September 21, 2016

Announcement No.: BAA-Global-Health-2016; Addendum 2 – Health and Research Program (HaRP) 2.0: Testing of systems approaches to scale and sustain treatment of possible severe bacterial infections in young infants

Amendment No.: 2

The purpose of this amendment is to provide revisions to the Addendum and to answer questions received.

Please note the following modifications to the BAA Addendum 2:

- The deadline for submission of EOIs has been extended to October 5, 2016.
- The anticipated timing of the co-creation workshop will be roughly 4 weeks from the closing date for EOI submissions.
- The likely location for the co-creation workshop will be in sub-Saharan Africa. Selected applicants should be prepared to travel to and participate in the workshop.
- Limited travel support will be available, with priority for participants from LMICs.
- We are pleased to announce that Save the Children is serving as a technical resource partner in this effort.

Questions & Responses

1. What is the estimated total program funding, award ceiling, and award floor?

The amount of funding provided will be driven by the solutions identified during the co-creation and co-design process, as well as available resources. USAID expects to share more information regarding funding at later stages of the process.

2. Is USAID interested in site-specific proposals within a country, country-specific proposals, or multi-country proposals?

Please propose to what makes sense to advance the objectives of the PSBI BAA addendum. As noted in the BAA Addendum, EOIs must "demonstrate the applicant's understanding of country and sub-country specific health system challenges related to reducing newborn and young child infection; and advantages and obstacles of potential implementation sites, including the **degree to which the site(s) are reflective of other parts of the country** as well as the "**real world"**

nature of the site(s) and a realistic assessment of existing infrastructure at implementation sites necessary to permit implementation research/program improvement processes".

3. **What is the optimal way to structure a team for the EOI? For example, what is the ideal composition of partners (i.e. research institutions, implementation, local organizations, etc.).**

It is up to the respondent to propose a structure, but we are seeking creative and innovative partnerships among researchers, implementers, and policy makers. These partnerships may include different levels of government as well as private sector actors. As noted in the BAA Addendum review criteria:

Identification of key national and/or district-level stakeholders whose involvement is critical to the success of this effort. Ideally, the EOI would articulate a partnership consisting of research, policy and service delivery entities.

Past efforts demonstrate research/evaluation and/or program experience in facilitating implementation in "real world" contexts as opposed to more controlled research or effectiveness or small pilot sites, and demonstrate the applicant's ability to create partnerships and linkages among technical, policy, and service delivery stakeholders to achieve results.

4. **What is total expected duration of the process (from the time of submission of EOIs to the final selection?)**

We estimate no more than 30 days from submission of EOIs to final selection of EOIs for participation in co-design/co-creation. Successful respondents should be prepared for travel in early November. The location of the co-design workshop may shift depending on the successful EOI responses.

5. **Is there a minimum co-investment requirement?**

EOI respondents are welcome to contribute resources, but this is not required.

6. **Under section III: "Specific rights reserved for the government under this BAA"; point 3 reads, "the right to accept proposals in their entirety or to select portion of proposals for award or co-investment". Does this mean that for some projects co-investment may not be mandatory?**

As noted above, co-investment is welcome but not required.

7. **We are considering submitting more than one EOI for the same country? Is this acceptable?**

There are no limits on EOI submissions. However, each EOI will be evaluated independently.

8. Does the BAA Addendum go straight targeting an health institution or as well a team of 2-3 persons of the similar field? i.e pediatricians and health providers dealing with newborns, who are not necessarily directly led by the institutions but are endorsed after self initiative?

See Question #3 above. It is up to the respondent to propose, but as noted in the BAA teams ideally would include key stakeholders from different sectors and institutions who are able to advance PSBI. Please note the guidance in the BAA addendum:

Identification of key national and/or district-level stakeholders whose involvement is critical to the success of this effort. Ideally, the EOI would articulate a partnership consisting of research, policy and service delivery entities.

Past efforts demonstrate research/evaluation and/or program experience in facilitating implementation in "real world" contexts as opposed to more controlled research or effectiveness or small pilot sites, and demonstrate the applicant's ability to create partnerships and linkages among technical, policy, and service delivery stakeholders to achieve results.

9. Under section 2, there is a sentence that reads: "USAID may partner with one or more organizations with advanced research, enabling factors for implementation, and policy knowledge of the health sector and systems analysis." We have two questions related to this statement:

a. Can an applicant organization claim themselves as one or more of these types of organizations?

Yes, but please see the response to part B below, as well as the response to question #3 above.

b. Is USAID looking for an organization that has all three attributes independently or can an applicant present a consortia of partners that have these attributes?

See response to question #3 above. No one organization is likely to have all the necessary attributes. A consortia of partners is more likely to be successful given the need for varying skill sets and in-country relationships that would ground the effort in the "real world" and lay a foundation for future sustainability.

10. Are applicants restricted to one application per organization? Given the diverse target geography and past experience with the implementation of the 2015 Guidelines, the methods needed to advance the goal of the BAA may vary by country.

There are no restrictions on the number of EOIs an organization can submit. See response to question #7.

11. Does USAID have a timeframe (period of performance) in mind for this work?

The timeframe is not fixed.

12. Please confirm whether a theory of change is a required element of the EOI.

While a theory of change is not a required element of the EOI, respondents are encouraged to consider a plausible theory of change, along with issues such as the context of the country health system, reaching difficult to reach populations, and embedding the research in an existing service delivery platform to enable continuous program learning and improvement.

13. Is USAID interested in pursuing preventive strategies under this BAA addendum or only curative strategies (e.g. administration of antibiotics, adherence to antibiotics)?

USAID is committed to a holistic approach to advancing care for newborns. This may include preventative and curative strategies. That said, the central focus of this addendum is improving quality of care of sepsis treatment and addressing the challenge of administration of and adherence to antibiotic regimens.

14. Can we expect additional addenda on other topics under this BAA? If so, can USAID provide any additional insight regarding the timeline for the release of such addendums and priority topics?

We are unable to provide information on additional Addenda to this BAA at this time. The BAA remains open until April 13, 2017.

15. Which were the settings for clinical trials in Africa and Asia-private, public or both?

Both. Please refer to the studies referenced in the BAA Addendum on page 1. These studies include: http://www.ncbi.nlm.nih.gov/pubmed/25842221 and http://www.ncbi.nlm.nih.gov/pubmed/25841891.

16. What level of health care system was included in the trial- primary, secondary or tertiary?

Primary and secondary. Please refer to the studies referenced in the BAA Addendum on page 1.

17. If private setting was used, what about qualifications of providers (prescriber, dispenser and injection provider)?

Please see response to question # 16. Additionally, the previous research was undertaken as part of a carefully controlled study to test effectiveness. The "real world" nature called for in the BAA EOI would be necessarily different.

18. Was there any cost involvement for patients including consultation, oral and injection medicines?

Please see responses to questions #16 and 17. In reference to the studies mentioned in the BAA Addendum, there was no cost involvement for patients. Please note, however, for this BAA Addendum USAID is interested in "real world" settings and characteristics.

19. Is it necessary for an institution/organization to be from the same country where the research is going to be conducted?

No, but please note that EOIs must identify "key national and/or district-level stakeholders whose involvement is critical to the success of this effort. Ideally, the EOI would articulate a partnership consisting of research, policy and service delivery entities."

20. Is there any scope for cross country collaboration among the organizations?

Cross country and cross organization collaboration are expected results of a successful engagement process between USAID and EOI respondents.

21. May activities include some implementation components or supports (e.g., training to the health care providers, developing materials, facilitating drug supply, etc.) or not?

While some implementation components may be possible, it is anticipated that a more competitive respondent would involve working in "real world" settings in conjunction with an existing implementation partner who delivers newborn services.

22. What is the maximum duration of implementation research? Is there a timeline?

The timeline will be addressed during the co-design process.

23. Can an RCT be conducted?

Please propose what makes sense in the context after reviewing the BAA Addendum. In brief, an RCT would need to be designed in such a way to reflect "real world" conditions and allow for real time adaptation and program learning and improvement.

24. Can the operational research be in a multicenter and a multi-district study?

Please propose what makes sense in the context after reviewing the BAA Addendum.

25. Since the efficacy of using intramuscular gentamicin and oral amoxicillin has already been proven, can a short pilot leading to a staggered implementation approach for a scale up be undertaken instead of a feasibility/operational research?

Please propose what makes sense in the context after reviewing the BAA Addendum.

26. What is the operational definition of scale up (expected population coverage)?

Please propose what makes sense in the context after reviewing the BAA Addendum. This definition will vary based on the country context.

27. Is there a design preference for evaluation (randomized, non-randomized, etc.)?

Please see response to question #23.

28. What will be the primary outcome of interest (process or outcome or impact)?

This will be determined collectively as part of the co-design process, but in general the primary outcomes are likely to focus on process and outcomes. If an evaluation is able to also measure impact that would be welcome.

29. What is the expected timeline to complete the selection process and award an organization?

Please see question #4 above regarding selection of EOIs. While it is not possible to predict an exact timeline for the selection and award process, our intent is to proceed as expeditiously as possible.

30. It seems to us that there will be a need to do process evaluation, impact evaluation, and assessment of safety as we go along. The BAA Addendum also states that embedded research and documentation is needed to enable continuous program learning and improvement. To what extent USAID is really interested in these types of activities (because they will consume substantial portion of energy and funding) compared to the REAL implementation of the option-2 antibiotic treatment program? Some countries may need minimal financial assistance in incorporating the treatment regimen whereas others will need lot more.

Please see the response to question #21.

31. What is USAID visualizing as the primary expertise of the grantee? Implementer of the short course antibiotic program in different countries? Or, with USAID's help put together entities and organizations who can implement on the ground, while the grantee designs, evaluates, assures safety, and incorporates changes that will be required for best output and sustainability? The former is best done by an NGO, while the latter by an academic partner.

Please propose what makes sense for the context after reviewing the BAA Addendum. As is described in the submission instructions, EOIs should identify key national and/or district level stakeholders whose involvement is critical to the success of the effort.

32. While co-creating and co-managing projects with other foreign agencies may provide impetus and help in sustainability, it may also hinder/delay plans made by USAID and

its U.S. implementing agency. Does USAID support the involvement of such agencies? Or, we are better off not bringing them into the loop?

Please propose what makes sense for the context after reviewing the BAA Addendum. USAID recognizes the importance of the involvement of governments and other development partners. USAID may also involve these parties separately in the co-design process as resource and/or technical partners.

33. What are USAID's expectations for the role of named key country stakeholders in the co-creation process and beyond?

Key country stakeholders will be critical for the success of the effort and should participate throughout the BAA Addendum process (co-creation, etc.) and in any resulting efforts.

34. Is there a minimum number of countries that should be included in expressions of interest?

The expectation is that an EOI would include at least one country.

35. Would procurement of pharmaceuticals, e.g., gentamicin and amoxicillin, be allowed under any funding resulting from this addendum?

Possibly. This will depend on the outcome of the co-creation process.

[End of Amendment No.: 02]