EVALUATING SAVING LIVES AT BIRTH

Cost-Effectiveness Analysis: BEMPU-TempWatch

AUGUST 2020

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ACRONYMS

CEA	Cost Effectiveness Analysis
G&A	General and Administrative
GCC	Grand Challenges Canada
GDP	Gross Domestic Product
HR	Human Resources
ICER	Incremental Cost-effectiveness Ratio
INR	Indian Rupees
KMC	Kangaroo Mother Care
LMIC	Low- and Middle-Income Countries
MOH	Ministry of Health
PV	Present Value
LBW	Low Birth Weight
R&D	Research and Development
SL@B	Saving Lives at Birth
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 – BEMPU TempWatch – in India. BEMPU TempWatch is a device that continuously monitors a newborn's temperature, and alerts parents and healthcare providers whenever the baby's temperature drops below the normal levels – a condition known as hypothermia. The CEA presented in this report quantifies the health and social impact of scaling BEMPU's TempWatch over the period 2018 to 2030 in fifteen states and fifteen tier one cities in India. Data on costs were collected from BEMPU, while impact estimates were obtained from models developed by Grand Challenges Canada (GCC), and reviewed by Duke University.

These data 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, and
3. incremental costs per year of life saved.

The estimated total costs of scaling up BEMPU's TempWatch device to reach 1,470,536 newborns is $20,035,359. This translates to 26,844 newborn lives saved over the analysis period and 789,005 years of life saved. The incremental cost effectiveness ratios (ICERs) estimated were $13.62 per beneficiary reached, $746 per newborn life saved and $25 per year of life saved (i.e. 1.2% of India's Gross Domestic Product (GDP) per capita). The 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 live 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 to BEMPU's TempWatch across fifteen states and fifteen tier one cities in India is very cost-effective and could make significant contributions to the reduction of newborn mortality in India.

1 INTRODUCTION

Eighteen percent of newborns are born underweight in India according to the 2015-2016 National Family Health Survey. Compared to normal weight newborns, underweight babies face a higher risk of developing hypothermia (i.e. body temperature below 36.5ºC), that might lead to death in the neonatal and post-neonatal period. The prevalence of hypothermia in homebirths in India ranges from 11% to 92% depending on the region and season, with increased risk in winter (Lunze, Bloom, Jamison, & Hamer, 2013). Early identification of hypothermia and subsequent treatment through Kangaroo Mother Care (KMC) – i.e. skin-to-skin contact between a parent and a newborn – is an evidence-based hypothermia management in low- and middle-income countries (LMICs). For KMC to be delivered in a timely manner, the newborn's temperature requires continuous monitoring, especially in the first month of life. More often than not, health care providers in public and private health facilities in India are overworked and fail to regularly monitor the body temperature of newborns using a thermometer. Failure to continuously monitor body temperature in newborns (especially if underweight) could leave hypothermia cases unidentified and increase the likelihood of newborn death.

To address neonatal hypothermia, BEMPU Health– an Indian technology company based in Bangalore and funded by the Saving Lives at Birth (SL@B) program – developed an electronic bracelet that continuously measures the body temperature of newborns, and alerts the health care professional if hypothermia occurs. In addition, due to the bracelet's simple design that does not require a lot of training, it can also be used in community settings for continuous post-discharge monitoring by caregivers at home.

BEMPU is in the process of scaling up the availability of its TempWatch devices across India. Its primary target buyer is the state government of India working through the state Ministries of Health and district officials in respective states, which can then distribute the devices to state hospitals and primary health clinics. BEMPU is also marketing the TempWatch to private sector hospitals in India and other international markets. This analysis includes beneficiaries from both the public and the private sector hospitals in India. **To assess the potential health and economic benefits of these scale up efforts, a cost-effectiveness analysis of BEMPU's fifteen-state and cities expansion in India was conducted**.

2 COST-EFFECTIVENESS ANALYSIS APPROACH

A decision-analytic framework was used to model costs and benefits of scaling up the availability of BEMPU's TempWatch in India over a thirteen-year period between 2018 and 2030. Cost data from BEMPU was collected using a Costing Tool developed by Duke University with financial support from SL@B program partners. Health estimates were obtained from the Grand Challenges Canada (GCC) impact model developed for BEMPU and validated by the Duke University team. In the sections that follow, details of data sources, analytic approaches, and results are described.

Estimation of Costs

Data used for cost estimation were obtained from BEMPU's profit and loss statements for 2018 and 2019, and its financial projections between 2020 to 2030 **using a costing tool that was developed by the Duke team**.[1]

BEMPU categorized its costs into four expense categories:

1. Cost of Goods Sold (COGS)
2. Research and Development (R&D)
3. Sales and marketing
4. General and administrative expenses

Cost data were provided in Indian rupees (INR) at an assumed exchange rate of 70 INR to 1 USD (per the rate on August 27th 2018) (PoundSterling Live, 2020).

Since the cost data were collected from BEMPU's internally generated estimates, it is important to note that they reflect certain key assumptions about BEMPU's scale-up strategy. For example, starting in 2018, as BEMPU expands its market to new regions in India, sales and marketing expenditure are expected to increase while its R&D costs are expected to decrease. In addition, the general and administrative expenses category is also expected to gradually reduce during scale up (2019-2030) as the innovator expands to new regions and markets. Moreover, the innovator also expects that as the organization expands to new states and cities, and its total sales increase, with the addition of new territories, COGS will see a constant rise because the production of additional bracelets will require more raw material, labor, etc. Data from all four cost categories listed above and the expected number of devices sold were used to estimate the average unit cost for each device sold each year.

Estimation of Health Impact

The health impact of BEMPU TempWatch was estimated as **the number of beneficiaries reached, number of lives saved, and the number of years of life saved**.[2] A decision-analytic framework was used and the analysis was based on the impact model developed by GCC. The GCC impact model (see Annex 1) estimates the number of lives saved through the introduction (or scale-up) of an innovation in a geographic area. The lives saved for years 2018 to 2030 was estimated assuming scale-up in public and private hospitals across fifteen states and fifteen tier-1 cities in India.

A literature review was conducted and additional data was collected from BEMPU to update the values for the variables and parameters used in the estimation of lives saved (see Table 1). **The health impact estimated in the lives-saved model is the total number of hypothermia-related newborn deaths averted due to timely administration of KMC by way of using TempWatch, both pre and post-discharge from a health facility**.

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.
2: GCC continually updates this model. For this analysis, we used the most recent version as of July 2019. This version was further reviewed and updated by the Duke University team.

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

Variable Name	Estimate (range)	References
Incidence of hypothermia in low-birth weight (LBW) babies, from birth until hospital discharge	**51%** (31%, 71%)	Gupta et al., 2006; Darmstadt et al., 2006; Lunze et al., 2013; Bhatia et al., 2017; Tanigasalam et al., 2018.
Percentage of hypothermia cases detected by BEMPU bracelet that would have been missed in a hospital with routine temperature monitoring	**39%** (29%, 49%)	Dragovich et al., 1997.
Percentage of hypothermia cases that result in death	**3.9%** (2%, 6%)	Kaushik et al., 1998; Zayeri et al., 2005; Lunze et al., 2013.
Incidence of hypothermia in LBW babies in first month, post hospital discharge	**40%** (20%, 60%)	Mullany et al., 2010.
Percentage of hypothermia cases that would have been detected by a mother/caregiver even in the absence of BEMPU bracelet	**24.6%** (19.6%, 29.6%)	Kumar & Aggarwal, 1996.
Effectiveness (sensitivity) of BEMPU bracelet in accurately identifying true cases of hypothermia	**98.6%** (97.2%, 100%)	Tanigasalam et al., 2018.
Effectiveness of KMC in restoring newborn's temperature to above 36.5 °C	**100%**	Bera, et al., 2014; Ramani et al., 2018; Conde-Agudelo & Díaz-Rossello, 2016.

Source: GCC Impact Model

To estimate Years of Life Saved (YLS) by BEMPU TempWatch, first, the average years of life lost (YLL) due to hypothermia-related premature deaths in India was calculated, and then it was multiplied by the estimated number of lives saved due to scale-up of BEMPU's TempWatch. A life expectancy at birth of 69.3 in 2018 was assumed (using the life expectancy at birth for India between 2014 to 2017, as reported in the World Development indicators) and a discount rate of 3% (See Annex 2 for details) (The World Bank (World Development Indicators), 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 of scale-up of BEMPU's TempWatch to fifteen states and fifteen tier-1 cities 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, and 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 resource allocation, day to day monitoring, and budgetary program mapping. Whereas, incremental cost per lives saved and cost per YLS are important from the perspective of Ministry of Health (MOH), funders, and for comparative purposes for selection of innovations.

The ICERs were estimated with and without discounting, and sensitivity analysis was performed to test the robustness of the findings when assumptions and model parameters change. Both deterministic and probabilistic sensitivity analysis were performed. In the deterministic sensitivity analysis[4], +/-20% and +/-50% changes to the model inputs were 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 on 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) 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. 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 TempWatch was found to be below the per capita GDP threshold for India 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 using (Darmstadt, et al., 2008) as a reference – a paper which used a +/-25% sensitivity variation.

KEY FINDINGS FROM THE COST-EFFECTIVENESS ANALYSIS

Table 2 summarizes the results of the cost-effectiveness analysis of the national scale-up of BEMPUs TempWatch in India. For the base case, estimates without discounting and with 3% discounting are presented. The findings from the sensitivity analysis conducted are also reported here.

Table 2: Cost-Effectiveness Analysis

Incremental cost per beneficiary (not discounted)	Incremental costs	USD 24,268,711
	New beneficiaries	1,867,860
	Ratio	USD 12.99
Incremental cost per beneficiary (discounted at 3%)[5]	Present Value (PV) of incremental costs @ 3%	USD 20,035,359
	PV of new beneficiaries @ 3%	1,470,536
	Ratio	USD 13.62
Incremental cost per life saved (not discounted)	Incremental costs	USD 24,268,711
	Lives saved	34,097
	Ratio	USD 711.76
Incremental cost per life saved (discounted at 3%)	Present Value (PV) of incremental costs @ 3%	USD 20,035,359
	PV of lives saved @3%	26,844
	Ratio	USD 746.36
Incremental cost per year of life saved (not discounted)	Incremental costs	USD 24,268,711
	Years of life saved	1,002,423
	Ratio	USD 24.21
Incremental cost per year of life saved (discounted at 3%)	Present Value (PV) of incremental costs @ 3%	USD 20,035,359
	PV of years of life saved @3%	789,005
	Ratio	USD 25

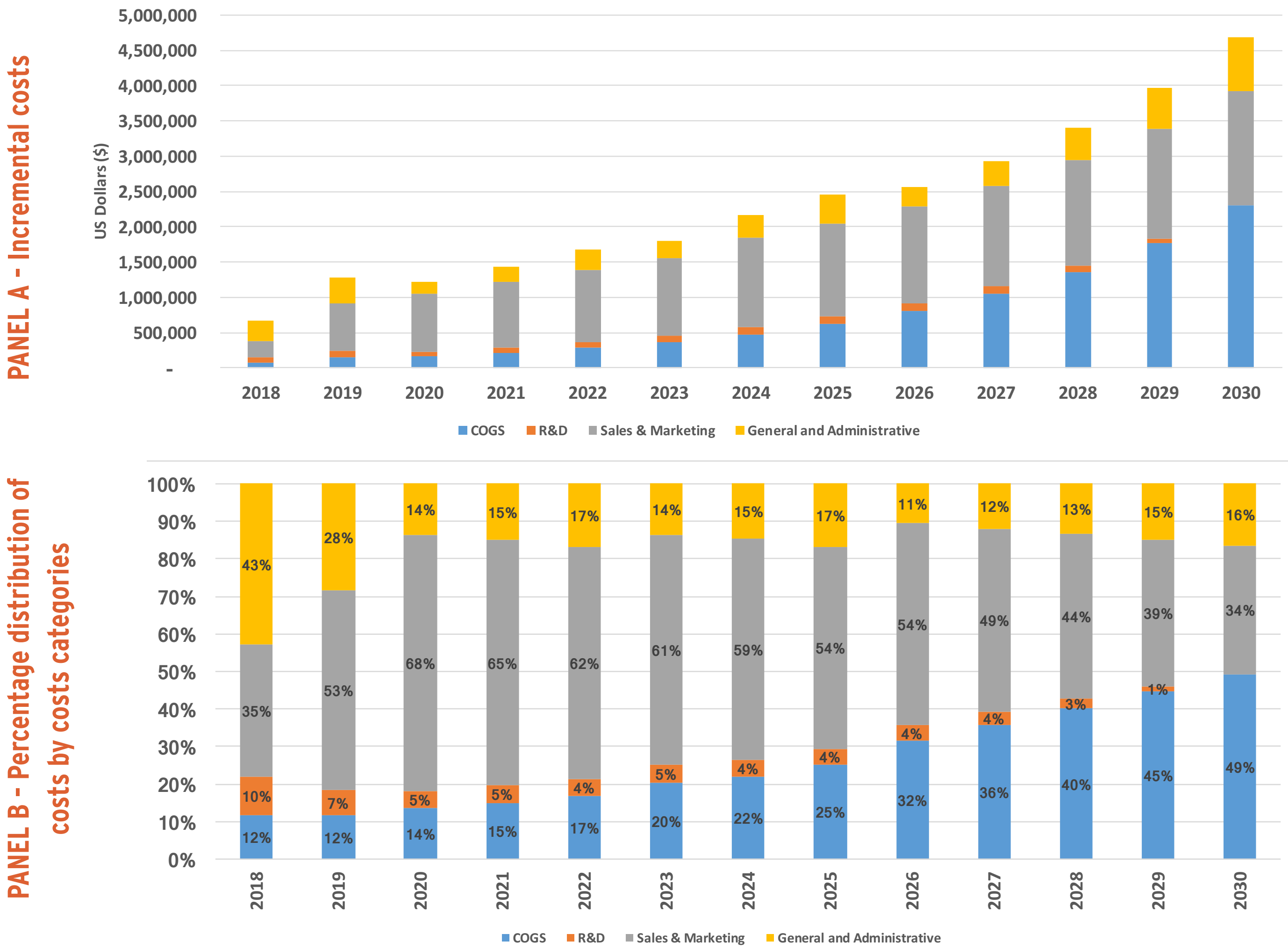
Source: Authors' calculation using data from Costing Tool and GCC Impact Report (Dixit, et al., 2019)

The costs of scaling-up BEMPU's TempWatch to reach an additional 1,470,536 beneficiaries over a 12-year period between 2018 and 2030 is $20,035,359 (discounted at 3%). However, the average annual costs ranged from $667,752 in 2018 to $4,683,032 in 2030 (see Figure 1, panel A). These costs include the cost of producing the TempWatch device, marketing, research and development, and general administration. The innovator assumes a 30% growth in revenues every year until 2030 which includes increasing sales in India's private sector as well as capturing markets outside India. The contribution of the different cost categories as a percentage of total cost of scale-up varied over time as shown in Figure 1, panel B.

> ***For example***, according to the innovator, General and Administrative (G&A) which includes Human Resources (HR), legal, and finance costs is assumed to gradually go down as a percentage of total cost, and this decrease aligns with the trend seen in G&A expenditure in many medical device companies as per the innovator. The innovator expects that G&A will decline from 43% in 2018 to 14% in 2020, and thereafter it will hover between 11% and 17% as a percentage of total costs. Sales and marketing include market building in India as well as other regions, clinical studies, and team building. It is expected that sales and marketing expenses will drop gradually, but the innovator will still incur a significant percent of the cost in sales and marketing as the organization will still be expanding and trying to capture new markets nationally and internationally as shown in Figure 1, Panel B. R&D cost starts decreasing from 10% of the total costs in 2018 and reaches zero in 2030 as the innovator does not expect any significant investment later in the scale up period. The innovator also expects that the same supply chain will be used even when Bempu TempWatch expands to new markets, and regions during the scale up. The Cost of Goods Sold (COGS), which includes labor, parts, and shipping of the parts, is assumed to grow from 12% in 2018 to 49% in 2030 as a percentage of total expenses as the innovator expands to new markets (Dixit, et al., 2019).

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

Figure 1: Incremental Costs of Scaling up BEMPU's TempWatch Disaggregated by Year and Cost Category



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

The health effects of scaling up BEMPU's TempWatch to reach additional beneficiaries were measured in number of lives saved and number of life-years saved. **Over the 12-year period (2018 to 2030), scaling-up BEMPU's TempWatch to reach 1,470,536 beneficiaries will result in a total of 26,844 lives saved, and 789,005 years of life saved**. The annual estimates of life saved ranged from 208 in 2018 to 4,239 in 2030, while the annual estimates of years of life saved ranged from 6,049 in 2018 to 125,104 in 2030. See Table 3 for details.

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

Years	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Lives Saved	208	208	242	1,232	1,906	2,353	3,154	3,720	4,120	4,239	4,239	4,239	4,239
YLS	6,049	6,055	7,071	36,028	55,782	68,935	92,525	109,216	121,113	124,719	124,848	124,976	125,104

Source: Authors' calculations using data from GCC impact model

Table 3 displays the number of lives saved and years of life saved. Based on the GCC impact model, BEMPU's TempWatch innovation is expected to expand to the planned fifteen states in India by 2026 and this is reflected in the lives saved numbers which stop increasing after 2026 as the innovation will have saturated the public hospitals in the fifteen states by 2026. It is also interesting to note that the profile of life saved and the years of life saved are almost identical. This is because the average YLL, which is used to calculate YLS, as explained in Annex 2, remains almost constant. The average YLL remained unchanged because it depends on the total life expectancy for India which also did not fluctuate much in the 12-year analysis period. Therefore, all the variability in the YLS comes from the changing life saved numbers from 2018-2030.

Over the 12-year period (2018 to 2030), scaling-up BEMPU's TempWatch to reach 1,470,536 beneficiaries will result in a total of 26,844 lives saved, and 789,005 years of life saved.

For incremental cost-effectiveness ratios, an incremental cost per new beneficiary of $12.99, an incremental cost per life saved of $712 and an incremental cost per year of life saved of $24.21 were estimated. When a 3% rate of discount[6] is applied, an incremental cost per new beneficiary of $13.62, an incremental cost per life saved of $746.36 and an incremental cost per life year saved of $25 (i.e. 1.2% of GDP per capita) were estimated.

The results of the sensitivity analysis are summarized in Table 4. A +/-20 percent variation in the estimates of discounted costs and lives-saved results in minimum and the maximum values of cost per life saved of $496 and $1,117. Using the same deterministic variation of +/- 20 percent on cost and YLS leads to a minimum and maximum cost per years of life saved of $17 and $38 respectively. Increasing the deterministic variation of the input parameters of cost and life saved to +/-50 percent results in an increase of the maximum value of cost per life saved and cost per years of life saved to $2,234 and $76 respectively, and a reduction in the minimum value of cost per life saved and cost per years of life saved to $248 and $8, respectively.

Table 4: Results of Sensitivity Analysis Using Deterministic Analysis (in 2018 USD)

COST PER LIFE SAVED			
+/- 20 percent			
Summary	Costs	Life Saved	Cost / Life Saved
Min	$16, 028, 287	21, 529	$496
Max	$24,042,431	32,293	$1,117
+/- 50 percent			
Summary	Costs	Life Saved	Cost / Life Saved
Min	$10,017,680	13,455	$248
Max	$30,053,039	40,366	$2,234

COST PER YLS			
+/- 20 percent			
Summary	Costs	YLS	Cost / YLS
Min	$16, 028, 287	631,204	$17
Max	$24,042,431	946,806	$38
+/- 50 percent			
Summary	Costs	YLS	Cost / YLS
Min	$10,017,680	394,502	$8
Max	$30,053,039	1,183,507	$76

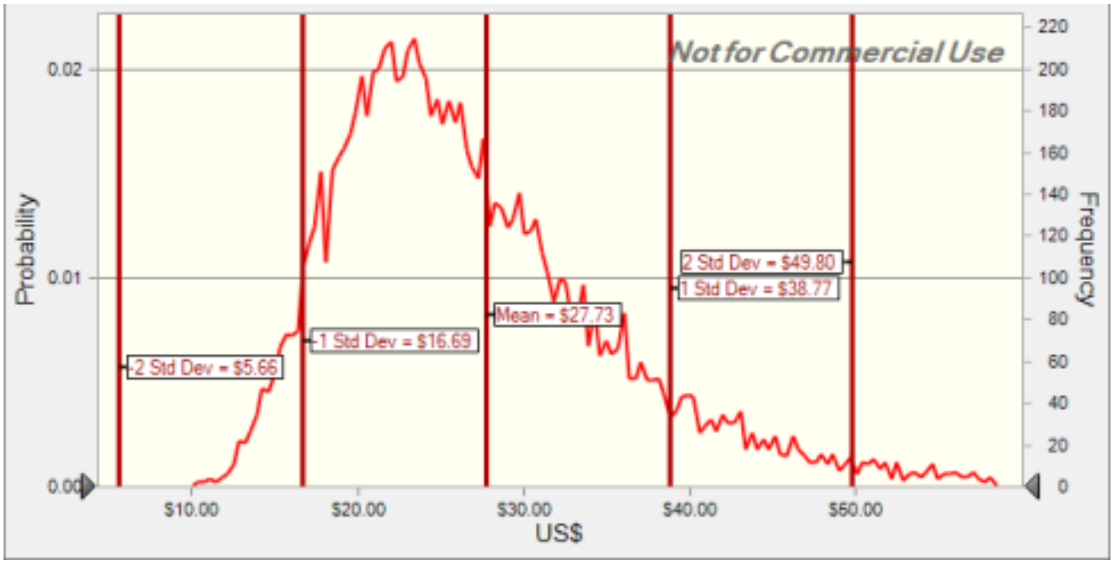
Source: Source: Authors' calculation using GCC Impact model and Costing Tool
Notes: Min Cost/Life saved = Min Costs / Max Lives saved, while Max Cost/Life saved = Max Costs / Min Lives saved
Min Cost/YLS = Min Costs / Max YLS, while Max Cost/YLS = Max Costs / Min YLS

Similar results were obtained when probabilistic sensitivity analysis was conducted as the results obtained using deterministic sensitivity analysis (See Figure 2). **The mean cost per years of life saved was $27.73 (95% CI: $6, $50). Likewise, the mean cost per life saved was $815 (95% CI: $166, $1,464)**.

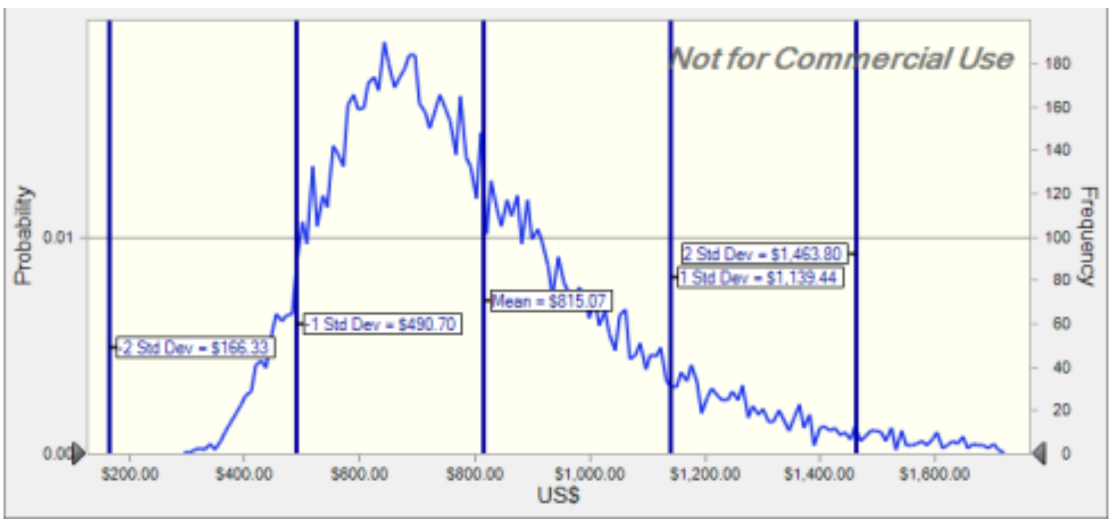
6: WHO's Global Burden of Disease Concept suggests using a 3% discount rate for cost-effectiveness studies in health and medicine. (World Health Organization (Global Burden of Disease Concept), p. 32)

Figure 2: Results of Sensitivity Analysis Using Probabilistic Analysis (in 2018 USD)

Distribution of Cost/YLS



Distribution of Cost/Life Saved



3 IMPLICATIONS OF KEY FINDINGS

The results of this study suggest that a scale-up of BEMPU's TempWatch in fifteen states and fifteen tier-1 cities to reach additional beneficiaries in India is cost-effective. The findings here suggest that the life of one additional newborn would be saved for every $746 spent scaling up BEMPU's TempWatch in India. This translates to an additional year of life saved for each $25 invested in scale-up efforts. The estimate of incremental cost per life-year saved ($25) fall below the GDP per capita for India[7], suggesting that scale-up will be very cost-effective according to commonly used criteria for cost-effectiveness.[8] Moreover, our estimate of incremental cost effectiveness per life-year saved is 1.2%[9] of India's GDP per capita which compares favorably with estimates from other life-saving interventions in India.

> The findings here suggest that the life of one additional newborn would be saved for every $746 spent scaling up BEMPU's TempWatch in India. This translates to an additional year of life saved for each $25 invested in scale-up efforts.

> ***For example***, Goldie and colleagues analyzed scale-up of a package of maternal interventions and estimated incremental costs per year of life saved that ranged from $150 to $350. When measured as a percentage of GDP per capita, their estimates ranged from 14% to 33% (Goldie, Sweet, Carvalho, Natchu, & Hu, 2010).

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 $4,683,032 in 2030 and a payer will need to evaluate its ability to pay for the costs of scale-up.

7: India's 2018 GDP per capita was $2,009. (The World Bank (World Development Indicators), 2020)

8: 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.

9: 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), it would also be cost-effective if DALYs were calculated.

4 LIMITATIONS OF THE STUDY

The assessment of cost effectiveness for BEMPU TEMPWatch is based on cost information provided by the innovator and the impact model created by GCC and reviewed by the Duke team. 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 BEMPU TempWatch with the status quo, which in India is monitoring that may not always be continuous.

Furthermore, the impact, as stated previously, is modelled for fifteen states and fifteen tier-1 cities in India, using assumptions ranging from BEMPU's capacity to scale-up the production of bracelets, to the incidence of hypothermia in India. These assumptions are derived from the latest peer-reviewed literature available at the time of the development of the model in 2019, along with the most recent scale-up plans shared by the innovator in May 2019. These plans and literature are subject to change over time, based on which the impact model can potentially be updated. For example, the current model assumes that the BEMPU bracelet can only be used once by a low-birth weight baby. However, BEMPU is working to develop a prototype bracelet that may potentially be fit for repeated-use by more than one baby. If the latter is scaled up in India, then the impact model would also need to be updated accordingly.

The assumptions on sensitivity analysis in the model have been retrieved from the latest academic literature. However, in cases where an estimate from India is unavailable, the model uses evidence from other countries that are comparable to India in terms of demographics and other health indicators. The unavailability of relevant data can thus decrease the model's accuracy. The model also estimates mortality, and not morbidity, in its calculation of the years of lives saved due to the use of TempWatch. Estimating the morbidity would require assumptions and data on the bracelet's impact on the occurrence and duration of diseases other than hypothermia – the evidence for which is not available nor reliable for a novel innovation like the TempWatch.

These limitations indicate that the impact model is a live document, the accuracy of which can be improved based on the availability of new evidence, or further information about the device from the innovator.

5 CONCLUSION

The planned scale-up of BEMPU's TempWatch to fifteen Indian states and fifteen tier one cities between 2018 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 2018-2030 period, this scale-up effort will require total investment of 20 million USD, reach 1.5 million beneficiaries, save 26,844 newborn lives, and contribute 789,005 years of life saved. On its part, BEMPU's cost structure is expected to change during the expansion with R&D costs declining, while sales and marketing and COGS will continue to increase as the innovation transitions to scale. **Overall, these results provide a reliable quantitative evidence that scaling up the availability of BEMPU's TempWatch in India could contribute significantly to improvements in newborn health care across the country**.

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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 GCC Impact Model

The following tables provides the GCC impact model which calculates the lives saved from BEMPU's TempWatch from 2018 to 2030 in India.

		Funding Period												
Access	**TOTAL**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Cumulative number of Indian state governments that will be purchasing the devices, in each year		**3**	**3**	**4**	**6**	**8**	**10**	**12**	**14**	**15**	**15**	**15**	**15**	**15**
Number of devices distributed in government hospitals each year		6,316	6,316	8,420	60,000	80,000	100,000	120,000	140,000	150,000	150,000	150,000	150,000	150,000
Cumulative number of tier 1 cities that will have BEMPU bracelets distributed in private markets, in each year		3	3	3	4	5	6	10	12	14	15	15	15	15
Number of devices distributed each year to private markets, in each year		6316	6316	6316	15,000	36,000	43,200	72,000	86,400	100,800	108,000	108,000	108,000	108,000
Total number of devices distributed to public hospitals and private markets, in each year		12632	12632	14736	75000	116000	143200	192000	226400	250800	258000	258000	258000	258000
Number of low birth weight (LBW) neonates accessing the device	**1,867,860**	11,369	11,369	13,262	67,500	104,400	128,880	172,800	203,760	225,720	232,200	232,200	232,200	232,200
Outcomes														
Number of LBW neonates wearing the bracelet who experience at least one hypothermic episode from birth until discharge from hospital		5,798	5,798	6,764	34,425	53,244	65,729	88,128	103,918	115,117	118,422	118,422	118,422	118,422
Number of hypothermia cases caught in hospital by the BEMPU bracelet that would not have been caught by a nurse's routine temperature monitoring		2,279	2,279	2,658	13,529	20,925	25,831	34,634	40,840	45,241	46,540	46,540	46,540	46,540
Number of deaths from hypothermia averted due to timely administration either KMC or some other intervention to increase temperature of the neonate, pre-discharge from hospital	14,601	89	89	104	528	816	1,007	1,351	1,593	1,764	1,815	1,815	1,815	1,815
Number of LBW neonates who experience at least one hypothermic episode post discharge that is caught by the BEMPU bracelet		4,484	4,484	5,231	26,622	41,175	50,830	68,152	80,363	89,024	91,580	91,580	91,580	91,580
Number of hypothermia cases caught post discharge by the BEMPU bracelet that would not have been detected by a caregiver's touch		3,381	3,381	3,944	20,073	31,046	38,326	51,387	60,594	67,124	69,051	69,051	69,051	69,051
Number of deaths from hypothermia averted due to timely KMC administration as a result of the BEMPU device, post-discharge from hospital	19,497	119	119	138	705	1,090	1,345	1,804	2,127	2,356	2,424	2,424	2,424	2,424
Total number of deaths from hypothermia averted due to timely KMC administration as a result of the BEMPU device, both pre-discharge from hospital and in the community	**34,097**	**208**	**208**	**242**	**1,232**	**1,906**	**2,353**	**3,154**	**3,720**	**4,120**	**4,239**	**4,239**	**4,239**	**4,239**

Source: GCC Impact Model

ANNEX 2

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

Years	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Life expectancy at birth	69.35	69.60	69.86	70.11	70.37	70.62	70.88	71.14	71.40	71.66	71.92	72.18	72.44
Lives saved (N)	207.53	207.53	242.10	1,232.19	1,905.79	2,352.67	3,154.42	3,719.58	4,120.46	4,238.75	4,238.75	4,238.75	4,238.75
Individual YLL ((1/r) *(1-e^(-r*L)))	29.14	29.18	29.21	29.24	29.27	29.30	29.33	29.36	29.39	29.42	29.45	29.48	29.51
YLS (N* (1/r) *(1-e^(-r*L)))	6,048.53	6,055.07	7,071.20	36,027.91	55,782.47	68,935.41	92,524.73	109,216.42	121,113.24	124,719.42	124,848.12	124,976.29	125,103.91
PV of YLS for individual years (YLL averted*1/ (1+r) ^t)	6,048.53	5,878.71	6,665.28	32,970.64	49,562.00	59,464.29	77,488.00	88,802.94	95,607.91	95,587.05	92,898.73	90,285.53	87,745.37
Total PV of YLS	789,005												

Source: Authors' calculation using GCC Impact Model and Costing Tool
Note: Only two decimal digits are presented here. However, there are more decimal numbers used in the excel calculation, which are not shown here. Therefore, there is some variability in the multiplication results of live saved and YLL.

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 – 2018 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 2018 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)[10] of the YLS is calculated by discounting the YLL for each year from 2018 to 2030 at 3 percent to bring the future life streams of individuals saved to 2018. The calculations and final values of life saved and YLS are shown in the table above.

10: 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 of different years gives the NPV.

ANNEX 3

Sensitivity Analysis

The cost and YLS (Year of Life Saved), and life saved information have 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 impact the CE ratios, thus altering the cost-effectiveness of the innovation calculated based on current projections. To that end, the cost-effectiveness of BEMPU TempWatch was pressure-tested by conducting sensitivity analysis to understand how changes in input parameters/assumptions could affect cost per YLS, and to assess if BEMPU TempWatch remains a cost-effective innovation in India 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 BEMPU TempWatch in India. **This method of sensitivity analysis only varies the cost and YLS by a fixed amount, and doesn't 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**.[8]

The paper titled "Saving newborn lives in Asia and Africa: cost and impact of phased scale-up of interventions within the continuum of care" by (Darmstadt, et al., 2008) used a sensitive range of +/-25 percent to calculate the cost per death averted. Therefore, using this as the reference, this CEA varied the cost and YLS (and life saved) by +/-20 percent. The effectiveness of BEMPU TempWatch was further pressure tested at an unlikely extreme range of +/-50 percent 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 was done to understand the variations in cost per YLS (and life saved). In this case, important **assumptions used in the GCC impact model, and the cost provided by the innovator were varied**. Table 1 (from the main report) provides the list of assumptions and ranges used for the probabilistic analysis. These ranges are based on the literature review, and in some cases, assumptions have been made by the experts due to lack of information. The cost provided by the innovator was assumed to vary by maximum 0.11 standard deviation for the simulation due to increase/ decrease in the market share, or other uncertainties of the BEMPU TempWatch. Normal distributions were assumed for 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 three 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.

ANNEX 4

PV (Present Value) Calculation of Cost and Beneficiary

Years	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Beneficiaries (B)	11,369	11,369	13,262	67,500	104,400	128,880	172,800	203,760	225,720	232,200	232,200	232,200	232,200
PV for individual years (@3%) (B*1/ (1+r) ^t)	11,369	11,038	12,501	61,772	92,758	111,173	144,717	165,676	178,185	177,962	172,779	167,746	162,860
Total PV of Beneficiaries	1,470,536												

Years	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Cost (Co.)	$ 1,350,780	$ 532,980	$ 458,500	$ 2,110,821	$ 2,123,794	$ 2,165,184	$ 2,685,806	$ 2,771,136	$ 2,455,834	$ 2,228,059	$ 1,984,129	$ 1,783,678	$ 1,618,010
PV for individual years (@3%) (Co.*1/ (1+r) ^t)	$ 1,350,780	$ 517,456	$ 432,180	$ 1,931,701	$ 1,886,964	$ 1,867,707	$ 2,249,320	$ 2,253,187	$ 1,938,658	$ 1,707,621	$ 1,476,378	$ 1,288,567	$ 1,134,840
Total PV of Cost	$ 20,035,359												

Source: Authors' calculation using GCC Impact model and Costing tool

The incremental cost per beneficiary was obtained using the simple average costs and simple average beneficiaries information. However, it is a 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 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 2018. To get the total Present Value in 2018, the following formula was applied to cost, and beneficiaries in each year from 2018 to 2030, and then all the discounted values for each year were added to get the total PV for cost, and beneficiaries, respectively (Bruce A Larson, 2013).

PV = (Cost / Beneficiary) *1/ (1+r) ^t (r= discount rate, t= time from 2018)

Discounting both the cost and the number of beneficiaries with a 3 percent rate of discount (using the same discount rate as recommended by WHO for discounting YLS), the incremental cost and incremental beneficiaries at USD 20 million and 1,470,536 respectively were obtained.

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