Saving Lives at Birth: A Grand Challenge for Development Addendum 04

to

The USAID Broad Agency Announcement (BAA) for Global Health Challenges (BAA-GLOBAL HEALTH-2016)

SECTION A. PROGRAM DESCRIPTION

Program Summary

United States Agency for International Development (USAID), the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada (funded by the Government of Canada), UK's Department of International Development (DFID), and the Korea International Cooperation Agency (KOICA) have joined together to launch the seventh round of Saving Lives at Birth: A Grand Challenge for Development.

Together, we call for groundbreaking prevention and treatment approaches for pregnant women and newborns in poor, hard-to-reach communities around the time of childbirth. An estimated 2.6 million stillbirths, 2.7 million neonatal deaths and 303,000 maternal deaths occur globally each year, signaling a major gap in interventions specifically around childbirth and the early postnatal period – a time when mothers and babies are most vulnerable and global progress in reducing mortality has been particularly poor. This gap in interventions is particularly acute in poor, underserved communities and among women who are disadvantaged.

Innovative ideas that can leapfrog conventional approaches to address inequities and inequalities of care are critical in surmounting these gaps. If we are to accelerate substantial and sustainable progress in reducing maternal and newborn deaths and stillbirths at the community level- and contribute to the goals and targets of Ending Preventable Maternal Mortality and the Every Newborn Action Plan - we need to foster and scale innovative prevention and treatment approaches across three domains:

- (1) Science & technology;
- (2) Service delivery; and
- (3) Demand-side innovation that empowers pregnant women, their families, and their communities to practice healthy behaviors and be aware of and access health care during pregnancy, childbirth and the early postnatal period, especially the first two days after birth.

We are particularly interested in investing in and supporting approaches that integrate the latest behavior change approaches with scientific and/or

technological advances and service delivery platforms into radical solutions for widespread impact on maternal and newborn health. We encourage these ideas that integrate scientific / technological, social and business innovation¹ to foster sustainability.

Achieving Impact

Significant breakthroughs in innovation often come about when new ideas and disciplines are applied to long-entrenched problems. To harness scientific / technological, social, and business ingenuity, and to catalyze successful implementation at sustained scale, we encourage:

- a) Development of partnerships that bring together diverse competencies, particularly from the private sector with co-funding.
- b) Formation of dedicated multidisciplinary/cross-sectoral teams

We believe that such collaborations and commitments will enable and deploy stronger and more sustainable solutions. We also believe that bold ideas must be championed by effective, results-driven leaders with the capacity to convene and engage with key influencers. Where partnerships include innovators from low-and middle-income countries, we encourage the designation of the low- and/or middle-income country partner as the Project Manager/ Principle Investigator (PI).

Achieving Impact at Scale

Critical to the sustained success of innovative solutions is a clear understanding of how best to implement them at scale. Successful applicants will take into account country programs, policies, and priorities. Development of new interventions, technologies or approaches and their successful scale up should complement efforts to strengthen health systems and address broader determinants of health including poverty, inequity, gender inequality, and access to water and sanitation resources, all of which are needed to address this grand challenge for development. Applicants should consider the overall health system readiness to support the introduction and scale up of a solution for sustained impact.

Funding

Through a rigorous review process, we will identify and support transformational, scalable approaches that advance equity and quality of care to dramatically – and sustainably – reduce deaths and poor birth outcomes for vulnerable women and newborns in the hardest to reach communities of the world. These audacious but achievable ideas with the potential for high-return will be swiftly funded through one of three streams:

- (1) **Seed Funds** to develop and assess the feasibility of innovative ideas,
- (2) **Validation Funds** to introduce and validate the effectiveness of innovations to reach proof-of-concept, and

¹ This approach is referred to as Integrated Innovation, for more information visit: http://www.grandchallenges.ca/integrated-innovation/

(3) **Transition Funds** to transition innovations with demonstrated proof-of-concept toward scale up.

For more information on the Saving Lives at Birth program and projects, please visit our website (www.savinglivesatbirth.net).

Problem Statement

While we have made remarkable progress in recent decades reducing maternal and child mortality globally, notable disparities still remain for mothers with even slower progress for newborns and stillbirths.

Critical Conditions

The onset of labor continues to mark the start of a high-risk period for both mother and baby that does not ease until at least 48 hours after birth. During this short period of time, an estimated 145,000 maternal deaths, 1.45 million neonatal deaths, and 1.2 million stillbirths occur annually.

- For the mother, the critical conditions occurring during pregnancy, labor, and delivery include hemorrhage, hypertensive disorders such as preeclampsia and eclampsia, serious infections, and obstructed labor.
- For the newborn, the critical conditions occurring after birth are serious infections (sepsis, meningitis, pneumonia, and diarrhea), intrapartum-related deaths (primarily "birth asphyxia"), complications of preterm birth, and metabolic conditions (hypothermia, hypoglycemia, etc).
- Important causes of stillbirth include intrapartum asphyxia, maternal and antepartum hemorrhage, fetal infection, obstructed labor, Rh disease, and birth defects, especially neural tube defects.

Fragmented Continuum of Care

Evidence-based interventions—such as skilled attendance at delivery; emergency obstetric and newborn care; early initiation of breastfeeding; hygiene; and rapid diagnosis and early treatment of infections—do exist to manage complications around the time of birth. However, these interventions are not always available to the women and children who need them. Many missed opportunities exist before, during, and after the time of birth that could be tackled to optimize maternal and newborn health outcomes:

- Care before Birth: Impeded by delays in seeking prenatal care, limited ability to determine gestational age without reliance on ultrasound technology, and lack of access and/or adherence to prenatal care services and proper nutrition.
- Care at Birth: Impeded by a lack of infrastructural and health system resources (e.g. material resources, electricity, oxygen, IV fluids, clean water and adequate transportation to travel to hospitals) and shortages of trained healthcare providers to provide basic and comprehensive emergency obstetric care. Where trained professionals and equipped facilities exist, quality of care can be further impeded by poor management and supervision, nonfunctioning supply chains, and lack of adherence to guidelines and protocols compromising dignity and respect.

 Care after Birth: Impeded by a lack of access to postnatal care services, including support for breastfeeding, and delays in seeking care, including family planning resources such as contraception. In fact, important causes of maternal and newborn complications result from births that are spaced too closely due to a lack of access and/or adherence to family planning.

Geographical Inequalities

Almost all of maternal and newborns deaths during the high-risk period of childbirth occur in low- and middle-income countries, especially in sub-Saharan Africa and South Asia, where access to quality care is also the poorest. Inequalities also persist within countries that leave vulnerable women and newborns even more disproportionately affected, as in urban slums or fragile settings of humanitarian emergencies.

Social Inequalities

Gender norms, cultural beliefs, and traditions that limit a woman's autonomy, inclusion, and decision making power contribute to poor enabling environments that may prevent women and their families from practicing healthy behaviors, and seeking and receiving life-saving care at and around the time of birth. For example, women, their partners and/or their families, and decision-makers may not recognize the signs of potentially life-threatening illness around the time of birth, the cause of those illnesses, or where timely appropriate care is available. Social norms may limit movement outside the household after birth for both the mother and baby; costs of care and transportation options may also limit ability to seek and receive appropriate care. Gender, social and cultural norms may also contribute to the fragmented continuum of care. Taken together, these barriers leave poor, underserved women—who have the greatest geographical, financial and structural challenges in securing quality care at the time of delivery—and their infants at the highest risk of poor pregnancy outcomes.

Objective

For the purposes of this Addendum, the Saving Lives at Birth partners are seeking creative solutions to address roadblocks to healthy pregnancies and births in three domains, alone or in combination:

- Science & Technology: lack of dissemination and uptake of the most recent scientific evidence applicable to delivery of care in low-resource settings; lack of affordable and effective medical solutions appropriate for the community or clinic setting;
- Service Delivery: lack of quality health services, including inadequate numbers
 of trained, supported, motivated, equipped and properly located and
 supervised health staff and caregivers; and limited by operational bottlenecks;
- Demand: lack of opportunity, agency, ability, motivation, and empowerment to access timely health care or adopt healthy behaviors before, during, and after pregnancy.

Since many opportunities to optimize maternal and birth outcomes occur before and after the time of birth, solutions do not need to focus solely on the window between labor and 48 hours post-delivery. Where life-saving interventions exist but

have not been successfully deployed or implemented, we invite bold ideas for overcoming specific barriers to scaling up.

What We Are Looking For

Interventions that:

- Substantially increase demand for and access to primary health interventions for women and newborns;
- Substantially improve the quality of care as measured by health outcomes;
 and
- Improve and sustain healthy behaviors, attitudes, and practices.

Solutions should be:

- Creative: Bold, "off the beaten track," daring in premise
- **Appropriate**: Designed with and for end-users in the target population or context to meet their specific needs and circumstances
- **Impactful**: Address one or more important adverse maternal, fetal, or neonatal health conditions described in the problem statement above;
- **Competitive**: Clearly differentiated from and superior to standard practice, particularly on factors of cost and ease of use;
- Sustainable: Demonstrate a clear path to obtain continued political and financial support for sustained implementation and/or use of the innovation. Partnerships important for scale and matched funding are highly encouraged for solutions transitioning to scale;
- Scalable: Demonstrate the potential to increase and sustain coverage and impact of the intervention both within and beyond the award period, and be implemented in contexts or settings outside of those reached during the award period
- Measureable: Able to be monitored, measured and evaluated for impact.

Strong Areas of Interest

We are particularly interested in novel innovations in any of the following areas, but not limited to:

- Promoting healthy behaviors and generation of demand for services, including voluntary timing and spacing of pregnancy
- Preventing and addressing the consequences of preterm birth
- Increasing access to and sustained use of evidence-based, appropriate, quality care with particular emphasis on:
 - Early uptake and retention in antenatal care and simple, low-tech methods of dating pregnancy
 - o **Equity**, including identifying and reaching the most vulnerable populations
 - o **Accountability** to stakeholders and families
 - o **Eliminating mistreatment** of women during birth
 - o **Improving working conditions** of and respect for birth attendants
 - o Better monitoring and management of labor to promote maternal and fetal survival and better monitoring and management of special newborn care
 - o Making the **"old and boring"** (but essential and good for maternal and newborn care) **seem exciting** (e.g. how to take, record, and act upon a blood pressure reading)
- Addressing key health system bottlenecks that have an outsized impact on maternal and newborn health services with particular emphasis on improving referral and transportation of mothers with complications and sick newborns,

- including links to facilities
- Addressing underlying gender, social and cultural barriers and/or opportunities
- Assessing and addressing the challenges of approaches or technologies proven to work in high-income settings but unproven in low-income settings such as antenatal steroids, progesterone, etc.

We encourage integrated solutions that bring together cutting-edge science and/or low-cost technologies, service delivery, and demand innovation in transformative new ways.

PLEASE NOTE: Solutions addressing HIV in vertical manner, e.g., HIV diagnostics, will not be considered for funding.

Innovation Pipeline

The Partners seek solutions across the three stages of development (seed, validation, or transition) described below. **Under this Addendum, the Partners will place a greater focus on identifying and supporting innovations to reach scale.**

Seed Funds

- Focus: Seed funds will be provided to support the development and feasibility assessment of ideas capable of impacting health outcomes for pregnant women and their babies in low-resource settings. It is anticipated that projects aiming to develop early-stage prototyes and/or conduct feasibility assessments, including those for scientific advancements, will enter the Saving Lives at Birth program at this stage.
- Eligibility: Proposed solutions for seed funds should demonstrate strong understanding of target user(s), such as preliminary evidence from these users that the solution solves a problem they face or meets a need they have.
- **Funding:** Funding levels will correspond to the scope and scale of the innovation but will generally be \$250,000 USD per project.
- Length of Award: Seed projects will be funded for up to two (2) years.

Validation Funds

- **Focus**: Validation funds will be provided to support the introduction and validation of prototypes and innovative approaches in achieving improved health outcomes for pregnant women and their babies in low-resource settings (i.e. reaching proof of concept).
- Eligibility: Proposed solutions for validation funds may have been preliminarily tested, but should not be current standard practice. However, innovative variations that aim to demonstrate superiority to existing approaches will be considered (e.g., a new means to deliver an existing service or a new way to make an old model demonstrably more effective or cost effective). Previous Saving Lives at Birth seed awardees are eligible to apply. However, applicants do not need a previous seed award to be eligible for validation funds.
- **Funding:** Funding levels will correspond to the scope and scale of the innovation but will generally be \$250,000 USD per project.
- Length of Award: Validation projects will be funded for up to two (2) years.

Transition Funds

 Focus: Transition awards are intended to further refine and rigorously test the impact of integrated solutions that have evidence in a controlled or limited

- setting of improved health outcome(s) and/or the reduction of significant barrier(s) to health and demand for the solution (i.e., proof of concept). These integrated solutions have the potential to credibly scale to improve the lives of millions of pregnant women and newborns in multiple countries.
- Eligibility: Projects for transition funds must have strong evidence of proof of concept (see above) and demand for the solution to warrant expanded support. Submissions must provide sufficient and credible evidence to demonstrate their proof of concept and the link to positive impact on maternal and newborn health that could be sustained and scaled. Without sufficent evidence, prospective partners should consider submitting an expression of interest for another type of award (seed or validation). Demand for the solution by target users and/or local partners must also be demonstrated. Successful applicants will note integration into country programs, policies, and priorities. Transition Funds will be limited to integrated solutions only (approaches that integrate science and technology, service delivery, and demand creation domains in innovative ways). Note that components should be integrated in a meaningful and complementary manner, merely combining three stand-alone components into one project is not considered an integrated solution. A key component of achieving sustainability and scale is partnerships. Reviewers will look for partnerships that contribute expertise relevant to the scale and sustainability of the idea. Co-funding and/or matched funding from partners is highly encouraged, as this demonstrates a key stake in project success by project partners, as well as demand for the solution.
- **Funding**: Funding levels will correspond to the scope and scale of the innovation but will not exceed \$2 million USD per project.
 - Some innovations may require testing at various levels (local, regional, and across several regions) in the transition stage. Strong justification should be made as to how the scale of implementation corresponds to the scope of the project.
- Length of Award: Transition awards will be funded for up to four (4) years.

SECTION B: SUBMISSION GUIDELINES AND INSTRUCTIONS

Submission Overview

Expressions of Interest (EOI) must indicate the research or development idea that will work towards discovering potential solutions with impact upon the Objective, above, by increasing knowledge and understanding of potential solutions and their implementation at scale; utilizing scientific discoveries or advancements in technology, processes, methods, devices, or techniques; advancing the state of the art; or using scientific and technical knowledge in the design, development, testing, or evaluation of a potential new product or service (or of an improvement in an existing product or service).

Submitters should use the instructions and format found at www.savinglivesatbirth.net/apply and note the following basic requirements:

- All EOI must be written in English. EOI should be written clearly and with minimal jargon as reviewers will possess a variety of backgrounds and technical expertise.
- The EOI must be no longer than 3 pages. Any charts or tables included with

the EOI will be considered within the page limits. References and citations to academic publications or other resources are not required but are encouraged. If included as a separate page as end notes, references and citations are not included in the page limits. Biographical descriptions and letters of support are not included in the stated page limits.

- All EOI must use a standard font no smaller than11-point font with one-inch margins.
- All EOI must be submitted through the online application platform, which can be accessed via the link found at www.savinglivesatbirth.net/apply.

Submission and Review Process and Timeline The following outlines the process and timeline for submission and review of EOI.

- 1. Expressions of Interest (EOI) shall be submitted by February 24, 2017 2:00 p.m. EST. EOIs shall state the BAA and Addendum Number. In this case, the BAA number is BAA-GLOBAL HEALTH-2016/Addendum #4.
- 2. Beginning mid-January, EOI shall be submitted electronically via www.savinglivesatbirth.net/apply. As noted above, more guidance and instructions on submission can be found on our website. For all submissions, it is the applicant's responsibility to ensure that files are complete and transmitted by the deadline. The applicant bears full responsibility for data errors or omissions.
- 3. If initial review indicates the EOI merits further consideration, selected organizations or consortia may be invited, individually or in combination, to discuss their proposals with the Saving Lives at Birth partners for co-creation and further due diligence. This process may result in applicants being invited to submit concept notes and attend the Development^xChange in Washington, DC July 25-27, 2017 (estimated dates).

Develoment^xChange: To take advantage of the presence of a variety of development actors together in one place, the Partners will host the Development^xChange in Washington, DC (estimated to be July 25-27, 2017). Finalists will display their innovations/innovative ideas in an open marketplace. As part of this event, finalists will have the opportunity to network with each other, with other development experts and innovators, and other potential funders. Finalists will also participate in a series of workshops tailored to the participants' needs such as business planning, fundraising and monitoring and evaluation. The Partners will cover the cost for one representative from each finalist team to attend the Development^xChange.

4. Validation and final selection

An Executive Committee or Governing Board for each of the respective funding organization will independently review and validate the panel recommendations to ensure consistency with applicable policies, procedures and practices of the respective funding organization, inclusive of past performance evaluation. As per the BAA, the Partners may engage in codesigning the project and assisting the partner to provide additional information with respect to the proposer's technical approach, capacity, management and organization, partnerships and resources, past performance, and budget, as well as representations and certifications, as

needed. The final decision regarding awards, including the amount of funding to award, is the responsibility of the respective funding organization. Award amounts and funding conditions may vary by funding organization.

Unsuccessful Projects: Applicants with unsuccessful projects will receive notice that their project was not selected.

Information Protection

Saving Lives at Birth's goal is to identify and scale up transformative prevention and treatment approaches for pregnant women and newborns around the time of birth. Understanding the sensitive nature of submitters' information, USAID will work with organizations to protect intellectual property.

Expressions of Interest should be free of any intellectual property that the submitter wishes to protect, as the EOI will be shared with Saving Lives at Birth partners as part of the selection process. However, once submitters have been invited to engage in further discussions, submitters will work with USAID to identify proprietary information that requires protection.

Therefore, organizations making submissions under the BAA Addendum hereby grant USAID a royalty-free, nonexclusive, and irrevocable right to use, disclose, reproduce, and prepare derivative works, and to have or permit others to do so to any information contained in the expressions of interest submitted under the BAA Addendum. As noted above, if Saving Lives at Birth engages further with the organization regarding its submission, the parties can negotiate intellectual property protection for the organization's intellectual property.

Organizations must ensure that any submissions under the Addendum are free of any third party proprietary data rights that would impact the license granted to USAID herein.

Evaluation Criteria

Seed, Validation, and Transition proposals will be evaluated in separate tracks based on the following criteria. **More detailed criteria for each stream of funding can be found on our website** (www.savinglivesatbirth.net/apply

The final award selection will be based on a combination of technical strength, cost, and pioneering innovation.

1. Innovation

Demonstration that the proposed solution offers a creative approach to the problem outlined in the challenge and is clearly differentiated from existing approaches approaches in the proposed setting (i.e. provides significant improvements in cost, quality, and/or access to essential health services relative to standard practice/current offerings in the proposed market).

2. Sustained Impact

Demonstration that an investment in the proposed solution could result in transformational gains in maternal and newborn survival and in the prevention of stillbirth globally.

3. Execution Plan

Extent to which the proposed project objectives and interim milestones are appropriate, feasible and technically sound within the budget and time allocated for either seed, validation or transition funding.

4. Evaluation Plan

Extent to which the project has proposed a clear, measurable and realistic monitoring and evaluation plan, including key indicators to measure project success.

5. Team Capacity and Partnerships

Demonstration that the applicant and its partners have the necessary depth and breadth of talent, experience and leadership in order to execute their project.

6. Pioneering

Proposals with highest potential to achieve sustainable, groundbreaking impact and/or to become true game changers in the field.