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Grand Challenges in Global Health: Vaccine Priorities

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The Problem

- ✦ 2/3 of the world's 6 billion people live in the developing world. More than 1 in 6 live on less than \$1 per day
- ✦ Millions die unnecessarily each year from diseases that are currently treatable or preventable
 - Just 3 diseases – AIDS, TB and malaria – kill 6 million people annually
 - Vaccine-preventable diseases kill 1.7 million children annually
- ✦ Access to existing, effective health interventions is severely limited for most of those in need
 - 95% of all new HIV infections occur in, and 99% of TB and malaria sufferers live in, developing countries
 - 120 million women – most of them poor – do not have access to the family planning services that they want and need

The Problem

- ✿ Inadequate attention is paid to the health problems that affect the majority of the world's people:
 - Medical research largely ignores the diseases that kill the most people
 - Of the \$70 billion spent annually on medical research, only 10% is devoted to the diseases that cause 90% of global illness and death
 - Product development is primarily focused on rich world diseases
 - Of nearly 1,400 drugs approved in the last 25 years by the FDA, only 20 were specifically for diseases that disproportionately affect the developing world

The Problem

	Annual deaths	Proportion in the developing world
HIV/AIDS	3.1 million	99%
TB	1.7 million	99%
Malaria	1.5 million	99%
Measles	800,000	98%

The Opportunity

- ✿ The world's greatest health challenges are solvable -- we can dramatically reduce the health gap between rich and poor countries
- ✿ There is growing recognition that in our globalized world we cannot ignore health disparities
 - Global Fund to Fight AIDS, TB and Malaria – New channel for funding
 - Millennium Challenge Account -- Increased support for foreign aid targeting health and economic development
 - Global Alliance for Vaccines and Immunization -- projected to save more than a million lives over the next decade
 - The global polio eradication effort is nearing completion

What's Needed – Access and Research

- ✦ Scale up access to existing health interventions and accelerate research on new tools to fight disease
 - Our financial commitments have to match the scale of the crisis – far greater resources must be devoted to build on the examples of what we know works
 - Existing health interventions (vaccines, pre-natal care, HIV prevention) must be delivered to those who need them
 - Medical research must be harnessed to tackle the health problems of the developing world

What's Needed - Innovation

- ✦ **Improve access to existing health interventions** and develop novel methods for introduction of health technologies
- ✦ **Accelerate evolution of available health interventions** for resource poor settings by addressing unique challenges of adaptability, usability, affordability, safety.
- ✦ **Develop new health interventions**, specifically for introduction in developing countries.

The Foundation's Approach

- ✦ **Vision:** Global health equity...every person having an opportunity for a healthy life
- ✦ **Mission:** The global health program seeks to improve the health of the developing world by accelerating the discovery, development, and adoption of the most effective and sustainable health interventions.
- ✦ **Scope:** The Global Health Program works to solve problems that:
 - Cause the greatest global burden of disease
 - Create the greatest inequities in global disease burden
 - Persist due to inequity in the global effort to develop solutions

Transforming Solutions – Grand Challenges

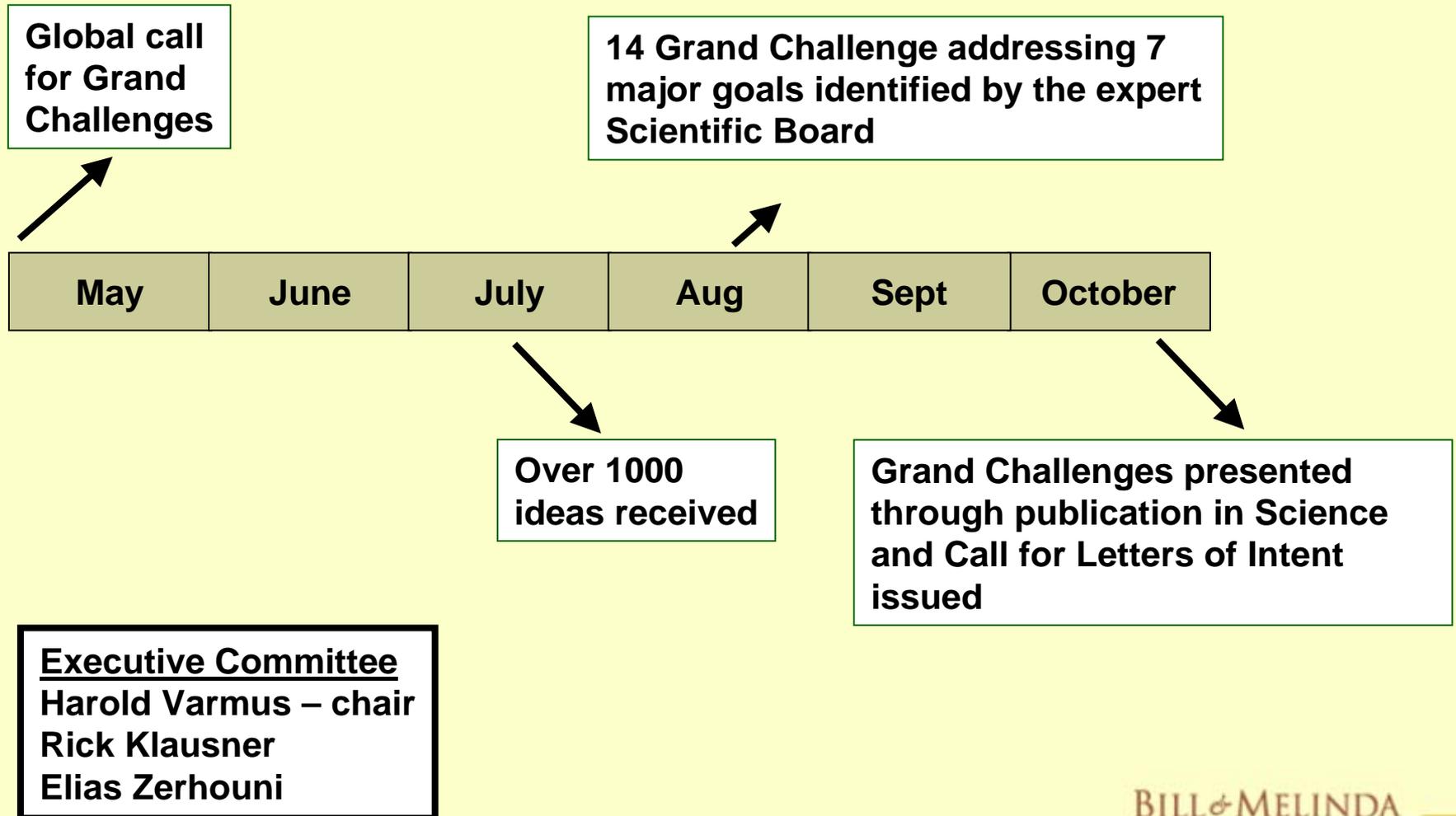
- ✦ Stimulate discussion in the international scientific community and increase the level of innovation in both the developed and developing world around these critical health problems
- ✦ Solicit input from the global research community to assist in identifying Grand Challenges in Global Health
- ✦ Harness the energy of the most creative and innovative researchers through a competitive grants program focusing on the top Grand Challenges in Global Health.

What is a Grand Challenge?

- ✦ A Grand Challenge is a call for a specific scientific or technological innovation that would remove a critical barrier to solving an important health problem in the developing world with a high likelihood of global impact and feasibility.
- ✦ A Grand Challenge is:
 - Neither the statement of the global health problem itself
 - Nor the request for a specific health intervention

Grand Challenges in Global Health

Defining the Challenges



How were Challenges prioritized?

- ✦ The magnitude of the health problem being addressed and its alignment with the scope of the program.
- ✦ The identification of the scientific or technical roadblock to achieving a solution and why this roadblock is limiting on a critical path to achieving the solution.
- ✦ The impact of solving the challenge on the health problem, including indirect benefits such as such as those on income or environment.

How were Challenges prioritized?

- ✿ The soundness of the scientific and technical foundation for the proposed challenge, not merely the ease or likelihood of success. (Novel and innovative ideas that may be risky, but nonetheless scientifically and technically well founded, were viewed to have value.)
- ✿ The feasibility of widely implementing any solution to the challenge in the context of the developing world.

Grand Challenges In Global Health

The 14 Grand Challenges target 7 global health goals:

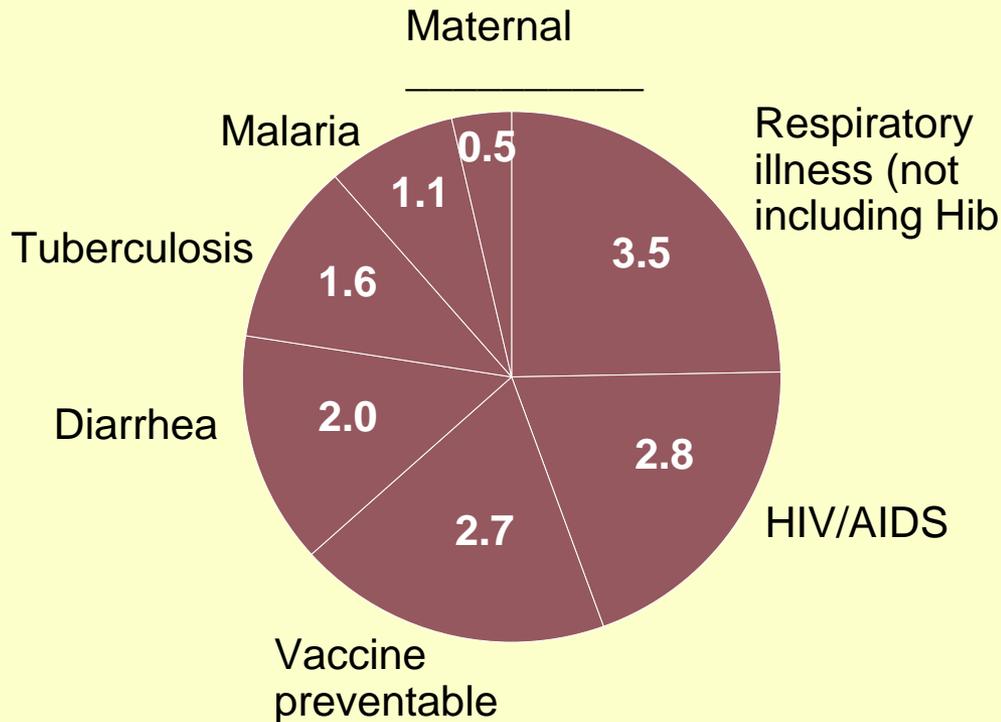
- To improve childhood vaccines
- To create new vaccines
- To control insects that transmit agents of disease
- To improve nutrition to promote health
- To improve drug treatment of infectious diseases
- To cure latent and chronic infections
- To measure disease and health status accurately and economically in poor countries

Vaccine & Immunization Challenges

Gaps in Coverage

- ✦ In some developing countries, less than one in three children are immunized during their first year of life
- ✦ Poorly functioning health service delivery systems
- ✦ Governments unable to meet the basic health needs of the population
- ✦ Some countries unable to deliver existing vaccines much less new more expensive ones
- ✦ Inadequate disease surveillance systems to establish the burden of disease and thus the cost-effectiveness of the new vaccines.

Nearly three million deaths a year could be averted with improved immunization efforts



14 million deaths per year, including 2.7 million deaths that could be averted

Hepatitis B	900,000
Measles	800,000
Hib	400,000
Tetanus	300,000
Pertussis	300,000
Other	50,000

Vaccine & Immunization Challenges

Research & Development Barriers

- ✦ Vaccine R&D agendas are not addressing the needs of developing countries
- ✦ A major disincentive for vaccine manufacturers has been the slow uptake of new vaccines in developing countries as well as the low prices previously negotiated for the six core vaccines.

Vaccine & Immunization Challenges

Vaccine Quality and Safety

- ✿ Vaccines lose their potency if exposed to too much heat, a problem in developing countries where climates are often hot and refrigeration may not be available.
- ✿ Many countries do not have effective national regulatory authority to ensure the quality and safety of imported or domestically produced vaccines.

Vaccine & Immunization Challenges

Injection Safety

- Surveys show that up to 50 percent of injections given in developing countries are not sterile, either because disposable syringes are reused or because reusable syringes are not properly sterilized.
- Unsafe injection practices in developing countries were identified as the cause of at least 8 million Hepatitis B infections, 2 million Hepatitis C infections, and 75,000 cases of HIV/AIDS a year, as well as cases of Ebola, Lassa fever, dengue, and malaria.

Grand Challenges In Global Health

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1. Create effective single-dose vaccines that can be used soon after birth

Goal: To improve childhood vaccines

Background

New discoveries have shown that stimulation of certain portions of the immune system can result in longer-lasting immunity and potentially more effective vaccination.

Roadblock

The current limited understanding of the mechanisms by which adjuvants stimulate and guide the immune response prevents optimal manipulation of the immune system to ensure long term efficacy through vaccination.

Challenge

To develop and clinically evaluate new adjuvants suitable for human use which could strengthen and guide immune responses to create vaccines that could produce specific and robust immunity after a single dose of vaccine and be capable of effectively stimulating the immune system of newborns.

Potential Benefits

- Increased effectiveness of immunization
- Decreased cost of immunization systems
- Decreased early childhood mortality and morbidity

2. Prepare vaccines that do not require refrigeration

Goal: To improve childhood vaccines

Background

New advances in materials science and the preparation of biological materials create the possibility of stabilizing vaccine products to protect against the effects of freezing and/or heating.

Roadblock

The current dependence of childhood vaccines upon refrigeration to maintain stability and viability, demands an intact cold chain, which is difficult and exceedingly costly to maintain.

Challenge

To develop general methods to stabilize vaccine materials to preserve immunological efficacy against the effects of either freezing or heat, eliminating the need for refrigeration.

Potential Benefits

- Increased efficacy of immunization systems
- Reduced cost of vaccine delivery

3. Develop needle-free delivery systems for vaccines

Goal: To improve childhood vaccines

Background

Multiple advances in formulation and drug delivery and new ideas for activating immune cells create the possibility of effective immunization routes that may optimize vaccination efficacy and eliminate the use of needles.

Roadblock

The current dependence of childhood vaccines on administration by syringe and needle is associated with increased risk of infections (HIV, HBV, HCV) and a major waste disposal problem.

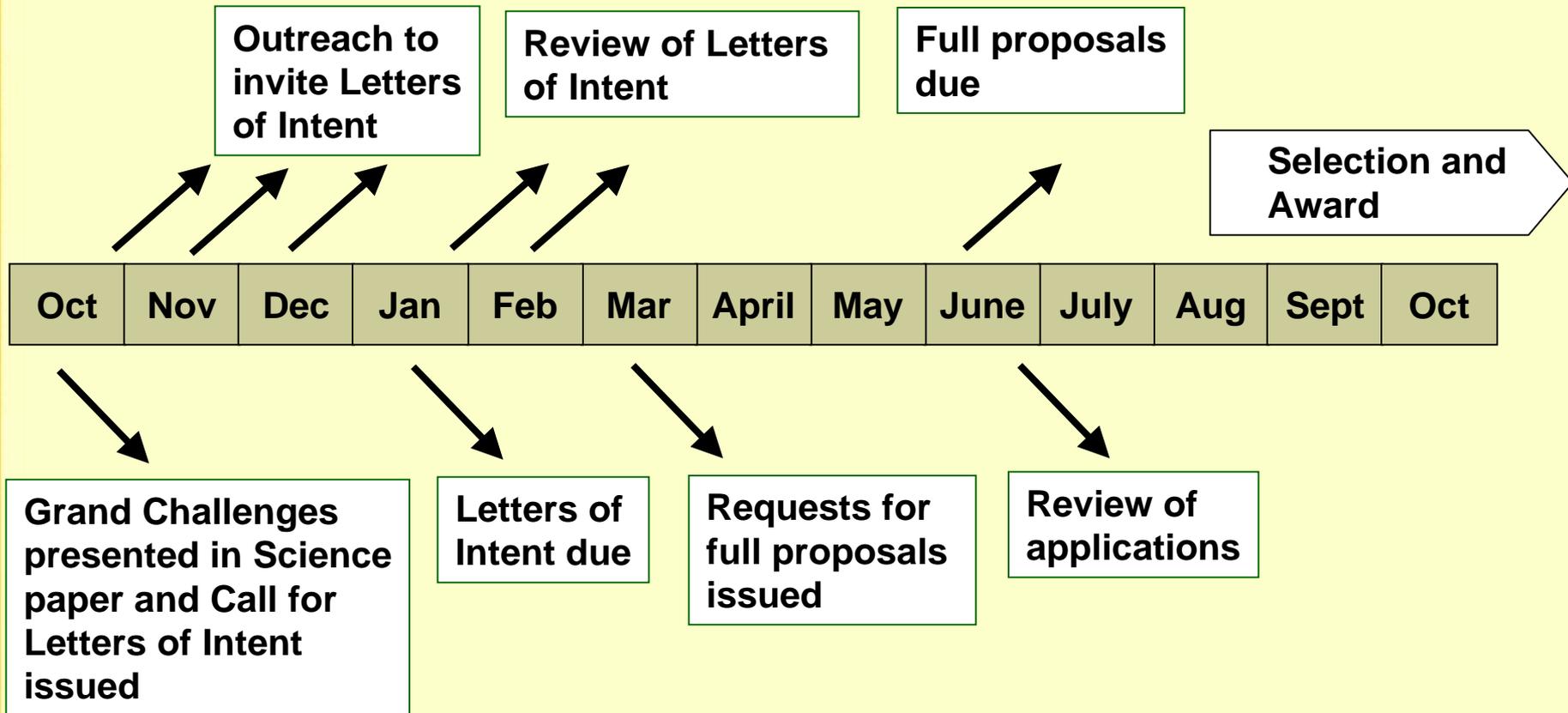
Challenge

To develop effective needle-free delivery systems for vaccine administration.

Potential Benefits

- Simplicity and ease of administration
- Avoidance of infection
- Improved access and compliance
- Reduction of logistic cost

Grand Challenges in Global Health Plans



Grand Challenges in Global Health

Grand Challenges in Global Health

December 5, 2003

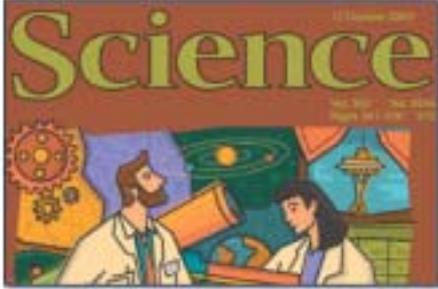
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Grand Challenges in Global Health

17 October 2003 Members of the Scientific Board's Executive Committee for the Grand Challenges in Global Health describe the deliberations that led up to this week's announcement of an initial list of Grand Challenges in Global Health
[► Read More](#)

Recent Highlights

Fourteen Grand Challenges in Global Health Announced in \$200 Million Initiative

17 October 2003 Washington, DC--The Foundation for the National Institutes of Health (FNIH) and the Bill & Melinda Gates Foundation today announced the first 14 scientific challenges that will be the focus of the Grand Challenges in Global Health initiative.
[► Read More](#)

UPCOMING EVENTS

9 January 2004 - Deadline for LOI Submissions

RECENT AWARDS

WORKSHOPS

www.grandchallengesgh.org/

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Grand Challenges in Global Health: Vaccine Priorities

Backup slides

4. Devise reliable tests in model systems to evaluate live attenuated vaccines

Goal: To create new vaccines

Background

The advent of genomics, molecular genetics, and high through put screening methods has raised the possibility of generating modified live agents (viruses, bacteria, protozoa) that could produce effective immunity

Roadblock

We currently lack suitable means for testing live attenuated candidate vaccine agents and predicting effectiveness, short of subjecting them to clinical trials in human subjects

Challenge

To develop suitable model systems for testing the behavior and potential efficacy of candidate attenuated live vaccines

Potential Benefits

- Accelerate the development of highly effective, stable vaccines
- Elucidation of principles to guide the development of additional live vaccines.

Priority Areas

- Viruses refractory to vaccine development (such as HIV, HCV, herpes viruses, etc.)
- Selected complex pathogens (protozoa, yeast, etc.)
- Pathogenic bacteria

5. Solve how to design antigens for effective, protective immunity

Goal: To create new vaccines

Background

The molecular revolution in biology has enabled the rapid identification of new antigens but not the prediction of whether the antigen will consistently produce a protective immune response.

Roadblock

We are currently unable to produce antigens that predictably elicit a consistently effective protective immune response

Challenge

To develop methods to construct antigens that predictably elicit an effective protective immune response

Potential Benefits

- Rapid development of effective vaccines
- Reduced development costs

Priority Areas

- HIV
- Malaria

6. Learn which immunological responses provide protective immunity

Goal: To create new vaccines

Background

New technologies offer the potential to assay a wide variety of biomarkers and immune state diagnostics that are biologically informative and could be used as a decision-support tool for the design and evaluation of new or improved vaccines.

Roadblock

Currently there are no reliable biomarkers for assessing disease states in the developing world, including immunization state, presence of asymptomatic infections or that correlate with protection.

Challenge

To define biomarkers and biomarker signatures for assessing disease states and predicting protective immunity and other outcomes.

Potential Benefits

- Biomarkers could be used to guide vaccine development and epidemiological evaluation of the long term impact of control measures.
- Novel diagnostic & prognostic tools for public health assessment.

Priority Areas

- HIV
- Malaria
- Tuberculosis
- Acute Respiratory Infection