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From Design to Adoption: Generating Evidence for New Technology Designed to Address Leading Global Health Needs

A comprehensive clinical evidence generation plan for the BD Odon Device™

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Introduction

In 2010, the United Nation's Secretary General launched the Global Strategy for Women's and Children's Health to catalyze the efforts of governments, international agencies and organizations, foundations, academia, civil society, NGOs, businesses and professional associations to save 16 million women's and children's lives by 2015 (1). To help accomplish this goal, the Global Strategy called for greater investment in innovations and the establishment of mechanisms such as the Grand Challenges initiative 'Saving Lives at Birth' and the Innovation Working Group to foster new technological developments with the potential to improve service quality and access (1,2).

It is estimated that this enabling environment has fostered the emergence of more than 1000 innovations for reproductive, maternal and child health which are now in the early development or pilot testing phase (1,2). The ultimate impact of these technologies on global health will depend upon how rapidly and successfully they can be transitioned from the prototype phase to large scale manufacturing and distribution (2).

The steps involved in this transition, from design to adoption to wide-scale introduction, should be evidence-based. The evidence generation process must provide the information needed to guide product development with the aim of addressing an unmet need, to ensure timely regulatory approval and market development, and to increase the likelihood of patient and provider acceptance and uptake (2,3,4,5).

We present here an outline of the clinical evidence generation plan for the BD Odon Device™ that will enable a more rapid and coordinated generation of the evidence needed to transition the device from design to adoption compared with traditional incremental approaches to product development and dissemination. Such an approach, if proven successful, could be adapted for other emerging technologies in the future. (5,6,7,8).

Proposed solution

The BD Odon Device is an innovative instrument for assisted vaginal birth with potential for preventing maternal, fetal and newborn deaths due to complicated second stage of labor. As with other developing global health technologies in the maternal and child health space, evidence is needed to:

- Retire and mitigate during product development all possible envisaged risks to assure the highest standard of safety, especially considering that beneficiaries will be vulnerable populations such as mothers, fetuses and infants.
- Define the target product profile that describes the medical indications for use and how the product will be used safely and effectively by the intended users.
- Prove that the device compares favorably in terms of safety, efficacy, cost/benefit and acceptability with other available technologies when tested in controlled trials and real life conditions to facilitate its adoption and use at global level.

While showing measurable clinical benefits remains a priority for regulatory purposes, evidence from clinical studies is increasingly required for other objectives such as reimbursement and procurement decisions, marketing and dissemination strategies and adoption (9). This need will be even more pressing for new global health technologies which can be scaled up only through

collaborative commercialization strategies based on public–private partnerships among industry, academic centers, nongovernmental organizations, foundations and governments (2,3,4). Solid evidence will be needed to motivate each stakeholder participating in this collaborative development and commercialization model to prioritize the investment of often scarce resources.

A single study is very unlikely to address all objectives related to product development, regulatory approval, marketing and dissemination strategies and adoption. However, it is important to avoid conducting fragmented and loosely related studies that would slow down the overall process of technology development and introduction and add to its costs, negatively impacting on affordability and access. Therefore, we have developed a comprehensive plan that will progressively generate the evidence needed by conducting a series of sequential and coordinated non-clinical, preclinical and clinical studies. The sequential approach will include milestones that have to be achieved prior to the decision to proceed to the next phase (9).

The clinical evidence generation plan addresses three major needs which are the drivers of the development strategy: 1) define the target product profile, 2) obtain regulatory approval and 3) support marketing and dissemination and adoption.

The definition of the target product profile aims at describing how the BD Odon Device should be safely and effectively used. Evidence is needed to develop device design features to assure effectiveness and safety before comparing it with available alternatives for assisted vaginal birth in randomized clinical trials. To achieve this objective, after completing non-clinical studies (bench testing for robustness, toxicity and durability), a series of preclinical studies (animal and simulation studies and human factors studies) were conducted.

Fulfillment of acceptance criteria for the preclinical studies will be the prerequisite to conduct a pivotal study (randomized clinical trial) that will generate the evidence to assess efficacy and safety of the product for registration purposes (CE Mark will be the first regulatory approval followed by country specific approvals). The pivotal study will be designed to fulfill recently proposed recommendations for rigorous -regulatory approval studies (10) and to provide data to support adoption. The pivotal study will also provide an initial indication that the device could be used by midwives in settings where they are allowed to perform assisted vaginal birth.

If the acceptance criteria for the pivotal study are met (i.e. the BD Odon Device is not inferior in efficacy and safety to a selected currently available instrument for assisted vaginal birth), country specific pivotal studies and post market studies will be conducted with the objective of obtaining registration in countries with specific regulatory requirements. These additional studies will align with recent recommendations for systemic long-term assessment of safety and efficacy by facilitating identification of any additional potential risks that might emerge only after the device has been tested in real-world conditions (10).

The global community has developed a new Global Strategy for Women's, Children's and Adolescent's Health to carry the momentum forward into the next 15 years (11). Although considerable reductions in maternal, newborn, and child mortality were accomplished under the Millennium Development Goal framework and significant commitments were made following the launch of the first Global Strategy in 2010, more progress is needed in ending preventable maternal and newborn deaths. This unfinished agenda must continue to be prioritized as part of efforts to achieve the more ambitious development agenda enshrined in the Sustainable Development Goal framework. The BD Odon Device represents an important

innovation in the area of assisted vaginal birth that could significantly contribute to this global goal.

Disclosure of interests

MM, RG, AS and ES are employees of BD. All other authors are members BD Odon Device Scientific Advisory Board. Members of the Board receive no honoraria, and solely receive travel and accommodation reimbursement to attend meetings of the Board.

BD holds an exclusive license to develop and market the BD Odon Device.

Contribution to Authorship

All authors contributed to conception and design of the evidence generation plan. MM prepared the first draft of the manuscript. All authors reviewed and approved the final version of the manuscript.

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