EVALUATING SAVING LIVES AT BIRTH

Cost-Effectiveness Analysis: Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) – Pratt Pouch

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ACRONYMS

ANC Antenatal Care
ARV Antiretroviral
CEA Cost Effectiveness Analysis
EGPAF Elizabeth Glaser Pediatric AIDS Foundation
GCC Grand Challenges Canada
HEI HIV-Exposed Infants
GDP Gross Domestic Product
MOH Ministry of Health
NVP Nevirapine
PMTCT Prevention from Mother to Child
PNC Postnatal Care
PV Present Value
R&D Research and Development
USD United States Dollars
USAID U.S. Agency for International Development
YLS Years of Life Saved
YLL Years of Life lost
DALY Disability-Adjusted Life Year

EXECUTIVE SUMMARY

PURPOSE OF THE REPORT

This report presents the cost-effectiveness analysis (CEA) of a Saving Lives at Birth (SL@B) funded innovation – **Pratt Pouch – in Uganda. Pratt Pouch is a novel way to deliver Nevirapine (NVP), an antiretroviral (ARV) prophylaxis, in a small sachet to HIV-exposed infants (HEI)**. These packets contain pre-measured NVP solution, which can be administered at home to neonates without direct supervision from a healthcare provider. The CEA presented in this report quantifies the health and social impact of scaling up the use of Pratt Pouch over the period 2019 to 2030 in Uganda. Data on cost of scaling up was collected from Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), while estimate on impact was obtained from a model developed by Grand Challenges Canada (GCC) and reviewed by Duke University. Together, the cost and impact were used to estimate three incremental cost effectiveness ratios at 3% discount rate:

1. Incremental costs per new beneficiary
2. incremental costs per newborn life saved
3. incremental costs per year of life saved

The estimated total cost of scaling up EGPAF's Pratt Pouch to reach around 187,771 neonates is $3.5 million (in current USD). This translates to 3,109 newborn lives saved and 87,949 years of life saved over the period 2019 to 2030. The incremental cost effectiveness ratios estimated were $18.90 per beneficiary reached, $1,141.31 per newborn life saved, and $40.30 per year of life saved (i.e. 6.2% of Uganda's GDP per capita in 2018). WHO-CHOICE criteria suggest that interventions are "very cost-effective" if the ICER of cost per disability-adjusted life years (or cost per years of life saved in this case) is less than the country's GDP per capita, "cost effective" if it is between one and three times the country's GDP per capita, and "not cost-effective" if it is greater than three times the country's GDP per capita. Therefore, the result suggests that **scaling up access of EGPAF's Pratt Pouch in all districts of Uganda is *very cost-effective*** and could make significant contributions to the reduction of infant mortality amongst HIV-exposed infants in Uganda.

1 INTRODUCTION

More than 700,000 women live with HIV in Uganda, and infants born to this population are at risk of contracting HIV during pregnancy, delivery, and breastfeeding (UNAIDS, 2020). Antiretroviral (ARV) prophylaxis is the cornerstone of prevention of mother-to-child transmission (PMTCT) of HIV programs. These programs are evidence-based, and can significantly decrease the risk of HIV transmission from mother to child during pregnancy, childbirth, and breastfeeding period.

Credit: Duke Global Health Institute

As per the World Health Organization's (WHO) recommended guidelines, all **HIV-exposed infants should receive six weeks of daily administration of infant ARV prophylaxis, beginning at birth** (WHO, 2016). **Ugandan health policy aligns with this guideline, and recommends using Nevirapine (NVP) as the preferred infant prophylaxis** (Ministry of Health, 2016). Under the current health system in Uganda, standard practice requires health workers to administer the first dose of Nevirapine to HIV-exposed infants delivered at health facilities. The health workers also counsel mothers to administer the rest of the doses at home using syringes and 100ml bottles of NVP (Ministry of Health, p. 2).

The process of measuring and administering NVP using syringes at home is prone to measurement and dosage error. Limitations in NVP drug storage and shelf life can also make it tedious to complete the 6-week regimen (EGPAF Final Report, 2020). In addition, close to 25% of infants in Uganda are born outside health facilities, and 45% mothers do not receive a postnatal checkup after delivery, thus missing access to infant prophylaxis altogether (Uganda Bureau of Statistics, Kampala, Uganda, 2018). This results in a **significant number of HEIs born in Uganda lacking access to infant NVP during the critical first 24 hours of life.**

The Pratt Pouch – a novel way of delivering NVP in a sachet – was developed at Duke University's Pratt School of Engineering and named after the institute. The Pratt Pouch is able to store NVP for up to a year without degradation (EGPAF Concept Note, 2015). In addition, the Pratt Pouch also ensures accurate dosage, given that it does not require manual measurement. A mother/provider can easily administer NVP to the infant by squeezing the pre-measured dosage stored in the pouch. The pouch also helps to maintain drug potency and increase ease of use by reducing contamination (via unclean syringes) and dosage error. The fact that it eliminates the use of syringes also promotes task sharing where lay counselors could effectively counsel mothers to use the pouch (EPFAF Concept Note, 2015).

Credit: pedaids.org

Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) is working closely with the government of Uganda to include the Pratt Pouch as a component of the Ministry of Health's (MOH) PMTCT program and plans to scale the innovation to all districts in Uganda. To assess the potential health and economic benefits of these scale-up efforts, **a cost-effectiveness analysis of national expansion of the Pratt Pouch in Uganda was conducted.**

2 COST-EFFECTIVENESS ANALYSIS APPROACH

A decision-analytic framework is used to model costs and benefits of scaling up of Pratt Pouch within Uganda's antenatal care (ANC), delivery, and postnatal care (PNC) services, over a twelve-year period between 2019 and 2030. Cost data was collected from EGPAF using a Costing Tool developed by Duke University with the support of SL@B program partners United States Agency for International Development and Grand Challenges Canada (USAID and GCC). Health estimates were obtained from the impact model developed by GCC for EGPAF and validated by Duke University. The following sections describe the details of the data sources, analytic approaches, and results.

Estimation of Costs

Using Duke's Costing Tool[1], EGPAF categorized their costs into eight expense categories: 1) Personnel, 2) Training, 3) Travel and transportation, 4) Supplies, 5) Meetings, 6) Research and Development, 7) Facilities and Overheads, and 8) Other project costs (includes fringe and indirect costs). Cost data was converted into United States Dollars (USD) from Ugandan Shillings by the innovator using the assumed 2016 (current USD) exchange rate of 3,300 Ugandan Shilling to 1 USD.

Since the cost data was collected from EGPAF's internally generated estimates, it is important to note that it reflects certain key assumptions about EGPAF's scale-up strategy. For example, starting in 2019, as EGPAF expands its operations to new districts in Uganda, supplies and facility costs will increase. It is also expected that EGPAF will make no further investments in Research and Development (R&D) after 2020. EGPAF also plans to hand over the operations to the government of Uganda by 2023. With the transition to the government in 2023, notable changes in the share of total costs of different cost categories include relatively stable personnel costs over time; the cost of supplies increases and EGPAF's other project costs (e.g. fringe benefits and indirect costs) decrease or stop completely with the handover. After the government handoff, the government employees working in various government projects and departments will be responsible for Pratt Pouch's implementation. Therefore, there will not be a need to hire separate staff for managing the project.

Estimation of Health Impact

The health impact of Pratt Pouch in Uganda was estimated as **the number of beneficiaries reached, number of lives saved, and the number of years of life saved.** A decision-analytic framework was used based on the analysis of the impact model developed by GCC and reviewed by the Duke University Team.

The Duke impact model (see Annex 1) estimates the number of lives saved through the introduction (or scale-up) of Pratt Pouch across Uganda. It makes use of certain parameters and assumptions (see Table 1) to generate baseline and intervention scenarios and calculates the difference between these scenarios to reach the lives saved number.

The baseline scenario projects the population of HIV-exposed infants (HEIs) in Uganda under the circumstances that they continue receiving routine standard care for PMTCT. The intervention scenario projects the number of lives saved if the Pratt Pouch is expanded and made available to HEIs who currently do not have access to, and therefore are not receiving any infant prophylaxis. **The projection is made using a scale-up plan shared by EGPAF, in which the Pratt Pouch is expanded from 14 districts in 2019 to all 128 districts by 2030.** The model also takes account of the differential HIV transmission rates across breastfeeding and non-breastfeeding women; the final estimate lies between these two different scenarios.

A literature review was conducted and additional data was collected from EGPAF to update the values of variables and parameters in the lives-saved model (see Table 1). **The health impact refers to the total number of HEIs not infected due to the use of Pratt Pouch across breastfeeding and non-breastfeeding populations in Uganda.**

1: The Costing Tool allows healthcare innovators extract cost data needed for economic analysis from their company/institutional records. It also allows users to develop future cost and cost-effectiveness projections. It was developed by the Duke University team and pilot tested with several healthcare innovators in the SL@B program.

Table 1: Variables and Parameters Used for Estimating the Number of Lives Saved

Variable Definition	Estimate (range)	References
Prevalence of females (ages 15-49) who are HIV-positive	**7.5%** (3.3%, 12.9%)	Ministry of Health, Uganda, 2019
Percentage of women delivering in health facilities	**73%** (57.4%, 88.6%)	Uganda Bureau of Statistics, Kampala, Uganda, 2018
Percentage of women receiving ANC from a skilled provider[2]	**97%** (95%, 98%)	Uganda Bureau of Statistics, Kampala, Uganda, 2018; The World Bank, 2020
Percentage of women delivering in the last year reporting getting tested for HIV	**90.9%** (85.2%, 94.6%)	Ministry of Health, Uganda, 2019
Postpartum women on ART (adherent)	**51%** (20.5%, 75.7%)	Jean B. Nachega, October 2012; Sarah Decker, June 2017
In-utero transmission rate	**8.1%** (5%, 10%)	De Cock KM, 2000; Peltier, et al., 2009; WHO, 2010; WHO, 2007
Percentage of HIV-positive women on replacement feeding	**12.3%** (8.5%, 27.2%)	Okong, et al., July 2010; Fadnes, et al., 2009; Ahoua, et al., 2010
Percentage of infants who receive ARV for HIV, as part of routine standard care for PMTCT (syringe method)	**65%** (55%, 75%)	Assumption made in consultation with an HIV expert and the innovator
Percentage of women who will be retained for treatment following delivery (i.e. not lost to follow-up between ANC and birth)	**80%** (70%, 90%)	EGPAF Concept Note, 2015; EGPAF representatives interview, 2020
Percentage of HIV-positive women who know their HIV status and have received >=1 ANC visit(s) receiving Pratt Pouch (during funding period)	**50%** (40%, 60%)	EGPAF Concept Note, 2015; EGPAF representatives interview, 2020
Percentage of HIV-positive women who know their HIV status and have received >=1 ANC visit(s) receiving Pratt Pouch (post- funding period)	**70%** (60%, 80%)	EGPAF Concept Note, 2015; EGPAF representatives interview, 2020
Percentage of women compliant with Pratt Pouch usage	**95%** (90%, 100%)	EGPAF Concept Note, 2015; EGPAF representatives interview, 2020
Postpartum transmission rate in breastfeeding (6 months) populations – neither mother nor infant receive ARV	**30%** (25%, 35%)	WHO, 2004; WHO, 2007
Transmission rate in breastfeeding populations – only mother receives ARV	**11.8%** (8.1%, 15.7%)	Jackson JB, 2003
Transmission rate in breastfeeding populations - both mother and infant receive ARV	**2.63%** (0.6%, 4.7%)	WHO, 2010; Peltier, et al., 2009
Transmission rate in non-breastfeeding populations – neither mother nor infant receive ARV	**20%** (15%, 25%)	WHO, 2007, p. 6
Transmission rate in non-breastfeeding populations – only mother receives ARV	**6.0%** (5.6%, 7.9%)	Renaud Becquet, January 2007; Renaud Becqueta, July 2008; Thior I, 2006
Transmission rate in non-breastfeeding populations - both mother and infant receive ARV	**1.0%** (0%, 3.4%)	Michele Magoni, 2005
Percentage of deaths among ART-naïve HIV infected children	**12.4%** (5.7%, 19.1%)	Munyagwa, et al., 2012

Source: Impact Model developed by the Duke University Team

2: Skilled provider includes doctor, nurse/midwife, and medical assistant/clinical officer.

To estimate Years of Life Saved (YLS) by Pratt Pouch, first, the average years of life lost (YLL) of HEIs in Uganda was calculated, and then it was multiplied by the estimated number of total lives saved due to the scale-up of the Pratt Pouch. A life expectancy at birth of 63.15 in 2019 (using the life expectancy at birth for Uganda between 2014 to 2018 as reported in the World Development indicators) and a discount rate of 3% were assumed (See Annex 2 for details) (The World Bank Group, 2020).

Estimation of Cost-effectiveness Ratios

The estimates of costs and effectiveness calculated above were combined to get cost-effectiveness ratios. **The base-case for this analysis compared a scenario with national scale-up of Pratt Pouch in Uganda to a scenario with no scale-up.** Therefore, these estimates reflect incremental cost-effectiveness ratios (ICERs).[3]

The following **ICERs** were estimated in the report:

1. Incremental cost per beneficiary reached
2. Incremental cost per life saved
3. Incremental cost per year of life saved

Different ICERs can be used to achieve diverse objectives, which resonate differently with various stakeholders. For example, from a management perspective, it is important to know the incremental cost per beneficiary to decide on the resource allocation, day-to-day monitoring, and for budgetary program mapping. Whereas incremental cost per lives saved and cost per YLS are important from the perspective of MOH, funders, and for comparative purposes for the selection of innovations.

The ICERs were estimated with and without discounting; sensitivity analysis was performed to test the robustness of the findings to changes in assumptions and model parameters. **Both deterministic and probabilistic sensitivity analyses were performed.** In the deterministic sensitivity analysis[4], +/-20% and +/-50% changes to the model inputs are presented, and then ICERs were computed for each combination, while the probabilistic sensitivity analysis used a Monte Carlo simulation approach to sample for input parameter distributions. Details of the sensitivity analysis can be found in Annex 3.

3: ICERs were estimated since the focus of this study is on the additional costs of scale-up (and not the total or average costs). Nevertheless, scaling up availability of an innovation within a functional health system will leverage some of the resources already invested to make that system work – this study did not account for those costs.
4: As per the literature, sensitivity analysis is a "subjective" variation of plausible values for input variables. (Hayward Medical Communication, 2009). The sensitivity analysis allows exploring ranges of values that affect the results of the ICER. This exercise also relates the deterministic sensitivity results to the simulation results, and expected probability ranges, with some statistical concentration around the base values. One and two standard deviations around the mean ICER have been reported here in the report. We find the two analyses (deterministic sensitivity and simulation) to be consistent. Therefore, in accordance with existing research practice, we conducted the deterministic sensitivity analysis with 10 percentage point increase and decrease ranging from 10% to 90% in the inputs of the model. The ICER of cost per year of lives saved for Pratt Pouch was found to be below the per capita GDP threshold for Uganda for the whole range of variation as per WHO's recommendation. We decided to present only the +/-20% and +/-50% deterministic variations in this report taking (Darmstadt, et al., 2008) as a reference which chose to show only +/-25% sensitivity variation in their paper.

KEY FINDINGS FROM THE COST-EFFECTIVENESS ANALYSIS

Table 2 summarizes the results of the **cost-effectiveness analysis of the national scale-up of Pratt Pouch in Uganda.** For the base case, estimates without discounting and with 3% discounting are presented. The findings from the sensitivity analysis conducted are also reported in the table.

Table 2: Cost-Effectiveness Analysis (CEA)

Incremental cost per beneficiary (not discounted)	Incremental costs	4,213,319
	New beneficiaries	231,908
	Ratio	**USD 18.17**
Incremental cost per beneficiary (discounted at 3%)[5]	Present value (PV) of incremental costs at 3% discounting	3,547,996
	PV of new beneficiaries at 3% discounting	187,771
	Ratio	**USD 18.90**
Incremental cost per life saved (not discounted)	Incremental costs	4,213,319
	Lives saved	3,842
	Ratio	**USD 1,096.65**
Incremental cost per life saved (discounted at 3%)	Present value (PV) of incremental costs at 3% discounting	3,547,996
	PV of lives saved at 3% discounting	3,109
	Ratio	**USD 1,141.31**
Incremental cost per year of life saved (not discounted)	Incremental costs	4,213,319
	Years of life saved	108,695
	Ratio	**USD 38.76**
Incremental cost per year of life saved (discounted at 3%)	Present value (PV) of incremental costs at 3% discounting	3,547,996
	PV of years of life saved @3% discounting	87,949
	Ratio	**USD 40.34**

Source: Authors' calculation using data from Costing Tool and GCC Impact Report (Dixit, et al., 2019)

The cost of scaling-up Pratt Pouch in Uganda by EGPAF to reach an additional 187,771 beneficiaries, based on impact model calculations, over an 11-year period between 2019 and 2030 is $3,547,996. However, the average annual costs ranged from $507,185 in 2019 to $1,279,910 in 2030 (Figure 1, panel A). These costs include the cost of salaries (personnel), travel, conducting meetings, supplies, research and development, facilities and overheads, and other project costs such as indirect costs. The contribution of the different cost categories to the total cost of scale-up varied over time as shown in Figure 1, panels A & B. The total cost is expected to see a sudden increase in 2020 because of the growth in the expenses on facilities and overheads due to required additional remodeling and equipment to meet the increased capacity as the pouch is scaled up to other regions in Uganda (Dixit, et al., 2019).

EGPAF is currently working with the government of Uganda and expects that, by 2023, Pratt Pouch will be integrated into the national supply chain as well as the national PMTCT program. They expect that the technical and support staff of MOH will continue to support the Pratt Pouch project as part of their routine PMTCT duties. Their level of effort will be covered by the MOH budget after 2023 as the Pratt pouch fully integrates into the national supply chain and becomes part of the health facility basic care package. This will reduce the standalone cost of the project because there will not be any extra personnel costs other than the salaries that MOH staff are already receiving. Hence, the cost will not increase rapidly with the expansion of the project across the country.

5: The calculation of PV or cost and beneficiary can be found in Annex 4.

It is estimated that the travel and training costs will remain almost constant and the expenses will be borne by the government as it takes over the operation from EGPAF. Routine mentorship after 2023 will be conducted as part of the quarterly prevention of mother-to-child transmission (PMTCT) program supported by the MOH, and hence, training costs will be incorporated in the PMTCT program costs and it is assumed that $20,000 will incurred each year. Similarly, travel will also be absorbed into routine PMTCT programming by the MOH, and an expense of $50,000 is assumed to be incurred each year. The research and development cost is expected to stop because EGPAF plans to focus more on implementation of the project after 2020. The innovator also expects that other costs, such as fringe benefits, and indirect costs will stop in 2024 after MOH takes over the management and the operations of the Pratt Pouch in Uganda.

The program will continue to expand each year and the costs like supplies, facilities, and personnel will continue to increase even after the Pratt Pouch program is embedded into the MOH PMTCT Program. The personnel, supplies and facilities costs will continue to rise gradually during the 11-year period (2019-2030), as Pratt Pouch expands to other districts in Uganda. The supply costs will continue to increase as the project expands to new regions and reaches additional beneficiaries. Supplies will be the major cost category starting 2021 as EGPAF starts to focus more on implementation and expansion to new areas. Thus, it will continue to capture a large percentage of the total cost of implementation of the Pratt Pouch—increasing from 33% in 2021 to 73% in 2030 (Figure 1, panel B). It is important to note that the analysis might be over-estimating the costs of personnel, and training, especially if a country already has a PMTCT program. Uganda already has large-scale trainings under the PMTCT program, and it might not incur separate personnel and training costs for the implementation of the innovation.

Figure 1: Incremental Costs of Scaling up Pratt Pouch Disaggregated by Year and Cost Category

Source: Costing Tool (Dixit, et al., 2019)

The health effects of scaling up Pratt Pouch to reach additional beneficiaries were measured in number of lives saved, and number of life-years saved. Over the 11-year period (2019 to 2030), scaling-up Pratt Pouch in Uganda to reach 187,771 beneficiaries will result in a total of 3,109 lives saved, and 87,949 life-years saved. The annual estimates of lives saved ranged from 51 in 2019 to 602 in 2030, while the annual estimates of years of life saved ranged from 1,443 in 2019 to 17,045 in 2030. See Table 3 for details.

Over the 11-year period (2019 to 2030), scaling-up Pratt Pouch in Uganda to reach 187,771 beneficiaries will result in a total of 3,109 lives saved, and 87,949 life-years saved.

Table 3: Annual Estimates of Life Saved and Years of Life Saved (YLS)

Years	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Lives Saved	51	100	163	209	246	297	345	382	425	465	556	602
YLS	1,443	2,835	4,614	5,926	6,967	8,406	9,748	10,819	12,028	13,145	15,720	17,045

Source: Authors' calculations using data from Impact Model

Table 3 displays the number of lives saved and years of life saved. Based on the impact model, **EGPAF plans to gradually expand Pratt Pouch to all 128 districts of Uganda by 2030**, and this is reflected in the lives saved numbers, which also increase in sync with the coverage of new districts each year, until 2030.

For incremental cost-effectiveness ratios, an incremental cost per new beneficiary of $18.17, an incremental cost per life saved of $1,096.65, and an incremental cost per year of life saved of $38.76 were estimated. When a 3% rate of discount is applied, an incremental cost per new beneficiary of $18.90, an incremental cost per life saved of $1,141.31, and an incremental cost per life-year saved of $40.34 (i.e. 6.23% of Gross Domestic Product (GDP) per capita) were estimated.

When a 3% rate of discount is applied, an incremental cost per new beneficiary of $18.90, an incremental cost per life saved of $1,141.31, and an incremental cost per life-year saved of $40.34 (i.e. 6.23% of Gross Domestic Product (GDP) per capita) were estimated.

The results from the sensitivity analysis are summarized in Table 4. A +/-20 % variation in the estimates of costs and lives-saved result in minimum and maximum values of cost per life saved of $761 and $1,712. Using the same deterministic variation of +/- 20% on cost and YLS leads to a minimum and maximum cost per years of life saved of $27 and $61 respectively. Increasing the deterministic variation of the input parameters of cost and life saved to +/-50 % results in an increase of the maximum value of cost per life saved and cost per years of life saved to $3,424 and $121 respectively, and a reduction in the minimum value of cost per life saved and cost per years of life saved to $380 and $13, respectively.

Table 4: Results of Sensitivity Analysis Using Deterministic Analysis (in 2016 USD)

COST PER LIFE SAVED			
+/- 20 percent			
Summary	Costs	Life Saved	Cost / Life Saved
-20% cost, +20% lives saved	2,838,397	3,730	$ 761
+20% cost, -20% lives saved	4,257,595	2,487	$ 1,712
+/- 50 percent			
Summary	Costs	Life Saved	Cost / Life Saved
-50% cost, +50% lives saved	1,773,998	4,663	$ 380
+50% cost, -50% lives saved	5,321,994	1,554	$ 3,424

COST PER YLS			
+/- 20 percent			
Summary	Costs	YLS	Cost / YLS
-20% cost, +20% YLS	2,838,397	105,539	$ 27
+20% cost, -20% YLS	4,257,595	70,359	$ 61
+/- 50 percent			
Summary	Costs	YLS	Cost / YLS
-50% cost, +50% YLS	1,773,998	131,924	$ 13
+50% cost, -50% YLS	5,321,994	43,975	$ 121

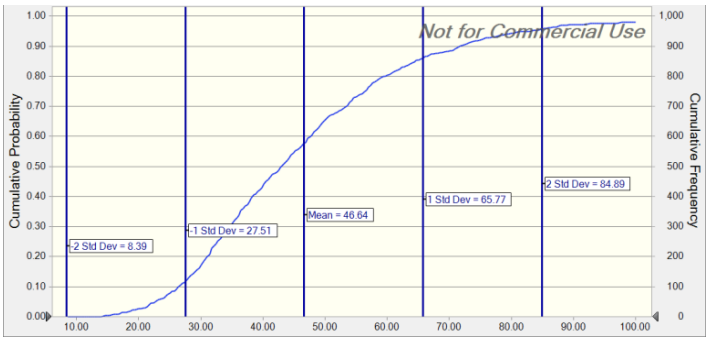
Source: Authors' calculation using Impact model and Costing Tool

Similar results were obtained when probabilistic sensitivity analysis was conducted (see figure 2). The mean cost per years of life saved was $46.64 (95% CI: $8.39, $84.89). Based on the cumulative probability distribution of cost per years of life saved, this means that there is 95% probability that the cost per years of lives saved will remain between $8.39 and $84.89. Likewise, the mean cost per life saved was $1,349.72 (95% CI: $242.59, $2,456.84). Similarly, based on the cumulative probability distribution of cost per life saved, this means that there is 95% probability that the cost per lives saved will stay between $242.59 and $2456.84.

Figure 2: Results of Sensitivity Analysis Using Probabilistic Analysis (in 2016 USD)

Distribution of Cost per Life Saved

Distribution of Cost per YLS



Source: Authors' calculation using Impact model and Costing Tool

In addition, sensitivity of individual parameters in Table 1 was also conducted to identify the parameters that had the highest impact on cost per years of lives saved, while keeping all other parameters constant. **The top three parameters whose variability affected cost per years of lives saved the most were 1) Percentage of deaths among ART-naive HIV infected children 2) postpartum women on ART (adherent), and 3) percentage of women delivering in health facilities.** These variables combined explain, according to sensitivity analysis, about 74% of the variability in cost per YLS. Therefore, the innovator should pay extra attention to these parameters while expanding the innovation to new areas.

3 IMPLICATIONS OF KEY FINDINGS

The results of this study suggest that a national scale-up of Pratt Pouch by EGPAF to reach additional beneficiaries in Uganda is cost-effective. **The findings here suggest that the life of one additional newborn would be saved for every $1,141.31 spent scaling up Pratt Pouch in Uganda.** This translates to an additional year of life saved for every $40.34 invested in scale-up efforts. The estimate of incremental cost per life-year saved ($40.34) falls below the GDP per capita for Uganda[6], suggesting that scale-up will be very cost-effective according to commonly used criteria for cost-effectiveness.[7] Moreover, our estimate of incremental cost effectiveness per life-year saved is 6.23%[8] of Uganda's GDP per capita, which compares favorably with estimates from other life-saving interventions in Ethiopia, a country in the same region and with similar per capita GDP as Uganda. Memirie and colleagues analyzed the scale-up of maternal and neonatal health interventions and estimated incremental costs per DALYs averted that ranged from $7 to $300. When measured as a percentage of GDP per capita of Ethiopia in 2018, their estimates ranged from 1% to 39% (Memirie, et al., 2019).

This translates to an additional year of life saved for every $40.34 invested in scale-up efforts.

However, being cost-effective does not automatically mean that an intervention will be affordable. Affordability depends on the ability of the payer to bear the costs of scale-up. According to our cost projections, the maximum annual cost needed during the scale up period will be $1,279,910 in 2030 and a payer will need to evaluate its ability to pay for the costs of scale-up.

6: Uganda's 2018 GDP per capita (current USD) was $643 (World Development Indicators , 2020).
7: The WHO-CHOICE criteria suggest that interventions are "very cost-effective" if the ICER is less than the country's GDP per capita, "cost effective" if the ICER is between one and three times the country's GDP per capita, and "not cost-effective" if the ICER is greater than three times the country's GDP per capita.
8: Although the WHO-CHOICE criteria referred to Disability Adjusted Life Years (DALYs), if an intervention is found to be cost-effective using the more conservative years of life lost (or years of life saved (YLS)), then the intervention will anyways be cost-effective if DALYs was used.

4 LIMITATIONS OF THE STUDY

The assessment of cost effectiveness for Pratt Pouch in Uganda is based on cost information provided by the innovator and the impact model created by the Duke University team and validated by GCC. **Collection of independent primary data through market research and pilot impact studies, which goes beyond the scope of the current study, could strengthen the analysis.**

The present incremental cost-effectiveness analysis is **based on the comparison of Pratt Pouch with the status quo**. The status quo, in this scenario, refers to receiving prophylaxis by visiting health facilities and administering it to neonates via the syringe method.

The impact model uses assumptions that are derived from the latest peer-reviewed literature available at the time of the development of the model, along with the most recent scale-up plans shared by the innovator. For certain assumptions, such as the HIV transmission rates in breastfeeding and non-breastfeeding populations, data was not always available from a study conducted in Uganda. In such cases, the model uses evidence from other countries that are comparable to Uganda in terms of demographics and other health indicators. The model also uses Ugandan Health Management Information System (HMIS) data, or data by the Ministry of Health, in Uganda. Such parameters were not validated by any external organization or entity before being included in the model. Overall, the unavailability of relevant and validated data can decrease the model's accuracy. In addition, any change in innovator plans for scaling up, along with the availability of new data from latest studies, could make the impact model outdated over time.

The impact model also **estimates mortality, and not morbidity**, in its calculation of the years of lives saved due to the Pratt Pouch. Estimating the morbidity would require assumptions and data on the impact of the Pouch on health outcomes and quality of life of populations, which are currently not fully available.

Lastly, as is true with any modeling exercise, the EGPAF impact model does not, and cannot, completely capture the situation as it plays out in the field. For example, the Pratt Pouch is replacing the already available syringe method of administering ARV to infants at facilities. However, the model only estimates the impact of the Pouch over and above the currently available method, in other words, only for infants who would not have received NVP had the Pratt Pouch not been implemented. Although this would lead to a more conservative estimate, the field implementation of the Pouch is far too complex for the model to fully replicate.

5 CONCLUSION

The planned scale-up of Pratt Pouch to all the districts in Uganda between 2019 and 2030 would potentially save thousands of newborn lives, and would be **very cost-effective** according to existing thresholds for measuring cost-effectiveness. Over the period, this scale-up effort will require a total investment of 3.5 million USD, reach 188 thousand beneficiaries, save about 3 thousand newborn lives, and contribute to over 88 thousand years of life saved. On its part, EGPAF's cost structure is expected to change during the expansion with travel and training costs becoming constant when the government takes over the operations, while personnel, supplies, facilities, and overhead costs will continue to gradually increase as the innovation scales to more districts in Uganda.

Overall, these results provide a reliable **quantitative evidence that scaling up Pratt Pouch in Uganda could contribute to saving many newborn lives, and improving newborn health in Uganda.**

BIBLIOGRAPHY

1. Ahoua, L., Ayikoru, H., Gnauck, K., Odaru, G., Odar, E., Ondoa–Onama, C., . . . Pujades-Rodríguez, M. (2010). Evaluation of a 5-year Programme to Prevent Mother-to-child Transmission of HIV Infection in Northern Uganda. Journal of Tropical Pediatrics, 43-52. Obtenido de https://academic.oup.com/tropej/article/56/1/43/1660313
2. Bruce A Larson. (2013). Calculating disability-adjusted-life-years lost (DALYs) in discrete-time. Cost Effectiveness and Resource Allocation, 11-18.
3. Darmstadt, G. L., Walker, N., Lawn, J. E., Bhutta, Z. A., Haws, R. A., & Cousens, S. (2008). Saving newborn lives in Asia and Africa: cost and impact of phased scale-up of interventions within the continuum of care. Health Policy and Planning, 101-117. Obtenido de https://www.ncbi.nlm.nih.gov/pubmed/18267961
4. De Cock KM, F. M. (2000). Prevention of mother-to-child HIV transmission in resource-poor countries: translating research into policy and practice. JAMA, 1175-82. Obtenido de https://www.ncbi.nlm.nih.gov/pubmed/10703780
5. Dixit, S., Finnegan, A., Fernholz, F., Ogbuoji, O., Biru, B., Udayakumar, K., & Baumgartner, J. (2019). Costing Tool for Health Innovators. Durham: Evaluating Savings Lives at Birth (E-SL@B) Program; Duke Global Health Institute Evidence Lab & Global Health Innovation Center at Duke University.
6. Doshi, R. H., Sande, E., Ogwal, M., Kiyingi, H., A. M., Kusiima, J., . . . Hladik, W. (2018). Progress toward UNAIDS 90-90-90 targets: A respondent-driven survey among female sex workers in Kampala, Uganda. PLoS ONE. Obtenido de https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0201352
7. Duke Global health institute. (27 de March de 2020). Duke Global health institute (DGHI). Obtenido de Promising Pratt Pouch Ready to Scale Up: https://globalhealth.duke.edu/media/news/promising-pratt-pouch-ready-scale
8. Edejer, T. T.-T., Baltussen, R., Adam, T., Hutubessy, R., Acharya, A., Evans, D., & Murray, C. (2003). WHO Guide to Cost-Effectiveness Analysis. Geneva: WHO. Recuperado el 13 de April de 2020, de https://www.who.int/choice/publications/p_2003_generalised_cea.pdf
9. EGPAF. (2015). Saving Lives at Birth. EGPAF. Obtenido de https://www.pedaids.org/wp-content/uploads/2017/09/SLAB_2pager_A4_072518-nc.pdf
10. EGPAF Concept Note. (2015). EGPAF Concept Note. EGPAF.
11. EGPAF Representatives Interview, 2020. (s.f.). EGPAF Interview.
12. EGPAF Final Report. (2020). 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 infact lives. EGPAF.
13. Fadnes, L. T., Engebretsen, I. M., Wamani, H., Wangisi, J., Tumwine, J. K., & Tylleskär, T. (2009). Need to optimise infant feeding counselling: A cross-sectional survey among HIV-positive mothers in Eastern Uganda. BMC Pediatrics. Obtenido de https://bmcpediatr.biomedcentral.com/track/pdf/10.1186/1471-2431-9-2
14. Hayward Medical Communication. (2009). What is Sensitivity Analysis. Hayward Medical Communication. Obtenido de http://www.bandolier.org.uk/painres/download/What%20is%202009/What_is_sens_analy.pdf
15. Jackson JB, M. P. (2003). Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: 18-month follow-up of the HIVNET 012 randomised trial. Lancet. Obtenido de https://www.ncbi.nlm.nih.gov/pubmed/13678973
16. Jean B. Nachega, O. A.-S. (October 2012). Adherence to Antiretroviral Therapy During and After Pregnancy in Low-, Middle and High Income Countries: A Systematic Review and Meta-Analysis. AIDS, 2039-2052. Obtenido de https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5061936/pdf/nihms510376.pdf
17. Memirie, S. T., Tolla, M. T., Desalegn, D., Hailemariam, M., Norheim, O. F., Verguet, S., & Johansson, K. A. (2019). A cost-effectiveness analysis of maternal and neonatal health interventions in Ethiopia. Health Policy and Planning, 289-297. Obtenido de https://academic.oup.com/heapol/search-results?page=1&qb=%7B%22Keywords1%22:%22Maternal%20and%20neonatal%20health%22%7D&SearchSourceType=1
18. Michele Magoni, L. B. (2005). Mode of infant feeding and HIV infection in children in a program for prevention of mother-to-child transmission in Uganda. AIDS, 433-437. Obtenido de https://journals.lww.com/aidsonline/Fulltext/2005/03040/Mode_of_infant_feeding_and_HIV_infection_in.9.aspx
19. Ministry of Health. (2016). Consolidated guidelines for prevention and treatement of HIV in Uganda. Ministry of Health. Obtenido de https://www.differentiatedcare.org/Portals/0/adam/Content/HvpzRP5yUUSdpCe2m0KMdQ/File/CONSOLIDATED%20GUIDELINES%20FOR%20PREVENTION%20AND%20TREATMENT%20OF%20HIV%20IN%20UGANDA.pdf

20. Ministry of Health. (s.f.). ARVs and eMTCT Medicines Order form and Patient (HMIS 084b). Ministry of Health.
21. Ministry of Health, Uganda. (2019). Uganda Population-Based HIV Impact Assessment (UPHIA) 2016-17. Kampala: Ministry of Health. Obtenido de https://phia.icap.columbia.edu/wp-content/uploads/2019/07/UPHIA_Final_Report_Revise_07.11.2019_Final_for-web.pdf
22. Ministry of Health, Uganda. (2019). Uganda Population-based HIV Impact Assessment (UPHIA) 2016-2017: Final Report. Kampala: Ministry of Health. Obtenido de https://phia.icap.columbia.edu/wp-content/uploads/2019/07/UPHIA_Final_Report_Revise_07.11.2019_Final_for-web.pdf
23. Ministry of Health-Uganda. (2008). National Antiretroviral Treatment and Care Guidelines for Adults, Adolescents, and Children. Kampala: Ministry of Health-Uganda.
24. Munyagwa, M., Baisley, K., Levin, J., Brian, M., Grosskurth, H., & Maher, D. (2012). Mortality of HIV-infected and uninfected children in a longitudinal cohort in rural south-west Uganda during 8 years of follow-up. Tropical Medicine and International Health, 17(7), 863-843. Obtenido de https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1365-3156.2012.03000.x
25. Okong, P., Namaganda, P. K., Bassani, L., Tabaro, M. M., Zanetto, F., Mwebaze, E. B., . . . Giuliano, M. (July 2010). Maternal HIV status and infant feeding practicesamong Ugandan women. Journal of Social Aspects of HIV/AIDS, 24-29. Obtenido de https://www.tandfonline.com/doi/pdf/10.1080/17290376.2010.9724952
26. Peltier, C. A., Ndayisaba, G. F., Lepage, P., Van Griensven, J., Leroy, V., Pharm, C. O., . . . Arendt, V. (2009). Breastfeeding with maternal antiretroviral therapy or formula feeding to prevent HIV postnatal mother-to-child transmission in Rwanda. AIDS, 23. Obtenido de https://oce.ovid.com/article/00002030-200911270-00005/HTML
27. Renaud Becquet, L. B.-K. (January 2007). Two-Year Morbidity–Mortality and Alternatives to Prolonged Breast-Feeding among Children Born to HIV-Infected Mothers in Côte d'Ivoire. PLOS Medicine. Obtenido de https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0040017
28. Renaud Becqueta, D. K.-B.-K. (July 2008). Early mixed feeding and breastfeeding beyond 6 months increase the risk of postnatal HIV transmission: ANRS 1201/1202 Ditrame Plus, Abidjan, Côte d'Ivoire. Preventive Medicine, 27-33. Obtenido de https://www.sciencedirect.com/science/article/pii/S0091743507004938?via%3Dihub
29. Sarah Decker, E. R. (June 2017). Prevention of mother-to-child transmission of HIV: Postpartum adherence to Option B+ until 18 months in Western Uganda. PLOS One. Obtenido de https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0179448
30. The World Bank. (3 de March de 2020). World Development Indicators. Obtenido de The World bank : https://data.worldbank.org/indicator/SH.STA.ANVC.ZS?locations=UG
31. The World Bank Group. (18 de March de 2020). World Development Indicators (WDI). Obtenido de The World Bank: https://data.worldbank.org/indicator/SP.DYN.LE00.IN?locations=UG
32. Thior I, L. S. (2006). Breastfeeding plus infant zidovudine prophylaxis for 6 months vs formula feeding plus infant zidovudine for 1 month to reduce mother-to-child HIV transmission in Botswana: a randomized trial: the Mashi Study. JAMA, 794-805. Obtenido de https://www.ncbi.nlm.nih.gov/pubmed/16905785/
33. Uganda Bureau of Statistics Kampala, Uganda. (2012). Uganda Demographic and Health Survey 2011. Kampala: MEASURE DHS ICF International Calverton, Maryland, USA. Obtenido de https://dhsprogram.com/pubs/pdf/FR264/FR264.pdf
34. Uganda Bureau of Statistics, Kampala, Uganda. (2007). Uganda Demographic and Health Survey 2006. Kampala: Macro International Inc. Calverton, Maryland, USA. Obtenido de https://dhsprogram.com/pubs/pdf/FR194/FR194.pdf
35. Uganda Bureau of Statistics, Kampala, Uganda. (2018). Demographic and Health Survey, 2016. Kampala: Macro International Inc. Calverton, Maryland, USA.
36. UNAIDS. (22 de March de 2020). Country-Uganda. Obtenido de UNAIDS: https://www.unaids.org/en/regionscountries/countries/uganda
37. UNICEF. (March 2013). Countdown To Zero (Uganda). Unicef. Obtenido de https://data.unicef.org/wp-content/uploads/country_profiles/Uganda/PMTCT_UGA.pdf
38. WHO. (2004). HIV transmissionthrough breastfeeding: A review of available evidence. WHO. Obtenido de https://www.who.int/nutrition/publications/HIV_IF_Transmission.pdf
39. WHO. (2007). HIV Transmission Through Breastfeeding: A Review of Available Evidence. WHO. Obtenido de https://apps.who.int/iris/bitstream/handle/10665/43879/9789241596596_eng.pdf?sequence=1

40. WHO. (2010). Antiretroviral Drugs For Treating Pregnant Women and Preventing HIV Infections in Infants. Geneva: WHO. Obtenido de https://apps.who.int/iris/bitstream/handle/10665/75236/9789241599818_eng.pdf?sequence=1
41. WHO. (2010). Towards the elimination of Mother-to-Child transmission of HIV. Geneva: WHO. Obtenido de https://apps.who.int/iris/bitstream/handle/10665/44638/9789241501910_eng.pdf;jsessionid=16E4E9960D185CED490EA1520C99AF7A?sequence=1%20
42. WHO. (2016). Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: WHO. Obtenido de https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf?sequence=1
43. WHO. (June 2013). Gobal update of HIV treatment 2013: Results, Impact and Oppurtunities. Geneva: WHO.
44. World Development Indicators . (26 de March de 2020). The World bank . Obtenido de The World bank: https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?locations=UG
45. World Health Organization (Global Burden of Disease Concept). (s.f.). The Global Burden of Disease concept. WHO. Obtenido de https://www.who.int/quantifying_ehimpacts/publications/en/9241546204chap3.pdf

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Duke Global Health Innovation Center

The Duke Global Health Innovation Center's (GHIC) mission is to study and support the scaling and adaptation of innovations and related policy reforms, to address critical health challenges worldwide. The GHIC strives to have an impact on healthcare through scaling of health innovations, promoting policy and regulatory changes, and implementation projects in health systems. The GHIC links global health, health policy, and health innovation efforts across Duke University.

Duke Global Health Institute Evidence Lab

The Duke Global Health Institute (DGHI) Evidence Lab blends theory and practice and draws upon the research and policy expertise across Duke University to inform evaluations and to disseminate new evidence to policymakers, donors and diverse stakeholders to inform decision-making. With deep, on-the-ground knowledge and experience with a wide range of global health projects, our team offers research and practice-based understandings of regional health challenges. A core principle of the DGHI Evidence Lab is to strengthen the evaluation capacity of local project counterparts on collaborative projects.

Duke Center for International Development

The Duke Center for International Development (DCID), a unit within Duke University's Sanford School of Public Policy, advances international development policy and practice through interdisciplinary approaches to postgraduate education, mid-career training, international advising and research. DCID faculty and staff continuously strive to create programs that meet the specific needs of each client and student.

ANNEX 1

Lives Saved Calculation in the Impact Model Developed by the Duke University Team

The following table provides the impact model, which calculates the lives saved from the scale-up of Pratt Pouch by EGPAF from 2019 to 2030 in Uganda.

		Funding Period											
Access	**TOTAL**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Total number of births	19,929,900	1,540,700	1,567,000	1,594,600	1,620,700	1,644,800	1,666,600	1,685,500	1,701,400	1,714,400	1,724,700	1,732,400	1,737,100
Districts covered	128	14	20	25	35	45	55	65	75	85	95	118	128
Births occuring in covered districts	11,242,387	210,780	408,600	469,349	602,742	708,690	855,032	991,690	1,100,785	1,223,745	1,337,522	1,599,106	1,734,346
Number of HIV Exposed Infants in districts covered (HEIs)	843,179	15,808	30,645	35,201	45,206	53,152	64,127	74,377	82,559	91,781	100,314	119,933	130,076
HEIs with mothers ever tested for HIV and receiving at least 1 ANC	743,456	13,939	27,021	31,038	39,859	46,865	56,543	65,580	72,795	80,926	88,450	105,749	114,692
HEIs affected by intrauterine and intrapartum transmission	60,220	1,129	2,189	2,514	3,229	3,796	4,580	5,312	5,896	6,555	7,164	8,566	9,290
Total HEIs in covered districts whose mothers know HIV status and received >= 1 ANC visit	683,236	12,810	24,832	28,524	36,631	43,069	51,963	60,268	66,898	74,371	81,286	97,183	105,402
~facility births (includes trend)	509,092	9,351	18,352	21,263	27,251	32,095	38,703	44,925	49,914	55,489	60,670	72,400	78,681
~home births	174,144	3,459	6,480	7,261	9,380	10,975	13,260	15,344	16,984	18,882	20,615	24,783	26,721
1. Baseline Scenario													
Postpartum women on ART (adherent)	348,451	6,533	12,664	14,547	18,682	21,965	26,501	30,737	34,118	37,929	41,456	49,563	53,755
HEIs receiving ARV ~ facility birth (includes trend)	346,421	6,078	12,251	14,470	18,480	21,841	26,315	30,596	34,066	37,873	41,443	49,256	53,753
HEIs receiving ARV ~ home birth	-	0	0	0	0	0	0	0	0	0	0	0	0
HEIs receiving ARV Total	346,421	6,078	12,251	14,470	18,480	21,841	26,315	30,596	34,066	37,873	41,443	49,256	53,753
Total HEIs with infant **and** mother receiving treatment (# of HEIs receiving NVP with *assumption* mother also receiving ART)	346,421	6,078	12,251	14,470	18,480	21,841	26,315	30,596	34,066	37,873	41,443	49,256	53,753
Total HEIs with infant **or** mother receiving treatment (# of HEIs whose mothers are receiving ART but infants are not)	2,029	455	414	77	202	124	186	141	52	56	13	307	2
Total HEIs with infant **nor** mother receiving treatment	334,786	6,277	12,168	13,977	17,949	21,104	25,462	29,531	32,780	36,442	39,830	47,620	51,647
Number of HEIs infected - mother **and** infant receiving treatment (Breast Feeding)	9,111	160	322	381	486	574	692	805	896	996	1,090	1,295	1,414
Number of HEIs infected - mother **or** infant receiving treatment (Breast Feeding)	239	54	49	9	24	15	22	17	6	7	2	36	0
Number of HEIs infected - infant **nor** mother receiving treatment (Breast Feeding)	100,436	1,883	3,650	4,193	5,385	6,331	7,639	8,859	9,834	10,933	11,949	14,286	15,494
Total number of HEIs infected (Breast Feeding)	109,786	2,097	4,021	4,583	5,895	6,920	8,353	9,681	10,736	11,935	13,040	15,618	16,908
Number of HEIs infected - mother **and** infant receiving treatment (Non-Breast Feeding)	3,464	61	123	145	185	218	263	306	341	379	414	493	538
Number of HEIs infected - mother **or** infant receiving treatment (Non-Breast Feeding)	122	27	25	5	12	7	11	8	3	3	1	18	0
Number of HEIs infected - infant **nor** mother receiving treatment (Non-Breast Feeding)	66,957	1,255	2,434	2,795	3,590	4,221	5,092	5,906	6,556	7,288	7,966	9,524	10,329
Total number of HEIs infected (Non-Breast Feeding)	70,543	1,343	2,581	2,945	3,787	4,447	5,367	6,221	6,900	7,670	8,381	10,035	10,867
2. Intervention Scenario													
Estimated HEIs eligible to receive PP	496,758	9,730	18,394	20,731	26,726	31,311	37,813	43,781	48,493	53,908	58,871	70,677	76,323
Estimated HEIs receiving Pratt Pouch (over and above the Syringe method)	231,908	3,366	6,291	9,838	12,706	14,860	17,954	20,771	22,983	25,548	27,890	33,549	36,154
Number of women who will be retained for treatment following delivery	185,526	2,693	5,032	7,870	10,164	11,888	14,363	16,617	18,386	20,439	22,312	26,839	28,923
Access: Number of women who will be retained for treatment following delivery, who are compliant with the treatment protocol	176,250	2,558	4,781	7,477	9,656	11,294	13,645	15,786	17,467	19,417	21,196	25,497	27,477
Total HEIs on PP or ART	522,671	8,636	17,032	21,947	28,136	33,134	39,960	46,382	51,533	57,290	62,639	74,753	81,230
Total HEIs with infant **and** mother receiving treatment (# of HEIs receiving NVP with assumption mother also receiving ART)	348,451	6,533	12,664	14,547	18,682	21,965	26,501	30,737	34,118	37,929	41,456	49,563	53,755
Total HEIs with infant **or** mother receiving treatment (# of HEIs whose mothers are receiving ART but infants are not)	174,221	2,103	4,367	7,400	9,454	11,169	13,458	15,645	17,414	19,361	21,184	25,190	27,475
Total HEIs with infant **nor** mother receiving treatment	160,565	4,174	7,800	6,577	8,495	9,935	12,003	13,887	15,366	17,081	18,646	22,430	24,172
Number of HEIs infected - mother **and** infant receiving treatment (Breast Feeding)	9,164	172	333	383	491	578	697	808	897	998	1,090	1,304	1,414
Number of HEIs infected - mother **or** infant receiving treatment (Breast Feeding)	20,558	248	515	873	1,116	1,318	1,588	1,846	2,055	2,285	2,500	2,972	3,242
Number of HEIs infected - infant **nor** mother receiving treatment (Breast Feeding)	48,169	1,252	2,340	1,973	2,548	2,980	3,601	4,166	4,610	5,124	5,594	6,729	7,251
Total number of HEIs infected (Breast Feeding)	77,892	1,672	3,189	3,229	4,155	4,876	5,886	6,820	7,562	8,406	9,184	11,005	11,907
Number of HEIs infected - mother **and** infant receiving treatment (Non-Breast Feeding)	3,485	65	127	145	187	220	265	307	341	379	415	496	538
Number of HEIs infected - mother **or** infant receiving treatment (Non-Breast Feeding)	10,453	126	262	444	567	670	808	939	1,045	1,162	1,271	1,511	1,649
Number of HEIs infected - infant **nor** mother receiving treatment (Non-Breast Feeding)	32,113	835	1,560	1,315	1,699	1,987	2,401	2,777	3,073	3,416	3,729	4,486	4,834
Total number of HEIs infected (Non-Breast Feeding)	46,051	1,026	1,949	1,905	2,453	2,877	3,473	4,023	4,459	4,957	5,415	6,493	7,020

Intermediate Outcomes BF/Non-BF	**TOTAL**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Total HEIs with infant **and** mother receiving treatment - difference between baseline and intervntion scenarios		-455	-414	-77	-202	-124	-186	-141	-52	-56	-13	-307	-2
Total HEIs with infant **or** mother receiving treatment - difference between baseline and intervntion scenarios		-1,648	-3,954	-7,323	-9,253	-11,045	-13,272	-15,504	-17,362	-19,305	-21,171	-24,883	-27,474
Total HEIs with infant **nor** mother receiving treatment - difference between baseline and intervntion scenarios		2,103	4,367	7,400	9,454	11,169	13,458	15,645	17,414	19,361	21,184	25,190	27,475
Number of HEIs not infected - mother **and** infant receiving treatment (Breast Feeding)	(53)	-12	-11	-2	-5	-3	-5	-4	-1	-1	0	-8	0
Number of HEIs not infected - mother **or** infant receiving treatment (Breast Feeding)	(20,319)	-195	-467	-864	-1,092	-1,303	-1,566	-1,829	-2,049	-2,278	-2,498	-2,936	-3,242
Number of HEIs not infected - infant **nor** mother receiving treatment (Breast Feeding)	52,266	631	1,310	2,220	2,836	3,351	4,038	4,693	5,224	5,808	6,355	7,557	8,243
Total number of HEIs not infected due to PP (Breast Feeding)	31,894	424	833	1,354	1,739	2,044	2,467	2,860	3,174	3,529	3,857	4,613	5,001
Number of HEIs not infected - mother **and** infant receiving treatment (Non-Breast Feeding)	-20	-5	-4	-1	-2	-1	-2	-1	-1	-1	0	-3	0
Number of HEIs not infected - mother **or** infant receiving treatment (Non-Breast Feeding)	-10,332	-99	-237	-439	-555	-663	-796	-930	-1,042	-1,158	-1,270	-1,493	-1,648
Number of HEIs not infected - infant **nor** mother receiving treatment (Non-Breast Feeding)	34,844	421	873	1,480	1,891	2,234	2,692	3,129	3,483	3,872	4,237	5,038	5,495
Number of HEIs not infected due to PP (Non-Breast Feeding)	24,492	317	632	1,040	1,334	1,570	1,894	2,197	2,441	2,713	2,966	3,542	3,847

Outcome - Cumulative Lives Saved	**TOTAL**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Number of HEIs not infected due to PP (Breast Feeding and Non-Breast Feeding)	30,984	411	808	1,315	1,689	1,986	2,396	2,779	3,084	3,428	3,747	4,481	4,859
Lives saved	**3,842**	**51**	**100**	**163**	**209**	**246**	**297**	**345**	**382**	**425**	**465**	**556**	**602**

Source: Impact Model Developed by the Duke University Team

ANNEX 2

Future Life Stream of Individuals who are Saved or YLS, and the Total PV of YLS (or NPV)

Years	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Life expectancy at birth (L)	63.15	63.15	63.15	63.15	63.15	63.15	63.15	63.15	63.15	63.15	63.15	63.15
Total Life Saved (N)	51.00	100.20	163.08	209.48	246.25	297.11	344.56	382.42	425.13	464.64	555.65	602.48
Individual YLL-- ((1/r) *(1-e^(-r*L)))	28.29	28.29	28.29	28.29	28.29	28.29	28.29	28.29	28.29	28.29	28.29	28.29
YLS (Years of Life Saved)	1,442.87	2,834.89	4,613.75	5,926.41	6,966.62	8,405.68	9,748.15	10,819.14	12,027.63	13,145.24	15,720.01	17,045.05
PV of YLS for individual years (YLS*1/ (1+r) ^t)	1,442.87	2,752.32	4,348.91	5,423.50	6,189.75	7,250.82	8,163.92	8,796.95	9,494.72	10,074.73	11,697.16	12,313.70
Total PV of YLS (NPV)	87,949.35											

Source: Authors' calculation using Impact Model and Costing Tool
Note: Only two decimal places are presented in the table. However, there are more decimal numbers in the original model's Excel calculation, which are not shown here. Therefore, there is some variability in the calculation of YLS.

This CEA calculates YLS (Year of Life Saved) using the life saved numbers, and utilizes the following formula to estimate the future life streams of an individual or YLL for an individual for each year – 2019 to 2030 (Bruce A Larson, 2013):

YLL=(1/r) *(1-e^(-r*L))

where r is the discount rate of 3% to years of life lost in future (as suggested by (World Health Organization (Global Burden of Disease Concept)), L is the standard expectation of life, and e is equivalent to 2.71.

This CEA pertains to newborn deaths; therefore, the life expectancy (L) at the time of birth is used for calculating YLL for each year. Moreover, the future life streams of the individuals who are saved or YLS for each year from 2019 to 2030 is obtained by multiplying the calculated YLL from the above equation with the corresponding lives saved number (N) in that year as shown in the following formula:

YLS (Years of Life Saved) = Lives saved (N) * average YLL

YLS= N * (1/r) *(1-e^(-r*L))

The Net Present Value (NPV)[9] of the YLS is calculated by discounting the YLL for each year from 2019 to 2030 at 3% to bring the future life streams of individuals saved to 2019. The calculations and final values of life saved and YLS are shown in the above table.

9: Net present value (NPV) is used to calculate what future values/returns are worth today. We use a discount rate to calculate the present value of future flows of a project. For the health and medicine projects, WHO uses a discount rate of 3% to convert future values into the present values. The addition of all the present values for different years gives the NPV.

ANNEX 3

Sensitivity Analysis

The cost, YLS , and life saved information has a tendency to vary, and might not remain the same as the current estimates. These values could increase or decrease and the variations in these parameters will affect the incremental ratios, thus altering the cost-effectiveness of the innovation calculated based on current projections. To that end, **the cost-effectiveness of the expansion of Pratt Pouch by EGPAF in Uganda was pressure-tested by conducting sensitivity analysis to understand how changes in input parameters/assumptions could affect cost per YLS, and to assess if Pratt Pouch remains a cost-effective innovation in Uganda under different parameter variations**. Two types of sensitivity analysis (deterministic and simulation) were conducted; both approaches are described below.

Deterministic Sensitivity Analysis

The deterministic sensitivity analysis was used to obtain the widest range of possible uncertainly to test the cost effectiveness of Pratt Pouch in Uganda. **This method of sensitivity analysis only varies the cost and YLS by a fixed amount, and does not change individual parameters.** Although this analysis does not include the range of upper and lower limits of all the assumptions in the probabilistic analysis, it still provides a broad direction on whether the innovation remains cost effective at larger, more unexpected, variations in cost and YLS. As mentioned earlier, deterministic sensitivity analysis was conducted from +/-10% to +/-90 for both the cost and YLS. **The innovation was cost effective for all the variation in this range as per the WHO criteria.**[10]

The study by (Darmstadt, et al., 2008) used a sensitive range of +/-25 % to calculate the cost per death averted. Therefore, taking the paper as the reference, this CEA varied the cost and YLS (and life saved) by +/-20 %. The effectiveness of Pratt Pouch was further pressure tested at an unlikely extreme range of +/- 50 % in cost, YLS, and life saved. The following paragraphs expound the steps taken for each variation of the sensitivity analysis.

a. +/- 20 percent variation

In this case, the minimum and maximum estimates of cost and YLS (and life saved) were calculated as follows by varying both these parameters by +/- 20 percent.

- Lower end of cost per YLS (and life saved) = obtained by Minimum value of calculated cost / Maximum value of YLS (and life saved).
- Higher end of cost per YLS (and life saved) = obtained by Maximum value of calculated cost / Minimum value of YLS (and life saved).

The minimum and maximum values of cost per life saved are also calculated using the same methodology.

b. +/- 50 percent variation

In this case, the minimum and maximum values of cost and YLS (and life saved) were calculated by varying both these parameters by +/- 50 percent. A similar calculation, as explained for +/- 20 percent variation, was followed to obtain the minimum and maximum values of cost per YLS (and life saved).

Probabilistic Sensitivity Analysis

Sensitivity analysis using the Monte Carlo simulation (10,000 simulation runs) was done to understand the variations in cost per YLS (and life saved). In this case, important assumptions used in the impact model, and the cost provided by the innovator are varied. Table 1 (from the main report) provides the list of assumptions and ranges used for the probabilistic analysis. These ranges are based on literature review, and in some cases, assumptions have been made by experts at GCC and EGPAF due to lack of information. The cost provided by the innovator was assumed to vary by maximum 10% standard deviation for the simulation due to increase/ decrease in the market share, or other uncertainties in the implementation of Pratt Pouch. Normal distributions were assumed for most of the input assumptions that affect the YLS (and number of lives saved) as well as variability for the costs of provision, with ranges of possible observations of two standard deviations from the mean. The analysis is based on incorporating the uncertainty induced by the variation of each input parameter in the cost per YLS model using the technique of Monte Carlo simulation.

10: The WHO-CHOICE criteria suggest that interventions are "very cost-effective" if the ICER is less than the country's GDP per capita, "cost effective" if the ICER is between one and three times the country's GDP per capita, and "not cost-effective" if the ICER is greater than three times the country's GDP per capita. "

ANNEX 4

PV (Present Value) Calculation of Cost and Beneficiary

Years (t)	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Beneficiaries (B)	3,366	6,291	9,838	12,706	14,860	17,954	20,771	22,983	25,548	27,890	33,549	36,154
PV of B for Individual Years (@r=3%) (b*1/(1+r)r^t)	3,366	6,107	9,273	11,627	13,203	15,487	17,395	18,687	20,168	21,375	24,963	26,118
Total PV of Beneficiaries	187,771											
Years (t)	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Cost (Co.)	$ 275,245	$ 378,565	$ 291,910	$ 308,909	$ 316,786	$ 278,569	$ 310,340	$ 336,500	$ 366,749	$ 394,954	$ 466,990	$ 487,805
PV of Co. for Individual Years (@r=3%) (b*1/(1+r)r^t)	$ 275,245	$ 367,538	$ 275,153	$ 282,696	$ 281,460	$ 240,296	$ 259,905	$ 273,605	$ 289,515	$ 302,699	$ 347,484	$ 352,400
Total PV of Cost	$ 3,547,996											

Source: Authors' calculation using Impact model and Costing tool

The incremental cost per beneficiary was obtained using the simple average costs and simple average beneficiary information. However, it is recommended practice to use the discounted costs and discounted number of beneficiaries for the same period of analysis using the same discount rate to obtain the Present Values (PV) (Edejer, et al., 2003, p. 69). The PV of costs and beneficiaries are calculated to get the value of future streams of the cost, and beneficiaries in 2019. To get the total PV in 2019, the following formula was applied to cost, and beneficiaries in each year from 2019 to 2030, and then all the discounted values for each year were added to get the total Present Value for cost, and beneficiaries, respectively (Bruce A Larson, 2013).

PV = (Cost / Beneficiary) *1/ (1+r) ^t (r= discount rate, t= time from 2019)

Discounting both the cost and the number of beneficiaries with a 3% rate of discount (using the same discount rate as recommended by WHO for discounting YLS), the incremental cost and incremental beneficiaries at USD 3.5 million and 187,771 respectively were obtained.

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PHOTO CREDIT, PAGE 4:
1) https://globalhealth.duke.edu/media/news/promising-pratt-pouch-ready-scale
2) https://www.pedaids.org/wp-content/uploads/2017/09/SLAB_2pager_A4_072518-nc.pdf

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