

**REDUCING THE THREAT OF INFECTIOUS DISEASES OF
MAJOR PUBLIC HEALTH IMPORTANCE:
USAID's Initiative
to Prevent and Control Infectious Diseases**

I. INTRODUCTION

Over the past half century, many in the U.S. have come to think that the threats posed by infectious diseases were a thing of the past. Advances in the development and use of vaccines to prevent childhood illnesses, in drugs to treat disease, and in improved sanitation have eased the burden of infectious disease. During these five decades, worldwide infant mortality was reduced by half. Virtually all these gains were achieved through decreasing deaths due to infections. Epidemics caused by plague, cholera, and influenza were largely brought under control, and smallpox was eradicated.

However, over the past decade we have been forcefully reminded that the threat posed by infectious diseases to the security and well being of the global community, developing and developed countries alike, is very real. We have witnessed the re-emergence of diseases previously thought to be largely under control, such as malaria and tuberculosis, and the emergence of newly identified infectious diseases as well as drug-resistant strains of widespread infectious diseases. The root causes of this public health threat include environmental changes due to urbanization and deforestation, rapid population growth, migrations of populations due to conflict and political transition, as well as the adaptation of the microbes themselves in response to pressures we have put on them with modern antibiotics. Moreover, recurring outbreaks of vaccine-preventable diseases such as diphtheria and measles in areas where they had been controlled signal the fragility and breakdown of public health infrastructures that are already strained and weak in many countries. These problems are amplified in many places by malnutrition, lack of clean water, inadequate sanitation, and overcrowding.

The capacity of all nations to recognize, prevent, and respond to the threat of emerging and re-emerging infectious diseases is the critical foundation for an effective global response. **Broadly effective and on-going disease control will only be possible when trained local staff have the basic tools to control disease on a routine basis.** Organizations such as the World Health Organization (WHO), the Pan American Health Organization (PAHO), the U.S. Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), UNICEF, the Department of Defense (DOD), and non-governmental organizations (NGOs) and private voluntary organizations (PVOs) have been engaged in the effort to prevent and control infectious diseases for many years. The work of these and other organizations range from building human and laboratory capacity to diagnose, monitor, and respond to infectious diseases, to strengthening public health systems with an emphasis on prevention and control, to emergency response in the face of disease outbreaks. Epidemiological surveillance and training, specific disease control efforts, basic and applied research, and support for on-going immunization programs are among the contributions made by these institutions.

The U.S. Agency for International Development's (USAID) strategy to address the threat of infectious diseases in a cost-effective and sustainable manner is built upon a clear development principle: we will work with our partners to prevent disease while at the same time utilizing and strengthening existing health systems for prevention, treatment and control programs. Waiting for an outbreak and employing massive external resources for containment will be our last resort rather than our first line of defense.

For decades, USAID has been engaged in the control and prevention of infectious diseases as part of our long standing efforts in child survival, maternal health and HIV/AIDS. USAID has been a leader in developing and implementing programs to address acute respiratory infections and diarrheal diseases in children, and has supported the development and delivery of integrated packages of interventions to address the main killers of children, which are carried out through our current programs. USAID continues to work with partners such as WHO, UNICEF and Rotary International to eradicate polio, and also supports the building of in-country capacity to undertake routine immunization programs. USAID is the world's largest single donor supporting activities in developing countries for the control and prevention of HIV/AIDS and other sexually transmitted infections (STIs). USAID's activities in infectious diseases have emphasized capacity building and systems strengthening in developing and transition countries; these are critical efforts ensuring long-term effectiveness and program sustainability. This new initiative, which will be a multi-year USAID effort, will complement on-going programs in infectious diseases by building on existing efforts and expanding into new areas.

In 1995, USAID participated in the U.S. inter-governmental examination of preparedness to prevent, control and respond to the emerging and global threat of infectious diseases under the auspices of the Committee on International Science, Engineering and Technology (CISSET) of the National Science and Technology Council. The CISSET report summarized key recommendations to be addressed at the local, national, and international levels. The resulting Presidential Decision Directive on infectious diseases of June 1996 identified USAID's role in this interagency effort. This role is to be carried out in the context of our on-going development effort to address the underlying root causes of the emergence of infectious diseases. To this end, through our overall development efforts, USAID works to improve the underlying social and economic conditions that allow infectious diseases to flourish and spread, such as poverty, malnutrition, illiteracy, lack of sanitation, overcrowding and environmental degradation. Through our health sector efforts, USAID strengthens health systems so developing and transitional countries themselves can prevent and control infectious diseases.

In 1997, Congress held a series of hearings on infectious diseases and the role of USAID. As a result of these discussions, and as an outgrowth of the CISSET process and the Presidential Decision Directive, USAID revised its overall health strategy in September 1997 to include an objective on infectious diseases, which was added to USAID's objectives aimed at improving child survival and maternal health, reducing the spread of HIV/AIDS and preventing unintended

pregnancies. This new objective complements these on-going activities, but is a focused strategic approach targeted directly at reducing the threat of infectious diseases.

II. USAID'S STRATEGY

A. USAID Strategic Objective and Expected Results

USAID's strategy is a multi-year effort to reduce the threat of infectious diseases of major public health importance by working in a manageable number of key priority areas:

1. Development and implementation of strategies and interventions to understand, contain and respond to the development and spread of **antimicrobial resistance**.
2. Sustainable reduction in incidence of **tuberculosis** among key populations in selected countries;
3. Sustainable reduction of deaths due to **malaria** and incidence of other infectious diseases of major public health importance among key populations in selected countries;
4. Improvement in the capacity of selected countries to obtain and use good quality data for **surveillance and effective response** to infectious diseases.

USAID'S STRATEGIC OBJECTIVE

Reduce the threat of infectious diseases of major public health importance.

USAID will achieve results in these four areas through:

- the provision of technical assistance to developing country partners
- applied and other relevant research in strategically critical areas; and
- building indigenous capacity to address these issues on a continuing basis

This strategy is designed as an eight - ten year effort as part of USAID's overall strategy. Progress toward the overall objective will be gauged by a reduction in the number of deaths due to infectious causes (excluding deaths due to HIV/AIDS), measured on a periodic basis. While in the early years, as USAID and its partners work to improve surveillance and data systems, these numbers may increase reflecting better data, by the end of the strategy period, we expect to see at least a 10% decline from 1997 levels.

The four components of this strategy reinforce each other in a variety of ways. Both surveillance and reduction of antimicrobial resistance are cross-cutting and important elements of all other

infectious disease efforts. In addition, several approaches are critical interventions within the four components:

- Mobilizing and participating in global partnerships, including coordinating strategies, activities and data needs with other donors;
- Improving the link between better data and action on data, including drug management;
- Improving community level interventions;
- Fostering policy dialogue to focus attention of partner governments on the continued importance of infectious disease control and prevention;
- Developing new tools, including methods to detect resistance and other diagnostics; and
- Strengthening laboratory capacity.

B. Country selection

While the description of each of the program areas below includes a wide range of potential activities, USAID will clearly not be able to support all these activities at any one time. Global strategies planned for tuberculosis and reducing antimicrobial resistance will help set priorities among the activities for these areas. Priorities will also be determined by needs and opportunities in a particular country setting, as well as the activities of other partners.

This strategy will be implemented in developing countries in Africa, Asia and the Near East (ANE), and Latin America/Caribbean (LAC) and transition countries of the Newly Independent States (NIS). Countries of focus will be selected by a combination of factors; global priority and need (i.e. 22 countries represent the biggest tuberculosis (TB) burden worldwide and USAID will focus its TB activities within a subset of those countries); severity of need within a particular country; strategic and geographic representation for pilot and research activities; activities of other partners and donors; and USAID mission capacity and opportunities.

C. Strategic choices

USAID's strategy is focused on reducing the threat of infectious diseases of major public health importance in developing countries. This strategy will not address HIV/AIDS, polio, or implementation of standard treatment of diarrheal disease and acute respiratory infections. Those issues are already addressed within USAID's HIV/AIDS and child survival programs. However, efforts under this strategy will complement those efforts by addressing antimicrobial resistance and improving surveillance capacity.

In order to ensure that USAID's efforts in infectious disease have as great an impact as possible, USAID has had to make difficult decisions regarding what will and will not be funded under this initiative. Many issues impact on the spread of infectious diseases, including population pressures, nutritional status, environment, food safety, industry and technology, and international travel and commerce. However, a functioning, effective public health system is central to the prevention and control of infectious diseases. Without appropriate interventions directed at this system, other related efforts will have at best limited impact. For that reason, at least in the early years of this strategy, USAID has chosen to focus essentially on issues related to health systems capacity.

USAID strategy is based on the recognition that maximum impact will be achieved by focusing on a few diseases which are sources of significant mortality and risk of spread, and by strengthening system-wide analytic and response capabilities. As such, the strategy focuses on two specific diseases -- tuberculosis and malaria -- which are among the top five infectious causes of mortality worldwide, (see Table 1; the other three, acute respiratory infections, diarrhea and HIV/AIDS are included in USAID's child survival and HIV/AIDS programs). Unless a specific disease is a major public health problem in a particular country, USAID will not address other categorical diseases under this strategy. In addition, issues such as water and sanitation and food-borne infections have been in general excluded from this strategy.

D. Partner consultation

In developing this strategy, USAID undertook extensive consultations with many key partners working to control and

TABLE 1

Leading causes of mortality among infectious/parasitic diseases (000)

Cause	Number of deaths (annually)
Acute respiratory infections	3,905
Tuberculosis	3,000
Diarrhea (incl. dysentery)	2,473
Malaria	1,500-2700
HIV/AIDS*	1,500-2,300
Hepatitis B	1,156
Measles	1,010
Whooping cough (pertussis)	355
Neonatal tetanus	310
Trypanosomiasis, African (sleeping sickness)	150
Dengue fever	138
Leishmaniasis (esp. kala-azar)	80
Amoebiasis	70
Hookworm diseases	65
Rabies	60
Ascariasis (roundworm)	60
Onchocerciasis (river blindness)	47
Trypanosomiasis, American (Chagas disease)	45
Meningococcal meningitis	40

Source: *The World Health Report, 1997*, WHO

* Also includes estimates from UNAIDS

mitigate infectious diseases to ensure that USAID's efforts would be complementary to the work of these other organizations and to identify areas of collaboration. By focusing on specific areas and through a concerted effort with WHO, CDC and other public and private sector partners, USAID expects to have a significant impact on control of infectious diseases, and on the long-term sustainability of these efforts.

III. USAID's COMPARATIVE ADVANTAGE

USAID has a strong field presence with on-the ground technical public health staff, and a long history of experience in developing countries. This ongoing relationship with developing country institutions and professionals, and established partnerships with other donors, assures that these activities will be carried out within the context of broader development efforts and makes it likely that they will be incorporated into the fabric of national development for lasting impact.

USAID's established partnerships and existing agreements with universities, NGOs, local government institutions, multilateral agencies and other implementing institutions with considerable experience in this area will enhance effective and timely implementation of the initiative. Decades of USAID support for a spectrum of research activities in developing countries has contributed to new knowledge that plays a critical role in today's global public health efforts; drawing on the pre-eminence of the U.S. research community, this experience will be put to use in developing long-range solutions concurrent with the efforts to address immediate problems.

IV. PROGRAM AREAS

A. ANTIMICROBIAL RESISTANCE

Over the past half century, antimicrobial therapies, especially antibiotics for bacterial diseases (e.g. pneumonia) and anti-parasitic drugs for parasitic diseases (e.g. malaria) have been important weapons against infectious microbes. However, the wide-spread, often indiscriminate use of these drugs has contributed to the emergence of drug resistant strains of infectious organisms. As a result, diseases such as pneumonia, bacterial dysentery, malaria, sexually transmitted infections, and tuberculosis, once manageable by available therapies, are becoming increasingly more difficult and costly to treat. These resistant strains move readily across national borders and many have already made substantial inroads in the U.S.

Antimicrobial resistance, while affecting nearly all global infectious diseases, raises particular concerns for current USAID health efforts, as indicated by the following:

- *Streptococcus pneumoniae*, a leading cause of bacterial pneumonia and meningitis, is now found to be resistant to penicillin (long among the preferred treatments) in 12-55% of cases;
- Shigella, a leading cause of dysentery, is showing resistance to ampicillin in 10-90% of cases and to trimethoprim/sulfamethoxazole (TMP/SMZ) in 5-95% of cases;
- Malaria is resistant to treatment with chloroquine in 30-50% of cases in many countries in sub-Saharan Africa;
- Sexually transmitted infections, notably gonorrhea, show tremendous variations in resistance to penicillin -- as high as 98% in some areas; and
- Tuberculosis is no longer susceptible to treatment with standard primary drugs in 2-49% of cases

The emergence and spread of drug resistance pose difficult challenges to planners, policy makers, and health care providers because of the complex array of contributing factors, many of which are poorly understood. The most widely recognized contributing factors are the extensive and often unwarranted use of broad-spectrum and other antimicrobial agents. Antibiotic use provides a survival advantage for resistant strains so that in a setting of extensive use, resistant organisms spread. Factors that impact on this inappropriate use and on the development of resistance include lack of access to appropriate drugs; weak regulatory authorities; inadequate national drug policies; sub-optimal curricula regarding antimicrobials in schools of pharmacy and medicine; lack of access to accurate, unbiased, up-to-date drug information; incorrect diagnosis and inappropriate prescribing practices by both public and private sector providers, including drug sellers; sub-standard pharmaceutical products; poor patient compliance with prescribed drug treatment; lack of public awareness of the consequences of inappropriate drug use; and extensive use of antibiotics and pesticides in agriculture and animal husbandry. These factors differ by pathogen or clinical problem and vary by country and region; in addition, the quality of data supporting the relative importance of each factor differs from very poor to reasonably good. Addressing these issues will require coordinated action and extensive policy dialogue at multiple levels and in a number of sectors.

Even when the biological basis for antimicrobial resistance and the importance of contributing factors are known, combating the problem poses a difficult challenge in developing countries due to limited human and institutional capacities and lack of financial resources. Effective drug treatment depends upon the capacity of national and international institutions to monitor antimicrobial resistance and susceptibility of the major human disease organisms and to respond appropriately. Detecting resistance, however, requires skilled laboratory personnel and observant clinicians as well as supplies and equipment which are often unavailable where the needs are greatest. For some drugs and micro-organisms there are no simple means to detect resistance

which correlate well with clinical outcomes. Further, although the technologies sometimes exist, the information generated may not be used for drug policy, procurement, distribution and prescribing decisions because the data is often of poor quality or simply does not reach the appropriate decision maker in a timely and usable manner. Perhaps the greatest challenge overall is effecting needed behavior changes both among providers and patients to slow inappropriate use of antimicrobials.

To date, activities to address antimicrobial resistance at the international and country level have been pursued on an ad hoc basis or within vertical disease control programs. There is a consensus that this issue requires a multi-pronged and integrated approach that includes preventing, detecting, and responding to resistance as it appears.

USAID's Strategic Approach: USAID will focus efforts on combating resistance in an integrated manner by directly addressing the major underlying causes and consequences of the emergence and spread of drug resistant diseases. As a result of these efforts, trends in antimicrobial resistance and antimicrobial use practices will be improved.

Since there is currently no global strategy for combating antimicrobial resistance, USAID has a unique opportunity to play a leadership role in the development of a comprehensive approach.

USAID will work with WHO and other partners to develop a global strategy for antimicrobial resistance. This strategy will be used to coordinate global efforts through the development of an action plan to outline priority activities and identify prospective funding and implementors. The strategy will be used as an advocacy tool at international, regional and country levels, and serve to mobilize resources to address key problem areas. This, in turn, will inform and guide more effective efforts at the national and regional levels.

USAID will give special attention to diseases for which antimicrobial resistance poses a major threat in developing and transitional countries because of high mortality and incidence, and for which antimicrobial treatment is currently, and in the near future, the most effective control strategy. These diseases include bacterial pneumonia, meningitis, diarrhea (dysentery) and gonorrhea. Other diarrheal disease pathogens such as salmonella and nosocomial infections will

EXPECTED RESULTS:	ANTIMICROBIAL RESISTANCE
1. Development of a global strategy and action plan for antimicrobial resistance and funding for implementation of activities leveraged.	
2. Improved understanding of antimicrobial resistance -- including epidemiology, public health impact, and contributing risk factors -- and information disseminated.	
3. Development and evaluation of methods to detect resistance to antimicrobial drugs used to treat pneumonia, meningitis, diarrhea, and gonorrhea.	
4. Enhanced capacity to use antimicrobial-resistance epidemiology and drug-use related data to inform decision making and design interventions.	
5. Improved assessment methodologies, therapies, behavior change strategies, management practices, and policies and regulations supporting appropriate antimicrobial drug use, developed, implemented, evaluated and information disseminated.	

be addressed as secondary priorities in areas where those diseases constitute an important public health threat. As part of focused efforts in addressing tuberculosis and malaria (see sections IV B and C), trends in drug resistance of these two diseases will also be monitored and appropriate responses identified. The efforts outlined above will directly support and complement ongoing USAID programs in child survival, HIV/AIDS and reproductive health.

At the global level, USAID's resources will be used to leverage the efforts of multilateral and domestic partners in areas such as applied research with global implications for the development of standards and norms; multi-country operations research which will contribute to the better understanding of implementation of effective interventions; and information dissemination and advocacy. Regional activities will focus on building capacity in the areas of research, obtaining and using quality surveillance data, and implementing measures that prevent and control the spread of resistance. Finally, country level activities will identify patterns of drug resistance for the target diseases of particular importance for individual countries, improve the use of surveillance information for policy and decision making, and build capacity to implement improved practices in drug selection, management, and use by health care providers and caretakers.

USAID recognizes that disease prevention is fundamental to slowing the emergence and spread of resistant organisms. Disease prevention activities such as infection control will be included under this initiative. As areas for disease prevention are identified as important factors for the emergence and spread of resistance and they are determined to constitute a global gap, USAID may consider additional investments in this area.

USAID is supporting selective preventive interventions as components of its current portfolio in child survival and reproductive health. Therefore, activities such as strengthening immunization programs, formulation and testing of nutritional interventions, development and testing of vaccines for pneumonia, implementation of nutrition and food security programs and environmental interventions will not be supported under this initiative.

Activities: USAID antimicrobial resistance efforts will focus on the following areas:

1. Establishing a global strategy and action plan

USAID, in collaboration with WHO and other partners, will develop and put in place a global strategy and action plan to combat antimicrobial resistance. Because of the complexity and scope of the drug resistance problem, a first step will include a review and synthesis of what is known and what critical information is needed, with particular attention to: documentation of the magnitude, incidence, patterns, trends, and public health impact of resistance; identification of the risk factors that contribute to the development of resistance, and an assessment of their relative importance; identification of known efficacious interventions to control resistance; and identification of gaps in the understanding of the problem, and related research needs. This effort

will help identify opportunities for advocacy, synergy, and leveraging of funds to achieve specific short and long term objectives.

2. *Improving the understanding of antimicrobial resistance*

USAID will contribute to improved understanding of antimicrobial resistance by supporting analytical work, applied research, and information dissemination. Based on priorities identified in the global strategy, areas to be examined might include: identification of populations at risk; analysis of surveillance data including patterns of resistance over time, especially as drug policies are changed and preventive interventions are implemented; economic impact of resistance; development of predictive models including models which explain the reasons for differences in resistance rates; identification of the multiplicity of institutions and population groups that influence antimicrobial use; development of progress and impact indicators for measuring reductions in resistance; generation of data to improve our knowledge of risk factors including therapeutic, socioeconomic, biologic, and commercial factors.

Communications targeted at multiple audiences will be essential to enhance the awareness and understanding of resistance. Information dissemination may take place through international and regional workshops, within the context of community gatherings, by strengthening information networks including the development of a web site, and by facilitating the timely incorporation of research results into policy and operational programs.

3. *Developing methods to detect resistance*

USAID will support the development and evaluation of cost-effective methods to detect antimicrobial drug resistance for priority diseases (i.e. pneumonia, meningitis, dysentery and gonorrhea), and assist countries to assess the extent of the resistance problem. These will include: clinical methodologies to detect resistance based on treatment failure, including practical criteria to define failure; inexpensive laboratory assays to monitor resistance that are appropriate for use in developing countries, including methods that are predictive of clinical outcomes; and tools for population based surveys of drug resistance. Such methods and tools will assist countries to assess the drug resistance problem and respond appropriately. In collaboration with the surveillance component (see section IV D), methodologies and tools developed will be tested and applied in selected countries.

4. *Responding to data on antimicrobial-resistance and drug-use*

Even when data on antimicrobial resistance and drug use is generated by applied research and surveillance systems, there is no guarantee that it will be used effectively. Contributing factors may include lack of access to available data, lack of analytic skills to adequately interpret the data, and lack of timeliness or credibility of the data. Consequently, data may not be analyzed and reported to decision makers, clinicians, or committees responsible for revising antimicrobial

drug policies, pharmacology training curricula, formulary drug lists or treatment guidelines.

However, surveillance and drug use data can play a key role in effecting policy and program changes. USAID will facilitate access to and use of information generated at the country or regional level by global policy makers. This process will help to accelerate revisions for global policy norms and standards such as disease treatment guidelines and essential drug lists. Country guidelines for making drug policy changes will integrate surveillance data and drug selection and procurement issues with treatment options. In selected countries, USAID will encourage data-based policy changes at the national, district and institutional levels. As a result, it is anticipated that national drug lists will reflect current guidelines on appropriate drugs for the treatment of targeted diseases, procurement plans will be updated, revised treatment guidelines will be incorporated into disease control programs and primary health care programs, and regulatory and legislative policies will be better informed and their enforcement strengthened.

USAID will work with selected countries to strengthen the capacity to carry out operational changes in response to information generated from clinical and laboratory activities and from socio-economic research on drug use. An assessment tool will be developed to identify country factors contributing to resistance. Research will be supported to develop, implement and disseminate communication strategies; targets for resistance information will be identified in order to enhance use of the data by the appropriate institutions (e.g. hospitals, insurance providers, universities, professional organizations, non-governmental organizations, and private sector institutions including the pharmaceutical and diagnostics industries.) Key areas where operational changes are likely to be incorporated include drug procurement, management, pricing, prescribing, dispensing and treatment. Workshops will be organized to bring together physicians, pharmacists, nurses, community health workers and others to review data; communication of data to consumers will be carried out as part of the follow-up to these workshops. Operational research will be supported in order to ascertain how effectively data is being used to effect program changes and how this process can be improved.

5. *Preventing and slowing the spread of antimicrobial resistance*

USAID will promote the implementation of interventions which slow the spread of antimicrobial resistance. At the country level, USAID will provide technical assistance to improve capacity to manage pharmaceuticals, including the selection, procurement, prescribing and dispensing of appropriate antimicrobial drugs. This will be accomplished by strengthening skills in drug policy analysis; designing management systems and regulatory mechanisms that would be most effective in controlling the use of antimicrobial drugs; promoting policies which provide financial and other incentives to encourage appropriate drug use; and promoting training, education and communication strategies that improve practices and increase awareness of antimicrobial resistance threats.

Other key areas will include improving the availability and use of unbiased drug information

(particularly by providers), and designing and implementing public and consumer education strategies to promote appropriate patient adherence to treatment regimens, and avoidance of inappropriate self-medication. Curriculum reform in training institutions will focus on the rational use of antimicrobials, the use of the formulary development process for drug selection decisions, and drug utilization and peer review programs to monitor and improve prescribing practices. Continuing education programs for doctors and pharmacists and innovative approaches for modifying accreditation procedures for members of professional associations will be used to support appropriate antimicrobial use.

USAID will support pilot activities and applied research to develop improved approaches and tools for interventions to prevent and slow the spread of antimicrobial resistance. Pilot activities in three to five countries will test packages of interventions to improve antimicrobial drug management and use, linking these interventions to operational programs such as Integrated Management of Childhood Illness (IMCI)¹. These packages are likely to include interventions which promote improved drug management, quality assurance, rational drug use, effective communication and improved infection control practices. Technical assistance will be provided to strengthen the capacity of countries to design and implement these packages.

In addition, approaches, tools and technologies to improve implementation will be developed. USAID will work with developing country institutions to conduct applied research on issues such as: testing of new drugs and drug regimens that may result in less selective pressure or be effective in treating resistant infections; evaluation of innovative ways to improve behaviors related to the appropriate use of drugs; development of treatment guidelines with increased specificity; and development and testing of diagnostics to improve the rational use of drugs.

B. TUBERCULOSIS

Rationale: Tuberculosis, after years of declining visibility, is again being recognized as a leading and growing cause of adult deaths. About three million TB-related deaths occurred in 1997, and one third of the world's total population is infected with the TB bacillus. The annual mortality due to TB could rise to 4 million people per year within the next five years if appropriate attention is not focused on the disease.

TB has been a persistent and incurable companion of humankind, particularly in environments characterized by poverty, crowding and malnutrition. The development of antibiotics in the 1950s transformed TB into a treatable illness. In the developing world however, growing urban decay, inadequate health care systems, the emergence of HIV, and the complicated nature of established screening, detection and treatment for TB -- which are labor intensive, costly, and

¹. Integrated Management of Childhood Illness (IMCI) is an integrated approach to assessing and treating sick children. The approach focuses on the five major conditions that kill children, and includes appropriate counseling on preventative measures, such as nutrition, vitamin A supplementation, breastfeeding, immunization and hygiene education .

long -- have dampened many of the important accomplishments made in our ability to treat this disease, and have contributed to this increasing public health problem. Inadequate treatment and poor compliance have also led to the emergence and spread of multi-drug resistant strains of TB, which are virtually untreatable and often fatal. Furthermore, the decreased immune response due to HIV infection has led to a resurgence of TB among millions in whom the disease has been dormant.

The success of a new strategy to address TB, Directly Observed Treatment, Short-Course (DOTS), has created optimism that the disease can be more effectively controlled on a much broader scale. Still, this optimism is tempered by the realization that DOTS is a relatively labor-intensive intervention which requires multiple contacts between a treatment supervisor and TB patient over a period of six to eight months, and can only be carried out in

situations in which effective program management can be assured. Appropriate TB control is contingent upon effective screening, appropriate diagnosis, effective treatment (DOTS), patient compliance, and monitoring of quality of service and ongoing review of case outcomes. In the context of poorly-managed programs with inadequate screening, diagnostic and treatment facilities, insufficiently trained and overextended staff, significant rates of incomplete treatment, and frequent shortages of drugs, there is considerable risk that poorly run TB control programs can lead to the emergence of more widespread multi-drug resistance. This outcome poses a real and significant risk to the world community, and would be worse than no program at all.

USAID's Strategic Approach: To date, USAID's work in TB has been limited, focusing on addressing the resurgence of TB in association with the HIV/AIDS pandemic and to a lesser extent, the spread of multi-drug resistant strains of the disease. Efforts in the NIS have also been underway to reform existing TB diagnostic, treatment and control practices in the region. This new infectious diseases initiative will target TB for significantly expanded action.

Existing health service delivery systems in developing countries are generally not well prepared to address TB on the scale which is required. In many transition countries, extensive systems are in place dedicated to TB, but are costly, inefficient and ineffective. It will be necessary to determine the most effective options for applying existing proven technologies in diverse settings and to evaluate health system modifications and treatment regimens to expand and sustain

EXPECTED RESULTS: TUBERCULOSIS

- Development of a collaboratively designed global plan and strategy which incorporates the most cost-effective, successful programs for surveillance, diagnosis, and treatment of TB.
- Establishment of model field sites capable of serving as national and regional reference laboratories, providing training of individuals at all levels, and conducting operations research in laboratory, treatment, training, surveillance, and behavioral areas to improve compliance and decrease incidence
- Accelerated development and implementation of tools to improve diagnostic and treatment options which are appropriate for developing and transitional countries.
- Improved surveillance and modeling techniques, incorporating the emergence of multi-drug resistant strains and the increasing epidemic among those who are co-infected with HIV.

program impact. Therefore, consistent with WHO's recommendations, USAID will not encourage initiation of wide scale TB control efforts in the absence of confirmable and strong program management and oversight (either in the public or private sector) and in the absence of a reliable source of appropriate drugs.

Activities: USAID's TB strategy will focus on four subcomponents:

1. Supporting the development of a global TB control plan and strategy

A comprehensive global plan and strategy for TB control is needed to ensure that the many agencies and organizations concerned with the international TB crisis will work closely together.

Viewpoints of partners from different regions and countries as well as those from international organizations (e.g., WHO, PAHO), international NGOs (e.g., IUATLD, ALA/ATS) as well as community organizations, major donors (e.g., World Bank, Soros), and research communities (NIH, CDC, academic institutions) will contribute to developing the plan, which would delineate control strategies, training, research, and advocacy activities. Once developed, it will become the basis for coordinated action and for building political consensus and support. Both the plan and its strategic components must be developed and implemented rapidly to marshal resources and to establish a baseline for regular evaluations of TB control efforts.

2. Establishing 3-5 major field sites to serve as models for innovative wide-scale TB surveillance and control

TB control is predicated on effective screening, rapid diagnosis and effective treatment of a high percentage of all cases of pulmonary TB with the ultimate goals of appropriate patient cure, minimizing the development of drug-resistance, and prevention of transmission. Optimal control requires several basic components which are outlined in the DOTS program. They include:

- Government commitment to a national TB program (political will);
- Case detection through “passive” case-finding (microscopic examination of sputum for patients presenting to public or private sector health care facilities);
- Short-course chemotherapy for all acid-fast bacilli (AFB)-positive pulmonary TB cases (under direct supervision for at least the initial phase of treatment);
- Regular, uninterrupted supply of all essential anti-TB drugs and availability of functioning microscopy network; and
- Systematic monitoring and accountability systems for program supervision and evaluation of each patient diagnosed, including case registries and cohort analysis.

Although the DOTS program describes the major areas which must be addressed, programs must be adapted to local needs, and be community-based and supported to ensure ultimate success and sustainability. It will be critical to examine models of public sector implementation as well as

the those of private sector/community implementation. We anticipate the establishment of three to five “model” centers representing a diverse set of communities in which TB poses a significant risk and where opportunities exist. These centers should build on existing institutions, and upgrade facilities to establish three main components:

(1) Laboratory

- Develop state-of-the-art facility with quality control capabilities
- Develop appropriate laboratory training materials and conduct training courses to improve microscopy techniques
- Refine methods to improve sensitivity and specificity of smear evaluation
- Provide field sites for evaluation of new laboratory tools and techniques (e.g. diagnostic tools)

(2) Training/evaluation (multilevel)

- Build local capacity by developing and refining training courses appropriate to the locality--covering laboratory (as above), management, surveillance, and therapeutic guidelines aimed at all levels of providers including program managers, health workers, technologists, and physicians/nurses (public and private sector)
- Support training programs to develop and maintain a cadre of TB experts capable of providing technical assistance to regional TB programs
- Create training/advocacy materials for local government functionaries which provide information about the burden of disease in the community and the necessary components of a program for control.

(3) Operations research--evaluation of DOTS strategy

- Evaluation of innovative laboratory, training, and treatment delivery schemes
- Exploration of innovative DOTS delivery systems, including those using local NGOs and community-based organizations
- Evaluation of treatment regimens (including provision of essential drugs during field trials if procurement mechanisms and alternative long-range funding options are available)
- Evaluation of alternate treatment approaches, using different community models for example.
- Evaluation of behavioral components of compliance, and of new techniques to improve compliance
- Evaluation of surveillance systems

3. *Investigating and implementing potential technologies and methodologies for TB prophylaxis, diagnosis, and treatment in selected sites*

Basic research in TB over the last several years has produced important information fundamental

to the development of new technologies for TB prophylaxis, screening, diagnosis, and treatment. Advancements include the sequencing of the *M. tuberculosis* genome, techniques to genetically manipulate mycobacteria, and insights into the biology, biochemistry, and microbiology of the pathogen. Smear (AFB) microscopy, while currently the suggested method of diagnosis, may detect only 50-70% of active pulmonary TB cases, requires a microscope, reagents, and a trained microscopist, and is time-intensive for both technicians (an average of one case is diagnosed for seven technician hours) and patients (requiring at least two clinic visits). The development of a highly sensitive and specific test which is simple, inexpensive, and rapid is important both from the perspective of public health/epidemiology (smear-positive cases are more infectious) and patient care (availability and assurance of timely and appropriate treatment). This research is also fundamental to the development of vaccines and prophylactic regimens. Operational research, field trials, and training of field workers will encourage and facilitate the development and use of tools to improve diagnostics, prophylactic regimens for exposed individuals, (particularly children and those infected with HIV), and treatment (such as improved drug delivery and monitoring systems and alternative cost-effective regimens for multi-drug resistant TB), which are appropriate to low-resource environments.

Where USAID's efforts are clearly part of a broader program, and provided there is confirmable and strong program management and oversight of the TB effort including a reliable source of drugs, USAID may support other country level activities other than the field trials and surveillance activities. These activities could also build on the lessons learned from USAID's experience in designing and implementing TB programs in places such as the Central Asian Republics.

4. *Supporting surveillance to monitor TB trends and to identify multi-drug resistant TB strains before they become widespread*

Global and national surveillance is essential for effective TB control. Currently, WHO has developed a surveillance system which utilizes systematic data collection, regional laboratory centers, and a centralized database. This database can be used to examine case notification rates and treatment results, identify strengths and weaknesses in national programs, describe the epidemiology of disease, and mobilize political commitment for TB control. USAID's initiative will support programs to improve the accuracy and management of data collection, utilization of data analysis, evaluation of recording and reporting systems (and their implementation), special surveys to evaluate local case-finding and notification systems, assessment of the DOTS strategy on TB transmission, information dissemination, and the expansion of these systems. In addition, the initiative will continue to support the collaborative (WHO, CDC, IUATLD) multi-drug resistance surveillance project, which has funded surveys, standardized reporting of results, and developed a global network of supranational reference laboratories. These will be expanded and integrated with concurrent surveillance systems to cover surveillance of both susceptible and resistant TB.

C. MALARIA AND OTHER INFECTIOUS DISEASES

Rationale: While malaria is a global problem, the epidemiology and public health impact of the disease varies among the major geographic regions. Malaria poses a particular challenge to public health and socioeconomic development in Africa. Africa currently accounts for 85 percent of the world's total malaria clinical cases, and 90 percent of the malaria deaths with infants, young children and pregnant women being especially vulnerable. Over the coming years the region can expect a 7-20% annual increase in malaria-related deaths and cases of severe illness.

In addition, Latin America and southern and central Asia have extensive areas with malaria transmission, but the public health impact has to date been limited in part due to the predominance of *P. vivax* infections, rather than those due to *P. falciparum*. However, ominous deterioration in malaria status has recently occurred in both regions. This deterioration is driven in the Americas by the opening of the Amazon region in the 1970s to unplanned development, which has exposed large numbers of people to malaria, principally adult laborers who did not have immunity to the disease and the spread of chloroquine resistant *P. vivax* malaria. In southern Asia, malaria resurgence is due to the emergence and spreading of multi-drug resistant strains of *P. falciparum* malaria. In both regions, the larger concern is further spread of the infection fueling more extensive outbreaks. Outbreaks of malaria of epidemic proportions have also occurred in the southern part of the NIS. In 1997, Tajikistan reported over 40,000 cases of malaria. Azerbaijan has also had an epidemic of similar proportions. These outbreaks are becoming more frequent and spreading to surrounding countries in the region.

Expected Results: Malaria

- Expanded application of proven interventions in targeted countries for the prevention and control of malaria at home, in the health facility and among pregnant women, including:
 - Improved management of pediatric fever and anemia, by health worker at the health facility, community providers and mothers and other caretakers in the home;
 - Improved access to and demand for malaria prevention and treatment of pregnant women;
 - Increased demand for, access to, and appropriate use of affordable insecticide treated materials;
 - Improved management of antimalarial drugs as reflected in revised national drug policies, training of health workers, drug distribution/logistics, and quality of services provided by public/private sector providers and caretakers;
- Increased understanding of the epidemiology and transmission of urban malaria in Africa resulting in: new models for prevention and control of urban malaria; improved understanding of clinical consequences of co-infections involving malaria and other infectious diseases, and appropriate prevention and control strategies formulated.
- Doubling or tripling of small malaria vaccine field trials over the next five years, including at least one additional clinical trial of a candidate vaccine conducted in the first year.
- Alternative preventive technologies, new chemotherapies for malaria and low-cost diagnostics suitable for rural health facilities field tested and ready for operational use.
- Selected national programs capable of routine surveillance and response to malaria drug resistance.

Other infectious diseases are also re-emerging as serious public health threats. These diseases are often epidemic in nature, and even though their global burden may not be of similar magnitude to malaria, pneumonia, diarrhea and TB, investments in their prevention and control on a country or regional basis may be warranted due to high case fatality, the potential for rapid spread, economic disruption, impact on highly vulnerable populations, and cross-border transmission.

USAID's Strategic Approach: Over the past decade the Agency's malaria activities have focused on the development of new technologies for its prevention and control, including support for the development of a malaria vaccine and, in the Africa region, pilot testing options for practical and sustainable prevention and control of the disease. The lessons learned from these programs have significantly increased our understanding of malaria impact and options for action.

With these lessons in mind, USAID's new initiative will concentrate on, but not be limited, to Africa. USAID will scale-up from earlier research and pilot studies in Africa and extend its malaria efforts into the Amazon region of Latin America and selected countries of south Asia and possibly the NIS -- capitalizing on USAID's extensive strengths and comparative advantages in strengthening maternal and child health services; building partnerships between public and private sectors; and promoting social marketing, behavioral change and communications skills.

At the core of an expanded malaria program is a package of health interventions which focus on improved health facility and household/community-level management and prevention of malaria. Furthermore, USAID will expand support for the development of new technologies and approaches for malaria control and prevention.

In addition to the activities discussed above, USAID will retain the capability to respond -- using limited resources -- to other diseases, such as dengue, yellow fever, meningitis, chagas, etc. when such other diseases are a significant public health threat in a particular country and there is a clear role for USAID.

Activities -- Malaria:

USAID's malaria efforts will focus on five major areas:

1. *Expanding the application of recently proven interventions for the prevention and control of malaria*

USAID-supported pilot studies and field trials have recently documented the efficacy of several interventions for the prevention and control of malaria, including malaria prevention and treatment under the aegis of IMCI. USAID's expanded efforts in malaria will scale up these trials in Africa, and include efforts in Latin America addressing the threat posed to adult health

by the re-emergence of malaria in the Amazon basin and in Asia. The NIS may also be a possible site for expanded activities, depending on the magnitude of the epidemic and the fact that it may spread to surrounding countries in Asia.

At the core of USAID's expanded malaria initiative will be a package of proven maternal and child health interventions for malaria control, developed under USAID's on-going child survival and maternal health efforts, but brought to scale with this initiative, with particular emphasis on:

The Home. When illness occurs, several of the critical steps necessary to improve a child's health can be taken at home, where in Africa at least, four out of five cases of malaria in children are treated. These include recognizing the signs and symptoms of malaria and its complications and determining what illness the child has, providing or seeking appropriate care, continuing care as needed/instructed, and recognizing the need for further care if the child's condition does not improve. The critical determinant in the case of treating a child's febrile illness is how promptly the caretaker recognizes its seriousness and takes appropriate action. Under the expanded initiative, USAID will promote strengthening the ability of mothers and other caretakers to manage fever and anemia in children under five in the home, as measured by improved caretaker recognition of signs and symptoms of illness and increased knowledge of appropriate treatment, proper health-seeking behaviors, and access to appropriate and affordable treatment by public and private providers.

The lack of suitable options for prevention in the home is a major constraint facing national and international programs to reduce the burden of malaria, especially among children and pregnant women. Trials of insecticide-treated bednets conducted recently in East and West Africa have demonstrated that this simple technology can reduce total deaths among young children by as much as 40%. These were mainly controlled trials in which bednets and insecticide were distributed for free. How effective bednets and other insecticide-treated materials, such as curtains, would be under conditions of *voluntary acquisition and use* is less clear. By undertaking an Africa regional initiative, USAID expects to develop sustainable options for addressing the challenges of, demand for, access to, and appropriate use of affordable insecticide-treated mosquito nets, including using social marketing.

The Health Facility. Malaria-related illness is one of the major causes of outpatient visits in Africa and one of the main reasons for inpatient admissions to pediatric wards. To manage malaria-related illness in a health facility requires skilled health workers capable of distinguishing between one or more potential causes of fever in addition to malaria, including acute respiratory infections (ARI), measles, and diarrhea. To ensure prompt and effective handling of a "febrile" child at the health facility, USAID will promote strengthening malaria case management capacity within the context of IMCI - an approach promoted widely by WHO, USAID, UNICEF, and others. IMCI's development of guidelines for integrated management of the major causes of pediatric illness and training of health workers to manage by clinical symptom (e.g., cough or difficult breathing, diarrhea, and fever) is consistent with a more

specific focus on strengthening the capacity of health care workers in "fever management" and creates new opportunities to address malaria within the clinic setting.

Malaria in Pregnancy. Malaria infection of the placenta is the most common of all infectious causes of low birth weight. It is also the most amenable to prevention. USAID's initiative will promote the use of anti-malaria drugs delivered through ante-natal services, either as routine prophylaxis or periodic treatment during pregnancy.

2. *Improving understanding of the immunology, epidemiology, and transmission of malaria*

Research to improve the understanding of the immunology and transmission of malaria will initially focus on two priority sets of questions, but will also address other issues as resources allow. Initially, USAID will examine the emergence of urban-malaria in the Africa region, and development and field testing options for its prevention and control, and will assess the interaction between malaria and other infectious diseases.

In 1990, less than 20% of the population of Africa was estimated to live in urban areas; by the year 2015 urban settlement is projected to exceed 50%. Population growth, political, and economic pressures have contributed to dramatic migration from rural to urban settings. Increases in the size of the urban population in Africa have introduced malaria into areas that had previously been malaria-free and thus have enlarged both the human and vector pools. This trend has been observed in major cities, which in recent years have lost their malaria-free status, for example in parts of Kenya, Madagascar, and the Congo. Urbanization also often takes over lands that have traditionally been ecologically unfriendly to *An. gambiae*, such as salt marshes and rain forests, and rapid and unplanned urbanization compounds the problems of generally deteriorating urban environments. Given the potential magnitude of the threat posed by urban malaria, a better understanding of the epidemiology of the problem which will then lead to rational options for its control and prevention, will be supported.

Recent findings from large cohort studies in different parts of Africa indicate that a biologic interaction between malaria infection and HIV infection may exist during pregnancy. First, HIV-infected women are more likely to have peripheral parasitemia, placental malaria infection and higher placental parasite densities than women who are not HIV-infected. Second, children born to HIV-infected women who had placental malaria infection have at least a three-fold increased risk of post-neonatal death than children born to HIV-infected women who had no placental malaria parasites. Other studies have indicated similar interaction between malaria and other infectious diseases. Given the high prevalence of malaria infection in the region, better characterization of these interactions is needed and options for mitigation examined.

Other key issues for study include research related to the impact of impregnated bednets on the epidemiology of malaria; the potential role of micronutrients to enhance treatment and prevention of malaria; the role of broader nutrition interventions; and applied research to

improve the differential diagnosis of child fever -- not only to reduce mortality, but also to slow emerging resistance; and cross-resistance of drugs used to treat pneumonia and malaria.

3. *Developing and field testing malaria vaccine*

In regions with intense malaria transmission, the establishment and maintenance of natural immunity takes place from an early age. However, natural immunity is short-lived and requires repeated boosting to be effective. A vaccine capable of reducing severe and complicated malaria and related mortality offers the single most important hope for sustained protection against malaria. Over the past 20 years, USAID has supported malaria vaccine research with the objective of reducing severe and complicated malaria and malaria mortality in children, with a major focus on Africa. Major breakthroughs have been achieved. In the 1980s, investigators supported by USAID, cloned the gene encoding the circumsporozoite protein of the parasite, enabling the rapid development of technology needed to produce experimental vaccines, many of which have been tested in clinics in the United States. USAID will expand the production and Phase I testing of investigated vaccines and support field tests of the most promising vaccines.

4. *Developing improved approaches and technologies for prevention and control of malaria*

While USAID's broader health efforts have contributed to significant improvements in the health status of children and other vulnerable populations throughout the developing world these efforts are too often constrained by existing technologies, which may be too expensive, fragile, or rendered ineffective by adaptive disease pathogens. In the case of malaria, the long-term success of malaria control programs requires the development of simple, effective and affordable interventions to counter the ever-evolving biology of the malaria parasite and its mosquito vector, and the changing social-behavioral context for malaria control.

Early diagnosis and prompt treatment -- disease management -- are fundamental to malaria control. Improving case management of malaria among children and pregnant women, for whom malaria's adverse impact is greatest, is a high priority. Antigen-based diagnostics offer the potential for reliable and easy-to-use means for peripheral health workers to rapidly confirm malaria parasite infection.

USAID will support the development and field testing of low-cost and reliable malaria diagnostics suitable for use at peripheral health facilities; and new approaches for improved household/community practices for prevention and management of malaria.

5. *Addressing the development and spread of parasite resistance to existing antimalarial drugs.*

As in Asia 20 years earlier, in Africa over the past decade the malaria parasite has rapidly developed a high level of resistance (often at the highest R3 level) to the antimalarial drug of

choice (chloroquine) and multi-drug resistance has also emerged. Antifolate resistance is prevalent in Southeast Asia and has emerged in sub-Saharan Africa. Inadequate drug policies, lack of training opportunities for health providers in diagnosis and treatment, and the lack of public awareness of appropriate antimalarial drug use exacerbate the effects of drug resistance. The spread of chloroquine resistant malaria and the corresponding increase in deaths and cases of severe malaria have posed an especially difficult challenge to planners and policy makers. Responding to the threat of drug resistant malaria requires a comprehensive approach that includes: strengthening country-level capacity to conduct routine mapping of antimalarial drug sensitivity; supporting the development of regional criteria for promoting a switch to alternative drugs; promoting national-level adoption and implementation of drug policies consistent with effective treatment; and promoting the development and field testing of alternative malaria drug therapies.

Activities -- other diseases

In some countries, USAID may support efforts to address other infectious diseases, such as dengue, meningitis, yellow fever, or Chagas etc. This support will only be carried out if such a disease presents a major public health threat in that country or region and if there is a clear role for USAID. As such, efforts to control other infectious diseases -- outside of surveillance activities and work in antimicrobial resistance -- will constitute only a small portion of the overall resources.

In addition to supporting specific disease control efforts in particular countries when required, USAID may also investigate other broader issues, such as the impact of nutrition and of micronutrient interventions on the control and prevention of infectious diseases.

D. SURVEILLANCE AND RESPONSE

Rationale: The ability to detect disease and to access data and mount an appropriate response is essential for establishing a line of defense and response to infectious diseases. However, health systems in many developing countries lack the necessary capacity for routine and sentinel disease monitoring. Surveillance and response capability is impeded by limited donor and in-country coordination, decision-making divorced from accurate information, poor data quality, incompatibility of disease reporting with information systems, lack of financial and political commitment, limited epidemiological, statistical and management expertise, and insufficient laboratory capacity. For countries with difficulties in implementing routine basic surveillance, the challenge of detecting and responding to the appearance of new organisms, disease outbreaks, and antimicrobial resistance often presents an impossible challenge.

USAID's Strategic Approach: To be effective, surveillance and response must be an accepted

national and local responsibility. International response to all but the most dramatic outbreaks relies on this local capacity. USAID will focus its resources primarily on building improved national capacity for surveillance and response.

Building local capacity is a key element of an effective global surveillance network. As has been done in the Americas for polio and measles, disease-specific surveillance activities can help create a foundation for more sensitive and sustainable systems to track infectious diseases of public health importance. USAID's efforts in this area will be targeted at improving the capacity of selected countries to obtain and use good quality data for the surveillance of and response to infectious diseases.

Activities: USAID's activities in surveillance will focus on five areas:

EXPECTED RESULTS: SURVEILLANCE

- Establish effective partnerships at the country level for collecting, managing and responding to high quality data; and at the regional and global level for supporting the improvement of data for action
- Improved use and quality of data for action by policy makers and program managers in responding to and preventing infectious diseases
- Laboratories strengthened and capable of providing timely and reliable information on a sustained basis as part of overall surveillance systems
- Development of improved tools, including diagnostics, epidemiological, and policy dialogue tools to improve surveillance and use of data for action
- Improved understanding of disease patterns and disease trends, including future threats

1. Building effective partnerships for global, regional and local coordination,

Effective surveillance requires a range of functioning partnerships at the local, regional, and global levels. At the local level, coordination between decision makers and data users and data collectors is key. Local coordination can include local technical, NGO, private sector, local university and public sector institutions, as well as other donors, to identify key areas of respective responsibility. Lessons from the polio interagency coordinating committee (ICC) model can help guide this effort, and in many cases may be a useful starting point for further in-country collaboration. Issues relative to decentralization can be considered when planning coordination at the local level.

At the regional and global level, coordination among a varied range of potential partners is important to improved surveillance. Key partners in this effort will be WHO and CDC, and may also include DOD, other donors, universities, NGOs and private sector institutions (including USAID cooperating agencies). USAID will support direct relationships among and between key partners to streamline support, enable resources to flow effectively, and leverage and mobilize increased resources for issues such as information systems and laboratory strengthening.

As an initial approach to surveillance, USAID will work closely with WHO in undertaking assessments of surveillance systems to identify weaknesses and requirements in selected

countries. This will inform USAID's approach in particular countries, as well as those of other partners.

A key issue in the gathering and use of surveillance data is lack of donor coordination at global, regional and country level, often with many donors asking for different data sets, and requiring different and burdensome data collection systems that are often not widely used. USAID will help provide a forum to coordinate among donors to simplify donor support and requirements. In order to successfully strengthen surveillance systems on the ground, we will also help to facilitate development of a common vision for the use of data, and a unified plan for its development among key donor and host government decision makers.

2. Improving use and quality of data for action

A priority for improving surveillance is improving the environment for action based on good data, and closing the links between data and decision making. Good quality data, used at the local level and available internationally, is the foundation for reliable data in global surveillance systems. Policy and decision makers will have access to networks of high quality, useful data across countries only when information systems are oriented to meet the needs of service providers and their supervisors. Facilitating information-based improvement by the end-users, and improving the flow of information to and from decision makers are good first steps in upgrading current surveillance and response systems. Success will be evidenced by more rapid decision making, efficient data collection and feedback processes, and improved programmatic response at the community level. USAID will support long- and short-term technical assistance both directly and through partner organizations, at country and regional levels. This will assist in surveillance systems development, focused on improving informed decision making at the technical level as well as for policy makers, and on orienting surveillance systems to ensure effective feedback loops throughout the system. This will often require policy dialogue with host country decision-makers concerning the use of data, channels of information flow, and importance of informed decision making in sustainable health systems development.

Key operational areas could include illness trends and drug management (e.g. malaria), outbreak monitoring and immunization delivery (e.g. measles and meningitis), disease epidemiology and seasonal change (e.g. outbreak prediction), resistance monitoring, and geographic analysis (disease mapping to pick up unusual events). Specific issues for surveillance information would be determined by the requirements of a particular country.

USAID will develop two to three initial model systems in selected countries to demonstrate how elements of good surveillance can be incorporated into existing systems. These models will ultimately be aimed at strengthening overall surveillance, but may initially focus on specific diseases (malaria, TB, acute respiratory infections, diarrhea). Every effort will be made to build on the polio acute flaccid paralysis (AFP) surveillance system, and on the fever and rash surveillance system for measles in Latin America. Realistically, these model systems will

comprise only part of a national system, but serve as a demonstration model for host government policy makers. Linkages to existing systems such as the Onchocerciasis Control Program (OCP), Famine Early Warning System (FEWS), polio, and other systems will be actively explored.

3. Building technical and laboratory capacity

Capacity building is a continuum, starting with skill enhancement, behavior change and culminating in sustained local support for institutions and personnel. Clinical and epidemiological training will be supported as a first step to increase the capacity of host countries to technically manage surveillance within their public and private sector institutions. Technical training, particularly in the host country setting, will be focused on applied skills in epidemiology, statistics, data management and system development. This will increase the capacity to monitor and interpret epidemiological trends for infectious diseases by local health officials. Instruction will be linked to in-country infectious disease priorities and problems. Technical, operational and administrative follow-up will be included as part of any training. In-country, third country and U.S. training for data management and administration will also be supported, including follow-up and support for trained managers. Support will be provided for in-country workshops, other training programs, and study tours for policy makers and senior technicians as an advocacy tool and as part of overall capacity building. South-South exchanges will be encouraged as appropriate to enable decision makers to share views and experiences which reflect developing country realities.

USAID will support the strengthening of selected laboratories in focus countries to reinforce in-country systems and improve the opportunity for regional centers of excellence. Donor dialogue on commodity support for key laboratories will also be promoted. Planning for and addressing the recurrent costs for laboratories relative to equipment maintenance and resupply of reagents and other expendables will figure prominently.

4. Developing improved tools

USAID will invest in the development and testing of new diagnostics and epidemiological tools to improve the surveillance of disease and antimicrobial resistance. As noted earlier, USAID will support the development of rapid, simple, accurate, safe, stable, and affordable diagnostics for malaria, pneumonia and methods to detect drug resistance.

USAID will support the development of a variety of policy and data gathering tools. These include country-specific advocacy tools (presentations, an infectious disease "RAPID" model derived from predictive models, data sets, economic analyses) for policy makers; computer-based, data management tools, (including options to build upon existing data management and statistical software such as Epi-Info); and new tools and approaches for evaluation and monitoring of system quality.

GIS mapping may be another valuable tool for surveillance and response. The importance of GIS methodology for surveillance lies in its ability to define point prevalence data, overlay numerous other data sets (often pre-existing), and clarify new relationships in the epidemiology of endemic and epidemic disease. This cost-effective technique builds the ability to use information to control diseases at the local level, and can be used flexibly to answer a variety of questions in different settings. USAID will explore opportunities to promote GIS and disease mapping in a practical and sustainable manner in focus countries, building on existing data bases such as the OCP, the Guinea Worm eradication program within UNICEF and the USAID FEWS.

5. Improving understanding of disease patterns and trends

The success of an infectious disease surveillance system is anchored in the capacity to identify disease trends and predict outbreaks, thus providing more time for appropriate response. USAID will explore supporting applied research on disease trend modeling with a lens on real-world testing and application relative to treatment, drug supply and epidemic prevention. Support might also include operational assessments to identify key data elements required for trend analysis and outbreak prediction for specific diseases. Epidemiological, environmental, demographic, economic, social and civic variables would be considered in developing robust models to predict trends in prevalence, illness and antimicrobial resistance in defined population groups. Focus would be initially on diseases which cause the majority of childhood illness such as respiratory infections, diarrhea, malaria and measles, and options for other modeling approaches will be considered as appropriate.

V. CONCLUSION

Achieving the results planned under this strategy will require a multi-year effort and close collaboration with USAID's local, international and U.S. domestic partners. The design of this strategy assumes that important complementary development issues such as malnutrition, population growth, environmental degradation, illiteracy, poverty reduction and civil society continue to be dealt with through other programs. It also assumes that USAID's investments in child survival, HIV/AIDS and health systems strengthening will continue to be a high priority.

Appropriate, balanced investments in each of the four components is critical to the overall success of the strategy. Each component is closely linked with others, and investments across the board are needed.

Implementing this initiative will require that USAID dedicate appropriate staff resources to these efforts, and bring on-board specialized staff with expertise in the component areas of USAID's strategy. It will also likely require some adjustment to strategic frameworks for a number of USAID's missions.

USAID is committed to this initiative and sees it as an effective complement to USAID's other objectives aimed at stabilizing world population and protecting human health: improving infant and child health and nutrition and reducing mortality; reducing deaths, nutritional insecurity and adverse outcomes to women as a result of pregnancy and child birth; reducing the transmission of HIV and the impact of the HIV/AIDS pandemic; and reducing unintended and mis-timed pregnancies. While many of the elements of this strategy are closely associated with on-going activities of these other areas, under this strategy USAID will either significantly expand activities, building on past investments, such as malaria prevention and control efforts within USAID's child survival programs, or take on new issues that have not received sufficient attention in the past, such as reducing the spread of resistance to drugs used to treat pneumonia -- the biggest single killer of children.

This new initiative presents an important opportunity for USAID to expand our on-going investments in health and directly address the growing threat of infectious diseases. We join with our partners in a concerted effort to make a difference in the lives and health of millions of people in the developing world, and thereby reduce the risk of infectious disease everywhere.

ACRONMYNS

AFB	Acid-fast bacilli
AFP	Acute flaccid paralysis
ANE	Asia and Near East
ARI	Acute Respiratory Infections
CDC	Centers for Disease Control and Prevention
CISET	Committee on International Science, Engineering and Technology
DOD	U.S. Department of Defense
DOTS	Directly Observed Therapy, Short-Course
FEWS	Famine Early Warning System
HHS	U.S. Department of Health and Human Services
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
ICC	Interagency Coordinating Committee
IMCI	Integrated Management of Childhood Illness
LAC	Latin America and Caribbean
NGO	Non-governmental organization
NIH	National Institutes of Health
NIS	Newly Independent States
NSTC	National Science and Technology Council
OCP	Onchocerciasis Control Program
PAHO	Pan-American Health Organization
PVO	Private Voluntary Organization
STI	Sexually Transmitted Infection
TB	Tuberculosis
USAID	U.S. Agency for International Development
WHO	World Health Organization