USAID's Support to Global Health Research and Development
Webinar Series:
USAID's Approach to Global Health R&D

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March 7, 2018
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Senior Medical and Scientific Officer
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USAID Has A Long History Supporting Global Health Research and Innovation

**Oral Rehydration Solution/Zinc**
- Low cost, life-saving treatment
- USAID supported pivotal R&D
- Engaged manuf. for supply/global introd
- Saved lives of over 1.5 million children (introd. in 10 of 15 highest burden countries)

**Vitamin A**
- USAID had key role in discovery/adoption
- Distribution costs 2-3 cents per capsule
- Reduced child mortality 28-34%
- More than 80 nations have vitamin A supplementation programs

**Insecticide Treated Nets**
- USAID large-scale efficacy trials across Africa
- Reduced under 5 mortality by 20%
- Reduced clinical malaria by 40-50%
- Scaled up throughout Africa

**Contraceptive Implants**
- USAID funded Phase III clinical trials for FDA approval and supported introd.
- Implants widely used, one of the fastest growing contraceptive methods

**AMTSL**
- High impact practice to prevent postpartum hemorhage
- USAID leadership role assessing utilization of AMTSL and influencing WHO policy adoption
- Scaled up around the world
Coordinating R&D Investments Across Different Stages
Stakeholder Consultations to Inform GH Research Strategy Development

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<th>Non-USG Stakeholders</th>
<th>USG Stakeholders</th>
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<td>DFID</td>
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<td>Health Systems Global, John Hopkins University</td>
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<td>Internal USAID Staff Discussion</td>
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<td>Field Advisory Council</td>
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Respondents listed here were interviewed
Additional feedback came via online survey
Key Themes From Stakeholder Consultations

Three key themes emerged from respondents on USAID’s unique role in GH research:

1. Implementation science is a critical niche for USAID.
2. USAID’s comparative advantage is the strong in-country presence and connection with local communities.
3. There is a critical need for investments in local research systems. Research should start locally and investments should be made in local institutions in order to be sustainable.
USAID’s “Research to Use” Approach
Vision, Mission, and Goals of USAID Global Health R&D Strategy

Vision
Research and innovation are translated into action to improve health, well-being, and resilience of people around the world.

Mission
To support collaborative research from the local to the global level, generating evidence on interventions, policies, approaches, and technologies that increase the impact of health programs globally.

To achieve its global health research and development mission, USAID will focus on three interrelated goals:

1. HEALTH TECHNOLOGIES, TOOLS, AND APPROACHES
To accelerate the development, introduction, scale-up, and sustained use of health technologies, tools, and approaches to address critical unmet needs and emerging challenges.

2. IMPLEMENTATION SCIENCE
To identify, generate, and apply evidence to influence the adoption, implementation, and health impact at scale of priority life-saving health and development interventions.

3. RESEARCH AND DEVELOPMENT SYSTEMS
To strengthen the capability and resilience of people, systems, and partnerships to conduct research and utilize results to improve health outcomes.
For More Information on USAID-Supported GH R&D

To download a copy of USAID's latest Global Health-Related Research and Development Report to Congress and 5-year strategy please visit:

Thank you for joining!
Matt’s email address: mbarnhart@usaid.gov
IAVI and USAID
Advancing HIV Vaccine Development and Africa-Centered Science

Mark Feinberg MD, PhD | March 7, 2018
CEO, International AIDS Vaccine Initiative (IAVI)
Getting to the End of AIDS

- 76 million people infected to date
- 35 million have died
- 37 million people are now living with HIV
- 17 million people living with HIV still do not have access to treatment

- Number of new infections continues apace (1.8 million in 2016).
  - Approximately two thirds of the world’s new infections occur in Africa.
  - One-third of new infections occur in people aged 15-24.
  - Still the leading cause of death among women of reproductive age.

Demographic trends, major challenges to reaching those who are still not in treatment, and potential difficulties in maintaining large scale treatment programs over decades threaten tremendous progress made to date.

Source: UNAIDS 2017
A Vaccine is Our Best Hope to End AIDS

Treatment alone has never ended an epidemic. Only vaccines have. We need a vaccine to end AIDS.

- Without a vaccine, we may actually see increases in infection rates.
- Vaccines are far less expensive to administer than daily, lifelong drug treatments.
- Rising resistance to life-saving HIV drugs threatens to compromise progress.
- A vaccine will bolster U.S. national security by restoring stable economies and social structures in countries hardest hit by AIDS.
USAID Support of HIV Vaccine Development and African Scientific Leadership

For the last 15 years, USAID has fostered innovative HIV vaccine development and leadership among African scientists.

• Current agreement between USAID and IAVI is called **ADVANCE: Accelerating Development of Vaccines against AIDS and New technologies to Combat the AIDS Epidemic.**

• Vision for **ADVANCE**: An African-centered model of global partnership, to accelerate the design and development of effective, accessible HIV vaccines for use throughout the world.
The ADVANCE vision for expediting HIV vaccine development

The work needs to begin and end with the individuals and communities at risk, and engage and build African scientific capacity at every stage.
IAVI’s Role: Linking Global Partners to Build Local Capacity and Accelerate Scientific Progress

**Discovery Laboratories**
- Neutralizing Antibody Center (Scripps, La Jolla)
- Design and Development Lab (IAVI Brooklyn)
- Human Immunology Lab (Imperial College, London)
- Translational Health Science and Technology Institute (Delhi)

**Clinical Research Network and Reference Labs**
- 8 clinical facilities in 5 countries; U.S. and EU partners
- Community engagement
- Human Immunology Lab (Imperial College, London)

**VxPDC**
- Translational development

**Advocacy**
- Evidence-based advocacy to help maintain HIV/AIDS funding as a global priority
The Impact of Sustained USAID Support in Africa

A highly valued network for HIV vaccine and related research

- Strengthened research and capacity for HIV vaccines and other health technologies
- Uncovered hidden epidemics
- Engaged policy makers and political leaders
- Strengthened health services and access and improved policies
- Positively impacted communities most at risk
- Built new generation of scientists and research institutions
Out of Africa: How Insights Emerging from Scientific and Community Engagement in Africa Have Transformed the HIV Vaccine Field

• The solution of the three-dimensional structure of the HIV Envelope glycoprotein overcame perhaps the most vexing and important scientific challenge to HIV vaccine development

• Moving from empiricism to testable hypotheses

• USAID-supported efforts to build scientific capacity in Africa generated insights, specimens, and reagents that have had tremendous benefit across the broader HIV field

• These insights continue to be greatly amplified by major investments and scientific contributions of other key research organizations – including the NIH, with the cutting-edge research at the intramural NIH Vaccine Research Center (VRC) and the extramural Centers for HIV/AIDS Vaccine Immunology (CHAVI) and the European Union (Horizon 2020 programs)
The Impact of Sustained USAID Support in Africa

HIV infection research providing information to inform vaccine design and prevention research

Samples from over 2,738 HIV-infected volunteers from 12 countries around the globe

*including 3 of the 5 most promising antibodies now in clinical trials

**IMPACT**

261 Identification of 261 new HIV-neutralizing antibodies*

40,000+ Samples shared

100+ Peer reviewed publications

30 Active research projects addressing key HIV challenges
Broadly Neutralizing Antibodies (bNAb) Case Study

These antibodies disable multiple HIV viral strains by binding to sites on the virus, which prevent HIV from infecting target cells.

bNAbsc are important:

- They inform *immunogen design*
- They are *prevention tools* in their own right
The Impact of Sustained USAID Support in Africa

Scientific leadership and laboratory infrastructure in Africa to accelerate R&D for HIV vaccine and respond to other emerging infectious diseases

- Promotion of gender equality
- Increased scientific local leadership
- Build capacity to respond to epidemics
- Improved health and economies
- Sustainable local research infrastructure
- Accelerated in-country research
The Impact of Sustained USAID Support in Africa

Engagement of local communities to support clinical trials, national policies, and the country ownership and leadership goals of PEPFAR

- Strengthening support of current and future vaccine trials: 85-90% retention in epidemiological and vaccine trials
- Informing national policies
- Facilitating national investment in HIV research and health infrastructure: 500,000 people received VCT and health care referrals
The Impact of Sustained USAID Support in Africa

Complement U.S. government investments in HIV/AIDS and support key principles of transparency, accountability, and partnerships

• IAVI and its partners are helping PEPFAR reach its goal of ending the epidemic through the discovery and testing of vaccines and other prevention tools.

• ADVANCE complements investments in HIV R&D by NIH and the Department of Defense by bringing African institutions and scientists closer to the center of the larger search for an AIDS vaccine.
Vision: Epidemic outbreaks of infectious diseases will be managed at an early stage to prevent them from becoming public health emergencies that result in loss of life, undermine social and economic development, and emerge into humanitarian crises.

Status:
- CEPI has now transformed from a concept into a functioning global non-profit with over $620 million in funding and offices in Norway, the U.K., India, and now the U.S.
- They have launched two calls for proposals for three priority disease areas, MERS, Lassa, and Nipah, which include: 1) candidate vaccine development against these priority diseases; 2) development of platforms that can be used for rapid vaccine development against unknown pathogens. They also intend to continue to make investments to help “finish the job” on Ebola.
What’s at Stake?

~5,000

people infected with HIV every day

The Opportunities, Obligations and Challenges Ahead

We need to develop effective models to ensure broad, sustainable, and affordable access to efficacious HIV vaccines and prevention technologies.

Achieving Global Access

- Global access
- Distribution & rollout
- Affordable Supply
- Community Engagement
- Discovery Science
- Translation
- Clinical Research
- Affordable Supply
- Discovery Science
- Translation
- Clinical Research
- Affordable Supply
- Discovery Science
- Translation
- Clinical Research
Imagine a world without AIDS
IAVI gratefully acknowledges the generous support provided by the following major donors:

- USAID
- PEPFAR
- Bill & Melinda Gates Foundation
- THE WORLD BANK
- Minis of Foreign Affairs of the Netherlands, Denmark, Japan, and Ireland
- Ministry of Foreign Affairs of the Netherlands
- Ministry of Foreign Affairs of Denmark
- Ministry of Foreign Affairs of Japan
- Irish Aid, Department of Foreign Affairs and Trade
- James B. Pendleton Charitable Trust
- Korean Women against AIDS
- The City of New York, Economic Development Corporation
- EMMES Corporation
- European Union
- Foundation for the National Institutes of Health
- The Gilead Foundation
- GlaxoSmithKline
- Google Inc.
- Government of Japan
- The Hearst Foundations
- Irish Aid, Department of Foreign Affairs and Trade
- Ministry of Foreign Affairs of The Netherlands
- Ministry of Science & Technology, Government of India
- National Institute of Allergy and Infectious Diseases
- Norwegian Ministry of Foreign Affairs
- Robert Wood Johnson Foundation
- The Starr Foundation
- U.K. Department for International Development
- The U.S. President’s Emergency Plan for AIDS Relief through the U.S. Agency for International Development
- The World Bank

And many other generous individuals from around the world

As of January 2018
Why Implementation Research & Delivery Science Matters

Troy A. Jacobs, MD, MPH, FAAP
Research & Policy Division
Office of Maternal Child Health & Nutrition
March 7, 2018
17 year lag from research to practice is unacceptable

• “Many interventions found to be effective in health service research studies fail to translate into meaningful patient care outcomes across multiple contexts. In fact, some estimates indicate that two-thirds of organizations' efforts to implement change fail.”

• Damschroder LJ et al. Implement Sci 2009; 4:50
Implementation challenges we’re trying to solve

• Policy makers define strategies, but often have limited influence on how they are implemented
• Strategies often can achieve their objectives but may produce unintended & unpredictable consequences
• Many health policies aim to serve the poor & vulnerable but rarely show HOW they have improved services for disadvantaged
• Equity in implementation continues to be elusive
• External validity limitations of “best practice” unknown
## How Strategies Are Implemented Matters

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<th>Strategy</th>
<th>Randomized Controlled Trials</th>
<th>All “Adequate” Studies</th>
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<tr>
<td>Community coordination and organization</td>
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<td>4.6**</td>
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<tr>
<td>Local adaptation of the intervention</td>
<td>9.3</td>
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<td>Broad-based support of various stakeholders</td>
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<td>Consultation and engagement of powerful interest groups</td>
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<td>Flexibility and modification through stakeholder feedback</td>
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<td>Representation from powerful interest groups</td>
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<td>Constraints reduction plans</td>
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* Pvalue < 0.05; ** Pvalue < 0.01
Timeline for Chlorhexidine

- 2005: Nepal Efficacy Study
- 2006: NIH-USAID CHX Consult Mtg
- 2007: Nepal Program Effectiveness
- 2008: 1st EML Application
- 2009: Nepal adopts CHX in Natl Guidelines; Asia Mtg
- 2010: Grand Challenge to JSI/Nepal for scale-up
- 2011: CHX WG-UNColl SC
- 2012: 15 new countries interested in CHX
- 2013: WHO Guidelines
- 2014: 3 new countries in introduction/scale-up
- 2015: 3 new countries in pilot/policy alignment
- 2016: WHO EML

Concurrent:
- Replication research: Pakistan, Bangladesh
- Feasibility research: Bangladesh, Nepal
- Product development: Nepal

- 21 countries now in pilot/policy alignment or introduction/scale-up phase
- 1 global and 7 local manufacturers
Scaling chlorhexidine in Nepal provides early exemplar and lessons learned...

Nepal scale-up tracking that of typical US drug launch... but continued funding and focus is critical to achieving and sustaining scale.

Scale-up Implications

Support from Saving Lives at Birth and strong partnership with MOH provided needed focus and funding in Nepal

- ~8,000 lives saved to date

USAID and the Chlorhexidine Working Group have paved the way for global introduction and scale

- Replicating rapid scale-up in other countries can have significant impact: (~65M live births in 24 priority MCH countries)

- ~300,000 lives saved per year from use of CHX in India and Sub-Saharan Africa
Hospitalization may not be possible for 80-90% of newborns with Possible Serious Bacterial Infections (PSBI) or “sepsis” – a known killer of newborns

- Hospital not available/accessible
- Other barriers to hospitalization
GUIDELINE
Managing possible serious bacterial infection in young infants when referral is not feasible
Policy Adoption in Bangladesh - Process

**May 13**
- **Policy Adoption**
  - 4 key newborn interventions for national scale up

**July 13**
- **High Political Commitment**
  - APR Declaration by Minister MOH on behalf of Honorable PM endorsed 4 key newborn interventions

**Oct 13**
- **Formation of 4 TWGs for developing guidelines/SOPs for 4 key newborn interventions**
  - SEPSIS TWG Formed
  - SNL provided support to TWGs

**Jun 13**
- **Sensitization of key stakeholders about AFRINEST & SATT**

**2015**
- **Disseminating AFRINEST & SATT in Dhaka**
  - Advocacy and consensus to incorporate Simplified regimen

**CHX, KMC, ACS scale-up & Neonatal sepsis management at PHC level**

**PSBI: Possible serious bacterial infection**

Courtesy: SAVE/SNL
Implementation research for operationalization of national guidelines:
- In three different settings -

- Kushtia - Implementation support by SNL, Evaluation by icddr,b
- Laxipur - Implementation support by MaMoni HSS, Evaluation by JHU
- Sylhet - Implementation support by and Evaluation by JHU

- Somewhat variable implementation
- Different demand generation approaches
- Different evaluation partners
- Using largely common evaluation framework

Courtesy: SAVE/SNL
Research Question and Objectives

What are the Coverage, Quality and Operational challenges of managing young infants at first level facilities as per the National Sepsis Management Guideline of Bangladesh?

Coverage
• Knowledge and awareness
• Care seeking practice

Quality of care:
• Provision: availability and readiness
• Process: adherence
• Outcome: treatment failure

Operational challenges:
• Care seeking
• Adherence
• Develop and test overcoming strategies

Process documentation:
• Capacity development,
• Health systems strengthening,
• Community follow up and community mobilization
• Data-driven decision making process
Respectful Maternity Care

- Physical Abuse
- Undignified Care
- Lack of informed consent
- Lack of confidentiality
- Discrimination
- Abandonment of Care
- Detention in Facilities

Source: Bowser and Hill, Traction Project 2010
Respectful Maternity Care

WHO Quality of Care Initiative

Respectful maternity care (RMC) is a universal human right that is due to every childbearing woman in every health system. Women's experiences with maternity caregivers can empower and comfort them, or inflict lasting damage and emotional trauma. While many interventions aim to improve access to skilled birth care, the quality of relationships with caregivers during maternity care has received less attention. Evidence suggests that in countries with high maternal mortality, the fear of disrespect and abuse that women often encounter in facility-based maternity care is a more powerful deterrent to use of skilled care than commonly recognized barriers such as cost or distance.

In 2011, WRA launched a global campaign to promote a clear standard for RMC that is rooted in international human rights. Working with other global organizations, WRA produced a ground-breaking consensus document, the Respectful Maternity Care Charter: The Universal Rights of Childbearing Women, which demonstrates the legitimate place of maternal health rights in the broader context of human rights. In 2016, White Ribbon Alliance continues to build visibility and coverage of this issue, and enforces a world in which a woman's right to RMC is embedded at all levels of maternal health systems.

Since its development, the RMC Charter has been translated into eight languages and is being used globally to talk about the problem of disrespect and abuse of maternity care. It is also being used as a tool to educate health workers about maternity care and human rights, and to increase awareness of the problem in a way that avoids blaming and shaming. To support this effort, WRA has produced a range of materials that include guidelines, infographics, films, and presentations to help increase visibility of this issue. Once the Charter gained momentum, it was endorsed by the World Health Organization, the International Federation of Gynecology and Obstetrics, and the International Confederation of Midwives.

White Ribbon Alliance (WRA) formed over a decade ago to give voice to the women at risk of dying in childbirth. WRA rapidly grew, as thousands of individuals and organizations joined the network, speaking as one voice, identifying problems in their own communities and finding solutions collaboratively at national level across Africa and Asia. Our mission is to inspire and convene advocates who campaign to uphold the right of all women to be safe and healthy before, during, and after childbirth. We help citizens recognize their rights and catalyse a global movement for respectful maternity care for every woman, everywhere.
**Design and Structural Barriers of Research to Use**

### Setting
- Competing Demands
- Financial/Organizational Instability
- Specific needs of clients and setting
- Limited resources
- Prevailing practices work against innovation
- Perverse incentives or regulations

### Intervention Characteristics
- Cost
- Intensive time demands
- Difficult to understand
- Not developed for user needs
- Not sustainable
- Highly specific to particular setting

### Research Design
- Not representative
- Failure to evaluate:
  - Cost
  - Reach
  - Setting
  - Adoption
  - Fidelity
  - Maintenance
  - Sustainability

### Interaction
- Participation barriers lead to low reach
- Interventions are not flexible
- Intervention is not appropriate for setting
- Staffing pattern does not match intervention needs
- Organization and intervention philosophies not aligned
- Organization is unable to implement intervention adequately

We need to focus on the “How” of implementation as a regular business practice

Adapted from Glasgow and Emmons, Annual Review Pub Health, 2007
The Promise of Implementation Research, Sept 2014

Statement on Advancing Implementation Research and Delivery Science

- Informs policy-makers, managers, the public, researchers, funders and other users on practical matters
- Builds capacity, ownership and accountability
- Strengthens problem-solving and learning
- Contributes to improved coverage, quality, efficiency and effectiveness of health interventions
Implementation Research Methods

• Determined by Question
• Modified by Context, Stakeholders, Nature of Intervention, Timeliness
Three Health Research Program Mechanisms

1. **Research Translation and Technical Assistance Coordinating Implementation Research to Communicate Learning and Evidence (CIRCLE) Contract**


3. **Implementation Research and Research/ Technology Utilization Broad Agency Announcement (BAA)**
First Mechanism: CIRCLE

- The CIRCLE project supports coordinated research-to-use activities to advance USAID global health priorities including Preventing Child and Maternal Deaths, Controlling the HIV/AIDS Epidemic, Combating Infectious Diseases, and Working with Global Partners.

- Activities under CIRCLE span programmatic, technical, logistical and administrative support, such as:
  - Convening and facilitating consultative meetings
    - Including Broad Agency Announcement (BAA) co-design process support
  - Mobilizing subject matter experts and subcontractors
  - Engaging key stakeholders from LMICs
  - Conducting or commissioning research, M&E activities
  - Facilitating research translation and utilization of findings
  - Establishing communities of practice
  - Knowledge management
Second Mechanism: HEARD

- The HEARD Project focuses on evaluative and targeted research that accelerates research-to-use processes and two types of research activities:
  1) Multidisciplinary applied & implementation research
  2) Evaluative research

- HEARD works through a partnership known as the Implementation Science Collaborative, comprised of seven global and sub-regional anchors as well as 24 technical resource partners. The four main strategies of the collaborative are:
  1) Partnership and agenda development
  2) Research and evaluation study design and implementation
  3) Data liberation and evidence strengthening
  4) Acceleration of evidence-to-use processes
The HEARD Approach

Multi-disciplinary applied and implementation research

Evaluative research

- Targeted questions, barriers and bottlenecks of interventions
- Technologies, products, policies that show promise for potential scale-up

- Surveillance of pilot programs
- Surveillance of at-scale tools, technologies, and policies around the main causes of maternal, child and neonatal deaths and morbidity

Accelerating the research-to-use process
The Health Research Program supports real-world research and translates findings into effective health interventions that can be adapted globally.
Thank you for joining us today!

Please join us for our second seminar
Population and Reproductive Health
Wednesday, March 14, 12-1PM
https://ghpod.adobeconnect.com/usaid_gh_rd/