USAID's Support to Global Health Research and Development Webinar Series:

USAID's Approach to Global Health R&D



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(IAVI)



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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 dissem / adoption
- Distribution costs 2-3 cents per capsule
- Reduced child mortality 23-34%
- More than 60 nationshave vitamin A supplementation programs

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

Insecticide Treated Nets



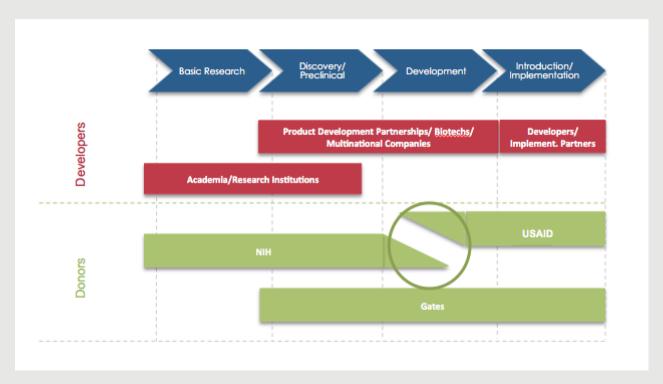
Contraceptive Implants

- USAID funded Phase III clinical trials for EDA approval and supported introd.
- Implants widely used; one of the fastest growing contraceptive methods

AMTSL

- High impact practice to prevent post partum hemorrhage
- 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

Non-USG Stakeholders

Consortium of Universities in Global Health

DFID

Bill & Melinda Gates Foundation

Health Systems Global, John Hopkins University

LMIC Partnerships (Asia, Bangladesh)

PATH

Policy Cures Research

Treatment Action Group

WHO

Respondents listed here were interviewed Additional feedback came via online survey

USG Stakeholders

CDC

Fogarty International Center, NIH

NIAID, NIH

Office of Population and Reproductive Health, USAID

PEPFAR

Group Consultations

R&D Council, USAID

Former USAID Employees

Center for Accelerating Innovation and Impact (CII)

Internal USAID Staff Discussion

Field Advisory Council

5

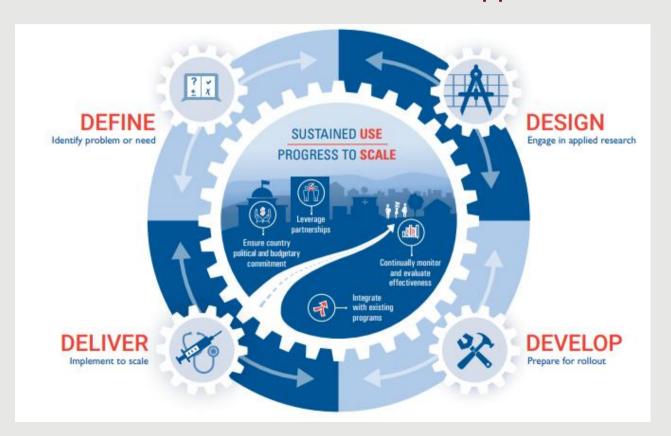
Key Themes From Stakeholder Consultations

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

- I. 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



3/16/2018

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, scaleup, 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:

https://www.usaid.gov/what-we-do/global-health/cross-cutting-areas/research

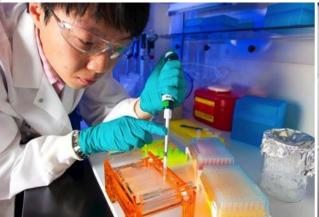






IAVI and USAID Advancing HIV Vaccine Development and Africa-Centered Science

Mark Feinberg MD, PhD | March 7, 2018 CEO, International AIDS Vaccine Initiative (IAVI)







Getting to the End of AIDS

76 million \Rightarrow 35 million \Rightarrow 37 million \Rightarrow people infected to date



have died



people are now living with HIV



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.



Pavi

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.

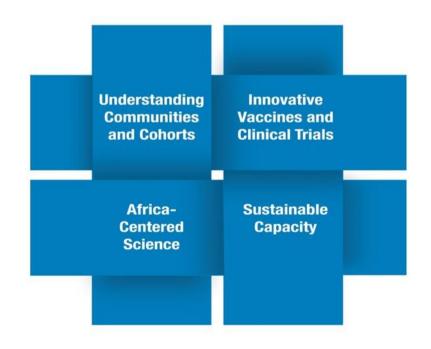
- Without a vaccine, we may actually see increases in infection rates.
- Vaccines are far less expensive to administer than daily, lifelong drug treatments.
- Rising resistance to life-saving HIV drugs threatens to compromise progress.
- A vaccine will bolster U.S. national security by restoring stable 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)

VxPDC

Translational development



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)

Advocacy

 Evidence-based advocacy to help maintain HIV/AIDS funding as a global priority



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









Pavi

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)

IMPACT

HIV infection research providing information to inform vaccine design and

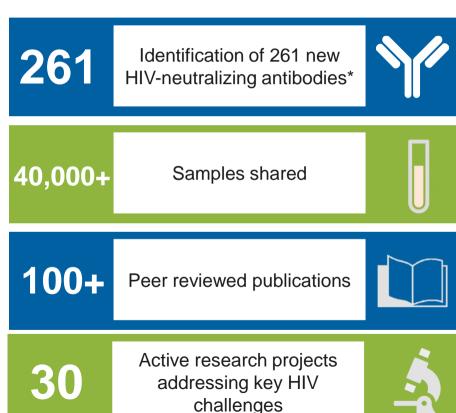
prevention research

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



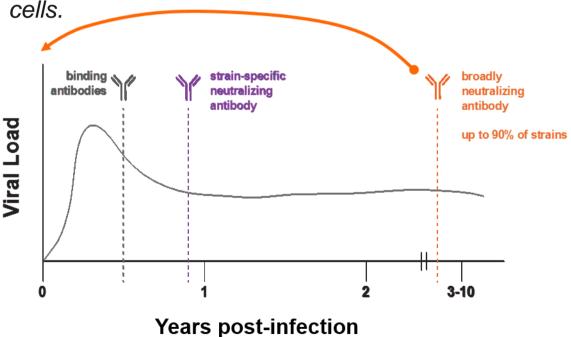
Charlotte Raymond Photography

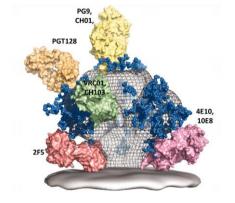
*including 3 of the 5 most promising antibodies now in clinical trials



Broadly Neutralizing Antibodies (bNAbs) Case Study

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





bNAbs are important:

- They inform immunogen design
- They are prevention tools in their own right

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



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



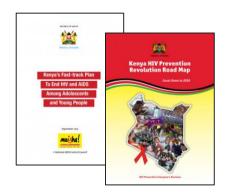
Strengthening support of current and future vaccine trials

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



Pavi

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.



Broad Benefit of Sustained USAID HIV R&D Support in Africa

Opportunity to sustain investment in Africa scientific research excellence and ensure local capacity to respond to new emerging infectious disease threats

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?

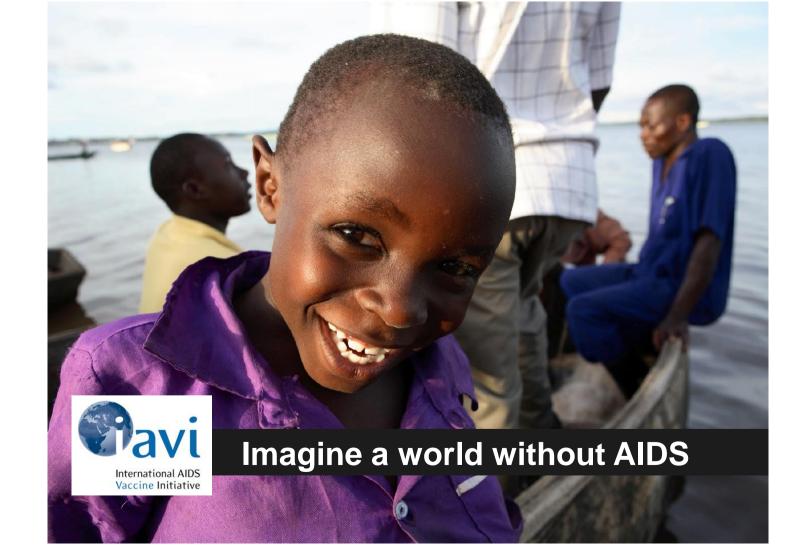
~5,000 people infected with HIV every day



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



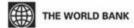


IAVI gratefully acknowledges the generous support provided by the following major donors



















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bgC3 LLC | Bill & Melinda Gates Foundation | Buimerc Core Investments Pvt. Ltd. | Broadway Cares/Equity Fights 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 | James B. Pendleton Charitable Trust | Korean Women against AIDS | Ministry of Foreign Affairs of Denmark | 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



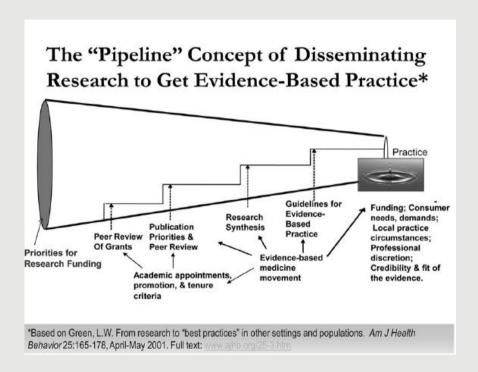
Why Implementation Research & Delivery Science Matters

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

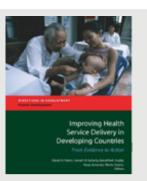
 Many health policies aim to serve the poor & vulnerable but rarely show HOW they have improved services for disadvantaged

- Equity in implementation continues to be elusive
- External validity limitations of "best practice" unknown



How Strategies Are Implemented Matters

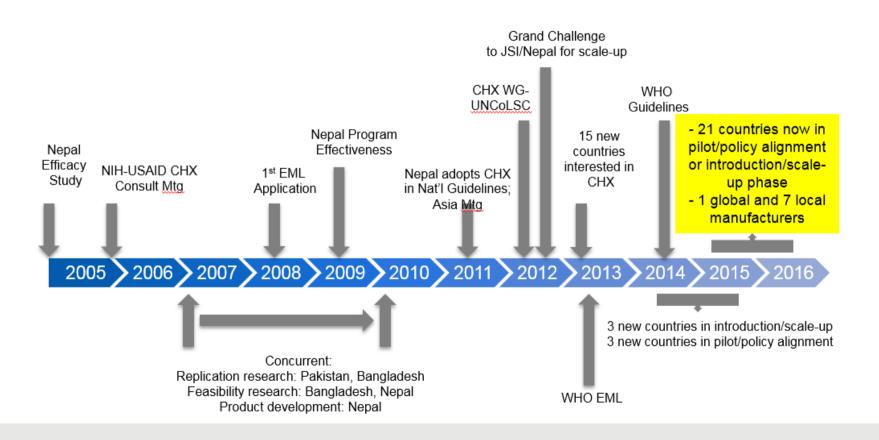
	Controlled Trials	All "Adequate" Studies
	Odds ratio	Odds ratio
Community coordination and organization		4.6**
Local adaptation of the intervention	9.3	4.3 *
Broad-based support of various stakeholders		3.9 *
Consultation and engagement of powerful interest groups	2.8	3.8**
Flexibility and modification through stakeholder feedback		3.4 *
Representation from powerful interest groups	2.4	3.0 *
Constraints reduction plans	6.7	2.7 *



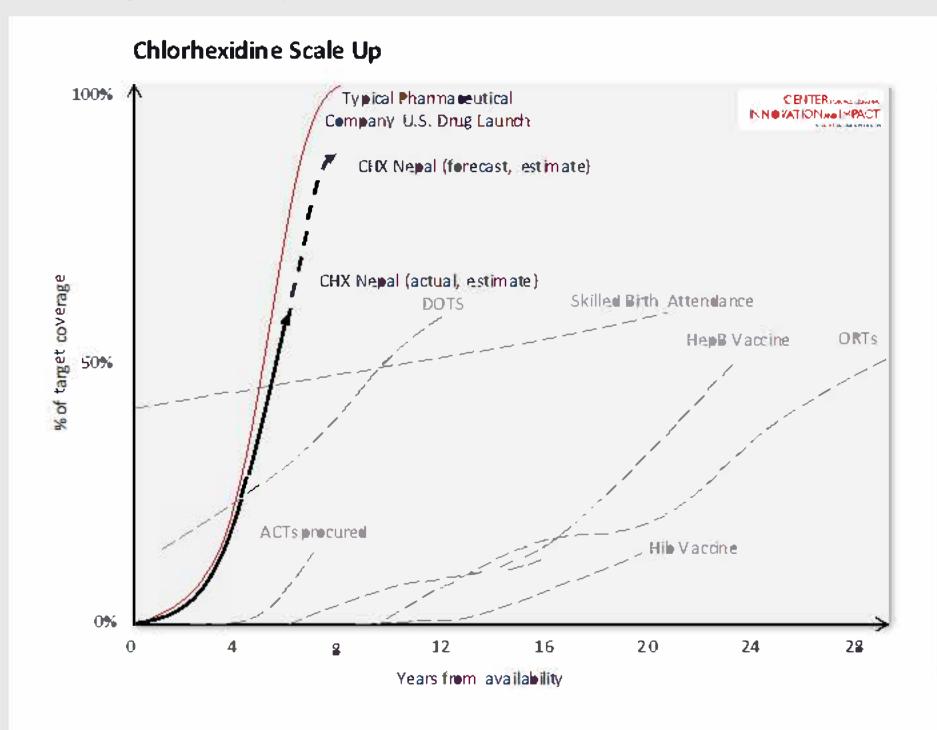
* Pvalue<0.05; ** Pvalue<0.01

Randomized

Timeline for Chlorhexidine



Scaling chlorhexidine in Nepal provides early exemplar and lessons learned...



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

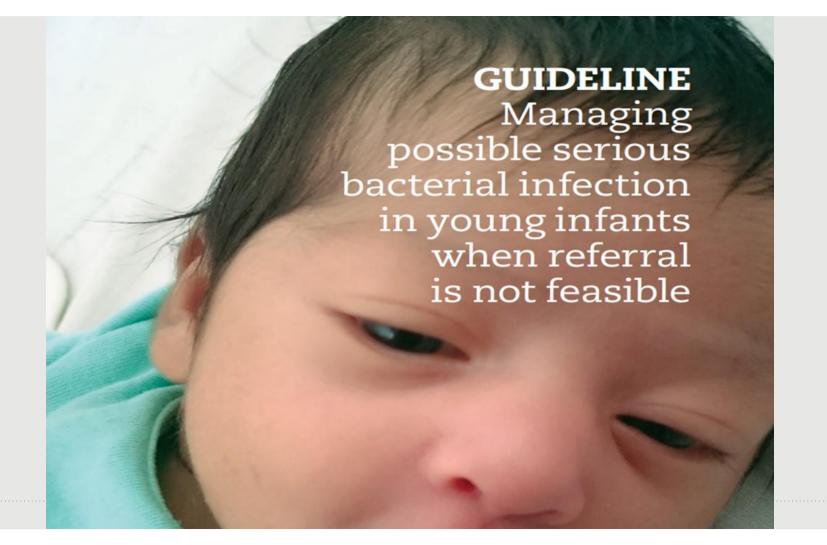
- Replicating rapid scale-up in other countries can have significant impact: (~65M live births in 24 priority MCH countries)
- ~300,000 lives saved per year from use of CHX inIndia and Sub-Saharan Africa

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

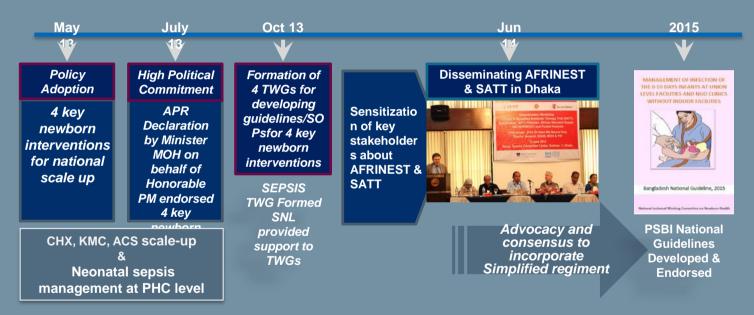
Hospitalization may not be possible for 80-90% of newborns with Possible Serious Bacterial Infections (PSBI) or "sepsis" – a known killer of newborns



- Hospital not available/accessible
- Other barriers to hospitalization



Policy Adoption in Bangladesh - Process



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

LaxipurImplementation
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



RESPECTFUL MATERNITY CARE

Respectful maternity care (RMC) is a universal human right that is due to every chilbbearing 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 Whenen, which demonstrates the legitimate place of maternal health rights in the broader context of human rights. In 2015, White Ribbon Alliance confusions to build visibility and covereign of this issue, and envisions 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 during maternity care. It is also being used as a tool to educate health workers about maternity care and human rights, and to raise awareness of the problem in a way that avoids batming and shaming. To support this eightru, WRD produced a range of materials that include guidebooks, 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 Mildwise.

WHO Quality of Care Initiative



RESPECTFUL MATERNITY CARE CAMPAIGN UPDATE
April 2015

White Ribbon Alliance (WRA) formed over a decade ago to a 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 a 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.

BACKGROUND

Respectful maternity care (RMCI) is a universal human right that is due to every childbearing woman in every health system around the world. 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



The Respectful Maternity Care Charter: The Universal Rights of Childbearing Women can be found on www.whiteribbonalliance.org/ campaigns/respectful-maternity-care/

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
 - -MAINTANCE
 - -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

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

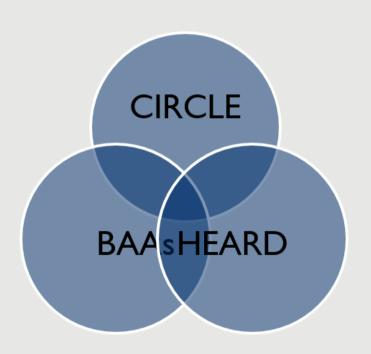
Implementation Research M

- Determined by Question
- Modified by Context,
 Stakeholders, Nature of Intervention, Timeliness



INNOVATION RESEARCH Proof of concept: Proof of implementation: Informing Scale-up: How does it work in Is it safe and does it Health systems integration work? real-world settings? and sustainability Implementation Implementation Implementation Implementation **Implementation** relevant but relevant but as primary not relevant studied as not considered effects reduced contributing focus Research question: factors Basic sciences, product Research Ouestions Research question: Research Ouestions: development, or inquiry Susceptible to implemen-Secondary question, e.g. rimary question, e.g. Research Ouestions unrelated to implementation variables, but not average effectiveness of How do parts of a considered a program program change and Context: Controlled or Context: Largely con-Context: Real-world why? What are the efnot related to implemenfects of implementation trolled, highly selected setting with partially population, factors afcontrolled intervention Context: Real-world Implementation fecting implementation Implementation Context: Real-world se strategies and fixed or ignored strategies: Identified ting and population variables: not relevant Implementation and described, but uses Strategies: One or more strategies: May be strategies: None or one one type only and effects type only, not considered are controlled in research Implementation Implementation Implementation variables: Assumed to variables: May be variables: Can influence be equal or unchanging or effects controlled (e.a. results but assumed adjusted as confounding to be controlled or not relevant factors) Examples: Basic science: Examples: Efficacy stud-Example: Pragmatic trials. Examples: Effectiveness-Examples: Mixed methods Phase I & II clinical trials: ies. Phase III randomized Implementation trials: Oband quasi-experimental Ouasi-experimental study Qualitativo studios unrocontrolled dinical trial: with intervention and comservational studies assessing studies to determine the lated to implementation Oualitative study on health parison areas: Observational implementation variables as changes in delivery or service use that does constudies with implementation secondary factors: Participaacceptability of a program: issues (e.g. perceptions of sider how well the services as secondary issue Observational studies on tory research are provided. adaptation, learning, and scaling-up of a programme

Three Health Research Program Mechanisms



- 1. Research Translation and Technical Assistance Coordinating Implementation Research to Communicate Learning and Evidence (CIRCLE) Contract
- 2. Applied Research Project Health Evaluation, Research and Development (HEARD) Cooperative Agreement
- 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



- 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









ABOUT

FOCUS AREAS

PROJECTS

IMPACT

RESOURCE LIBRARY

SAVING LIVES THROUGH REAL-WORLD RESEARCH



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/

