REQUEST FOR PROPOSALS:
MICRONEEDLE PATCH USABILITY & ACCEPTABILITY EVALUATION

TERMS OF REFERENCES

BACKGROUND

WHO’s mission is to improve and increase vaccine coverage against preventable diseases, as well as to accelerate development and approval and uptake of new vaccines and delivery technologies. As such, the Department of Vaccines and Biologicals is addressing these needs through facilitating the development of innovative vaccine improvement and delivery technologies that will improve coverage though easier administration, enable the vaccine to remain viable until the last mile, and increase uptake by reducing vaccination costs and simplifying logistics.

Microneedle patches (MNPs) are a novel vaccine delivery technology that may offer many potential benefits for vaccine delivery in low- and middle-income countries’ (LMIC) immunization programs, such as increased thermostability, efficacy, ease of delivery, safety of disposal, and low cost. MNPs are currently in development for a number of vaccines, including influenza, tetanus toxoid, measles-rubella, inactivated poliovirus vaccine (IPV), and rotavirus (inactivated) and could offer significant benefits as compared to current needle and syringe based immunization program strategies through either:

1) **Routine immunization** by eliminating sharps waste and providing vaccine in ready-to-use, single-dose formats, while also enabling distribution through a controlled temperature chain (CTC). Exploring the operational fit of using MNPs for routine immunization, exclusively and in combination with injectable and oral vaccines, would inform future programmatic decisions related to the introduction of MNP vaccines into a country’s EPI.

2) **Supplemental immunization** by facilitating delivery through fixed-post, mobile-post, or house-to-house (HtH) campaigns by trained community health workers rather than health care workers (HCWs), similar to campaign strategies currently used for delivery of oral poliovirus vaccine.

The acceptability and logistical fit of immunizing children with MNPs in LMIC campaign settings has yet to be investigated, and is key to evaluating the potential utilization of this technology beyond its technical feasibility.

OBJECTIVES OF THE EVALUATION

I. To evaluate the usability (human factors) of an MNP among intended users: health care workers (HCWs) vs. community health volunteers (CHVs).

II. To evaluate the acceptability of an MNP among potential vaccine recipients: children two months to five years and their parents.

III. Evaluate the fit of an MNP as it would apply to the following target use scenarios: clinic or fixed post, with or without outreach, as well as immunization through mobile services (potentially including school based) immunization, and HtH immunization as part of evaluation of MNP use within outreach based SIAs.

TARGET USE SCENARIOS AND EVALUATION CRITERIA

1. HCWs administering to children two months to five years, in routine fixed-post, outreach or community based settings. Evaluation criteria: HCW usability of MNP, operational fit in routine immunization scenario, child/parental acceptability.
2. HCWs administering to children two months to five years, in a campaign setting (such as current campaigns for measles/IMR vaccine or IPV). Evaluation criteria: HCW usability of patch, operational fit with campaign scenario, child/parental acceptability.

3. CHVs administering to children two months to five years, in community based routine or campaign setting (such as current campaigns for OPV). Evaluation criteria: CHV usability of patch, operational fit within mobile campaign scenario, child/parental acceptability.

SCOPE OF WORK

Pre-requisites:

- Request proposals to evaluate up to 2 MNP technologies.
- Assume activities will be performed in at least one country with an immunization campaign, with option to adapt study design if campaign timing doesn’t fit project schedule.
- Studies must be undertaken in at least 3 low/middle income countries from the following WHO regions: AMRO, AFRO, SEARO, EMRO or WPRO (no more than one country per region).
- Assume MNPs for application to participants’ skin will be prototypes with no microneedle projections or vaccine, but otherwise similar with respect to design, packaging and application method.
- The participants should be invited to have the MNPs applied and worn for up to 5 minutes before completing the questionnaire.
- SOW must be completed by Sept 2016.

Activities:

- Identify three countries and institutions within different WHO regions to conduct the proposed research, in collaboration with WHO/EPI.
- Develop methodology and questionnaire framework to assess pre-existing awareness/perception of MNP vaccine delivery technology, as well as MNP evaluation process in each of the target scenarios described (ease of use during preparation and application, acceptability, logistical fit), in consultation with WHO/IVB. Include capture of potential technology improvements.
- Conduct interviews with HCWs, MTVs, patients, program managers and other stakeholders (please propose as appropriate) to gain insight into issues with respect to pre-conceptions, training, usability, and operational fit and potential improvements to MNPs.
- Potentially include focus group discussions during in clinic or community based evaluations to enable broader data capture
- Analyse and draft report information gathered during evaluation by Sept 2016.

IV. DELIVERABLES

The contractual partner will report to the WHO/EPI team
- Agreed country selection - December 6th 2015
- Draft evaluation protocol (to include methodology) and project plan: December 13th 2015
- Draft report on methods and findings: 19th August 2016
- Final report on methods, findings and conclusions: 15th September 2016

V. SUBMISSION OF PROPOSAL
WHO/EPI is inviting proposals for the execution of the above work by a reputable institution or individual.

a. **Requirements:**
   - Proven experience in designing and conducting device-specific evaluations
   - Demonstrated familiarity with immunization programs and associated issues; particularly in terms of vaccine licensing, prequalification and logistics;
   - Experience in public health and/or development program evaluation;
   - Proven capacity to generate highly professional English language reports;
   - French language skills an asset.

b. **Essential proposal content:**
   - Cover letter/statement of interest justifying candidacy and how the above requirements are met;
   - CVs of proposed project personnel;
   - Two examples of similar evaluation work;
   - Annotated Budget and timeline.

c. **Submission deadline:**
   All proposals must be sent by 23rd October 2015 in electronic format to:

   **Birgitte Giersing**
   **IVB/EPI**
   **World Health Organization**
   **20, Avenue Appia**
   **CH-1211 Geneva 27, Switzerland**
   **E-mail: giersingb@who.int**

d. **Award of contract:**
   A decision will be communicated by 6th November 2015.

   The award shall be made to the bidder whose proposal best meets the requirements of the request for proposals in terms of demonstrated expertise, quality and cost. All team members will be required to demonstrate the absence of any conflict of interest.

   WHO reserves the right to contact bidders subsequent to submission of proposals and prior to award for clarifications. Revisions may be permitted after submission of a proposal, and prior to award.

   WHO reserves the right to reject any or all proposals submitted.

   WHO shall not be responsible for any costs incurred by the agency in preparing, submitting or presenting its proposal.