SAVING LIVES AT BIRTH
Development of a Model for National Scale-up of the Pratt Pouch to Expand Infant Nevirapine Prophylaxis in Uganda, Prevent Mother-to-child Transmission of HIV, and Save Infant Lives

Background
Globally, Uganda has the fourth highest number of HIV-exposed infants (HEI). 1 Annually, 20,000 HEI are born in Uganda with 3,500 becoming HIV-infected. 2 Evidence shows that antiretroviral drugs (ARV) when taken by HIV-positive women can dramatically reduce the risk of mother-to-child HIV transmission (MTCT), and the World Health Organization (WHO) guidelines recommend all HEIs receive six weeks of infant Nevirapine (NVP) ARV prophylaxis beginning at birth to further reduce this transmission risk. 3 According to the Ugandan Ministry of Health (MoH), only 38% of HEIs receive NVP, which is distributed at labor and delivery, and postnatal care (PNC), but not antenatal care (ANC). 4 In Uganda the MTCT rate at six weeks stands at 13% and 2.9% post breastfeeding. 5 With 42% of infants born outside of health facilities, at least 50,000 HEIs born every year lack the proper access to NVP during the first critical 24 hours of life. 6 Even HEIs born in facilities may miss NVP initiation due to medication stock-outs or midwives who fail to distribute or educate women on NVP and its administration. Health workers are supposed to give a 100 ml bottle of NVP and one syringe to all HIV-positive women and are expected to show the mother how to measure the high-viscosity liquid NVP and mark the syringe with the correct dosing line. But, the sticky liquid is difficult to measure and the syringe marking tends to rub off easily. Therefore, most mothers estimate rather than measure correct infant doses.

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), in partnership with Pratt Pouch Consulting, are implementing the Saving Lives at Birth (SLAB) project which will introduce and scale-up the Pratt Pouch in ANC, delivery, and PNC services in at least 476 health facilities in 23 districts throughout Central and South West regions of Uganda.

The pouches will be centrally filled using an automated filling process to meet the high production needs, while ensuring strict quality standards.

The easy-to-use pouches will empower women to immediately initiate NVP after delivery and encourage them to deliver in a health facility or bring their infants for PNC within 14 days. The primary endpoint will be the proportion of HEIs receiving the full NVP regimen from birth to six weeks, and the impact will be measured by the number of HEIs diagnosed with HIV from six to eight weeks of age. By achieving these outcomes, 40,000 infants will be reached in three years.

2 The Ministry of Health, DHIS2 Data 20 15
4 The Ministry of Health, MoH Spectrum estimates 20 15/16
5 Uganda Bureau of Statistics (UBOS) and ICF International Inc. 20 12. Uganda Demographic and Health Survey 20 11. Kampala, Uganda: UBOS and Calverton, Maryland: ICF International Inc.
Objectives

1. Increase infant NVP prophylaxis uptake
2. Simplify dosing with improved dosing accuracy by providing women with pre-measured, single NVP doses
3. Increase mother-infant PNC visits and potentially facility births
4. Improve access to infant NVP for home births to empower women to immediately initiate prophylaxis with NVP after delivery
5. Simplify counseling messages and instructions resulting in decreased health care worker time in labor/delivery and PNC
6. Decrease wastage of NVP by only providing those doses required to complete six weeks of prophylaxis

Key achievements and Program Successes

1. The remodeling work at the repackaging facility at Hospice Africa Uganda (HAU) have been completed, and the equipment installed
2. Production staff at the repackaging facility have been trained on Good Manufacturing Practice as well as the equipment protocols
3. The Pratt pouch training curriculum, job aid, standard operating procedures (SOP), roll out plan, additional indicators, and tools for monthly reporting and bimonthly ordering have all been approved by the Ministry of Health
4. Primary packaging design has been approved by the National Drug Authority
5. Secondary packaging design for the Pratt pouch has been approved
6. Formative study was conducted
7. Effectiveness study protocol approved by the local IRB and awaits implementation
8. The Pratt pouch task team continues to provide technical oversight to the project as well as advise on future scale-up

Final Project Year

Final regulatory approval and production of repackaged Nevirapine

The project will complete the regulatory approval process by NDA and get a certificate of GMP and suitability of premises. Production will begin and the Final Finished Product provided to NDA for approval for full scale production.

Capacity building of health workers and NVP Pratt Pouch roll-out

The training of health workers from over 476 health facilities in 23 districts will focus on areas such as client education, stock management, dispensing, data management, and reporting. These health workers will be continuously mentored by EGPAF staff in partnership with the MoH on the use of the repackaged NVP and trained in the roll-out of the Pratt Pouch distribution plan and monitoring of the logistical supply chain process.

Implementation

Active implementation will commence to ensure all eligible mothers are enrolled into the program and provided with the correct messaging on the dosing and suspension, timely initiation, and completion of the full six-week regimen of prophylaxis. Ten thousand HIV-positive pregnant and lactating mothers and their HEI will be enrolled into the program in project year two, and 30,000 will be enrolled in year three.

Monitoring and Evaluation

Routine program data will be collected monthly to monitor outputs of the project. Evaluations on effectiveness, acceptability, and feasibility will also be conducted.

Proposed Scale-up Map

[Map of Uganda showing phase one and phase two areas]