

THE IMPACT OF AIDS VACCINE RESEARCH ON HEALTH SYSTEMS STRENGTHENING

OUTLINE

- Background on AIDS Vaccine Research
 - Why AIDS vaccine research?
 - Challenges and possibilities
 - AIDS vaccine research in developing countries

- An added benefit: The impact of AIDS vaccine research on Health Systems Strengthening (HSS)
 - Training and retention of human resources
 - Infrastructure development
 - Improved regulatory processes
 - Improved health services
 - Enhanced HIV services



OBJECTIVES

By the end of this presentation, we hope you have a better understanding of:

1. Why AIDS vaccine research is important
2. What some of the challenges associated with AIDS vaccine research are
3. The key ways that AIDS vaccine research is contributing to health systems strengthening, and why this is important



WHY AIDS VACCINE RESEARCH?

- Vaccines are the most effective public health technology for controlling epidemic infectious disease
- Preventive vaccines enhance the body's immune defenses, enabling the immune system to fight off diseases that it cannot naturally control
- A safe, effective, affordable and globally accessible preventive vaccine offers the greatest promise for reducing global rates of HIV infection
- Part of comprehensive HIV prevention
 - Structural changes
 - Existing prevention methods, including behavior change
 - Research into new prevention technologies
 - Treatment



AIDS VACCINE RESEARCH: CHALLENGES AND POSSIBILITIES

- Vaccine research takes a long time, often decades
 - E.g. polio vaccine: 47 years; rotavirus (diarrheal disease): 33 years
 - So far 25 years since HIV was linked to AIDS
 - AIDS vaccine effort has only become robustly funded in recent years
- There are significant scientific challenges in AIDS vaccine development including:
 - HIV integrates into genetic material
 - HIV does not induce protective immunity
 - HIV has a high mutation rate
 - HIV has immune evasion mechanisms
 - HIV infects humans and there are no ideal animal models
 - HIV infects by multiple routes



AIDS VACCINE RESEARCH: CHALLENGES AND POSSIBILITIES(CONT.)

- Recent setbacks are discouraging but help answer important research questions
 - AIDSVAX Phase III clinical trial
 - Merck Ad5 candidate Phase IIb clinical trials (STEP and Phambili)
- Evidence exists that an AIDS vaccine is possible
 - Protection against simian immunodeficiency (SIV) in non-human primates
 - HIV viral load is normally suppressed for a substantial period of time
 - A small number of people suppress HIV viral load to undetectable levels for long periods of time and some individuals remain uninfected despite evidence of repeated exposure



AIDS VACCINE RESEARCH IN DEVELOPING COUNTRIES

- Research is taking place in low- and middle- income countries
 - Demonstrates feasibility of research in resource poor settings
 - Developing countries have historically waited longest to benefit from new health technologies
 - Given disproportionate burden of HIV and AIDS in developing countries, imperative to avoid delay in access
 - Research occurs with the targeted sub-types (clades) to ensure future effectiveness in particular areas
 - Potential to strengthen political, social and cultural commitment and acceptance of vaccine when it becomes available



AN ADDED BENEFIT OF AIDS VACCINE RESEARCH: HEALTH SYSTEMS STRENGTHENING

- Individuals and communities participating in vaccine research are benefiting along the way
- Reinforcing research capacity and contributing to health system functioning more broadly
- A **health system** consists of all the organizations, institutions, resources and people whose primary purpose is to improve health.
- **Strengthening health systems** means addressing key constraints related to health worker staffing, infrastructure, health commodities (such as equipment and medicines), logistics, tracking progress and effective financing.



THE IMPACT OF VACCINE RESEARCH ON HSS: FIVE KEY AREAS

1. Training and retention of human resources
2. Infrastructure development
3. Improved regulatory processes
4. Improved health services
5. Enhanced HIV services



1. TRAINING AND RETENTION OF HUMAN RESOURCES

- Training of research personnel in methodology, good clinical practices, good clinical laboratory practices, standard operating procedures, gender sensitization, research ethics, quality assurance and data management
- Transferable to other areas (e.g. vaccine trials for malaria, microbicides trials)
- New opportunities for career advancement
- Formation of regional scientific networks



2. INFRASTRUCTURE DEVELOPMENT

- Upgraded laboratory equipment- left behind after trials to be used in future research or health care services
- Combined with training of staff, laboratory performance is at same level as facilities in developed countries
- For example, at Kenyatta National Hospital in Nairobi, additional floor to hospital was built and equipped for vaccine research



3. IMPROVED REGULATORY PROCESSES

- Regulatory processes involve obtaining approval from national regulatory institution
- Includes ethics approval, based on established international guidelines. Ethical guidelines include:
 - All potential volunteers receive counseling on informed consent
 - Trial employed competent and highly trained research staff
 - All necessary steps taken to ensure confidentiality
 - All trial participants receive extensive risk reduction counseling and access to other prevention methods
 - Volunteer can leave the study any time without explanation



3. IMPROVED REGULATORY PROCESSES (CONT.)

- Governments can strengthen regulatory processes, including ethics approval, as a result of undertaking vaccine trials
- For example, International AIDS Vaccine Initiative (IAVI) supported effort to review and update Uganda's "Guidelines for Conducting Research on Human Subjects" based on international standards



4. IMPROVED HEALTH SERVICES

- Training and retention of human resources
- Development of health infrastructure
- Increased diagnosis and treatment of previously undiagnosed illness
- During volunteer screening overall health is assessed and other illness identified (e.g. hypertension)
- Health monitoring throughout the trial with treatment or referral for health issues that arise



5. ENHANCED HIV SERVICES

- Entry point for delivery of HIV services
- Counseling and testing
 - Provided for all potential participants
 - Opportunity to introduce rapid HIV-testing kits to the community
- Prevention
 - Participants receive extensive HIV-prevention information and resources
- Community-wide education
 - Dispel misinformation and raise awareness about HIV and vaccine trials
 - Role of researchers in advocacy to combat stigma against trial participants



5. ENHANCED HIV SERVICES (CONT.)

- Provision of ARVs
 - All major trial networks have committed to making ARVs available to trial participants who become infected during the course of trials
 - Importance of Community Advisory Boards (CAB) in setting appropriate guidelines for provision of ARVs
 - Some research programs expand treatment to community beyond trial participants (e.g. “wrap-around prevention and treatment services for communities located near trials in Kenya, Uganda and Tanzania)



CONCLUSION

- Primary goal of AIDS vaccine research is safe and effective vaccine
- Sustained and sufficient investment in AIDS vaccine research is a crucial component of comprehensive HIV prevention
- AIDS vaccine research has demonstrated potential to contribute to health systems strengthening
- All of those involved in AIDS vaccine research should continue to harness this potential to ensure that the communities that make research possible continue to benefit from the process and are equipped to benefit from a vaccine when one is developed



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