The Essential Health Interventions Project (EHIP) Background Paper

October 1995

Contents

Acronyms

AMMP	Adult Mortality and Morbidity Project
CIDA	Canadian International Development Agency
DALY	Disability-Adjusted Life Year
DANIDA	Danish International Development Agency
DHMT	District Health Management Team
DMO	District Medical Officer
EDP	Essential Drugs Programme
EHIP	Essential Health Interventions Project
EPI	Expanded Programme on Immunization (now the Global Programme of Vaccines - GPV)
GBD	Global Burden of Disease
HIV	Human Immunodeficiency Virus
ICIDH	International Classification of Impairments, Disabilities, and Handicaps
IDRC	International Development Research Centre
MOH	Ministry of Health
NGO	Nongovernmental Organization
NIMR	National Institute of Medical Research (Tanzania)
ODA	Overseas Development Administration
PHC	Primary Health Care
PMO	Prime Minister's Office
QALY	Quality-Adjusted Life Year
RCT	Randomized Controlled Trial
RMO	Regional Medical Officer
STD	Sexually Transmitted Diseases
TB	Tuberculosis
TFNC	Tanzanian Food and Nutrition Centre
UNICEF	United Nations International Children's Emergency Fund
WB	The World Bank
WDR'93	World Development Report 1993 - *Investing in Health*
WHO	World Health Organization

P I E S

Projet d'interventions essentielles en santé
Documentation général : Résumé

Le Projet d'interventions essentielles en santé (PIES) est une initiative de recherche-développement en santé qui a émané d'une série de consultations et d'activités internationales. Ce texte donne des renseignements généraux sur les activités qui ont mené au PIES, décrit les étapes préliminaires de l'élaboration d'un projet à ce sujet en Tanzanie et justifie les choix qui ont été faits au moment de la conception du PIES.

Selon l'une des conclusions du Rapport sur le développement dans le monde de 1993, *Investir dans la santé*, en permettant un accès équitable à un ensemble intégré minimum d'actions de santé publique et d'interventions cliniques essentielles, les pays à faible revenu pourraient réduire considérablement leur charge de morbidité. Par la suite, la *Conférence sur un futur partenariat pour accélérer l'amélioration de la santé* a eu lieu à Ottawa, en 1993. Plus de 150 représentants des pays en développement, des organismes subventionnaires, du milieu universitaire et des gouvernements y ont assisté et ils ont recommandé le financement d'un projet visant à examiner la faisabilité et les répercussions de l'adoption d'un tel ensemble intégré d'interventions au niveau du district.

Pour donner suite à cette recommandation, le CRDI, en collaboration avec l'ACDI, l'OMS, l'UNICEF, la Banque mondiale et la Fondation Edna McConnell Clark, a lancé un projet en ce sens, au cours duquel seront mises en application et évaluées, dans quelques districts, la planification et l'élaboration de services de santé de district fondées sur la mesure de la charge de morbidité, ainsi que la prestation de services essentiels réputés d'un bon rapport coût-efficacité. Il a été convenu que le projet aurait lieu en Tanzanie et la planification a débuté dans ce pays en mai 1995.

Le rapport *Investir dans la santé* met de l'avant la conception d'un ensemble d'actions de santé publique et de services cliniques essentiels fondée sur la charge de morbidité et sur le choix d'interventions d'un bon rapport coût-efficacité. Il propose en outre que les gouvernements veillent à ce que ces interventions soient offertes à 80 % de la population au moins et conformément à certaines normes minimales de qualité. Le PIES a ajouté deux critères additionnels pour le choix des interventions : la capacité du district d'absorber des ressources additionnelles et la prise en compte des préférences de la collectivité.

Par conséquent, le PIES porte sur la mise à l'essai d'un *processus de planification* qui a recours à la mesure de la charge de morbidité et au calcul du rapport coût-efficacité pour en arriver à des choix en ce qui concerne l'affectation des ressources aux services de santé. Le PIES a pour but :

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- d'évaluer la faisabilité de la planification en santé au niveau du district fondée sur les interventions ayant le meilleur rapport coût-efficacité pour réduire la charge totale de morbidité dans le district;
- d'évaluer le rapport coût-efficacité d'un ensemble intégré d'actions de santé publique et de services cliniques; et
- d'en apprendre davantage sur les processus d'élaboration de politiques, de planification et de gestion qui sont nécessaires à la réaffectation des ressources financières et humaines requises à l'appui de ce programme intégré en santé.

La plus grande partie des fonds octroyés au PIES iront à la prestation de services de santé plus complets au niveau du district. Les deux principes de la *viabilité* et de l'*équité* seront d'une importance primordiale dans les districts participants. Ce projet fournit une occasion sans précédent de vérifier l'une des prémisses fondamentales du Rapport sur le développement dans le monde de 1993.

Exécuté au niveau du district, le projet comporte un volet de démonstration et un volet de recherche. On passe en revue, dans ce texte, les questions d'ordre théorique, méthodologique, éthique et de procédure qui ont été soulevées lors de l'élaboration du plan du projet. Ces questions avaient trait au choix du cadre conceptuel de l'étude, aux aspects liés à l'intégration dans le processus de planification, au choix du district et des interventions, à la mesure de la charge de morbidité et au calcul des années de vie corrigées du facteur invalidité (AVCI), à l'analyse du rapport coût-efficacité, à la coordination des activités et aux considérations d'ordre éthique. On insiste sur l'évaluation non seulement parce qu'elle est essentielle pour mesurer les changements dans la situation sanitaire et la charge de morbidité, mais aussi parce qu'elle est employée pour déterminer l'efficacité du nouveau processus de planification en ce qui concerne l'établissement des priorités et l'affectation des ressources.

Le PIES est un projet complexe qui doit être planifié de façon judicieuse en Tanzanie. Cela représente en effet tout un défi que de simultanément procéder sur le terrain à des mesures exactes de la charge de morbidité et à des calculs précis du rapport coût-efficacité tout en intégrant ces données au processus de planification, en consolidant une infrastructure faible, en offrant un ensemble coordonné d'interventions et en surveillant le déroulement du processus. Et tout cela est plus compliqué lorsqu'il faut tenir compte des préférences de la collectivité. Exécuter ces activités en fonction d'un budget serré et s'assurer que ce qui est établi sera viable une fois le projet terminé ajoutent encore à la complexité de la tâche.

On ne peut attendre du PIES qu'il fournisse des précisions sur la composition de la charge de morbidité dans les districts qui font l'objet de l'étude. Il se peut aussi qu'il ne réponde pas à toutes les questions ayant trait à la satisfaction des usagers et à l'évolution des tendances au niveau individuel ou collectif. Il ne vise pas à mettre au point une *formule* efficace pour la planification des services de santé et l'affectation des ressources qui pourrait ensuite être généralisée. Il a plutôt pour but de *vérifier* certains principes quant au *processus* qui, s'ils se révèlent pertinents, pourraient être appliqués dans bon nombre de pays en développement (et industrialisés).

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The majority of EHIP funding will be directed toward the delivery of expanded health services at the district level. The two principles of *sustainability* and *achievement of equity* in the participating districts are of paramount importance. This opportunity to test one of the central premises of the WDR'93 is unprecedented.

Operating at a district level, the project involves both a demonstration and a research component. The theoretical, methodological, ethical, and procedural issues that have arisen during the elaboration of the project plan are reviewed in this paper. These issues include: choices in study design, issues surrounding integration into the planning process, district selection, selection of interventions, burden of disease measurements and Disability-Adjusted Life Year (DALY) calculations, cost-effectiveness analysis, coordination of activities, and ethical considerations. Assessment and evaluation are stressed, not only because they are essential for measuring changes in health status and burden of disease, but also because they are also used to determine the effectiveness of the new planning process for defining priorities and allocating resources.

EHIP is a complex undertaking that requires careful planning within Tanzania. The difficulties of simultaneously conducting accurate burden of disease measurements and cost-effectiveness calculations in a field situation, incorporating this information into the planning process, strengthening a weak infrastructure, delivering a coordinated package of interventions, and monitoring the entire process is a formidable challenge. It is further complicated by the need to integrate community preferences. Carrying out these activities within the constraints of a limited budget and ensuring that what is instituted is sustainable past the life of the project add further to the complexity of the task.

EHIP will not be able to provide details on the full spectrum of the disease burden in the study districts. It may not answer all questions related to user satisfaction or detection of change at the individual or community level. EHIP is not about finding a *formula* for efficient health care planning and resource allocation that can be universally applied. It is about *testing* certain principles of *process* which, if found workable, could have applications in a variety of developing (and developed) countries.

Summary

The Essential Health Interventions Project (EHIP) is a health research and development initiative that has grown out of a series of international consultations and activities. This paper provides background information on the steps that led to EHIP, describes the preliminary steps which were taken to develop a project in Tanzania, and discusses the rationale for the choices made during the overall design of EHIP.

One conclusion of the 1993 World Development Report (WDR'93), *Investing in Health*, was that an integrated package of minimum essential public and clinical health interventions could significantly reduce overall disease burden in low-income countries. Subsequently, a conference entitled *Future Partnerships for the Acceleration of Health Development* was held in Ottawa in 1993. This conference, which brought together over 150 representatives from developing countries, donors, academia, and governments, recommended that a project be funded to examine the feasibility and impact of introducing such an integrated package of interventions at the district level.

In response, IDRC, in collaboration with CIDA, WHO, UNICEF, The World Bank, and the Edna McConnell Clark Foundation, undertook to support such a project. This project will implement and evaluate, in a few study districts, the planning and development of district health services on the basis of burden of disease measures, and the provision of essential services that were deemed to be cost-effective. It was agreed that this project would take place in Tanzania. In-country planning began in May 1995.

Investing in Health proposed that a package of essential public health and clinical services be designed, based on burden of disease and the selection of cost-effective interventions. Further, it proposed that governments ensure that these interventions are provided to at least 80% of the population in a manner consistent with certain minimal standards of quality. EHIP added two additional criteria for selection of interventions: district capacity to absorb additional resources, and the inclusion of community preferences.

Therefore, EHIP is about testing a *process of planning* that uses burden of disease and cost-effectiveness measurements as tools for making choices in resource allocation to health services. EHIP seeks to:

- test the feasibility of district-level health planning that selects the most cost-effective health interventions to reduce the overall burden of disease in the district;
- evaluate the cost-effectiveness of an integrated package of public health measures and clinical services; and
- learn about the policy, planning, and management processes that are needed to reallocate the financial and human resources required to sustain this integrated health program.

Introduction

There is a critical need to improve health in most areas of the world. As many governments and international aid agencies have been forced to tighten spending in recent years, however, funds for essential health activities are now in short supply. The challenge which now faces many developing countries is to improve health delivery systems such that there is a sustainable allocation of limited health resources, and that the health status among all people is improved.

The Essential Health Interventions Project (EHIP) is a response to this challenge. EHIP is a health research and development initiative designed to generate new knowledge about the planning and delivery of essential public and clinical health services. The EHIP concept grew out of a number of meetings and consultations that were the direct result of the global recommendations contained in *The World Development Report 1993: Investing in Health.*

The Ministry of Health in Tanzania is using the EHIP approach to examine the feasibility of using burden of disease and cost-effectiveness measurements as tools for setting priorities and allocating health resources at the district level. This approach will involve the selection of essential clinical and public health interventions at the district level and will place emphasis on community participation. The Government of Tanzania is using the opportunity presented by EHIP to determine the feasibility of the policy directions set out by its proposed health sector reform. The project will examine whether the government can achieve more rational and efficient decisions on health allocations on the basis of information obtained at the district level.

This paper provides background information on the steps that led to EHIP, describes preliminary steps which were taken to develop a project in Tanzania, and discusses the rationale for the choices made during the overall design of EHIP.

The Evolution of EHIP

In June 1993, The World Bank published its sixteenth World Development Report (WDR'93). The first to focus exclusively on health, *The World Development Report 1993: Investing in Health* (World Bank 1993) was the product of several years of participatory consultations, commissioned studies, and background papers. It was an important document because it accepted the proposition that an integral and vital component of any country's development agenda should be to improve and maintain the health of its people.

There have been great improvements globally in life expectancy and infant-mortality rates, a result of a combination of growing incomes, increased education, expanded health services, and technological advances. Enormous problems remain, however, particularly in low-income countries. Despite improvements in mortality rates, the level of disabilities remains high. In low-income countries, new health challenges such as AIDS, drug-resistant malaria and tuberculosis, and noncommunicable diseases in growing elderly populations threaten to overturn the gains that have already been made.

Investing in Health identifies a number of problems that continue to hamper the delivery of health services and limit reductions in mortality and disability. These include:

- the allocation of funds to interventions with low cost-effectiveness sacrifices highly cost-effective interventions;
- inequities mean that the poor (the least healthy segment of the population) lack access to basic health services, while the affluent benefit the most from spending on health;
- inefficiencies abound in the purchase of supplies, the deployment of health workers, the utilization of facilities, and the planning process; and
- costs are increasing for physician services, sophisticated tests and treatments, and health system maintenance.

In low-income countries, these problems are often compounded by "highly centralized decision-making, wide fluctuations in budgetary allocations, and poor motivation of facility managers and health care workers" (World Bank 1993, p. 4).

Investing in Health justifies a role for government in financing health services on both ethical and economic grounds (to reduce poverty, promote "positive externalities", ensure widespread coverage, and regulate costs). However, it also argues that public resources allocated to health must be made on a rational basis, and proposes that the cost-effectiveness of interventions be used to guide government allocations.

Three policies are proposed for governments to improve health.

- Governments should foster an environment that enables households to improve health. This would include implementing economic growth policies which benefit the poor, investing in education, and promoting the rights and status of women.

- Governments should promote diversity and competition, and provide incentives for cost containment. This could be achieved through the provision of private insurance for nonessential clinical services and the delivery of clinical services by the private sector, even when they are publicly financed.
- Governments should improve spending on health by rationalizing health care expenditures through reduced spending for tertiary care facilities, emphasizing the financing and delivery of cost-effective interventions, ensuring the delivery of a package of essential clinical services tailored to local needs, and improving service management through decentralization.

Although the authors of *Investing in Health* presented a comprehensive agenda for improving health in low-income countries, EHIP will only focus on two items: the financing and delivery of essential clinical and public health intervention packages, and the improvement of health services management at the district level.

WDR'93 also suggests that the following components of public health and clinical services be considered as *essential*, as they are cost-effective and have the potential to improve health:

- childhood immunizations;
- school-based health services;
- information and selected services for family planning and nutrition ;
- programs to reduce tobacco and alcohol consumption;
- improvement of the household environment;
- AIDS prevention;
- prenatal and maternal services;
- tuberculosis control;
- control of sexually transmitted diseases (STDs);
- care for serious childhood illnesses such as diarrhoeal diseases, acute respiratory infection, measles, malaria, and acute malnutrition; and
- selective emergency and trauma services.

The report postulates that widespread adoption of essential clinical and public health packages could result in a 32% reduction in the burden of disease in low-income countries and a 15% reduction in middle-income countries. This package could save more than 9 million infant lives per year on a global basis. The report estimates the annual cost of this interventions package at USD12 per capita in low-income countries (World Bank 1993, pp. 10–11).

This estimate, however, is greater than the health budgets of most low-income countries. WDR'93 proposes that the costs of this essential interventions package be borne through increased spending on health by governments, donors, and communities (patients), and through a reorientation of public spending on health.

Investing in Health makes several recommendations on how governments should reorient public spending on health.

- Governments should shift spending away from specialized personnel, equipment, and supplies in tertiary facilities, and towards widely accessible care in community facilities and health centres.
- Governments should develop more effective policies to finance training for primary care providers (particularly nurses and midwives), and for public health, health policy and management personnel. They should also limit subsidies for specialist training.
- Governments should increase support for health information systems and operations research to guide public policies, including estimates of the national burden of disease and cost-effectiveness of different interventions.
- Governments should develop national essential drug lists, new treatment protocols, and alternative uses of facilities.
- Governments should increase capacity and accountability at lower levels of the national health system.
- Governments should place greater reliance on the private sector, both for essential and nonessential services, and provide subsidies to the private sector for the provision of essential services.
- Governments should regulate the quality of health services, both public and private, and of health insurance schemes.

While the relevance of these recommendations will vary from country to country, in low-income countries a "renewed emphasis on basic schooling for girls, strengthening of public health programs, and support for expanded public financing of essential clinical services should be at the top of the policy agenda" (World Bank 1993, p. 14). The international community must be prepared to provide increased assistance for health policy reforms and for health research that focuses on the major health problems of developing countries.

EHIP — The Idea is Born

In response to the recommendations made in the World Bank report, more than 150 representatives from developing countries, multilateral and bilateral development assistance agencies, international and national organizations and foundations, academia, and government met in the autumn of 1993 for a meeting entitled *Future Partnerships for the Acceleration of Health Development* (referred to as the Ottawa Conference). This conference, cosponsored by IDRC, The World Bank, and WHO, "sought to examine weaknesses in national and international programs for equity-oriented health development in developing countries and agreed on practical steps to increase the scope and effectiveness of partnerships and investments for health" (IDRC 1993).

Using WDR'93 as a starting point, the participants analyzed three interrelated problems.

- How can we build capacity in developing countries to undertake health policy reform in support of sustainable health development?

- How can we strengthen the relevance, coordination, and contribution of health research for health reform in developing countries?
- How can we increase, redirect, and enhance investments in health development?

A common concern was to ensure that both national and international resources for health would be used to move the health sector toward:

- greater equity for and access to health care,
- greater congruence with the needs of populations,
- greater effectiveness and efficiency in the allocation of resources,
- greater participation and accountability to the people being served, and
- greater sustainability for the long-term.

The Ottawa Conference arrived at a broad consensus in several areas and recommended several items for immediate action (IDRC 1993). Most pertinent to the subsequent development of EHIP, the conference recommended that joint support was needed to test the development and implementation of nationally-defined health intervention package(s), health policy reforms, and improved donor coordination in six to ten interested countries. This initiative could entail estimates and analyses of national disease burdens, development of adapted public health and clinical intervention packages, work with countries in the pilot implementation of the packages, and research efforts to evaluate the approaches. The objective was to be able to draw generic lessons for possible application in other countries (IDRC 1993).

Based on the recommendations from the Ottawa Conference, discussions were initiated between IDRC and CIDA, and with The World Bank and WHO. In April 1994, IDRC received funds to begin developing a project in eastern and southern Africa that would carry out the specific recommendation of the Ottawa Conference concerning essential interventions. EHIP is unique in that funds were obtained at the *conceptual* stage, prior to the development of a set of specific objectives or a detailed methodology.

A secretariat for the initiative was established at IDRC, and a full-time project manager was seconded to IDRC from Health Canada. During April and May 1994, letters were sent to the ministries of health in seven countries in eastern and southern Africa to explain the background and broad scope of the initiative, and to invite letters of interest.

EHIP in Tanzania

Tanzania was one of the first countries to express interest in the EHIP approach. A group representing IDRC, WHO, The World Bank, and other interested parties spent three weeks in Tanzania in late November and early December 1994. Joined by representatives from Tanzania's Ministry of Health and the National Institute of Medical Research, the group met with officials from other Tanzanian ministries, the main groups conducting health research in the country, and the representatives of the major health donors in Tanzania. As a result of these meetings, it was decided that Tanzania would be the first country to adopt the EHIP approach.

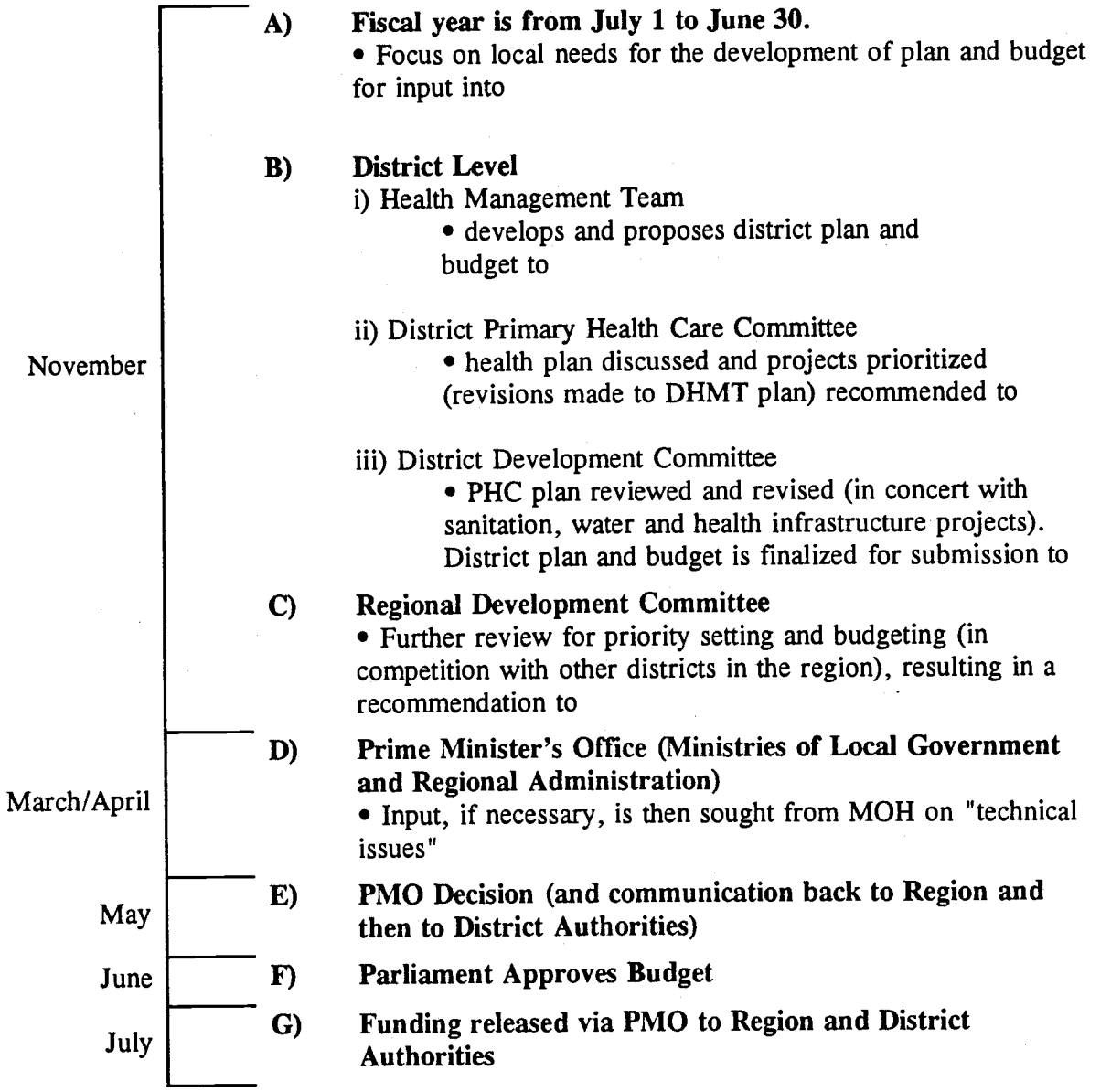
Four districts [Rufiji, Mafia Island, Kisarawe, and Morogoro (Rural)] were proposed as study sites by the Tanzanian Ministry of Health. During this preliminary assessment, each district was visited. Representatives met with the district health management team (DHMT) and other district officials, learned about the planning and management processes in the district, examined the health information systems, and visited health facilities (district and mission hospitals, health centres, and dispensaries).

Integration of EHIP into the Planning Process

The health system in Tanzania is extremely complex. Health resources arrive at the district level from the Ministry of Health, and from the Prime Minister's Office through the Ministry of Regional Administration and the Ministry of Local Government. Other health institutions in the country, particularly those involved in health research, have their own linkages. For example, the National Institute of Medical Research (NIMR) and the Tanzanian Food and Nutrition Centre (TFNC) are independent from the Ministry of Health. The Muhimbili Medical Centre and the University of Dar es Salaam, on the other hand, are linked to the Ministry of Education.

The current planning cycle in Tanzania (Figure 1) begins at the community or district level in November and ends in the Prime Minister's Office (PMO) in April and May. Village or ward development committees focus on local needs and advise the DHMT, which develops and proposes the district plan to the District Primary Health Committee. Here the DHMT plan is revised and priorities are stated. The District Development Committee reviews and revises the design in light of those of other sectors. The Regional Development Committee then reviews the strategy in relation to those from other districts in the region, and makes a recommendation to the PMO, i.e., the Ministries of Local Government and Regional Administration. At this point, the Ministry of Health may be asked for advice on technical issues. The PMO makes decisions and sends the plan to Parliament, where the budget must be approved. Funding is released from the PMO to the regional and district authorities in July, the beginning of the government's fiscal year.

Figure 1. The District Planning Cycle in Tanzania.



Notes: (1) Fiscal year is from July 1 to June 30; (2) Planning cycle begins in November and concludes in PMO in April/May; and (3) District Health Plan has two components: recurrent activities; and development activities.

Four questions arise:

- On what factors do the districts base their budget requests?
- On what information do the Ministries base their policy decisions?
- How efficiently and effectively does the present system work?
- What is the degree of communication at each stage to ensure that modifications to proposed priorities match available resources?

District health plans, because of severe resource constraints, are often wish lists. As little as 20–30% of requested funds may be allocated in any one year. Only a limited portion of this is available to maintain facilities or support basic health infrastructure. Gilson et al. (1994) studied decision-making in Tanzania's decentralized health structure and found wide variations among the districts they studied. There was little correlation between the amounts requested by the districts, amounts approved, and actual expenditures.

Several information sources have been postulated to account for the decisions that ministries take on health policy. These include:

- local health statistics of dubious quality;
- pressure from donors or special interest groups;
- health crises, i.e., responding only to immediate needs;
- economics, i.e., money available;
- ideology;
- status quo; and
- common sense.

It is EHIP's hypothesis that more rational and efficient decisions on health care allocations could be made on the basis of burden of disease and cost-effectiveness analyses carried out at the district level. A challenge for EHIP is to create a process to accomplish this within the current structure of the health system.

District Selection

Given the amount of donor activity in the health field, and the health sector reforms currently taking place, it would be unrealistic to expect to find a district untouched by development. Such a district would be inappropriate in any case, given that one goal of EHIP is to integrate a new approach into the planning of ongoing activities. Nonetheless, it was also felt that it would be better not to use a district where other large-scale research or intervention projects were occurring (e.g., malaria vaccine trials) because these districts would likely have an atypical health status and be subject to the impact of these other interventions.

Guidelines for selecting districts were identified during the June 1994 design meeting (see page 41). The EHIP process must, by definition, work at the district level. Testing a district-wide intervention introduces the risk that the project may become unmanageable if the district is too large. It was proposed that the ideal study population would be 150,000–200,000.

In consultation with the Tanzanians, Rufiji District (population 175,000) and Morogoro (Rural) District (population 490,000) were selected in April 1995. Morogoro (Rural) District was selected, despite its size, because baseline burden of disease data had already been collected for the previous 3 years by an ODA-supported research project (Adult Morbidity and Mortality Project - AMMP).

A country program coordinator was also identified at this time. The other districts (Mafia Island and Kisarawe) were rejected for a variety of reasons.

Coordination

In a project as complex as EHIP, one of the factors crucial to its success or failure is the level of coordination established both within the project and in relation to other programs and activities inside and outside the health care system. EHIP contains several components: burden of disease measurements, infrastructure support, delivery of a package of clinical and public health interventions, development of improved health information systems, determination of community preferences and mobilization of community involvement, and reform of the planning process. Each of these activities is a *necessary but not sufficient* determinant of the successful execution of the entire project. At the same time, each component could be regarded as a project in its own right. It will be necessary to ensure that the resources of the project are balanced between the operational imperatives of each of these components.

It has been proposed that the implementation of project activities in Tanzania will be facilitated by the creation of a national coordination mechanism. Representatives of the various agencies having a stake in EHIP activities (e.g., Ministry of Health, Ministries of Local and Regional Government, DHMT, national health research institutes, and major health donors) should work closely with the in-country Project Coordinator and be the link between the study districts and the outside participating agencies.

Because EHIP will be working within, and building upon, ongoing activities, it will be essential to liaise with ongoing programs. In Tanzania, these will include the Expanded Programme on Immunization (EPI), the Essential Drugs Programme (EDP), the Tuberculosis Programme, the AIDS Control Programme, Family Planning Programmes, and other initiatives such as the WHO/UNICEF supported initiative on the Management of the Sick Child. It will be necessary to maintain close links not only with the programs themselves, but also with their respective donors.

Coordination in the delivery of services will also be necessary to achieve cost-effectiveness. At present, because there is little coordination between programs, the potential exists for duplication of facilities, equipment, personnel, and planning processes. EHIP has the potential to rationalize some of this duplication if it succeeds in facilitating consultation between programs and agencies involved in the delivery of health services at the district level.

EHIP is not the only initiative addressing health care and delivery issues. Discussions on reforms in the health and social sectors are well-advanced in Tanzania, as they are in many sub-Saharan countries. EHIP will have to coordinate, and perhaps modify, its activities in light of policy changes that may occur during the life of the project. The project may be both a contributor to, and a beneficiary of, the reform process, but close monitoring of developments will be essential.

Project Considerations

Research Needs and Sustainable Service Delivery

The balance between the research needs of the project and the provision of sustainable service delivery is a recurring theme in the EHIP planning process. It is highlighted most acutely in discussions surrounding the burden of disease measurements.

A reasonable picture of mortality statistics could be developed through demographic surveillance and verbal autopsies on deaths. One suggestion was that expensive accuracy of diagnosis of morbid conditions should be sacrificed in favour of a more general picture of burden of morbidity. For example, questions about symptomatology such as urethritis, dysuria, or genital ulcers would serve as a measurement of STD prevalence, and no attempt would be made to differentiate between syphilis, gonorrhoea, and chlamydia. This may work in practice for some conditions, but in the case of STDs it begs the question of diagnosis in women, in whom most STDs are largely asymptomatic.

Another suggestion was that morbidity surveys should only be done on those conditions that are of high prevalence but do not usually result in death (such as STDs or helminth infections), and that have a long "lag-time" between disease and pathology (such as Hepatitis B or tobacco-associated conditions).

Yet another suggestion was that burden of disease measurements need not be done as a special survey, but could be taken from the clinical records of dispensaries, health centres, hospitals, and first-aid posts. These would be supplemented by household surveys to confirm the health facility data and monitor events for which care-seeking did not occur. This suggestion is premised on the assumption that accurate diagnosis and record-keeping now exist at the health facility level, which is not the case. If population-based surveys are done well, they will provide a much more accurate reflection of the morbidity burden than facility-based data.

Efforts are underway in a few districts in Tanzania to strengthen the health management information system through a DANIDA-funded project. It is hoped that the EHIP study districts will become part of this process. However, it is not clear whether this system will be in operation in the study districts by the time of the baseline study.

Many of the logistical problems of measuring burden of disease at the field level remain to be solved. One of the tasks of future planning workshops in Tanzania will be to address these issues, examine alternative approaches, and define the minimum amount of data-gathering needed to meet the needs of the project, both in terms of planning and of impact assessment.

There are at least six strongly interlinked components to EHIP:

- estimates of burden of disease and cost-effectiveness;
- training and motivation of DHMTs to incorporate burden of disease, cost-effectiveness, and community preferences into their planning and priority setting;
- strengthening skills of district health personnel and rehabilitating infrastructure;
- service and delivery of a package of "essential" interventions;
- research; and
- sustainable capacity-building.

The approach to defining the scope of the project has emphasized that these components are not independent elements. The project objectives do not provide for an artificial split between these components. As a result, the project design will accommodate all six elements in an integrated manner.

Burden of Disease Measurements

The issue of burden of disease and cost-effectiveness measurements is integral to the development of the district health plan, but is an area that has created much discussion. Burden of disease was defined by Musgrove (1994) as

> the total amount of healthy life lost, to all causes, whether from premature mortality or from some degree of disability over some period of time. These disabilities can be physical or mental. A given disease, deficiency, or trauma may produce more than one kind of health damage, and a given disability may arise from more than one cause. The burden of disease can in principle be attributed to distinct risk factors, each of which may contribute to the likelihood or severity of one or more diseases or conditions.

At any moment, the burden of disease in a population is a reflection of both the amount of health care already being provided and the effects of all other actions that protect or damage health. For *Investing in Health*, an attempt was made to estimate the burden of disease against a common measure, both globally and by region, and to estimate the cost-effectiveness of interventions against the various conditions that contribute to the burden.

The GBD survey conducted for *Investing in Health* attempted to move beyond traditional surveys that focused only on mortality to include conditions that lead to disability (such as residual paralysis or depression), and to quantify their effects on individuals and the health system. On the basis of the *International Classification of Diseases*, diseases were classified into 109 categories that covered most possible causes of death and disability.

Burden of disease measurements serve two purposes within the framework of EHIP:

- as a tool to assist the district in its planning process, and
- as a research tool to assess the impact of the intervention(s).

The desire to create a large database for analysis (which may not be sustainable) must be balanced with the need to develop a process of burden of disease measurement in the district that is sustainable for the ongoing district planning and evaluation cycle.

It would be impossible, both logistically and financially, to take measurements on all 109 diseases and conditions used by the WDR'93, even if acceptable field instruments were available. Choices must be made, perhaps based on what are assumed to be the major causes of burden of disease. A baseline study in a Tanzanian district could focus only on all-cause mortality and not attempt to quantify, for example, the degree of hearing loss, other paraesthesia, or chronic depression in the population.

Much useful information on the pitfalls and problems of measuring burden of disease will be gained by EHIP's collaboration with AMMP in Morogoro (Rural). This project has been carrying out a survey of mortality among a sample of the Morogoro population (about 20,000 households; population sample of 95,000), and has made DALY[1]-like calculations on cause-specific deaths. It has also carried out similar work in two other districts in Tanzania (Hai District near Mount Kilimanjaro and a part of urban Dar Es Salaam).

Over thirty different categories of causes of death have been identified. The annual DALYs lost per 1000 range from a high of 100.8 for *acute febrile illness* and 30.4 for *HIV with or without TB*, to less than 1 for *acute abdominal pain, diabetes*, and *urine retention* (AMMP 1995). Of interest is the fact that in Morogoro (Rural) District, almost one-third of all-age mortality is due to the first condition (acute febrile illness), and that over 80% of the deaths can be attributed to the first ten conditions listed. The implications of this finding for planning an appropriate package of essential interventions are evident.

Unfortunately, the AMMP has been measuring only mortality. Despite the fact that in sub-Saharan Africa it is estimated that death-related events comprise at least two-thirds of the total burden of disease in the population (World Bank 1993, p. 3), it is still essential to measure morbidity-related conditions. The AMMP has recently begun to conduct measurements of the morbidity load in their study populations. It is hoped that EHIP will be able to collaborate with AMMP in burden of disease measurements, to benefit from their experiences, and to use the instruments they have developed.

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[1] The DALY, which is "an indicator of the time lived with a disability and the time lost due to premature mortality" (Murray 1994) is used to measure both the burden of disease and the effectiveness of health interventions, as indicated by reductions in disease burden. The DALY is a universal measure that can be used to make comparisons between and among different populations. A full discussion of the detailed calculations and rationale behind the GBD survey and DALYs are beyond the scope of this paper. They are explained in detail in the WDR'93 (pp. 26–27 and 213–225). As well, a series of articles by Murray, Murray and Lopez, and Murray, Lopez, and Jamison on the technical details of the GBD survey and DALY calculations, which appeared in the *Bulletin of the World Health Organization* 72, 429–509, have now been collected with additional data in *Global Comparative Assessments in the Health Sector: Disease Burden, Expenditures and Intervention Packages* (Murray and Lopez 1994).

It is difficult to conduct morbidity surveys. Ideally, one would like to be able to diagnose conditions on the basis of (in ascending order of complexity and expense) a sensitive and specific questionnaire, a rapid noninvasive physical examination, or a simple laboratory test appropriate for use at field level. However, sensitive and specific questionnaires do not exist for many conditions, physical examinations are time-consuming and require more highly trained field workers, and the laboratories in the health centres and district hospitals would have to be upgraded before even the simplest diagnostic procedures could be envisaged.

It might be argued that for research purposes and for the duration of the project, it would be advisable to provide the means by which accurate diagnoses could be made (e.g., special field diagnostic equipment, mobile laboratories, and extra trained personnel). However appealing this might be from the research point of view, it runs counter to the underlying nature of EHIP, in which issues of linking into existing structures and sustainability take precedence. Obviously, a certain amount of strengthening of district-level infrastructure and facilities will be required. This should be kept to a minimum, however, if the project is to be successful in creating a strategy and *modus operandi* for monitoring burden of disease and health planning that will be sustainable, cost-effective, and replicable in other districts.

Measuring Changes in Burden of Disease

Measuring burden of disease is difficult. For most developing countries, accurate statistics, including prevalence and incidence figures, are either not available or are unreliable extrapolations of small data sets.

The problems of collecting baseline and follow-up data, how much of it to collect, and the setting up of a health information system that will serve the ongoing needs of the health system as well as that of the project are issues that need to be addressed during the development of the detailed protocol.

The use of changes in burden of disease as the sole indicator of the effectiveness of an intervention can present some difficulties, as the effects of an intervention on health status and illness are multidimensional (they involve, for example, physical pain and impairment, mental state, and mortality). As well, *health status* is an nonfixed, value-laden concept. In theory, some of these factors are captured by the DALY measurement, but this depends on the accuracy of the data-gathering instrument.

Calculating DALYs

A DALY is defined in the WDR'93 as

> a unit used for measuring both the...burden of disease and the effectiveness of health interventions, as indicated by reductions in disease burden. It is calculated as the present value of the future years of disability-free life that are lost as the result of the

> premature deaths or cases of disability occurring in a particular year (World Bank 1993).
>
> The fundamental problem with DALYs as with all such measures of health status is in getting the appropriate weights for mortality and for all the possible forms of morbidity. Questions here relate to whom to ask to do the valuing; how one (year of) life is to be compared to another - normally assumed to be the same; how to allow for uncertainty; and many other issues, including whether the only output of health services is improved health status.
>
> The development of DALYs is difficult. However it is done, attaching weights to different morbidity states in relation to death, so that, ideally, mortality and all forms of morbidity can be placed on a single index, involves value judgements (Mooney and Creese 1993, pp. 734-735).

These quotations summarize a lengthy debate about DALYs, indeed about all attempts to create indices of health. A major issue in planning the research agenda for EHIP will be the relevance and degree of detail that can be expected for the indices used for burden of disease, cost-effectiveness, and subsequent DALY calculations. Issues such as the following three will have to be considered.

Discount Rates

Because "a healthy day of life in the present has a greater intrinsic value to the individual than a day in the future" (Barnum 1987), future benefits and costs of an intervention are discounted in the calculation. This results in a weighting over time that gives more weight to current effects, less weight to those effects in the near future, and still less weight to effects in the distant future. However, there is no standard of what discount rate should be used, and rates anywhere between 3% and 10% have been applied.

Life Expectancy

The WDR'93 used a life-table model equivalent to the life expectancy of a Japanese female (the longest in the world) as the standard with which to calculate DALYs. Is this appropriate for EHIP? Should an African "estimate" be used? A regional estimate? An estimate for Tanzania?

Age-weighting

In the DALY calculation, life-years lost to death or disability are age-weighted against "productive" years. However, decisions about productive years are to a certain extent value-laden, and most certainly culturally determined. Are years of "motherhood" to be considered more productive than years of "grandmotherhood"? What about the situation in much of the developing world, where children begin to work and be "productive" at an earlier age?

For the purposes of the WDR'93, the GBD survey assigned values to these and other indices. These values were largely based on incomplete data or "best judgement" approximations by

experts. The GBD made global estimates, and its comparisons between regions can be regarded only as rough estimates. Little work has been done on making accurate DALY calculations at the district level, and to a certain extent EHIP will be creating this methodology (see Cowley et al. 1994).

It should be reemphasized that

> choices of age distinctions and discount rates express people's feelings about the value of life in youth and age and in the future versus today: they are ethical judgements. There are no objectively correct answers to these questions, and simply treating all ages and all future years equally also constitutes a subjective choice. The subjective choices determine the number of DALYs associated with a given pattern of death and disease, so the expenditure that appears justified to gain one DALY also depends on these choices (Musgrove 1994).

Essential Packages

The effectiveness of an intervention is measured by the reduction in disease burden it produces. An intervention can reduce the burden for several reasons: because the disease or condition is made less probable, less severe, of shorter duration, or less likely to result in death. Because both costs and results depend on the particular setting in which a health system operates (including the burden of disease the system confronts), no universally appropriate package of interventions exists. However, the WDR'93 postulates that "for any country, an essential package can be defined on the basis of detailed epidemiological, clinical and financial information, and that the definition of such a package should form part of any thorough-going systemic reform" (Mosgrove 1994).

Effectiveness and disease burden can both be measured in DALYs; therefore, they can be compared across interventions which treat different problems and produce different outcomes. The ratio of cost to health gain is the cost-effectiveness of the intervention, expressed as dollars per DALY.

Investing in Health, in proposing the delivery of a package of essential public health and clinical services which must be ensured by governments, used the results of the GBD survey and subsequent DALY calculations to identify the interventions in the package and to justify them on cost-effectiveness grounds. That is, cost-effectiveness was seen as the principle criterion for the allocation of resources.

A number of implications arise from this approach. First, anything that is not part of the essential package could be viewed as either discretionary or not in the purview of the public sector. Where the line is drawn between essential and discretionary services would depend on a country's epidemiological situation and on the government's willingness and ability to pay for health care. Second, it must be recognized that most interventions will reduce, but not totally eliminate (either through incomplete coverage or the nature of the disease or intervention), the disease or condition in question. This complicates burden of disease and cost calculations. Third, if two interventions are equally cost-effective but one deals with a

larger disease burden, it should have priority because it will reduce the number of interventions necessary in the essential package and increase the capacity of the health system to deliver the package (also see WHO 1993; Bobadilla and Cowley 1995).

Cost-Effectiveness Analysis

The WDR'93 (World Bank 1993, pp. 59–60) defines cost-effectiveness in health care as the net gain in health or reduction in disease burden from a health intervention in relation to the cost (measured in dollars per DALY). This implies that several types of information related to costs, the burden of disease, and the changes as a result of the intervention are available.

Costs

Several types of cost must be considered when estimating the total resources needed to carry out an intervention (Mooney and Creese 1993). These include:

- fixed costs, e.g., infrastructure, salaries, and transport;
- opportunity costs, i.e., the benefits foregone in the best alternative use of resources.
- marginal costs, i.e., the cost of the change being considered;
- other costs that fall not necessarily on the health system but on relatives, family, and the private sector; and
- transfer payments, i.e., sickness benefits or other payments paid by one section of the community to the other.

Some of these costs are difficult to calculate with any degree of accuracy even in a developed country. One of the problems for EHIP will be to allocate fixed costs across interventions, given that no such system for doing this currently exists. Neither is there a system for measuring variable costs, which depend on coverage levels; that is, the costs for an intervention change per unit of output (for example, the cost per child vaccinated is different depending on whether 100, 1,000, or 10,000 children are vaccinated).

There is a paucity of data for measuring these costs. In practice, one may be forced to use crude "guesstimates" based on average costings or marginal-cost estimates by local officials on what added resources would be needed to initiate or top-up an intervention. This provides another example of project research needs requiring more accurate data. A methodology must be developed to arrive at more accurate cost estimates.

Measuring Effectiveness

The effectiveness of an intervention depends on a variety of factors, including diagnostic accuracy, efficiency of the system, provider compliance, patient compliance, efficacy, and timeliness of the patient's visit. Each of these will be difficult to measure accurately.

Many interventions are based on a treatment protocol, but in real-life situations health care workers may not follow the protocol (because of time factors or difficulty of the protocol) and may not note this in the medical record. This makes it difficult to estimate both costs and effectiveness. As well, it emphasizes the need for proper record keeping.

Indicators, Outputs, and Outcomes

For all the potential outcome variables, a key question will be whether it is reasonable to expect that there will be a measurable impact on that outcome within the time frame of the project. If not, then low priority should be given to measuring that particular outcome. The issue will particularly affect health status outcomes. Not only will these often require substantial efforts in data collection, but there may well be a time delay between the initiation of an intervention and the impact of that intervention on health status (however, this could be circumvented by the measurement of other process indicators, such as seroconversion of Hepatitis B markers rather than disease).

This could mean that the overall impact of the interventions will be greatly underestimated by a short-term project such as EHIP. Therefore, a prerequisite for any outcome variable to be selected should be the possibility that it will change measurably within the time frame of the project. Perhaps the overall burden of disease will not change. Therefore, it may be better to focus the assessment on variables that are likely to be changed substantially within a short time by the specific interventions.

This argument suggests a focus on mortality indicators rather than morbidity when looking at changes in the burden of disease and health status. Mortality may contribute to over 80% of the DALYs lost in sub-Saharan Africa. A relatively simple demographic surveillance system, which includes verbal autopsies to determine the major causes of mortality, may provide enough information to detect changes in the burden of disease over the life of the project.

Even this will require extensive local development or modification of verbal autopsy questionnaires and close collaboration with the DHMT to improve the health information and record-keeping system. The combination of monitoring all-cause mortality, plus a few indicators of selected morbidity (such as new cases of tuberculosis or number of STD diagnoses), would provide a relatively accurate and comprehensive picture of the majority of the factors contributing to the total burden of disease. It is hoped that it would also be able to detect measurable changes.

However, a lengthy discussion of indicators and outcomes related to burden of disease diverts us from the essential aspect of EHIP – that the "intervention" under study is not the essential package of clinical and public health interventions, but the changes in the planning and resource-allocation process. For the measurement and evaluation of the processes involved (for example, the development of the district health plan, the delivery of the package within the district health program, quality and coverage, and feedback into the system) the 3- to 4-year life of the project should be sufficient to detect changes and evaluate their effect.

The project must emphasize the measurement of the effects of the project on inputs (e.g., cash), processes (planning processes and management systems), outputs (interventions done and their quality), and outcomes (use, coverage, and quality), as well as try to measure changes in health status. In essence, a protocol for operational research will be needed to

understand the factors that facilitate or constrain the use for planning of the information generated through project activities.

Many indicators could be used to monitor and evaluate the changes in the planning process, the allocation of resources, and the use and coverage of specific interventions. To a certain extent, some of the outcomes of EHIP will also have to be determined on the basis of factors that may not be as amenable to quantitative analysis.

- Do the DHMTs themselves note any changes for the better or worse? If so, what are they?
- Does the new system of planning and allocation "feel" better or worse? If so, why?
- Does it make the work of district health care delivery any easier or more difficult? If so, how?
- Does it facilitate planning discussions at the dispensary, health centre, or district level, or planning and resource-allocation negotiations with the region?

It will not be easy for the project to balance the research aspects of the project with the service requirements within the districts. Because the potential for interesting data collection within this project is almost unlimited, it would be possible for data collection to swamp other project activities and result in little actual change in the provision of health services.

Core Indicators

WHO, in cooperation with IDRC, convened a meeting at its Headquarters in Geneva in October 1994 to examine the potential indicators that could be used in EHIP. Attended by a large group of international experts, WHO staff from both the Geneva and Africa offices, representatives from Tanzania, and several observers from both other African countries and other donor agencies, the meeting attempted to list and describe the various indicators that could be used to:

- measure the burden of disease in the study districts,
- determine the effectiveness of the technical interventions,
- assess and evaluate the planning and management process,
- quantify the social and contextual variables, and
- evaluate the overall project.

This meeting confirmed that the challenge of EHIP would be enormous. For example, for many diseases and conditions, there are very few diagnostic "instruments" that are of a high enough sensitivity and specificity to be used to measure the burden of disease in population surveys. Measurements of cause of death through verbal autopsies are subject to wide variation because of difficulties in standardizing and validating. Non-laboratory diagnosis of disabilities and chronic conditions suffer from similar problems.

Long lists of possible indicators and indications of their likely feasibility and validity were produced. The task remains to identify core indicators, use proxy measurements, and prioritize sets of indicators. Because it is a demonstration project, the inputs, processes,

outputs, and outcomes must all be carefully identified and monitored. While EHIP will attempt to evaluate itself in terms of all these levels, key indicators must still be selected to cover the various components and steps in the planning process.

Selection of Interventions

Investing in Health suggested that a package of about twelve public health and clinical interventions could reduce the burden of disease by up to 32% in low-income countries. The report also states that not all these interventions need necessarily be applied.

The choice of interventions should be based on the use of local burden of disease data and cost-effectiveness calculations, and would, necessarily, be modified by local community priorities. Although the need for community input is not referred to in *Investing in Health*, the analytic approach to planning that it proposes will need to accommodate community perceptions and preferences for health services if the project is to gain local acceptance.

The concept of spreadsheets for potential interventions has been proposed to capture basic data such as current coverage, current burden of disease, target coverage, proposed changes from current practice, infrastructure implications, unit recurrent costs, annual recurrent costs of the intervention, and targeted reduction in disease burden from that intervention.

Some critics of WDR'93 question the unrealistic expectations and high cost of introducing twelve interventions. In reality, some (if not most) of these interventions may already be ongoing successfully at the district level (for example, childhood immunizations and family planning services).

One of the challenges facing EHIP is to integrate these programs into the planning cycle more efficiently, supplement existing cost-effective interventions, and only introduce new cost-effective interventions that are indicated by the burden of disease baseline data. However, to carry out burden of disease and cost-effectiveness analysis, a minimum of five or six interventions would be necessary to test the premise proposed in WDR'93. All decisions on which interventions should be included should rest with the DHMTs.

Planning the Design

The Ideal Design

The ideal intervention study is one in which several factors are optimally realized (Rothman 1986, Smith and Morrow 1991):

- a discrete intervention, with measurable outputs;
- the presence of a control population;
- random allocation of study subjects into intervention and control groups;
- an appropriate design and sample size, such that validity and precision of the results will be obtained (high power, narrow confidence intervals); and
- control for confounders and effect modifiers either in the design or in the analysis.

This ideal is best realized in a randomized controlled trial (RCT) in which study subjects are randomly allocated either to the intervention or control groups (which receive a placebo or alternative intervention). Neither the study subjects nor the investigators are aware of the allocation until the results have been analyzed (double-blind trial). This type of trial is extremely expensive, and for a variety of technical and ethical reasons cannot usually be achieved in community intervention trials.

Developing country governments are rightly suspicious of any kind of "development experiments," especially those that seem to have no purpose other than to collect data and have no interventions planned that might benefit the population. There would probably be political repercussions in the control districts in which burden of disease measurements are made but where there are no demonstrable changes in planning or services.

Before-and-After Design

At the other end of the spectrum is a before-and-after design. In this case, only a few districts are studied, and in each district, the study would include three phases:

- a baseline study to determine existing levels of service, modes of delivery, and burden of disease;
- the intervention, i.e., a burden of disease planning approach with or without additional resources;
- monitoring of the change in burden of disease over time (3–5 years).

This before-and-after design can accommodate certain comparisons, such as using different planning approaches in two different districts. The advantages of this approach are that it is less expensive and will produce results that can be used to draw inferences of plausibility that are of value to planners and policymakers.

Because of a variety of financial, logistical, and practical factors, the EHIP project planners are leaning toward this before-and-after demonstration model, which has been a standard approach in development projects.

Comparison Design

The quality and breadth of the baseline surveys, and the process measurements and their integration into the planning process, could make EHIP unique. Nevertheless, the EHIP planners realize that EHIP should collect and present findings and results that are as scientifically valid as possible.

EHIP could make use of other research and data surveillance in Tanzania. This would provide data on trends in health status in districts not included in EHIP. These trends could be compared with the trends in the EHIP intervention districts. However, it would not be possible to determine if the hoped-for impacts in the study districts were primarily due to increased funding, planning, or the process of being observed (Hawthorne Effect).

A Stepped-Wedge Design

Another option is to use a stepped-wedge design to implement the interventions (Smith and Morrow 1991, pp. 26–27). Under this design, the interventions would be introduced in some areas first, and then sequentially introduced into other parts of the district over the life of the project. Areas that had not yet had the intervention would act as controls for the intervention areas. However, this approach does not lend itself to the project's objective. The objective is not to test the effectiveness of a variety of clinical and public health interventions, but rather to examine the utility of using a certain planning process in the delivery of a package of interventions. The stepped-wedge design would not help assess the value or cost-effectiveness of the integrated planning approach because the lowest level of governmental planning and administration is the district. It could only be of use if several districts (at least five to ten) were included in the project design.

It is assumed that the efficient delivery of a package of clinical and public health interventions will change the burden of disease. For example, if the project can demonstrate that good-quality, short-course, multi-drug therapy for tuberculosis (TB) has been given to a high proportion of people with TB in the district, and that TB was a major contributor to the burden of disease in the district, then a substantial health impact can be assumed. It may even be possible, using existing data from other studies, to estimate the impact. The project is, by definition, selecting interventions that are already known to be effective if they are applied correctly and with sufficient coverage. Where this is the case (other examples would include measles vaccination and vitamin-A supplementation), the project will not have to prove the effectiveness of the interventions yet again.

However, the effectiveness of other interventions has not been well proven, such as prevention of HIV in rural Africa through health education and the promotion of condoms among commercial sex workers. Although researchers may want to place more effort on evaluating the health impact of interventions such as these, the project design (the packaged approach and lack of comparison nonintervention districts) will not lend itself to this type of evaluation.

What is being tested is a process of planning that uses measurements of burden of disease and cost-effectiveness analysis as criteria for setting priorities for resource allocation. That is, the EHIP intervention is as much the new approach to the planning process as it is the "package of interventions." Therefore, a study design that does not meet the ideal randomized controlled trial is justified.

Design Meetings

A group of more than twenty international health experts met in Ottawa in late June 1994 to address the design issues of EHIP. The discussion was centred on generic issues and hypothetical situations, but the focus was on sub-Saharan Africa. One outcome of this meeting was a number of recommendations, assumptions, and suggested criteria to guide the planning process.

- The unit of study (intervention) would be the lowest administrative level with responsibility for planning and resource allocation, i.e., the district;
- Resources provided for EHIP-related interventions would supplement the existing level of health services funding.
- The planning of new or intensified interventions would require either the reallocation of existing resources or the allocation of additional resources.
- At the district level, the selection of interventions would not be based on the prescribed global list in *Investing in Health*, but on the principle by which that global list was derived (i.e., burden of disease and cost-effectiveness analysis).
- Monitoring could have a modifying effect on both the study and comparison districts (Hawthorne Effect).
- The delivery of interventions in a coordinated manner will improve the *technical efficiency* of the interventions.
- The project will build and strengthen capacity for health impact monitoring systems.
- The largest component of the burden of disease in sub-Saharan Africa is contributed by premature mortality in childhood; therefore, a reduction in burden of disease would be most evident from measures of mortality rather than disability.

This consultation also formulated guidelines for the selection of districts. The districts:

- should have a district health management team (DHMT) in place. (All EHIP interventions should be planned within district and regional planning cycles, and any reallocations of existing resources should be carried out by the DHMT as part of district-level project planning);
- should have facilities for first-level contacts and have a referral capacity to facilities with in-patient services;
- must have the capacity to absorb an increased level of intervention services;
- must have an existing health monitoring capacity or the capacity and willingness to develop, strengthen, and maintain such a system; and
- should not be a district that is on the extreme of an epidemic or contains a large, displaced population.

This consultation began to examine the methodologies that might be used in the EHIP initiative. It examined the advantages and disadvantages of various options for district selection and allocation; the choice of control or comparison districts; the sources of information and other measurement processes for burden of disease, inputs, outputs, processes, and coverage; and a preliminary list of the sorts of indicators of outcomes, process, and management that would have to be defined. However, it recognized that the actual intervention in EHIP would be the *changed planning process* at the district level as much as the delivery of the package of *interventions*. Finally, the consultation made a first attempt to specify the key hypotheses, research questions, and objectives of EHIP, and recommended the next steps in the project development process.

A second meeting was held in February 1995 to examine the basic hypotheses and objectives of the project, the financial realities facing the proposed activities, the time frame in which activities could be undertaken, and the next steps in project development.

This meeting reaffirmed that EHIP was about testing a process of planning that used burden of disease and cost-effectiveness measurements to make choices about resource allocation. The capacity of the districts to absorb additional funding in order to increase service levels was also introduced as a factor to be considered in the district planning process. It was agreed that such activities as measuring the burden of disease, undertaking a series of interventions, measuring the change in burden of disease, and evaluating all steps in the cycle were the indicators that would be used to reflect changes in the planning process.

The three key research questions for EHIP, which were initially defined in June 1994, were then restated.

- In the context of decentralization, how and to what extent can DHMTs establish priorities and plan the allocation of resources according to local estimates of burden of disease and knowledge of the cost-effectiveness of relevant interventions?
- How and to what extent can these district health plans be translated into the delivery and use of the essential health interventions?
- How, to what extent, and at what cost does this have an impact on burden of disease?

The time frame of project activities can be related to answering these three questions. Over the course of the project (which may be as long as 5–7 years) the focus will be on clearly defining the problems to be addressed, collecting baseline information, establishing specific objectives and targets, developing process evaluations and measurements, and measuring impact. In practice, the steps in the process will probably not be sequential because baseline measurements will be needed for all indicators in both the process and impact evaluations.

It is important to note that budgetary concerns will place constraints on project design. With a minimal topping-up of the per capita health care allocation and a minimal package of interventions, EHIP would still not have enough funds to carry out all hoped-for service delivery and research activities. Rather than sacrifice vital public health and clinical interventions, it was agreed that the number of districts be limited.

A variety of other issues and suggestions were also noted at this time.

- Mechanisms must be negotiated to ensure that existing funding levels from non-EHIP sources are maintained in the participating districts.
- Before work begins, sociocultural information should be collected as part of the situational analysis using a combination of existing and new data.
- Secondary data should be assembled and baseline data should be collected from November 1995 (or earlier) to July 1996 to cover a range of topics such as mortality, utilization of services, and private spending.
- Good pre-intervention data must be obtained for Rufiji. Estimates may be good enough for the initial planning process, but will not be sufficient for the burden of disease estimates that are needed as baseline data for the subsequent evaluation of health impact. Accurate baseline data are equally important for the evaluation of costs, inputs, processes, outputs, outcomes, coverage, and quality.
- As existing AMMP data are available, Morogoro (Rural) has substantial baseline data on burden of disease.

Ethical Considerations

Any intervention research project that involves individuals or groups of individuals (i.e., communities) as study subjects must address a set of ethical issues related to informed consent of study subjects, the use of a control group, withholding or dispensing treatment to those found suffering from the condition being studied, and publicizing the results of the study to research subjects. EHIP, because of its broad mandate to work simultaneously at both the district level (planning) and in the community (delivery of interventions and burden of disease measurements) must address these issues, as well as several factors that, while considered political, also have ethical overtones.

These problems are associated with the use of a district as a control group. In addition, many populations of developing countries, even those in *isolated* rural areas, are very well aware of development activities in their own and neighbouring regions. Therefore, it would be very difficult to find a control population that would be amenable to being subjects of an intensive survey if they knew that their compatriots in another district were also being surveyed, but were receiving the putative benefits of an intervention.

As with any data-collection exercise at the individual level, the project will seek informed consent of its study subjects, assure the confidentiality of responses, and provide similar benefits (e.g., treatment) whether the subjects agree to participate or not. Similarly, during the burden of disease surveys that may be carried out at the community level, provision can be made to direct those found suffering from treatable conditions to the nearest appropriate health facility for treatment and care. However, the critical issue of access to transportation for patients who are referred to other facilities will need to be addressed.

The implication of the WDR'93 is that less cost-effective interventions will no longer be publicly financed. The WDR'93 proposes that these services will become *discretionary*, that is, physicians will be able to offer these services privately. Micromanagement of physicians is not part of the WDR'93 thesis, but it assumes that there is a cadre of physicians who are available to provide private services not covered by the essential package. This issue is a policy consideration that the Government of Tanzania will be addressing as part of its proposed health sector reform.

The premise of the WDR'93 revolves around not only cost-effectiveness but also the issue of equity in the provision of health care. "It is important to recognize that equity and efficiency goals can sometimes conflict. Such a conflict may mean that minimizing the burden of illness is not the goal or at least that such a goal is constrained by concerns for equity" (Mooney and Creese 1993, p 736). For example, the effect of an intervention may be the same for two people, but it may cost much more to treat one of them, perhaps because of the difficulty of

delivering services in remote or underpopulated areas. A perfectly efficient solution might exclude the hard-to-reach, and would therefore be inequitable. "Each society or health care system must choose between equity and efficiency in these circumstances, and there is no clearly correct answer" (Musgrove 1994).

Evaluation

There is also the question of project monitoring and evaluation by the partner organizations. The process of project development and collaboration that has taken place among IDRC, The World Bank, WHO, and the Government of Tanzania is unique. Whether or not EHIP is the harbinger of a "better model" of development initiative should be of interest to the participating agencies. The factors that will be used to assess whether EHIP will be considered a successful collaboration have yet to be determined.

Conclusion

EHIP has the potential to test and demonstrate the effectiveness of a coordinated and rational approach to district-level health planning and service delivery. It will do so based on the measurement and use of burden of disease and cost-effectiveness indicators, and it will elucidate the factors that either facilitate or mitigate this approach. In theory, this should result in more efficient planning and allocation of resources. EHIP could be modified and replicated in other developing countries with the ultimate outcome being sustainable improvement in the health status of populations. However, the complexity of this undertaking should be apparent. This discussion paper has only touched on some of the major issues, but the difficulties pose a formidable challenge:

- simultaneously setting up a workable health information system,
- conducting accurate burden of disease measurements and cost-effectiveness calculations in a field situation,
- incorporating this information into the planning process,
- strengthening a weak infrastructure,
- delivering a coordinated package of interventions, and
- monitoring the entire process.

Carrying out these activities within the constraints of a limited budget and ensuring that what is instituted is sustainable past the life of the project adds further to the complexity of the task.

There are some questions that EHIP will not be able to answer. It will not provide details on the full spectrum of the disease burden in the study districts. Because of its focus on planning and priority setting at the district level, it may not answer all questions related to user satisfaction or detect changes at the individual or community level. Integration of the private or alternative sector may not be an important issue in the Tanzanian study districts, but may need to be addressed elsewhere. Even if EHIP "works" in the study districts, there is no guarantee that it will work in another country, or even elsewhere in Tanzania.

However, EHIP is not about finding a *formula* for efficient health care planning and resource allocation that can be universally applied. EHIP is about testing certain principles of *process* - which, if found workable, could very well have applications in a variety of developing (and developed) country situations. The opportunity to test one of the central premises of the WDR'93 is unprecedented. However, it is crucial that projects such as EHIP be carried out through a process as well-designed and carefully considered as is possible. The process of defining the scope of EHIP followed a series of consultations and discussions wherein issues

and problems of design, methodology, evaluation and process have been identified, itemized and analyzed. This process will continue for the duration of the project and beyond, and this paper should be regarded as a "state of the discussions to date" document. Hopefully, it will act as a stimulus to further discussion, with the end result being a project that will answer its core questions to the satisfaction of health planners, donors, the Tanzanian officials (both national and district level) and the development research community.

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