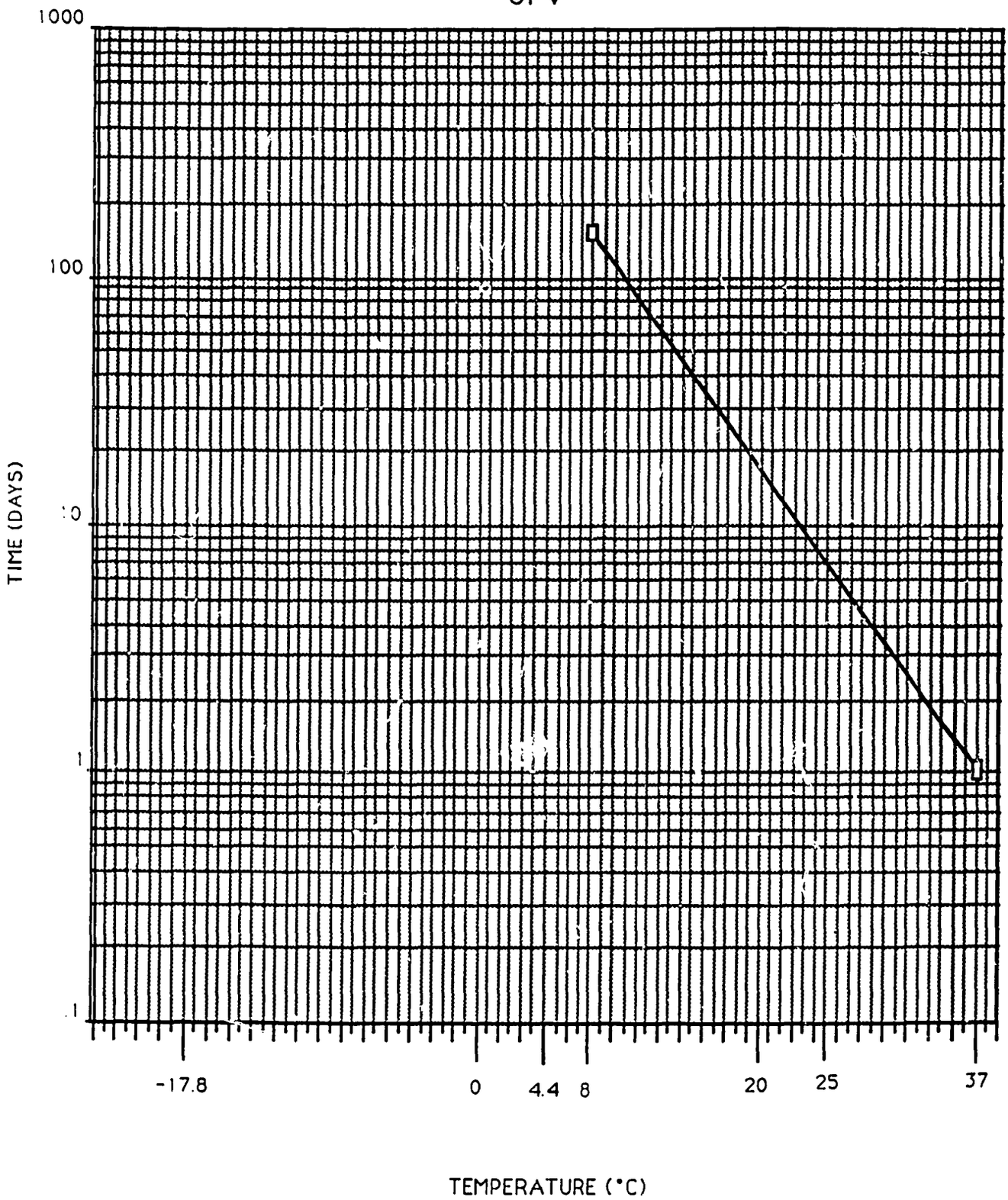

Figure 2

Meetings with WHO/EPI and pharmaceutical manufacturers
(Evans Medical Limited and SmithKline R.I.T.)
to discuss the logistics of attaching Polio Markers
and Vaccine Markers to vials of vaccine purchased for the
Expanded Programme on Immunization by WHO and UNICEF

Meeting with Peter Evans of WHO/EPI, London, ENGLAND, June 11, 1990

IMPLEMENTATION PLAN

WHO and UNICEF will include a specification in their 1992 tender for vaccines mandating that the time/temperature indicators be attached to oral polio, measles, BCG and DPT vaccines purchased for the EPI. WHO and UNICEF will accept quotations for the tender in June 1991 for purchases in the beginning of 1992. Pharmaceutical manufacturers will, therefore, need to have fully explored the costs of purchasing, shipping, and attaching the indicators by mid-1991 in order to include these costs in the price of the vaccines. The integration of the indicator attachment into their packaging and labelling processes must be in place by January of 1992. The required annual volume for each of the two types of indicators, i.e., Polio Marker and Vaccine Marker, is expected to be in the tens of millions.

ROLE OF 3M MONITOR MARK

The 3M Monitor Mark will become a monitor for equipment only, i.e., refrigerators, freezers.

TIME/TEMPERATURE RESPONSE CURVE FOR POLIO MARKER

Peter Evans verbally approved the time/temperature response curve for Polio Marker (see Attachment I, Figure 2). Written approval is forthcoming.

DOCUMENTS PROVIDED TO WHO/EPI

I provided the following documents to Peter Evans: "Disclosure Document for Manufacturers of Oral Polio Vaccine" (Attachment I), "Dossier of Evidence of Safety" for Polio Marker, and "Guidelines for Design Stage Field Trials of Polio Marker." These documents did not contain

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confidential information. Peter prefers not to receive confidential information about the indicators at this time, as he is still discussing another time/temperature indicator with a manufacturer.

ANOTHER TIME/TEMPERATURE INDICATOR

WHO/EPI is reviewing a time/temperature indicator that is dropped onto vial caps as a liquid. Mechanical activation is required, which can take place during the packaging process. WHO/EPI does not consider this indicator to be a significant competitor to PATH indicators. This other product is only in the early stages of development.

FURTHER DOCUMENTATION REQUIRED BY WHO/EPI

PATH can submit mechanical and functional test protocols for the indicators to WHO/EPI in approximately six months. This will provide PATH with sufficient time to set specifications for the indicators and test prototypes.

PRICES FOR 10-DOSE VACCINE VIALS PAID BY UNICEF AND WHO

Peter will provide this information to PATH. The indicator ceiling price is expected to be 10 percent of the price for a 10-dose vial.

NEW HEAT STABLE MEASLES VACCINE

I asked Peter if he had information on the new measles vaccine mentioned in a generic UNICEF letter to PATH from Hugh Downs in May 1990. According to the letter, the vaccine was developed in the last year and a half and does not require refrigeration. The cost is projected to be US$0.15 per dose. Peter was unaware of such a vaccine but very interested.

COLOR CODING OF VACCINE VIALS

A recent EPI Cold Chain Newsletter stated that UNICEF has requested all vaccine suppliers to use color coded labels for vaccines (DPT=yellow, TT=green, DT=lime, measles for nine months=orange, measles for six months=red, BCG=blue). This is to prevent cold chain workers from confusing vaccine vials with other vaccines and with other pharmaceuticals. Fortunately, the color coding is part of the existing manufacturer's label and not a separate label, e.g., the print is in the requested color. Therefore, the coding should not affect the indicator placement on the vials. OPV was not included in the information on color coding in the newsletter. However, Peter believes that a color has been assigned and will let us know what it is.

THERMOPAC

We briefly discussed the appropriateness of the Thermopac system, a low temperature (-20°C and above) transport and storage container, for shipment of the indicators from the indicator manufacturer to the pharmaceutical manufacturers (in lieu of dry ice). The price per container is apparently too high, US$700, to be practical.

JULY/AUGUST MEETING DATES

The next round of visits to European pharmaceutical manufacturers by Michael Free and Peter Evans will occur between July 16-27. Peter intends to visit PATH on August 20 and 21. Peter and I will then visit Canadian manufacturers on August 23 and 24.

<u>Meeting with WHO/EPI and Evans Medical Limited, West Sussex, ENGLAND, June 11, 1990</u>

ATTENDING

Moyra Brookes, New Product Development Manager, Evans Medical Limited
Ian G. S. Furminger, Ph.D., FRSC, Biologicals Development Manager, Evans Medical Limited
Tony Pawson, Evans Medical Limited (Speke Factory)
Peter Evans, WHO/EPI
Debra Kristensen, PATH

BACKGROUND

Peter Evans chose Evans Medical as one of the initial pharmaceutical companies to visit because he expected the integration of the indicator to be especially difficult for them due to the fact that their equipment is older and their profit margin and volumes are less than those of other vaccine manufacturers.

TYPES OF VACCINES PRODUCED FOR EPI BY EVANS MEDICAL

Measles: 10-dose vials (freeze-dried)
BCG: 10- and 20-dose vials (freeze-dried)

Note: Evans Medical is already including the color-coding required by UNICEF on their labels.

PRICE

A price of US$0.10 or less per indicator was acceptable to Evans Medical.

LABELLING ISSUES

Because more rapid degradation of freeze-dried vaccine occurs once it is reconstituted, indicators for freeze-dried vaccine will be placed on the vial lids so that they are not referred to after reconstitution. The measles vaccine vials have aluminum "tear-off" caps over the rubber stopper which do not entirely cover the stopper. The BCG vaccine vials have aluminum caps with a plastic, tamper-evident, "flip-off" top. The "flip-off" top is a smoother surface for adhesion of the indicators. The aluminum cap and "flip-off" top are a one-piece sterile part when purchased. Therefore, the indicators could only be attached to the top of the vial after the "flip-off" top is in place. WHO/EPI does not currently require tamper-evident packaging because of the resulting increase in product cost but may add it to their specifications in the future. However, Evans Medical is willing to add the "flip-off" top immediately to all of their measles vaccine vials because there is a trend towards tamper-evident packaging in the United Kingdom. The time required for Evans to add the new top to their production line would be six months, if only a parts change is involved, or one year, if a new machine must be added.

The indicator could be added to the top of the vials at the same time that the side of the vials are labelled. The vials move through the track in an upright position. Evans Medical uses a Newman labeller with an over-printer and the vials move down three tracks. They would therefore require either three machines to attach the indicators or could allocate one modified Newman labeller for the indicator application, if modification is technically feasible. Evans Medical currently uses a hand-packing operation.

Evans Medical was enthusiastic about the inclusion of the indicators with their vaccine products and expressed interest in purchasing additional indicators for vaccine used in the United Kingdom cold chain. The United Kingdom cold chain is apparently one of the worst in the world.

Evans Medical would like to receive notification of the indicator size decision, indicator samples to forward to their labelling experts, and the curve for the measles/BCG/DPT indicator. Note: The shelf life for their measles vaccine is two years.

PILOT TRIAL

Evans Medical is interested in performing a pilot trial using hand-labelling. They believe that the experience would force them to look more closely at the impact of the indicators upon their labelling and packaging operations. They are also willing to distribute vaccine with these hand-labelled indicators into the cold chain for validation field trials and/or to return vials with indicators to PATH for mechanical integrity testing. Evans Medical representatives believe that a

dialogue with end-users of similar indicator products in the food industry would be beneficial.

GOVERNMENTAL RESTRICTIONS

Peter Evans requested that Evans Medical verify with the Department of Health that no restrictions apply to the indicators.

FREEZING INDICATOR

Evans Medical suggested that a freezing indicator for TT might also be helpful because TT should not be frozen and yet is commonly shipped with OPV, which must be frozen. While DPT gets granular when frozen (due to AlOH), one cannot visually detect if TT has been frozen.

<u>Meeting with WHO/EPI and SmithKline R.I.T., Rixensart, BELGIUM, June 13, 1990</u>

ATTENDING

Luc Vanden Houten, Director Sterile Operations and Packaging, SmithKline Biologicals
Eunice Miranda, Customer Relations Manager, SmithKline Biologicals
Julien Peetermand, Technical Director, SmithKline Biologicals
Peter Evans, WHO/EPI
Debra Kristensen, PATH

BACKGROUND

Peter Evans chose SmithKline as the second vaccine manufacturer to visit because they represent the other extreme end of the spectrum. SmithKline is the largest vaccine producer for EPI, is strong financially, and has highly automated manufacturing, labelling, and packaging processes.

TYPES OF VACCINE PRODUCED FOR EPI BY SMITHKLINE

Oral Polio Vaccine: six to seven million vials annually (SmithKline makes OPV in plastic tubes but does not supply them to EPI due to their higher cost.)
Measles Vaccine: one million vials annually

Note: Eunice Miranda will send us samples of the range of vial sizes and types that are used for EPI. SmithKline previously only sent OPV vials to PATH, some of which are not used for EPI.

PRICE

SmithKline also easily accepted a price of US$0.10 or less per indicator.

OPV INDICATOR RESPONSE CURVE

The half-life for SmithKline OPV is three to four weeks at 20°C and three days at 37°C. SmithKline management therefore finds the Polio Marker response to be overly conservative for their product. While they are not interested in the indicators for private sector markets, they have no objections to placing them on vaccines for EPI. They understand the need for conservatism, e.g., SmithKline's measles vaccine titer does not drop for five years when stored at -20°C, however, they use a two-year expiration date because monitoring of stock for a five-year period is difficult and expensive.

LABELLING ISSUES

SmithKline uses both aluminum "tear-off" caps and plastic "flip-off" caps over the aluminum "tear-off" caps. Both have ridges or raised lettering that may interfere with the adhesion of the indicators. Alternatively, the indicators could be placed on the bottom of the vials (except for the freeze-dried vaccines). Testing of the mechanical integrity of the indicators on the vial tops should be performed as soon as prototypes are available.

SmithKline prints their labels on-line. They use a thermal sensitive labelling process, so the attachment of labels to the sides of the vials must occur prior to attachment of the indicators. Labelling occurs at ambient temperatures and the shipment is prepared at +4°C. The indicator attachment will definitely require additional machinery. SmithKline's current line speed is 600 vials per minute. SmithKline management was not completely convinced that automated machinery could be acquired for attachment of a one centimeter label. They suggested that they would calculate the costs based on hand labelling. I provided them with information on a variety of automated labellers and will check to see if Label-Aire systems, suggested by the indicator manufacturer, has a distributor in Europe. SmithKline is also interested in receiving indicator samples to show their labelling experts.

SmithKline R.I.T. management was extremely cooperative and will work with PATH and WHO to implement the necessary equipment into their highly automated packaging and labelling processes.

QA ISSUES

SmithKline intends to validate the response curve for each lot of indicators as part of their routine QA procedure for raw materials.

They are currently testing each lot of 3M monitors that they receive. Therefore, the larger the batches of indicators sent, the better.

HEPATITIS B INDICATOR

The possible need for a third indicator type, with slower conversion, for Hepatitis B was discussed.

SOLOSHOT™/SafeTject™

Dr. Peetermand is very interested in SoloShot. Peter Evans showed him a prototype but did not reveal the manufacturer. Dr. Peetermand also wonders why he was never contacted again about "Ezeject."

ACTION ITEMS

1. Send samples (1,000) from the first production run of Polio Marker to Evans Medical and SmithKline to aid them in their study of automated attachment methods. Send the Evans Medical samples to the Speke factory and have Moyra Brookes in Horsham make the arrangements. Send the SmithKline samples to Eunice Miranda. **(D.Kristensen)**

2. Notify SmithKline and Evans Medical of the indicator size decision and the response curve for the measles/BCG/DPT indicator. **(D.Kristensen)**

3. Provide Evans Medical with information on differential pricing for public and private sector markets as soon as it is available. **(D.Kristensen)**

4. Provide SmithKline and Evans Medical with contact information for European distributors of Label-Aire labellers. **(D.Kristensen)**

5. Obtain the following from Peter Evans:

   a. price ranges for 10-dose vials of vaccines procured for EPI (to establish the 10 percent ceiling for indicators);

   b. information on the UNICEF assigned label color for OPV;

   c. WHO/EPI confirmation on the response curve for the measles/BCG/DPT indicator (the present specifications are eight days at 37°C and six months at 8°C); and

   d. written approval from WHO/EPI for the Polio Marker response curve. **(D.Kristensen/M.Free)**

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6. Start a data base to log correspondence and materials and information sent to each pharmaceutical manufacturer. **(D.Kristensen)**

7. Contact Dr. Peetermand at SmithKline R.I.T. regarding SoloShot and SafeTject if appropriate. **(J.Green)**

8. Perform mechanical integrity tests on indicators attached to vial tops with raised ridges or lettering as soon prototypes indicators are available. **(D.Kristensen, Lab)**

9. Submit mechanical and functional test protocols for the indicators to WHO/EPI by January 1991. **(D.Kristensen)**

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Attachment
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Attachment 14

SAFETJECT™ END-USER STUDY

Summary of Results

Prepared by

Program for Appropriate Technology in Health
(PATH)
4 Nickerson Street
Seattle, Washington 98109

August 1990

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I. Introduction and Background

Program for Appropriate Technology in Health (PATH) is a nonprofit organization whose overall mission is to improve health in resource-poor areas of the world. One result of PATH's product development work is SafeTject™, a low-cost, prefilled, single-dose syringe system.

In 1989, PATH engaged Communicore Research Consortium, a market research firm with extensive background in medical devices and pharmaceutical markets, to assess end-user impressions of SafeTject™. This paper provides a brief summary of the results of the Communicore SafeTject™ end-user study.

II. Study Objectives and Methodology

The study's specific objectives were to (1) document end-user perceptions of the advantages and disadvantages of SafeTject™ compared to standard prefilled syringes, (2) identify areas of concern about SafeTject™, and (3) explore training and instructional issues of SafeTject™ use.

The study was conducted using an initial response format. This format, which measures participants' immediate impressions, usually produces the most critical evaluation of a new product concept. Participants first answered a pretest questionnaire to gather demographic information and assess disposition toward prefilled-syringe systems. Participants were then given either verbal or written instructions in the use of SafeTject™ and asked to perform simulated injections with both SafeTject™ and a standard prefilled syringe (Vetter). An orange was used as surrogate human tissue. Following the use of the two devices, participants completed a post-test questionnaire.

III. Participant Demographics

One hundred and forty-one U.S. health care workers (132 female and 9 male) were surveyed. Of these:

A. The median age was 40, with a range from 20 to 69.
B. The majority had been licensed tc give injections for at least six years.
C. Seventy percent were registered nurses.
D. Over 50 percent gave more than two injections in an average week.
E. Most had some prior experience with standard prefilled syringe and needle systems.
F. At the outset of the study, a slight majority favored prefilled syringes over nonprefilled syringes.

IV. Procedural Note

The post-test questionnaires from the initial group of participants showed a significant misperception that SafeTject™ did not allow for aspiration of blood prior to injection. Subsequent groups received additional specific clarification that aspiration is possible with SafeTject™. This change in participant instruction was noted so that separate analyses of each group could be performed.

V. Study Results

A. Basic Evaluation of SafeTject™

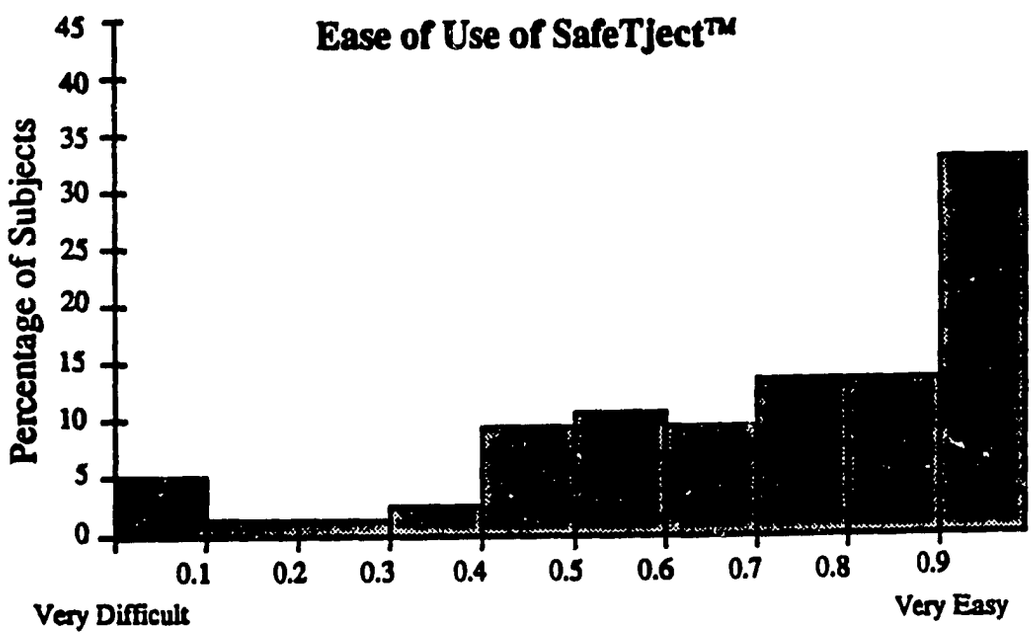
1. Overall Performance

Nearly three-quarters (72 percent) of the total study population rated the overall performance of SafeTject™

in the simulation as either good or very good. Problems with aspiration or the activation steps were the primary negative issues cited by those who reported poor performance.

2. Overall Ease of Use

Over three-quarters of the group (81 percent) rated SafeTject™ as easy or very easy to use. The vast majority of participants reported no difficulty in both learning and performing the activation step. SafeTject™'s injection technique presented no problems for 83 percent of the group.



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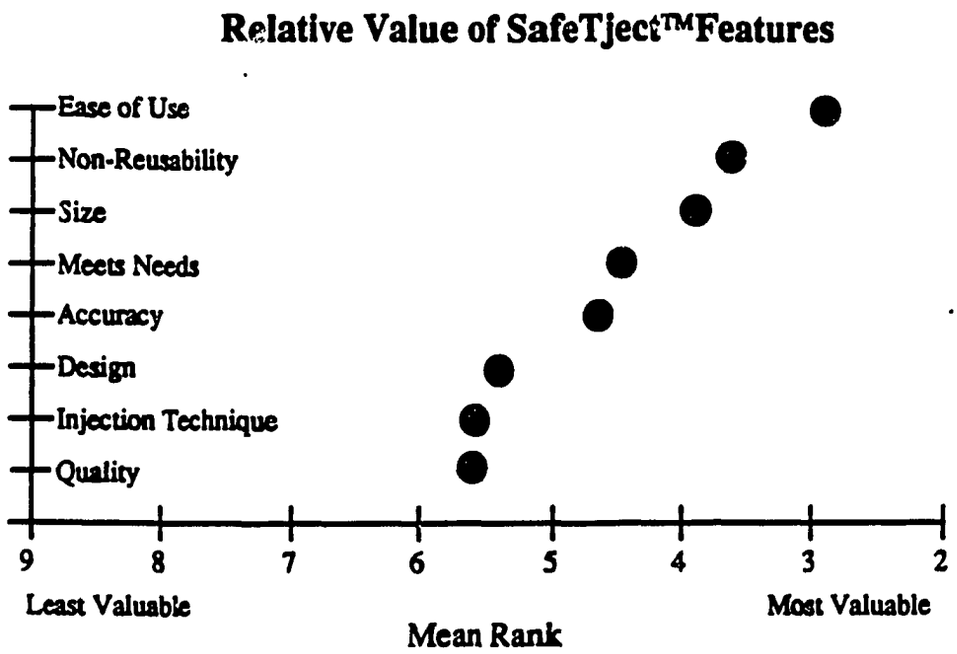
3. Relative Value of Features

Participants judged ease of use, nonreusability, and size as SafeTject™'s most valuable features.



4. Additional Information

A slight majority of respondents (55 percent) felt that SafeTject™ delivered the correct dose, while the remainder were less confident of accurate dosage delivery. The lack of dosage measures printed directly on the SafeTject™ device and the fact that some medicament was present after the injection (a normal occurrence) contributed to this skepticism. Factors considered key in proper usage included a need for

familiarization with the activation step and general practice with the device. Eighty-five percent of the respondents felt that SafeTject™ could easily and effectively be used by all qualified health professionals.

B. Comparison of SafeTject™ to Standard Prefilled Syringes

1. Advantages and Disadvantages

Sixty-two percent of study respondents felt that SafeTject™ had advantages over standard prefilled syringes, with particular emphasis on its smaller size, nonreusability, and single-piece design. While 55 percent cited some disadvantages with SafeTject™, the majority of these were related to aspiration misperceptions.

2. Technique and Ease of Use

Sixty-five percent found no disadvantage in the technique of injection with SafeTject™ compared to a standard prefilled syringe. Aspiration was again cited as the primary disadvantage. SafeTject™ was rated as easier to use than a standard prefilled syringe by 70 percent of the respondents.

3. Overall Rating

A majority of participants rated both SafeTject™'s and the standard prefilled syringe's overall performance as good to excellent (83 percent and 88 percent, respectively, when corrected for the aspiration bias). SafeTject™ was preferred by 60 percent of the respondents who did not mention the aspiration issue,

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while the standard prefilled syringe was preferred by over 70 percent of those who doubted SafeTject™'s ability to aspirate.

4. Additional Information

When asked to select one of the two devices as a delivery system for various classes of drugs, SafeTject™ was clearly the preferred choice for vaccines. Preferences were mixed for other pharmaceuticals.

VI. Study Conclusions

In both stand-alone and comparative evaluations, SafeTject™ performed very well. It satisfied most of the attributes considered by the participants prior to the study to be most desirable in an improved, easy-to-use, prefilled, disposable, single-unit syringe and needle-delivery system. It was also considered an appropriate system for a wide variety of health care workers administering a variety of pharmaceuticals. Ease of use, small size, and nonreusability were considered to be its most important attributes. In head-to-head comparisons with previously available prefilled syringes, SafeTject™ was the preferred system among participants who understood its ability to aspirate. Overall, SafeTject™ appears to be a valuable new delivery system for injectable pharmaceuticals.

As with any new product, there are areas in which potential misunderstandings about SafeTject™ will need to be addressed. U.S. health care workers clearly place importance on aspiration to confirm that a blood vessel has not been entered. SafeTject™'s capacity to complete this step will need to be clearly and convincingly communicated. SafeTject™'s consistency in delivering the correct dose (which has been shown

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to be within 5 percent in other studies) was also not completely understood by the group. This issue must addressed in instructional materials and possibly through enhanced product labeling.

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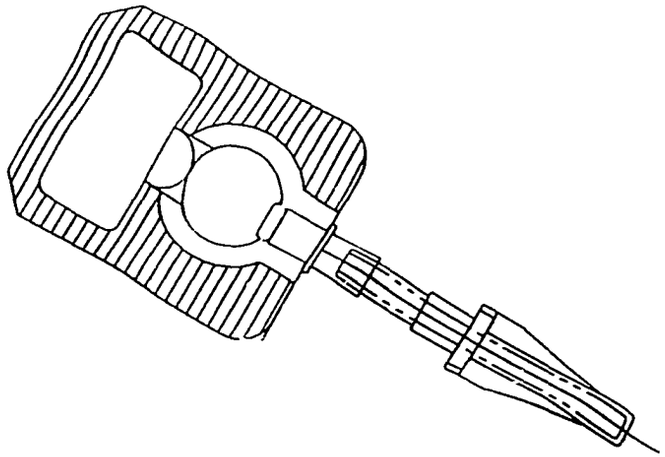
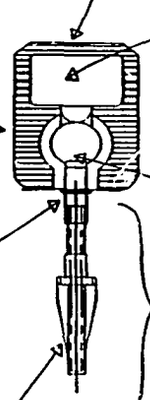
Attachment 15





filling port
(not visible
after filling)

Lot and Date code

Blister

reservoir

Blister Assembly

Injection Port

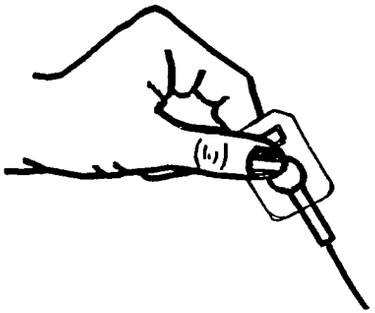
Needle Assembly

Hub

Needle

Protector Cap

Injection Assembly



Acacia Laboratories	
1006 Hathaway Ave. Santa Ana, CA 92705	
title	Nomenclature
drawing file	Legend.dpf
drawn by	R Thomas date

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Attachment 16

Information for TIP Presentation
SafeTject™*
June 1990

Need for SafeTject

There is a long-standing concern on the part of health care providers about the risk of transmitting infections through the use of improperly sterilized syringes and needles. This concern has been heightened in recent years by the recognition of the substantial risk of hepatitis B infection and associated liver diseases, by the epidemic of acquired immunodeficiency syndrome (AIDS), and by the greatly increased scope of immunization coverage. In addition, the need to increase immunization coverage for hard-to-reach groups, such as pregnant women and newborns in developing countries, has led to the consideration of training health workers at the periphery of the system in the delivery of certain vaccines.

PATH's response to need

SafeTject was developed in response to the need for a low-cost immunization device which would reduce the risk of contamination and cross-infection. It is a combination package and injection device for the delivery of vaccines and other injectable medicaments. Because it has simplified delivery by eliminating the need to sterilize equipment and measure dosages, it is especially well suited for use by groups such as midwives and traditional birth attendants. SafeTject's unique features are optimally used when it is filled with relatively heat-stable products, such as tetanus toxoid and hepatitis B vaccines, allowing it to extend the cold chain while still being kept in a "cool chain."

For general EPI use, SafeTject is currently restricted to vaccines stored in liquid media and that are delivered in a 0.5 ml dose. In the future it will be adapted to accommodate dosages from 0.2 ml to 2.0 ml. The device will provide increased safety, improved logistical control, and reduced training burden. The increase in required cold storage volume will be offset, to some degree, by reduced vaccine wastage, improved program efficiency and outreach, and reduced cost of equipment.

SafeTject's major advantages compared with a disposable syringe and vial are:

- accurate dosage
- sterile
- nonreusable
- reduced wastage of medication
- improved program efficiency
- potential for use by auxiliary health care workers such as midwives and TBAs
- lower cost

* SafeTject is a registered trademark of the Program for Appropriate Technology in Health.

- smaller, easier to handle
- faster administration
- reduced training burden

Potential disadvantages are:

- increased cold storage space
- new technology creating initial training burden

Brief history of SafeTject

An existing patent for this technology, owned by Merck, Sharp and Dohme, was licensed to PATH for advancement in order to meet public sector needs. Early development efforts using this technology, which was created to achieve specific design objectives, was unsuccessful, and the Merck, Sharp and Dohme technology was abandoned. It was replaced by an essentially new approach for which a patent was received in 1989.

Although the current design appears extremely simple, its execution has required many iterations of tooling. In order to meet the conflicting requirements of nonreusability and aspiration, a shape had to be developed that would allow suction for aspiration when the reservoir is full, yet prevent suction when the reservoir is empty. In addition, the design had to achieve a dispensing accuracy equal to or better than that of a standard syringe. The continuing development process required to render SafeTject even more tamper-proof and nonrefillable is complex and time-consuming.

SafeTject was developed to meet the following specifications:

- Be rendered unusable after delivery of a single dose;
- Deliver an accurate dose to within ±5 percent;
- Not allow any liquid to be forced into the reservoir at pressures under 35kPa.;
- Allow filling and sealing of the device under standard manufacturing conditions and employ affordable sterile filling and sealing machinery;
- Be tamper-proof and display clear evidence if the device is tampered with;
- Be composed of plastic that is rated excellent according to a standard test for opalescence; and
- Not allow water loss from the sealed reservoir to exceed 1 percent over a six-month period at 37° C and 60 percent humidity.

Current status

Manufacture: PATH has negotiated an agreement with Acacia Laboratories, Inc. for scale up and commercial development of SafeTject. Acacia is working towards validating the design, materials, and filling of

SafeTject and implementing a marketing and sales campaign in exchange for the option of an exclusive US license and nonexclusive worldwide license to make, use, and sell the device. Sterile SafeTject empties are provided by Acacia to pharmaceutical firms in reels of 1,000 units ready for filling. The filling, sealing, lot coding, and shaping processes are achieved on one machine specifically designed for these purposes.

Discussions have taken place with a number of vaccine and medicament manufacturers considering filling and marketing their products in SafeTject. Pasteur Merieux (France), Merck, Sharp and Dohme (USA), Evans Biomedical Ltd. (UK), Merieux Institute (France), Connaught Laboratories (Canada), SmithKline Beecham (USA), and Korea Green Cross Corporation (Korea) have all expressed interest in the device. Pasteur Merieux is filling SafeTject with its tetanus toxoid vaccine in September 1990 for storage stability and shelf-life tests prior to clinical and design-stage field trials.

Stability and characterization studies: Several studies have recently been undertaken on SafeTject including a characterization study and abbreviated storage stability experiments. The objectives of the characterization study were to determine potential migrants from the plastic film, the oxygen and water vapor transmission rates of the materials, and to evaluate the effectiveness of the material as a primary pharmaceutical package. Results indicate that no additional improvements to the film are needed. Results of the storage stability experiment have thus far indicated that samples stored for 120 days at ambient temperatures and at 37°C have remained at 0.9 percent sodium chloride concentration. After 120 days, the 45°C samples moved to 0.91 percent, and the 55°C samples moved to 0.92 percent.

Pricing: Cost estimates for SafeTject suggest that ultimately it will cost less than a standard disposable syringe and single-dose vial of medication, providing it is manufactured and marketed in large quantities. By promoting commercial use, as well as public sector use, necessary economies of scale can be achieved. Public sector pricing is expected to be between $0.07 - 0.15 per unit, not including cost of the medicament.

Field studies:

- Design feedback studies were carried out among health care workers in Guatemala, Kenya, and Thailand in 1989. Input from these studies has lead to certain modifications of the device.

- An end-user study was undertaken among medical personnel in the United States in 1989 to determine the acceptability of SafeTject in commercial markets. The device was favorably received and, in a majority of cases, it was preferred in comparisons to other disposable needles and syringes.

- A design-stage field trial of SafeTject filled with tetanus toxoid (TT) is planned for the Machakos District of Kenya beginning in the first half of 1991. A protocol is being developed in conjunction with the African Medical Research Foundation (AMREF). In the

first phase, the trial focuses on the development of training materials for the use of SafeTject; in the second phase, it trains midwives in the use of SafeTject and supervision of the traditional birth attendants, who will be trained, in the third phase, to deliver TT in SafeTject.

TBAs will initially use SafeTject in a health center setting under close supervision before taking a small supply to the village for delivery to postpartum women. Used and unused SafeTjects will be returned to the health center on a monthly basis for evaluation, and a new supply collected. This project has been included as part of PATH's HealthTech II proposal to USAID.

- The International Task Force on Hepatitis B Immunization plans to carry out a validation field trial of SafeTject filled with hepatitis B vaccine as part of the model immunization program in Cameroon and potentially one other country.

- A design-stage field trial of SafeTject filled with tetanus toxoid will be undertaken in Lombok, Indonesia through PATH's Child Survival - Plus Two project, recently approved by USAID's Office of Private and Voluntary Cooperation. In this project a new cadre of village-based health care workers, Puskesmas Pembantu, will be trained in the use of SafeTject. This activity will begin in late 1991.

Interest has also been expressed by USAID/Jordan and UNICEF/Nepal in the possibility of carrying out SafeTject field trials and/or technology transfer for local filling of SafeTject blanks.

Future plans

Tamper-proofing: It has been found that under conditions of willful misuse, current production prototypes of SafeTject can be refilled from a pressurized vial. High priority is being placed on examining several possible modifications which will render SafeTject more tamper-proof and non-refillable. These refinements will be made in tandem with the initial design-stage field trials mentioned above and incorporated into subsequent prototypes of the device.

Field Trials: Design-stage field trials will yield useful information on the device's acceptability to users, durability, design, disposal methods, effectiveness of training new cadres of workers, such as TBAs, to use SafeTject, and a number of logistical issues. This input will be valuable in making refinements in the final design of SafeTject.

Outstanding issues and concerns

- Potential for refilling:

  As mentioned above, further tamper-proofing of SafeTject to render it totally nonreusable is of the highest priority. A design team at PATH is working with Acacia Laboratories on several concepts which would not require any change in the materials or the basic design of the product.

- Use by TBAs:

  A concern has been raised by certain Ministry of Health staff in Kenya that there may be resistance from the medical and nursing staff currently responsible for giving injections to the training of midwives and TBAs in the use of SafeTject. However, the protocol calls for an initial training in the use of SafeTject by the nursing staff who supervise midwives and TBAs. Once supervisory staff see how simple it is to use and to train others to use, their fears may be dispelled and they may welcome the added benefit of reducing the workload of health center staff.

  In addition, the first activity of the field trial will be to carry out focus group discussions among health center staff, midwives, TBAs, and mothers to gather qualitative information on the attitudes and concerns of these groups with regard to immunization by traditional health workers. Training and education materials will be developed which will address the concerns raised in the focus group discussions.

- Disposal procedures:

  Each of the field trial protocols is addressing this important question by finding out current disposal recommendations for disposable needles and syringes. A disposal container for sharps may be the safest procedure, although in rural areas where health centers lack incinerators, disposal in a pit latrine, as was suggested by health workers in Kenya, may be a more realistic option.

- "Cool chain":

  Methods of extending the cold chain by storing and transporting SafeTject filled with relatively heat-stable vaccines within a "cool chain" are being explored for the Kenya field trial. The possibility of using a locking wooden box or a clay pot in the earth for storage in the home and a midwifery bag or styrofoam box for transportation are being considered.

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Attachment 17

Prize Projects

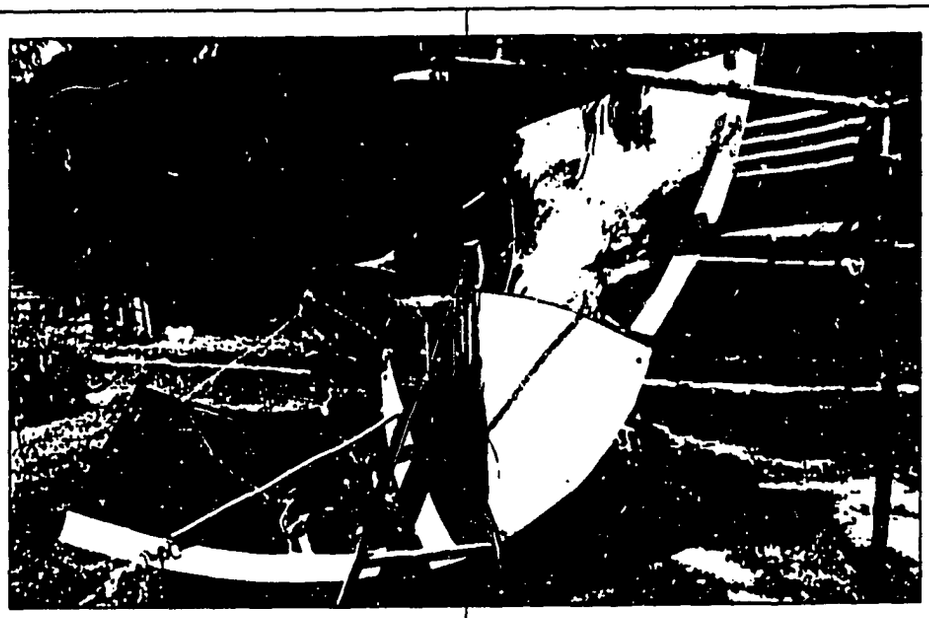
Solar Refrigeration Brings Ice To Developing Countries

In the Book of Genesis, when the Lord tells Abraham that his wife Sara will soon bear him a son, Abraham responds with a laugh, pointing out that both he and his wife are over 90 years of age. The Lord's answer is that this child should be named Isaac, the Hebrew name meaning "he laughs."

Energy Concepts Company has a "baby" named Isaac also, and a lot of people have been laughing at it for the past few years. But based on the results of two current demonstrations of performance, the laughter is about to be replaced by wonderment.

Donald Erickson is president of Energy Concepts Co., an Annapolis, Maryland-based research and development firm whose most recent product makes ice from the sun, raising questioning eyebrows and skeptical looks when people first hear about it. "Our product name, ISAAC, is really appropriate for what we are doing. It actually stands for Intermittent Solar Ammonia Absorption Cycle refrigerator," he explained, "but the laughs it often causes make the Biblical reference very accurate."

His refrigerators combine the dependability of an ammonia absorption refrigeration cycle with state-of-the-art solar technology. ISAAC units consist of large, curved mirror-like solar collectors which manually tilt on hinges to permit seasonal adjustment to maximize the sun's rays. The heat which the panels generate yields compressed ammonia gas, by boiling it out of an aqueous ammonia solution. The ammonia is condensed to liquid during the day. At night, the liquid ammonia evaporates to cool the ice container. It's a technology similar to that which existed before the availability of electricity, in which refrigerators created compression with a flame instead of solar or electric power. Because this product pressurizes ammonia vapors through a thermally-driven phase change, there is no need for a compressor. As a result, the process is 30 percent more efficient than compression heat pumps, making the ISAAC system



the first in the world to use the absorption technology to provide enough refrigeration efficiently for commercial applications.

For the past four years, Erickson's firm has been developing and testing his solar-powered Icelander to make it suitable for manufacture and use in Third World countries. Nine prototypes have been built and subjected to a variety of tests, resulting in one patent and several innovative product uses so far. Now there are two full-scale demonstration units being tested in the field, and Erickson is receiving reports that bring a smile to his face. "We're very pleased with the results so far. Our unit in Thailand has been up since last May and has proven extremely reliable. It even withstood the monsoon season's strong winds and rain, which wrecked other test systems nearby, but left our unit unscathed. In November, we installed a unit in Micronesia, and I'm confident we'll hear the same positive results as it gets more use."

The ISAAC system is simple, reliable, uses low-cost materials, and does not require advanced maintenance or manufacturing skills. "We designed it for remote locations which need refrigeration but have no reliable or reasonably-priced electricity available," he explained. "Many of the people in these locations have long relied on kerosene-fired ammonia absorption refrigerators, even though they've faced the problems of high consumption and high cost of kerosene, limited ice production, and difficulty in obtaining good quality kerosene which won't damage the basic equipment."

"Basically, we have three major advantages over conventional fuel systems — absorption refrigeration is inherently simple and low tech, it's cost-competitive, and on a first-cost par with diesel or kerosene, and the absorption technology is already well-known and widely used in developing countries."

That's not to say that Erickson's product is fully developed and ready for widespread use. Noting that nine different prototypes have been built so far, Erickson explained that they're still perfecting the technology. "Right now, I think our biggest drawback is the fact that we need to keep fairly low temperatures at night for

ice-making. Our unit gets down to around 15°F at night, then coasts up to about 35 degrees in the daytime. Future models will incorporate new features to reduce this temperature fluctuation. Based on our demonstration systems in use so far, we've found a couple of other things we'd like to change in the future. We planned for the Thailand system to produce 60 pounds of ice per day, but have found that our evaporator was undersized for their climate, so they've only been able to make about 40 pounds each day. We're going to have to work a little more on the evaporator system, not just for its size, but also to improve its current rudimentary design and prevent ice from freezing on the coils."

Erickson isn't worried about the product improvements still needed. "Each model we've built has solved problems and added important features that improve performance," he said. "Our truncated compound parabolic collector, thermal wall, auxiliary generator and other features all came about because of the tests on prototypes. Our goal has always been to reduce the cost, simplify the manufacture, and optimize performance. We've got to meet this goal if we're to bring the benefits of affordable ice and refrigeration to the large portion of the world population that is not serviced by an electric grid. I can see a wide variety of uses, ranging from rural health stations and central health care clinics which supply ice for vaccine storage, to fisheries needing longer storage or shipping times and private citizens in remote areas wanting ice and/or food cooling."

Energy Concept's long-range goal is to see their product providing better health and nutrition to millions of people in developing countries. Funding from the U.S. Department of Energy and the Agency for International Development has helped bring the ISAAC system to its present stage. They soon plan to send a unit to Sandia National Labs for more extensive tests, and to get field units into Africa, where they see the biggest need today.

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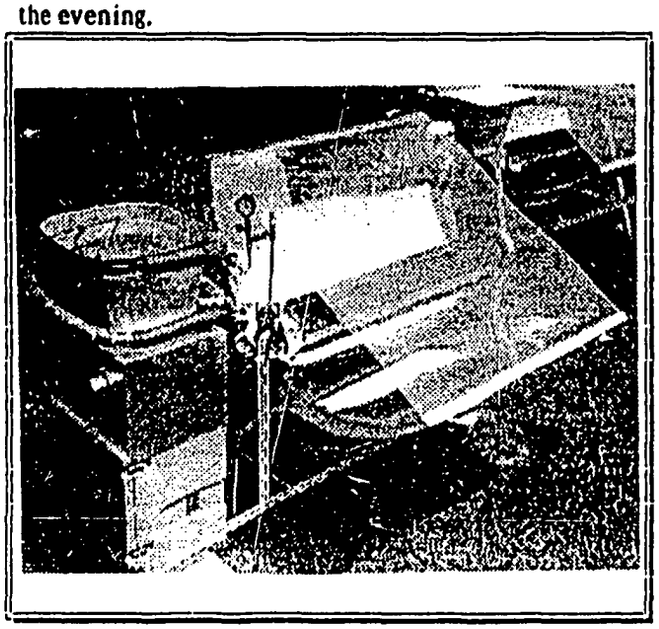
ISAAC Solar Powered Ammonia Absorption Refrigerator

Solar Powered Refrigeration from Energy Concepts

The **ISAAC™** solar powered refrigerator combines the dependability of an ammonia absorption refrigeration cycle with state of the art solar collector technology. The result is a design that incorporates simplicity, reliability and affordability. **ISAAC** refrigerators produce more ice per square foot of collector area than comparable photo-voltaic powered refrigerators and cost only a small fraction of the price. Unlike diesel, kerosene and gas fired refrigeration, the **ISAAC** solar powered refrigerator obtains its efficient output from the energy of the Sun.

Reliable-The **ISAAC** solar powered refrigerator is reliable because of its design. There are no moving parts. It is virtually maintenance free and only requires one valve to be turned, once in the morning and once in the evening.



Easy to Operate-The **ISAAC** solar powered refrigerator has four primary components: the reflector, the ammonia vaporizing cylinder, the condenser and the ice box. When the sun is reflected to the black surface of the ammonia vaporizing cylinder, the ammonia vaporizes and is routed to the condenser where it is condensed back into a liquid. When the sun goes down, the operator turns a valve to the "ice-making" mode which allows the ammonia to enter the cooling tubes of the refrigerator where it rapidly lowers the temperature by absorbing heat to create ice. In the morning, the operator turns the valve to the "generate" mode and the vaporizing cylinder is once again exposed to the high intensity heat of the reflector.

The **ISAAC** solar powered refrigerator requires no pumps nor any form of electricity to operate.

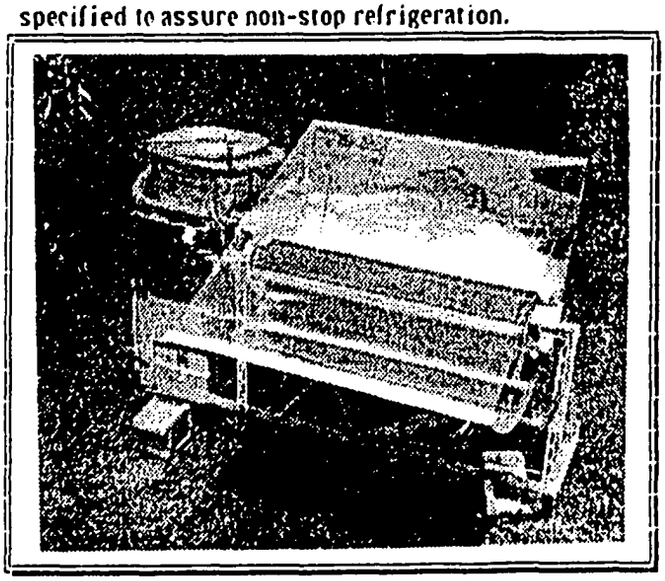
Applications-The **ISAAC** solar powered refrigerator provides low cost refrigeration to any area of the world that is exposed to continual sunshine and lacks public utility power grids for electricity.

Rural Heath Stations-Perfect for medicine and vaccine storage.

Fisheries/Farms-Allows extended storage of fresh food products.

Remote Homes and Villages-Ice making and Food/Medicine cooling.

The **ISAAC** solar powered refrigerator is available in two standard models that have a capacity to produce 12 to 16 pounds of ice per day or 60 to 80 pounds of ice per day. Custom models can be designed for specific areas of the world that may require a larger reflector area or for increased ice production. For cloudy days, a wood/coal burning backup unit may be specified to assure non-stop refrigeration.



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