Evaluation of Bebi Kol Kilok Implementation in Papua New Guinea: Feasibility and Utility of Implementing Bebi Kol Kilok Medical Device for Detection of Hypothermia

Prepared for

UNICEF Papua New Guinea

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Date

24 May 2019

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Acknowledgements

We would like to express our sincere gratitude to Dr. Ghanashyam Sethy for his invaluable contribution and support for this evaluation. We would also like to extend our appreciation to the Ministry for Health and Department of Public Health in Papua New Guinea.

We would also like to thank the Pediatric Association of Papua New Guinea, University of Goroka and University of Papua New Guinea School of Medicine and Health Services as well as the medical directors and CEO's of the sites included for data collection, who graciously invited us into their facilities and the healthcare staff who welcomed us.

We would also like to give a special thanks to the research assistants who assisted in organizing interviews and finding patient charts. A special appreciation goes out to the people who participated in our evaluation. It was their honest and thoughtful answers which made this evaluation a success.

- Study Team

Disclosures

The authors of this manuscript certify they have no relevant financial or nonfinancial relationships to the program evaluated in this report, nor conflict of interests or financial support from UNICEF with the exception of travel costs for data collection.

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Abbreviations

ANC – Antenatal Care
BKK – Bebi Kol Kilok
CDC – Centers for Disease Control and Prevention
CHW – Community Health Worker
CO – Country Office
EAPRO – East Asia and Pacific Regional Office (UNICEF)
ELBW – Extremely Low Birth Weight (<1000g)

EENC – Early Essential Newborn Care
EHP – Eastern Highland Province
ERRB – Emergency Response and Recovery Branch
FGD – Focus Group Discussion
HFA – Health facility assessment
ID – Identification
IV – Intravenous
KMC – Kangaroo Mother Care
LBW – Low Birth Weight (<2500g)
MCH – Maternal and Child Health
MOH – Ministry of Health
NICU – Neonatal Intensive Care Unit
NGO – Non-Governmental Organization
OECD-DAC – Organization for Economic Cooperation and Development and Development Assistance Committee
ODK – Open Data Kit
PNC – Post-natal Care
PNG – Papua New Guinea
POMGEN – Port Moresby General Hospital
RO – Regional Office
SAS – Statistical Analysis System
TTU – Touching the Untouchables
UN – United Nations
UNICEF – United Nations International Children's Fund
US – United States
VA – Verbal autopsy
VHV – Village Health Volunteer
VLBW – Very Low Birth Weight (<1500g)
WHO – World Health Organization
WPRO – Western Pacific Regional Office (WHO)

EXECUTIVE SUMMARY

Overview of the Intervention

Bebi Kol Kilok (Pidgin English creole for "baby cold clock") is a medical device used to detect neonatal hypothermia. The device is applied to a newborn's wrist and continuously monitors the child's temperature during the first month of life. Whenever the infant's temperature decreases to <36.5°C, an alarm will begin to sound and an orange light will flash, prompting trained caregivers to warm the neonate via KMC. If the alarm continues despite warming techniques, this could indicate hypothermia due more systemic processes such as sepsis. At these times, caregivers are counseled and encouraged to present with their children to health facilities for further care.

Due to relatively high neonatal mortality in Papua New Guinea, PNG MOH piloted Kol Kilok beginning in June 16th, 2017. Implementation was meant to adjuvant the country's ongoing Early Essential Newborn Care (EENC) programs with the goal of "understanding the feasibility and scalability to rural and urban high risk newborns in PNG." The expected results included "survival outcomes, identification of danger signs, early referral management of hypothermia/infections and key behaviors like Kangaroo Mother Care (KMC) and breastfeeding for weight gain." Additional results expected were to "promote positive health seeking behaviors and practices for caregivers of high risk newborns," "improve weight gain and survival," and "feasibility and scalability of [the device] to rural and urban high risk new-borns."[1]

After nearly a year of use in Papua New Guinea, an evaluation of the Kol Kilok program is necessary to assess good practices and challenges of implementation, its feasibility in low-resource settings, and utility in improving care services to address hypothermia in neonates. Thus, an evaluation of the program is necessary to ensure efficient and effective use of this technology in an effort to scale up equitable, quality EENC and improve newborn health in PNG. In February 2018, United States (US) Centers for Disease Control traveled to PNG, with the assistance of UNICEF, to conduct an evaluation of the Bebi Kol Kilok program as a part of the community-based interventions related to EENC.

Evaluation Purpose, Objectives and Intended Audience

The purpose of this evaluation is to assist UNICEF in assessing whether Kol Kilok is meetings its goals of detecting and encouraging early interventions for neonatal hypothermia. In addition, the evaluation will identify strengths and challenges of using the medical device in both community settings, where the device has not yet been studied, and hospital settings.

Objectives of Evaluation

- To assess the feasibility and acceptability of implementation of Bebi Kol Kilok in hospital and community settings;
- To evaluate the utility of Bebi Kol Kilok as an alert device to improve newborn care management associated with hypothermia, including KMC and EENC, in facility and home-based settings;
- To assesses potential strengths and challenges of the program and its implementation;
- To make recommendations on areas for improvement in order to improve upon programmatic and general EENC practices

This report is intended for UNICEF Papua New Guinea, PNG's MOH, UNICEF WPRO, and UNICEF HQ.

Evaluation Methodology

The program was evaluated using the Organization for Economic Cooperation and Development and Development Assistance Committee (OECD-DAC) criteria of programmatic relevance (or appropriateness), connectedness, coherence, coverage, efficiency, effectiveness and impact (see Appendix 9). The evaluation framework sought to address whether the Kol Kilok program was meeting its stated goals and objectives. The evaluation was designed as a descriptive, exploratory and quasi-experimental assessment utilizing both qualitative and quantitative mixed methods. Qualitative interview questions were used to assess stakeholder attitudes and opinions, and quantitative data collection forms were utilized to standardize data extraction from charts, registers and logs. Data collection consisted of health facility assessments (HFA) at pilot facilities, register and chart reviews, kangaroo mother care (KMC) diary reviews and qualitative interviews with program participants and key informants.

Data collection occurred in the Eastern Highland Province (Goroka Hospital and Henganofi, Komperi, and Kafentina health center communities) from February 25 to March 2, 2018, and in Port Moresby (POMGEN) from March 4 to 13, 2018 (see Table 3). Caregiver interviews, health care provider interviews, focus groups, health facility assessments, and chart reviews were conducted at two hospitals (Port Moresby General Hospital [POMGEN] and Goroka Hospital). Village health volunteer, focus group, and household caregiver interviews as well as health facility assessments were conducted in community settings at Henganofi and Komperi Health Centers and the communities within their catchment areas.

Key Findings

Relevance/Appropriateness

In POMGEN, 43% of neonatal temperature readings were hypothermic and 19% of readings in Goroka were <36.5^{o}. In addition, in Goroka, three-fourths of infants had at least one temperature indicating hypothermia. In discussion with caregivers, 59% of current Kol Kilok users reported daily alarms from their devices and 15% reported weekly alarms. Caregivers in the community were more likely to report daily alarms compared to the hospitals – 86% daily in the community, 44% in Goroka, and 31.1% in POMGEN. Of those with daily alarms, on average, caregivers in the community noted 4.3 alarms per day, compared to 3.5 in Goroka and 2.3 in POMGEN.

Connectedness

Partnerships with local NGOs have largely been helpful to the program. The Kol Kilok program was implemented in the community setting utilizing a network for Village Health Volunteers (VHV) through the NGO Touching the Untouchables (TTU). TTU was highly praised in community and Kol Kilok device users who have VHV as counselors had the highest rates of training, recall of actions to be taken during sustained alerts, and ability to accurately describe KMC. In addition, the network connects the program to the community and allows for community buy-in and local advocacy of counseling topics related to Kol Kilok device and overall EENC. Attempts are being made to link the program to government support, however, no formal allocation has yet been made.

Coherence

Prior to Kol Kilok, the TTU VHV network was utilized for other neonatal and maternal health work such as vaccinations or antenatal care. Kol Kilok has doubled the work load for any VHV, but at a total of 18 hours per week. In addition, Kol Kilok counseling topics overlap with prior commitments of VHV such as encouraging EENC with KMC and returns to clinic for vaccination. Overall, VHV liked the Kol Kilok program and thought it had been well received in the communities. Specifically, VHV liked that the device detected hypothermia, increased KMC, or was easy to use. The majority of VHV noted a major challenge with Kol Kilok was transportation with other challenges including issues with communication, need for additional training, or the device itself being too small for users.

EENC programs in PNG have attempted to promote KMC since their implementation. To supplement EENC programs, VHV and healthcare workers were provided additional training related to hypothermia and Kol Kilok through TTU and their health facilities, respectively. Overall, this training was well conducted for VHV and, to a smaller extent, hospital staff**.** However, recall of training specific to EENC training was mixed. Per technical leads, EENC training for VHV focused primarily on breastfeeding and KMC. However, only three VHV reported training on breastfeeding and two on KMC during their recent training.

Coverage

The Kol Kilok program is a pilot by definition and does not have the goal of full geographic coverage within its implemented areas. Within implemented facilities, however, interventions are limited due to limited availability of resuscitation and warming equipment, particular in community sites. KMC diary information from the area demonstrated that LBW infants were disproportionately under-enrolled in the community.[a] If the program is expanded for full coverage of those most likely to benefit from Kol Kilok, the device should principally be given to LBW neonates. Geographical factors may have limited distribution of the device as three-fourths of caregivers reported transportation as a barrier to healthcare. Thus, VHV networks allow for distribution of the device and general health information to more remote, rural areas.

Efficiency

Given the current costs of the devices, prioritizing distribution to LBW neonates would likely be the most cost effective strategy during implementation. The device's technical efficiency was mixed – very few caregivers reported malfunctioning devices, however the device's sensitivity was lower than previous studies. The VHV are well trained and the caregivers they serve have higher recall of counseling topics compared to hospitalized caregivers. Three-fourths of health providers noted an improvement in their clinical practice due to Kol Kilok and nearly a third reported the device saved them time during work, though half of healthcare workers across sites reported limited human resources at their facilities. Healthcare workers training focused on clinical care, and overall had moderate-to-high recall of correct clinical aspects surrounding hypothermia and EENC. When disaggregated by training level, lower levels of knowledge correlated with less training, which highlights the effectiveness of healthcare worker EENC training.

Effectiveness

Overall, Kol Kilok users performed statistically significantly more KMC compared to controls. Weight gain was also higher amongst the average Kol Kilok user compared to controls. In both hospitals, the percentages of temperature readings indicating hypothermia decreased following the implementation of Kol Kilok. However, there was no apparent difference in percentage of hypothermic temperatures between Kol Kilok users and controls. Device users performed an average of four KMC instances per day at 48 minute durations. However, these same users noted this was below the ideal frequency and duration of KMC they were counseled to provide.

Kol Kilok users reported almost universally receiving training on their devices and generally had high recall of counseling topics on KMC and hypothermia. Generally, caregivers who received training on Kol Kilok were more likely to give correct answers regarding its use. By contrast, knowledge, attitudes and practices concerning the prevention and management of hypothermia was generally low in focus groups discussions (FGD) with non Kol

[a] Of note, admission weights were not available from Henganofi, and therefore the first recorded weight in the program was Week 1

Kilok users. However, spillover effects were noted from the program with some non device users who noting observing, learning and attempting KMC after seeing Kol Kilok users use the practice.

Coordination

There are issues with poor data management within the program such as lack of consistent identifiers across sites, limited electronic information from sites, lack of alert recording on diaries, and mixing of numerical and categorical data in Excel sheets. Kol Kilok program data from KMC diaries are not currently captured by routine HMIS reports, and could be used to contribute to surveillance in implemented areas with augmentations.

Impact

Caregivers overwhelmingly had positive responses to the Kol Kilok program with reports of increased bonding with their neonates. There was understanding of the risk of hypothermia and KMC, which contrasts with findings from focus group discussions with non Kol Kilok users. The program may also be leading to unintended spillover of health information into uncounseled or non user community, as some caregivers and healthcare workers without reported training were still able to describe some aspects of KMC and Kol Kilok. Subjective reports from VHV and healthcare worker interviews noted increased follow-up for one month neonatal visits following Kol Kilok's implementation which may allow additional vaccinations or counseling. While caregivers liked many aspects of the device, several statements raised concerns for elevated expectations, and it is possible messaging is being misinterpreted or promotional materials for the program may be conflating its benefits.

Questions remain regarding the sustainability and cost effectiveness of the Kol Kilok program, particularly the Kol Kilok device. Financial support is entirely dependent on donors, and PNG's financial situation remains strained with limited funds available to supplement programs. The use of Kol Kilok has introduced a new technology in implementation hospitals and communities, but it is unclear if the long-term impact of this change will be beneficial. Some healthcare workers thought the device "saves time," but others reported it may negate the need for regular temperature checks or encourage less frequent checks. Upon completion of the program, most users noted they returning their device which limits the environmental impact of this rubber and stainless steel device.

Key Conclusions

Overall, the Kol Kilok program has been very well received by caregivers of infants, VHV and healthcare workers. General knowledge surrounding Kol Kilok device was high, though highlighted several areas for improvement and additional training. Increase in knowledge and attitudes around KMC and hypothermia among caregivers, VHV and healthcare workers has also been reported. Focus group discussions highlighted misconceptions about childcare and hypothermia (e.g. "*cold baby is normal in the cold environment*"). By contrast, Kol Kilok users recognized the need for KMC during these periods and indirect questions regarding cold infants (i.e. specifically without mentioning Kol Kilok) yielded similar responses. Thus, the primary intervention of the Kol Kilok program appears to have promoted knowledge and attitudes – the importance of recognizing and taking care of cold infants. KMC has been increasingly been initiated compared to controls. Additional conclusions are organized per the WHO Health System Blocks as below (see Appendix 10):

Health Services Delivery

The evaluation demonstrated that all implementation facilities evaluated were open daily with available healthcare workers, labor wards and maternity wards. However, select facilities were missing key areas, resources, or infrastructure which limits the feasibility of using these sites for referrals with continued alerts. Caregivers of sick newborns reported they had restrictions on entrance to nursery which was cited as an

impeding factor for providing breastfeeding and KMC. Healthcare workers also identified a lack of space for providing KMC, which further limits the overall feasibility of utilizing the device in hospitals. By contrast, VHV were highly praised by community caregivers as improving access to care. The VHV network was vital to the implementation of the Kol Kilok program and overall healthcare delivery in community settings, though limited transportation affects the feasibility of referrals for continued alerts in these areas. Focus Group Discussions (FGDs) underscored some misconceptions and myths surrounding hypothermia and essential newborn care among caregivers in general, hence the importance of health promotion, education and counseling in the community and health facility settings.

Health Workforce

Healthcare providers occasionally reported being understaffed and some noted this limited their ability to respond to Kol Kilok alarms. In contrast, VHV noted spending limited time on additional tasks and reported only having an average of one Kol Kilok user per month. Thus, task shifting VHV could be studied and considered which may have the twofold benefit of improving quality and access to care as well as decreasing the work burden of healthcare workers. The effectiveness of training for providers appeared mixed. Healthcare workers at hospitals infrequently recalled training on hypothermia, EENC or Kol Kilok. This highlights the need for not only increased quantity of healthcare providers, but also increased quality and frequency of training and supportive supervision amongst providers. Similarly, while VHV were lauded by caregivers in their communities, interviews with VHV demonstrated that training around community EENC was insufficient.

HMIS and Surveillance

Data collected under the Kol Kilok program is not yet incorporated into health facility HMIS, does not contribute to implementation area surveillance, and does not produce regular reports. However, the cross sectional, epidemiologic findings from this evaluation were entirely derived from data routinely collected by the Kol Kilok program, and with modifications to existing data collection tools, some aspects or methods of the evaluation could be adopted/adapted into HMIS for routine surveillance. Overall, linking Kol Kilok and hospital data was not possible at some sites. This limitation may contribute to the Kol Kilok program's lack of regular reporting on device user temperature data or instances of infection during, or requiring, hospitalization.

Medical Product and Technology

Kol Kilok device appears to be a complimentary utility for promoting KMC and weight gain, though its exclusive effect is difficult to delineate. Chart data from hospitals showed the percentage of temperatures indicating hypothermia decreased after implementation of Kol Kilok. However, when disaggregated by Kol Kilok users and non users at Goroka, both groups appeared to have similar percentages of hypothermia after the intervention. It remains unclear if it is appropriate to use Kol Kilok in normal birth weight infants as a clear benefit of using the device in this group has not been demonstrated. The need for additional training on the use of the device was also frequently cited as an issue by interviewees. A full cost-benefit analysis should be considered prior to expanded use of the product and efforts to limit the cost of the device should be pursued.

Financing and Resources

When the Kol Kilok program and Early Essential Newborn Care (EENC) are introduced, facilities need to be equipped to treat both hypothermia and identified infections among other newborn sickness. Overall, these limitations of resource decrease the availability and quality of care provided at these facilities and could be an area the program could supplement by regularly reviewing available resources in facilities. Caregivers, VHV, and healthcare workers all cited limited transportation resources as a major barrier to healthcare access. In addition,

the need for additional financial allocation was noted for community-based service provision, health promotion activities, and training for health professionals and lay workers.

Leadership and Governance

Implementation leads highlighted general support from government officials for the Kol Kilok program and have committed to the promotion of EENC. However, given the mixed results from VHV and healthcare providers on EENC, additional promotion of training should be encouraged from all levels. The Kol Kilok program lacks a standardized training module or guidelines for implementation areas. Furthermore, treatment guidelines would also assist VHV and healthcare providers by following algorithms or step-by-step procedures for addressing specific health events. Supervision was mixed amongst providers, thus standardization or routine mechanisms of supportive supervision could assist the program and newborn health interventions. Furthermore, successful models from implementation sites could be utilized across all intervention areas (e.g. POMGEN).

Key Recommendations

- *Health Services Delivery*
    - Ensure health centers where the Kol Kilok program has been implemented have appropriate materials/equipment/supplies
    - Designate areas/spaces for KMC in implementation facilities routine KMC and amend hospital policies to allow mothers to be able to provide regular KMC to sick newborns
    - Expand use of VHV in some of the EENC delivery
    - Study changes in relevant infant and child care, such as vaccination rates
    - Update and revise counseling and health promotion materials
- *Health Workforce*
    - Study and consider task shift in hospital/health facility settings
    - Provide additional, standardized training to healthcare providers/VHV and counseling
    - Provide additional, refresher trainings on EENC and hypothermia to providers/VHV
    - Create an analysis-ready dataset containing updated and consistent data from infants
    - Use monthly reports from facilities to create a monthly bulletin from Kol Kilok program
    - Standardize KMC Diary Reports and additional training regarding how to complete the form
    - Improve data management of Kol Kilok data
- *Medical Product and Technology*
    - Prioritize allocation of devices to neonates who meet the criteria for LBW or prematurity
    - Update and modify use of the device to increase sensitivity, feasibility and overall device cost
- *Financing and Resources*
    - Expand use of Goroka's emergency services for referrals in remote areas
    - Consider strengthening support for health financing and relevant advocacy
- *Leadership and Governance*
    - Guidance should be issued from MOH to hospitals to develop a supportive hospital policy for mothers to provide KMC for sick newborns
    - Establish routine mechanisms for quality improvement and supportive supervision
    - Encourage continued advocacy to government leaders for commitments to long term funding
    - Acknowledge the provincial leadership and coordination mechanism in the EHP as an excellent model, such sub-national model could be replicated in other provinces.
    - Conduct additional studies on the effectiveness and cost effectiveness of community based intervention to identify a scalable model

1. INTRODUCTION

In Papua New Guinea, deaths from children under five years of age have decreased by 33% from 1996 to 2016, however, neonatal mortality rates have not reduced at the same rate.[2] Thus, innovative approaches to neonatal care must be taken to continue further reduce neonatal mortality. Hypothermia is often associated with neonatal mortality, and prolonged hypothermia can lead to additional complications in newborns such as hypoglycemia, kernicterus, and brain damage.[3] In addition, hypothermia also can be a marker for infection, the cause of death in nearly 1-in-4 neonates in Papua New Guinea, and thus the early detection of hypothermia could also encourage interventions against infection.[4] Given the morbidity and mortality associated with neonatal hypothermia in developing nations, reducing neonatal hypothermia would contribute to additional reduction of neonatal mortality and be in line with the United Nation's (UN) Sustainable Development Goals.[5]

The recognition and management of hypothermia remains a challenging issue outside of highly-resourced hospital settings. Fortunately, morbidities and mortality related to hypothermia can generally be prevented by simple techniques such as performing regular kangaroo maternal care (KMC) and routine Early Essential Newborn Care (EENC).[6] These interventions also have the added benefit of encouraging weight gain and breastfeeding which can provide passive immunity to children from mothers.[7] In particular, low birth weight infants have been shown to particularly benefit from these interventions with reduction in mortality rates, neonatal sepsis and hypothermia.[8]

Early Essential Newborn Care (EENC)

EENC is a service package to reduce neonatal mortality adopted by WHO including early breastfeeding, hygienic practices and thermal care such as KMC. Papua New Guinea's (PNG) Ministry of Health (MOH) introduced EENC with the support of UNICEF and WHO, and adopted the practice as defined by the regional action plan for health newborn infants (2014-2020) by WHO Western Pacific Regional Office (WPRO) and UNICEF East Asia and Pacific Regional Office (EAPRO).[9] The service package includes essential newborn care to prevent and manage hypothermia, such as KMC for sick newborns, skin-to-skin contact for healthy newborns, and early initiation and continuous breastfeeding. In PNG, during the process of the EENC implementation and scale up, the hypothermia alert device called "Bebi Kol Kilok" was piloted to adjuvant EENC practices in selected sites in Port Moresby (PNG's capitol) and Eastern Highlands Province (EHP).

Bebi Kol Kilok

Developed in India in 2013, under the original name Bempu, Bebi Kol Kilok (Pigdin creole for "baby cold clock") is a medical device used to detect neonatal hypothermia. The device is applied to a newborn's wrist and continuously monitors the child's temperature during the first month of life. Whenever the infant's temperature decreases to <36.5°C, an alarm will begin to sound and an orange light will flash, prompting trained caregivers to warm the neonate via KMC. If the alarm continues despite warming techniques, this could indicate hypothermia due more systemic processes such as sepsis. At these times, caregivers are counseled and encouraged to present with their children to health facilities for further care. Studies in India have shown the device is generally well received by caregivers, demonstrates high sensitivity and specificity, and has increased KMC during early weeks of life.[10]

Due to relatively high neonatal mortality in Papua New Guinea, PNG MOH piloted Kol Kilok beginning in June 16th, 2017. Implementation was meant to adjuvant the country's ongoing EENC programs with the goal of "understanding the feasibility and scalability to rural and urban high risk newborns in PNG." The expected results included "survival outcomes, identification of danger signs, early referral management of hypothermia/infections and key beheaviors like Kangaroo Mother Care (KMC) and breastfeeding for weight

gain." Additional results expected were to "promote positive health seeking behaviours and practices for caregivers of high risk newborns," "improve weight gain and survival," and "feasibility and scalability of [the device] to rural and urban high risk new-borns."[11]

Bebi Kol Kilok was implemented in two locations where EENC had been previously introduced and implemented: Port Moresby (PNG's capital) and the Eastern Highlands Province (see Figure 1).[12] In Port Moresby, Bebi Kol Kilok was used primarily in Port Moresby General Hospital (POMGEN) with discharged participants following up at regular intervals. Similarly, in the Eastern Highlands Province, Bebi Kol Kilok was used in Goroka General Hospital, but was also implemented in rural community settings using a network of village health volunteers (VHV) affiliated with local health centers (Kafentina, Komperi and Henganofi health centers).

At POMGEN and Goroka hospitals, devices were primarily distributed to low birth weight or premature neonates. In the Eastern Highlands Province Kol Kilok was given to all neonates, regardless of birth weight or term, due to the generally colder environment and higher elevation. Caregivers were primarily mothers of the neonates, though all available family members could receive counseling on the device and were encouraged to participate in the neonate's care (e.g. fathers, grandparents, siblings).

Figure 1: Map of Papua New Guinea with Goroka and Port Moresby

Implementation sites included Port Moresby (POMGEN) and Eastern Highlands Province (Goroka, Henganofi, Komperi, Kafentina)[13]

After nearly a year of use in Papua New Guinea, an evaluation of the Kol Kilok program is necessary to assess good practices and challenges of implementation, its feasibility in low-resource settings, and utility in improving care services to address hypothermia in neonates. Thus, an evaluation of the program is necessary to ensure efficient and effective use of this technology in an effort to scale up equitable, quality EENC and improve newborn health in PNG. In February 2018, United States (US) Centers for Disease Control traveled to PNG, with the assistance of UNICEF, to conduct an evaluation of the Bebi Kol Kilok program as a part of the community-based interventions related to EENC.

A. 1.1 Implementation of Kol Kilok

In March 2017, PNG's Medical Research Advisory Committee approved Kol Kilok for implementation. In April 2017, a study addressing Kol Kilok's sensitivity and specificity was implemented at Port Moresby General Hospital (POMGEN) and Goroka Hospital in the Eastern Highlands Province. The study enrolled 170 neonates. Participants had their temperature measured following Kol Kilok alarms, as well as at regular intervals to assess sensitivity and specificity.

Following the implementation of the sensitivity and specificity study, Bebi Kol Kilok received further approval for a case-control outcome study. Two thousand devices were procured through the parent company and began distribution on June 17, 2017. Distribution occurred in two locations and two different settings: hospital settings (POMGEN in Port Moresby, and Goroka Hospital in Eastern Highlands Province (EHP) and community settings (Komperi, Kafentina, and Henganofi communities in EHP).

B. 1.2 Program Structure, System and Human Resources

The Kol Kilok program is organized differently in hospital and community settings. In hospitals, the primary manager and focal person is the research assistant. Research assistants are employed by UNICEF Country Office (CO) and dispatched to the participating hospitals. In the community, the primary focal person is the village health volunteer (VHV). In both settings, newborn infants are identified and recruited by the respective focal person. If caregivers (i.e. mothers) agree to enrollment, the caregiver(s) receive additional counseling and the device is applied to the infant's wrist.

a. Hospital Setting

In both POMGEN and Goroka Hospital, research assistants identify newborn infants for enrollment and serve as the caregiver's counselor and focal person while using Kol Kilok. Upon enrollment, research assistants provide counseling on the device, KMC, and weekly KMC diaries (see Appendix 1).[b] The child remains enrolled in Kol Kilok throughout their hospital stay, and based on their level of care (e.g. admitted to general ward vs. intensive care ward), alerts are responded to by either caregivers (at the bedside with KMC) or nurses (with swaddling or heat lamps). If the device continues to alarm after interventions, clinicians are contacted for further evaluation and management.

Upon discharge, infants continue to wear the device for a total of four weeks and are brought back to the clinic for weekly visits. At these visits, KMC diaries are reviewed, anthropometric measurements recorded, and additional counseling provided by research assistants. On the fourth week follow-up, the device is removed and the participant discharged from the program.

b. Community Setting

In PNG, the Ministry of Health introduced select EENC interventions in the community and have committed to scale up the intervention per their two-year roadmap/country plan developed in 2017[c]. In the Nupuru,

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[b] KMC diaries keep track of daily KMC at home, and upon weekly clinic follow-ups, are used to record a patient's weight, length and head circumference

[c] A two-year road map/country plan for EENC developed by the MOH during the biennial regional EENC meeting in August 2017. The meeting report will be available online. WHO. (2018). Second biennial progress report (2016-2017). Besides, in the East Asia and Pacific region, community-based essential newborn care has been considered, tested and/or implemented under the leadership of the MOH and support from UNICEF (e.g. Myanmar) including sick newborn care such as skin-to-skin.

Henganofi (containing Kafentina), and Komperi communities of the Eastern Highlands Province, a system of village health volunteers (VHV) are utilized to implement and maintain the Kol Kilok program. VHV are recruited, trained and managed by a local NGO Touching the Untouchables (TTU). VHV's undergo a four week training course prior to their work, consisting of two weeks at a health facility and two weeks at the provincial hospital in postnatal and labor wards. Training focuses on community-based EENC, referring community members to health centers and Kol Kilok.

Similar to research assistants, VHV identify newborn infants for enrollment in their communities, or at community health centers, and provide counseling on the Kol Kilok device, KMC and completion of KMC diaries. However, in contrast, VHV live in their community and are available to caregivers for questions, technical assistance and potential referrals to health facilities. In addition, based on circumstances, VHV may provide the device and initial counseling to caregivers if there are homebirths unable to travel to nearby health centers.

If device continue to alarm in community settings despite a caregiver providing KMC, caregivers are counseled and encouraged to contact their VHV and/or present to a health facility for evaluation. Weekly checks can also occur during home visits or at nearby health centers (Henganofi, Kafentina, or Komperi). During weekly checks, VHV assist in reviewing KMC diaries, taking anthropometric measurements and facilitating additional counseling. Similar to hospital settings, on the fourth week follow-up, the device is removed and the participant is discharged from the program.

c. Upper Level

In POMGEN, data from KMC diaries and charts (e.g. recording Kol Kilok alarms, temperatures) are collected and analyzed by research assistants, then forwarded to UNICEF for review and collation. In Eastern Highlands Province (EHP), both the hospital and community components are overseen by the Deputy Director of Curative Health at Goroka Hospital. Data from KMC diaries and charts are collected by both Goroka Hospital and TTU, then forwarded to the Deputy Director for additional collation and analysis.

VHV collect KMC diaries and send data to upper levels for additional analysis (Komperi and Kafentina communities send data directly to TTU; Henganofi community and Goroka Hospital to the University of Goroka). TTU staff and research assistants then collate data and send to the Deputy Director of Curative Health at Goroka Hospital. Papua New Guinea UNICEF program staff assist with compilation of data, routine supervision, and technical guidance. Additional technical assistance is provided through UNICEF Regional Office and UNICEF Headquarters.

2. EVALUATION PURPOSE, OBJECTIVES AND SCOPE

Purpose of Evaluation

Kol Kilok was introduced in Papua New Guinea by UNICEF in June 2017, and has been implemented in two hospital settings as well as at the community level through three rural health centers. However, after nearly a year since implementation, the device's utility and feasibility for detecting newborn hypothermia in various settings of Papua New Guinea has not been fully assessed. Thus, an evaluation of the program is necessary to ensure efficient and effective use of this technology.

The purpose of this evaluation is to assist UNICEF in assessing whether Kol Kilok is meetings its goals of detecting and encouraging early interventions for neonatal hypothermia. In addition, the evaluation will identify strengths and challenges of using the medical device in both community settings, where the device has not yet been studied, and hospital settings. The evaluation will provide recommendations for improving the program in an effort to improve upon EENC, scale up implementation of the device and strengthen overall health systems for newborns. The findings of this evaluation will go on to inform and improve use of Kol Kilok in Papua New Guinea to better serve caregivers and healthcare workers using its technology as well as contribute to general knowledge surrounding hypothermia, KMC and EENC.

Objectives of Evaluation

- To assess the feasibility and acceptability of implementation of Bebi Kol Kilok in hospital and community settings;
- To evaluate the utility of Bebi Kol Kilok as an alert device to improve newborn care management associated with hypothermia, including KMC and EENC, in facility and home-based settings;
- To assesses potential strengths and challenges of the program and its implementation;
- To make recommendations on areas for improvement in order to improve upon programmatic and general EENC practices

Scope of Evaluation

The evaluation was conducted in two hospitals (Port Moresby General Hospital and Goroka Hospital) and three health centers in the Eastern Highlands Province where Kol Kilok has been distributed and utilized at the community level. The evaluation of multiple sites illustrates the feasibility of implementing hypothermic alert devices in various settings and assess whether appropriate management of hypothermia through kangaroo mother care (KMC) and other EENC practices has been consistently conducted.

Knowledge, attitudes and practices of key persons were covered at all implementation sites including Kol Kilok users, healthcare workers, village health volunteers, and implementation leads. Information from charts, registers and Kol Kilok logs from six-to-eight months before implementation and after implementation were reviewed when available at all sites. Indicators were then be compared prior to implementation and following use of the device to assess changes in newborn outcomes.[d]

Data collector training included justification for the purpose of the investigation, inclusion and exclusion criteria, and the informed consent process. Data collected were stored and maintained in secure networks to ensure participant privacy. Data analyzed and reported for the purposes of dissemination were de-identified to ensure confidentiality. Data collectors read the consent form script to participants in their local language to ensure

[d] Specifically, mortality rates before and after the intervention will be compared. However, a mortality reduction study was not possible without additional data

these persons wished to provide their consent and participate in the investigation. Awareness of confidentiality of responses and the ability to opt-out at any stage of the investigation were ensured.

3. EVALUATION METHODOLOGY

A. 3.1 Evaluation Criteria

The program was evaluated using the Organization for Economic Cooperation and Development and Development Assistance Committee (OECD-DAC) criteria of programmatic relevance (or appropriateness), connectedness, coherence, coverage, efficiency, effectiveness and impact (see Appendix 9).[14]

B. 3.2 Evaluation Framework

The evaluation framework sought to address whether the Kol Kilok program was meeting its stated goals and objectives. This required the evaluation to answer key questions on the program's inputs and outcomes including whether the device's implementation had been acceptable, feasible, and useful to stakeholders, led to changes in observable neonatal outcomes, and increased public health education, healthcare provider knowledge and health seeking behaviors. Finally, the evaluation sought to frame challenges and lessons learned from implementation and operations to inform future practices (see Appendix 2 for *Evaluation Matrix*).

C. 3.3. Evaluation Design

The evaluation was designed as a descriptive, exploratory and quasi-experimental assessment utilizing both qualitative and quantitative mixed methods. This allowed for an assessment of whether program services were meeting the communities' perceived needs and standards, identification of areas for improvement and an assessment of whether the program was improving knowledge, skills, behavior and attitudes surrounding newborn care and hypothermia. In addition, mixed methods allowed for triangulation of evidence, description of various observable outcomes in beneficiaries and description of the program's utility in different settings.

Qualitative interview questions were used to assess stakeholder attitudes and opinions, and quantitative data collection forms were utilized to standardize data extraction from charts, registers and logs. Data collection consisted of health facility assessments (HFA) at pilot facilities, register and chart reviews, kangaroo mother care (KMC) diary reviews and qualitative interviews with program participants and key informants (see Table 1) (Appendix 2 for *Evaluation Matrix*). All HFA and interviews were conducted using electronic tablets utilizing Open Data Kit (ODK) software (Kobo Toolbox).[15] Register, chart and KMC diary reviews data abstraction were conducted using Microsoft Excel.[16] The study protocol, data collection tools and terms of reference were developed by CDC Atlanta. CDC served as co-principal investigator along with UNICEF PNG CO and EAPRO as fellow co-principal investigator (see Appendix 1).

Table 1: Evaluation Data Collection Tools, Sources and Purpose of Method

Data Collection Tool and Source	Source	Purpose
Health Facility Assessment	- Individual interview with facility senior administrator	- Assess facility readiness and provider capacity for delivering ENC related to hypothermia
Patient Register and Chart Review[+]	- Document review of health facility medical charts from neonates and mothers - Document review of health facility neonatal and maternal patient registers	- Assess hypothermia prevalence and mortality in the year preceding, and following, the intervention - Ascertain number and rate of LBW and premature births - Sub-analysis documenting interventions and outcomes of all babies receiving the Kol Kilok device

KMC Diary Review	- Document review of weekly KMC diaries provided to caregivers during first month of life	- Review of KMC diary data on weekly changes in weight and KMC in both Kol Kilok users and controls
Participant and Key Informant Interviews		
Health Providers	- Individual interviews with all available healthcare providers at sites	- Assess provider satisfaction with use of Kol Kilok - Assess clinical knowledge regarding detection and management of hypothermia, EENC and Kol Kilok - Ascertain human resource capacity for implementation and programmatic operations (hospital setting)
Caregiver (e.g. Mothers)	- Individual interviews with available caregivers (i.e. Kol Kilok users) at evaluation sites and nearby communities	- Assess counseling and knowledge of hypothermia and the use of Kol Kilok - Assess caregiver satisfaction with use of device - Ascertain knowledge and practices surrounding KMC - Evaluate concerns, opinions, challenges and perceived benefits amongst participants
Village Health Volunteer (VHV)*	- Individual interviews with VHV available at evaluation sites and nearby communities	- Assess general knowledge regarding use of Kol Kilok, appropriate techniques for intervening on alerts - Ascertain human resource capacity for implementation and programmatic operations (community setting)
Focus Group Discussions	- Focus group discussions with non Kol Kilok users at evaluation sites and nearby communities	- Assess knowledge, attitudes, perceptions, opinions and perceived barriers for hypothermia care and essential newborn care
Verbal Autopsy	- Individual interviews with caregivers of deceased Kol Kilok users	- Assess signs, symptoms, interventions and demographics of Kol Kilok users who died while using the device - Describe causes of death of Kol Kilok users from vital statistics, and delineate possible causes of mortality from signs and symptoms
Implementation Lead	- Individual interviews with key persons involved in the implementation of the Kol Kilok program	- Construct a timeline of the intervention along with dates of final approval and implementation - Assess for best practices, lessons learned and challenges identified during implementation

		- Describe the financial requirements of implementation (e.g. cost of the device)

[+]Hospital settings only
*Community settings only

i. Health Facility Assessments

All health facilities where Kol Kilok had been implemented were selected for evaluation. Four facilities were assessed along with an additional assessment for each ward addressing neonatal care in POMGEN (i.e. for a total of six conducted assessments).[e] Health facility assessments were used to determine the capacity of facilities to provide EENC and to utilize Bebi Kol Kilok as an alert device in detecting and supporting the management of hypothermia (see Table 2).

Table 2: Key Inputs from Health Facility Assessments (HFA)

Input	Proccess
Human resources, equipment and supplies	Number and quality (i.e. functioning)
Provision of Emergency Newborn Care	Newborn resuscitation - Antenatal corticosteroid - Antibiotics for pPROM - Antibiotics for neonatal infection - Kangaroo Mother Care - Administratio of oxygen - Administration of IV fluids

Health provider readiness knowledge assessment and implement	- Early Essential Newborn Care (EENC)
	  ○ Care of the baby at the time of birth
	  ○ Examination of the newborn baby
	  ○ Care of the newborn baby until discharge
	  ○ Special situation
	- Management of newborn resuscitation and birth asphyxia
	- Diagnosis and treatment of newborn infection
	- Management of complications of prematurity and low birth weight (LBW) children including hypothermia and Kangaroo mother care (KMC)
	- Other special training

ii. Chart, Register, and KMC Diary Review

Patient chart and register review was conducted from select periods at each health facility using standardized data collection tools. Data were collected on care provided to newborns and their respective outcomes (e.g. hypothermia, mortality) for 6-8 months prior to the implementation of Bebi Kol Kilok. A second exhaustive chart review was conducted on data 6-8 following implementation to determine changes in neonatal morbidity and

[e] Of note, Kafentina Health Center had been damaged during civil unrest and was not operational during the evaluation. Therefore, it was removed from assessment and analysis

mortality after implementation of the device. All available charts and register entries were reviewed on newborns during these time periods.

A second, separate analysis of charts and registers was conducted reviewing temperature data of all neonates who received Kol Kilok during hospitalization since implementation. The analysis assessed the number of alerts, temperature at the time of the alert, and alert response from providers (including whether or not KMC was performed or other clinical interventions were needed).

In order to assess adherence to KMC practices associated with the device, all KMC diary data collected by the program (i.e. log books kept by caregivers to record daily KMC provided to infants) were reviewed and data extracted regarding the number of alerts seen per week and whether or not KMC was given following alerts.

iii. Participant and Key Informant Interviews

Caregiver interviews were administered to caregivers of Kol Kilok users (e.g. parents, guardians) to assess level of knowledge, attitudes, practices, satisfaction and suggestions surrounding the use of the device as well as general newborn care. These interviews were collected separately among caregivers seeking facility-based care and those using the Kol Kilok device in their own homes (i.e. community setting). All available caregivers at implementation sites on the day of their evaluation, or in the nearby community, were interviewed (i.e. total of 138). All interviewed caregivers were female though age was not assessed.

Health provider interviews were administered to all consenting providers who provide neonatal care at each health facility. Providers included nurses, clinicians, administrators, community health workers, and midwives. This questionnaire assessed training of healthcare providers, provider understanding of Bebi Kol Kilok, knowledge of best practices for detecting/managing hypothermia, and changes in clinical care due to use of the device. All healthcare providers available at implementation sites during the day of their evaluation were interviewed (i.e. total of 51).

Village Health Volunteer (VHV) interviews were conducted with all available VHV during field visits (i.e. total of 127). The questionnaire focused on volunteer's training and knowledge of providing Bebi Kol Kilok services and interventions for neonatal hypothermia. Interviews also reviewed VHV opinions of the device, perceived benefits, challenges, and recommendations.

Focus Group Discussions (FGDs) were conducted with caregivers in community and hospital settings who did not receive the Kol Kilok device. FGDs assessed knowledge, attitudes and opinions regarding neonatal hypothermia as well as care associated with addressing hypothermia. The FGDs also addressed perceived barriers to healthcare in these settings. At least one FGD was conducted in each setting (i.e. two in the community of EHP and two in POMGEN, with a total of 57 participants between all sites). All FGD participants were female who were either mothers of infants (i.e. under one year of age) and/or caregivers of infants, though age was not assessed.

Verbal Autopsy (VA) was conducted with all available caregivers of newborns who died during the intervention of Bebi Kol Kilok to attempt to determine symptoms, signs, conditions, interventions, and, if possible, cause of death (i.e. total of seven completed). VA is a technique used to determine the cause of death by asking caregivers, friends, or family members about signs and symptoms exhibited by the deceased in the period before death.[17] Where death certificates were available and informed consent given, information on causes and details of death were extracted.

Implementation lead interviews were conducted with all available persons involved in the program implementation process. The questionnaire focused on how the Kol Kilok program was designed, funded, and

implemented. Questions also focused on plans for the program in the coming months and years as well as identified best practices and lessons learned during the implementation process.

iv. Sample Methods, Size and Justification

Due to geographic and timing constraints in the evaluation, a convenience sample of available caregivers and village health volunteers at each implementation site (or in the nearby community) was utilized for the evaluation. For caregiver interviews, any available Kol Kilok users who consented to interview were included in the evaluation. For the outcome of assessing acceptability via caregiver interviews, sample sizes were calculated assuming a conservative prevalence of 50% acceptance of the device, a desired precision of 10% and 95% confidence interval, yielding a desired sample size of 107 interviews of caregivers. In addition to current device users, all consenting caregivers were interviewed if they received Bebi Kol Kilok following birth or had received a Kol Kilok in the past.

In VHV interviews, all available VHV who consented to interviews were included in the evaluation. For the outcome of assessing knowledge of best practices and opinion of the Bebi Kol Kilok among VHVs, two different samples sizes were calculated. For the outcome of assessing knowledge of best practices, sequential yes or no questions were be asked of the VHV to determine whether correct action had be taken. Assuming a mean overall score on all questions of 0.75 and a conservative standard deviation of 0.2, a sample size of 62 observations was calculated to produce an estimate with ±5% standard error around the mean estimate. Assuming 10% non-response or non-participation, 69 VHVs would need to be interviewed to achieve adequate precision.

For the outcome of determining opinions on whether the Bebi Kol Kilok was found to be useful and was liked, we assumed a conservative estimate that 50% of VHVs would find the device useful. Assuming a 95% Confidence Interval and 10% non-response, a sample size of 107 VHVs was found to be necessary in order to achieve a precision of ±10% around the prevalence. Given that 107 interviews were required for the outcome to assess utility and acceptability, we ensured the knowledge questionnaire was conducted with at least 107 VHVs.[f]

Healthcare worker, VA, HFA, and implementation lead interviews were exhaustive and included all available personnel at implementation sites or in nearby communities.

D. 3.3 Field Investigation

i. Training

All team members who conducted interviews, document review or focus groups underwent a one-day training session prior to the evaluation. The training was led by CDC staff and included didactic sessions and step-by-step overviews of each questionnaire form. The training included introductions to the study purpose, methodology, ethical considerations, consent process, and tablet use.

ii. Field Investigation

Data collection occurred in the Eastern Highland Province (Goroka Hospital and Henganofi, Komperi, and Kafentina health center communities) from February 25 to March 2, 2018, and in Port Moresby (POMGEN) from March 4 to 13, 2018 (see Table 3). A total of 15 study team members and four study leads participated in the evaluation between the two locations. Study team members included staff from hospitals (POMGEN and Goroka), Eastern Provincial Health Authority, PNG Ministry of Health, UNICEF Country Office, WHO Country

[f] By design, 107 interviews with VHV were planned. However, due to higher than expected response to requests for interviews, a near exhaustive number of interviews were conducted (i.e. 127 of the 140 VHV in the TTU network)

Office and NGOs (Touching the Untouchables (TTU). Study leads consisted of three CDC staff and one UNICEF EAPRO member.

Table 3: Timeline of Evaluation in Papua New Guinea

Date	**Feb 23**	**Feb 24**	**Feb 25**	**Feb 26**	**Feb 27**	**Feb 28**	**Mar 1**	**Mar 2**	**Mar 3**	**Mar 4**
Location	**Port Moresby**		**Eastern Highlands Province**							
Facility	**POMGEN**		**Goroka**		**Komperi**		**Goroka**	**Henganofi**	**Goroka**	
Activities	-Briefing stakeholders -Training of team members		**Travel to Goroka** -Training of team members	-Chart and reg. review; interviews	-Chart and reg. review; interviews		-Chart and reg. review; interviews	-Chart and reg. review; interviews	-Data Analysis -Stakeholder presentation	**Travel to Port Moresby**

Date	**Mar 4**	**Mar 5**	**Mar 6**	**Mar 7**	**Mar 8**	**Mar 9**	**Mar 10**	**Mar 11**	**Mar 12**	**Mar 13**	**Mar 14**	**Mar 15**
Location	**Port Moresby**											
Facility	**POMGEN**									**-**		
Activities	**Travel to Port Moresby**	-Chart and reg. review; interviews								-Data Analysis		-Stakeholder presentation

Caregiver interviews, health care provider interviews, focus groups, health facility assessments, and chart reviews were conducted at two hospitals (Port Moresby General Hospital [POMGEN] and Goroka Hospital). Village health volunteer, focus group, and household caregiver interviews as well as health facility assessments were conducted in community settings at Henganofi and Komperi Health Centers and the communities within their catchment areas. KMC diary information was obtained through the village health volunteer NGO, Touching the Untouchables (TTU). Implementation lead interviews were conducted at all sites, as well as PNG Ministry of Health and NGO locations.

E. 3.4 Evaluation Ethics

The evaluation adhered to UN Evaluation Group (UNEG) Ethical Guidelines for Evaluation and UNICEF Procedure for Ethical Standards in Research, Evaluation and Data Collection and Analysis.[18,19] Enumerators were trained to conduct interviews impartially, honestly, respectfully and without bias. In addition, study personnel received training on research ethics and procedures for protecting participant confidentiality and autonomy during interview.

Informed consent was obtained from all participants who assented to interviews. Interviews were voluntary and designed with a Pigdin language option to account for non English speaking participants. Efforts were made to ensure fair representation of stakeholders by traveling to both health facilities and communities in rural locations for participant interviews. All data were stored securely and confidentially with personal identifiers removed after data collection. Immediately following field data collection in PNG (i.e. March 2018), preliminary evaluation findings were presented and discussed with stakeholders in both Goroka and Port Moresby. The study was approved by CDC's Institutional Review Board.

F. 3.5 Data Entry and Management

Participant and Key Informant Interviews

Team members entered data collected during interviews directly onto Samsung Galaxy tablets using Kobo Toolbox (an Open Data Kit (ODK; open-source) for data management).[20] Tablets were collected daily by study staff, and data transferred from tablets to ODK software. Completed records were then deleted from each tablet at the end of the evaluation. Data were converted from Kobo Tool to Microsoft Excel (Microsoft Corporation; Redmond, Washington; USA).

Focus Group Discussions (FGDs)

Team members recorded responses from FGDs with non Kol Kilok users on paper notes, following paper-based questionnaires/interview guides. Microsoft Excel (Microsoft Corporation; Redmond, Washington; USA) was used for data management.

Implementation Lead Interviews

Team leads recorded responses from implementation lead interviews on Microsoft Word (Microsoft Corporation; Redmond, Washington; USA).[21]

Chart, Register, and KMC Diary Review

Paper charts and registers were reviewed by team members and abstracted data entered daily into Excel sheets on secure CDC laptops. KMC diary information was obtained via Microsoft Excel (Microsoft Corporation; Redmond, Washington; US) compiled by Touching the Untouchables (TTU). Data were transferred using secure USB sticks.

G. 3.6 Data Analysis Tools and Methods

Data from the health facility assessment were summarized using Microsoft Excel and SAS version 9.4 to provide descriptive statistics on the availability of equipment, availability and quality of newborn care given, and management of clinical conditions.[22] Data from the two hospitals and three health centers were assessed separately and jointly to determine differences in capacity and readiness. To address the feasibility of using the device in each facility, percentages were then calculated of facilities with available supplies, equipment, services and providers.

Data obtained from chart and register review were analyzed using SAS version 9.4 and R Version 3.4.3.[23] To assess outcomes in Kol Kilok users and controls, means procedures were used to assess health facility mortality and morbidity rates among newborns. Frequency Kol Kilok diary data were summarized using means and frequencies, as well as linear regression, to determine the total and mean number of KMC, and assess whether cases used KMC or changed weight with differing frequency when compared to controls (i.e. those without a BKK bracelet). Where possible to link alert and temperature data to the KMC diary data, adequacy of KMC given per alert was calculated and compared to weight at week 1 and week 2 to determine whether adequacy of KMC was related to weight gain. Finally, to assess the efficacy and utility of the device, temperature and alert data were used to calculate then sensitivity and specificity of the Kol Kilok in detecting hypothermia.

Register data was analyzed using SAS version 9.4 to assess complications in Kol Kilok users and controls, including prematurity and low birth weight prevalence by hospital, using frequency and means procedure. Chi-square tests were done to compare complications and low birth weight among those premature versus full-term and to compare complications between low birth weight (LBW) categories (i.e. LBW, very LBW [VLBW], extremely LBW [ELBW]). Further chi-square analyses were performed to determine if the prevalence of complications, low birth weight, and prematurity differed pre-and post-implementation (i.e. outcomes).

Participant and key informant interviews were analyzed using SAS version 9.4 and Microsoft Excel. As healthcare provider and village health volunteer (VHV) interviews were exhaustive (see *Sample Size* section above), complex sampling procedures were not necessary for analysis and no survey weights were used for these two interview types. Basic descriptive statistics were provided on the knowledge of practices for managing hypothermia and degree of training of hypothermic response. This allowed for the assessment of key evaluation questions surrounding changes in healthcare practices, recognition of hypothermia and the efficacy of training. Where the number of healthcare providers allowed, the analyses were stratified by type of provider (e.g. doctor, nurse), type of counseling provided, and facility location.

Analysis of the caregiver interviews were conducted using complex survey procedures in SAS 9.4 to account for variability caused by the sampling strategy. Assessing acceptability of the Kol Kilok device, one of the main study objectives, was calculated individually for community and for facility interviews using the SurveyFreq procedure in SAS. SurveyFreq produces frequencies and cross tabulation tables from sample survey data, and based on the sample size compared to the large population, includes estimates of population proportions, standard errors, and confidence limits. A second objective of the caregiver interviews was to measure utility of the device for caregivers in responding to hypothermia alerts. Knowledge, attitudes and perceptions of Kol Kilok (asked in multiple choice and open-ended questions) were assessed using SurveyFreq and open-ended answers assessed by coding. Using the Surveymeans procedure in SAS, the mean response percentage among all community users were calculated and weighted against the total number of Kol Kilok users enrolled in the area.

To delineate underlying beliefs and practices surrounding hypothermia, qualitative data obtained from focus group discussions among community members who did not receive the Bebi Kol Kilok device were analyzed by coding to examine common responses and trends across various participants. This allowed for comparative descriptions between caregiver interviews and focus group discussion participants and permitted assessment of standard beliefs and practices surrounding hypothermia and EENC had the program not been implemented in these areas.

Key informant interviews with identified implementation leads were analyzed through qualitative methods. Descriptions of event were used to extract data on the timing, process and key actors during implementation. A description of the implementation process was then formulated using these narratives, highlighting challenging areas and overall lessons learned.

H. 3.7 Methodological Limitations

The evaluation was subject to several methodological limitations. First, the study relied on convenience samples of available caregivers, VHV and healthcare workers at the time of the evaluation. Second, due to finite numbers of VHV and caregivers enrolled in the program, desired precision was modified when calculating sample size (i.e. precision of 10%). Third, recall bias was intrinsic to interviews with prior device users. Fourth, we were unable to calculate mortality reduction with the current cohort. Fifth, sensitivity and specificity calculations were conducted using previously collected data by other sources and evaluators could not assess the internal validity of these findings. Sixth, the collection of data through use of tablets introduced aspects of interviewer bias for new users. Seventh, mortality, morbidity and prevalence studies were limited to retrospective data previously collected on only hospitalized neonates.

4. FINDINGS

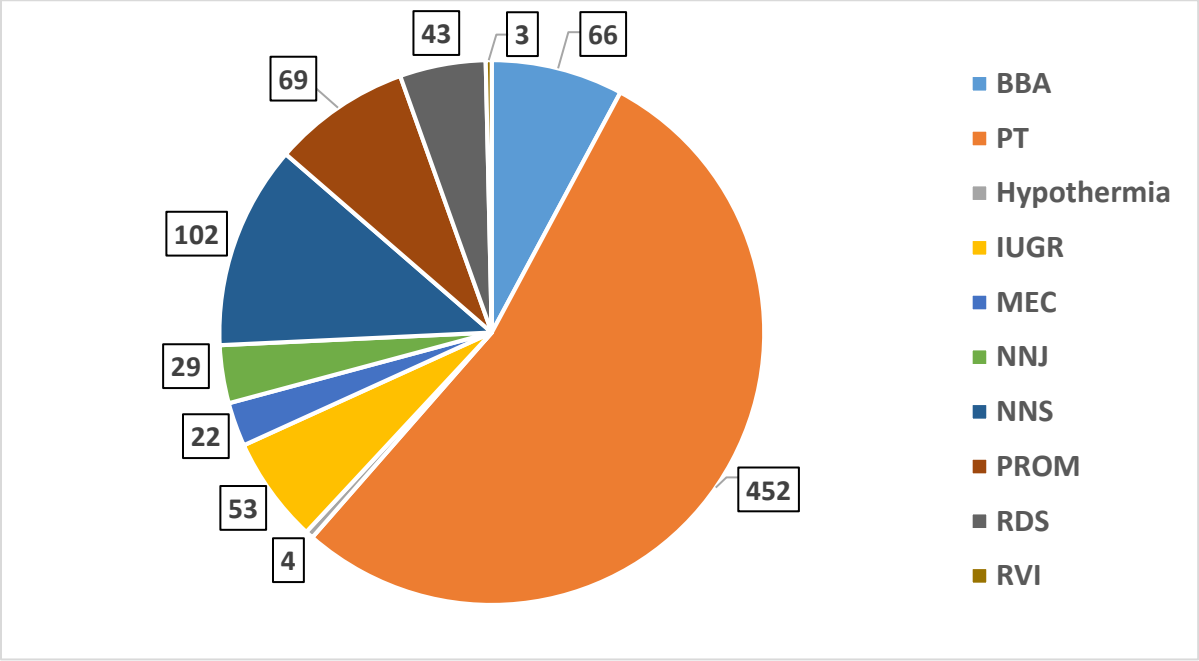
A. 4.1 Relevance/Appropriateness

Hypothermia and Infection Prevalence from Chart Review

To assess the prevalence of hypothermia in Kol Kilok implemented areas, a chart review was conducted at the two hospitals. Overall, 2,903 temperature readings from 58 neonates in POMGEN and 4,022 temperature readings from 157 neonates in Goroka were reviewed. In POMGEN, 43% (n=1260/2,903) of readings were hypothermic and 19% (n=760/4,022) of readings in Goroka were <36.5°. In addition, in Goroka, 76% (n=119/157) of infants had at least one temperature reading indicating hypothermia. Hypothermia has long been recognized as a detriment to neonatal health and can lead to hypoglycemia, hypotension and even death in severe cases. Thus its prevalence in these facilities demonstrates an ongoing risk for additional complications in vulnerable neonates.

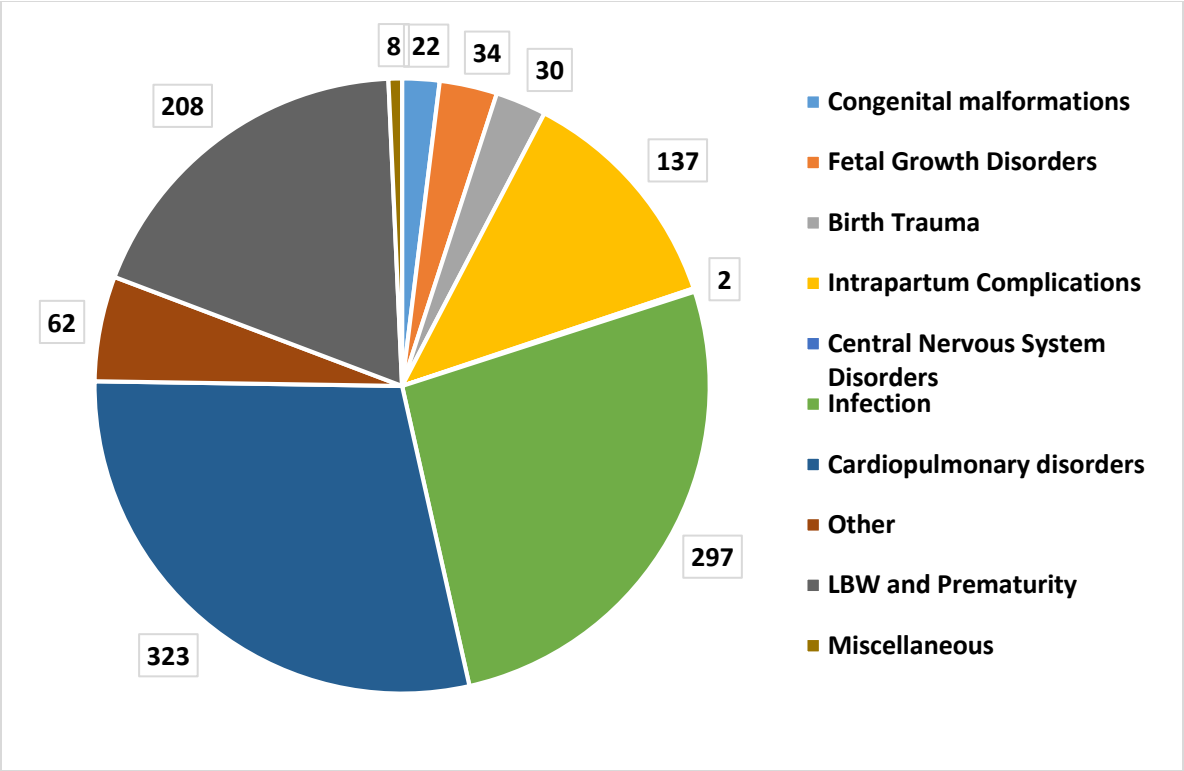
The majority of deaths in PNG in children under five years of age are from preterm complications, asphyxia and infection (see Figure 2, Figure 3).[24] In POMGEN, 102 neonates (12% of those with registered complications) were diagnosed with neonatal sepsis. In Goroka, 297 (26% of those with registered complications) were diagnosed with an infection during their inpatient stay. Hypothermia can be an indicator of infection, and therefore early detection of low temperatures could allow for early response to one of the most prevalent killers of newborns in PNG.

Figure 2: Specific Complications amongst Infants Admitted to POMGEN Special Care Nursery (n=843)



Legend: Clockwise – BBA (born before arrival), PT (preterm), IUGR (intra-uterine growth retardation), MEC (meconium aspiration), NNJ (neonatal jaundice), NNS (neonatal sepsis), PROM (premature rupture of membranes), RDS (Respiratory Distress Syndrome), RVI (Retroviral Illness)

Figure 3: Infant Complications Recorded in Goroka Hospital Neonatal Register (n=1,123)



Frequency of Alarms and Discussions with Stakeholders

Kol Kilok has been generally demonstrated to be a sensitive and specific device for detecting hypothermia, and alarm rates can be used as a proxy for the frequency of hypothermia in infants.[25] In discussion with caregivers, 59% of current Kol Kilok users (n=80) reported daily alarms and 15% (n=16) reported weekly alarms (i.e. weighted, 74% (n=96) reported daily or weekly alarms indicating hypothermia). Those noting daily alarms reported, on average, reported four alarms per day. Those with weekly alarms reported on average alarms two times per week. When divided based on gestational age, data suggested that term and premature infants had similar rates of alerts. Overall, 61% of caregivers for term infants reported daily alarms compared to 59% of premature infant caregivers (see Table 4), while 17% of premature infant caregivers reported weekly alarms and 13% of term infant caregivers.

Caregivers in the community were more likely to report daily alarms compared to the hospitals (86% daily in the community, 44% in Goroka, 31.1% in POMGEN) (see Table 5). Of those with daily alarms, on average, caregivers in the community noted 4.3 alarms per day, compared to 3.5 in Goroka and 2.3 in POMGEN. Alternatively, nearly 1-in-4 caregivers at POMGEN (n=11/45, 22%) reported only having seen an alert once or never at all, compared to only one caregiver at Goroka (11%) and one caregiver in the community (1%). The higher rates of hypothermic alerts in community settings could be due to the colder environment, higher frequency of precipitation, decreased sunlight and higher altitude in the Eastern Highlands Province compared to Port Moresby.[26] In addition, hospital settings continuously keep infants indoors, regularly monitor temperatures and have ready access to radiant warmers. The lower recall of alarms amongst hospitalized Kol Kilok users may also reflect a potential recall bias of caregivers in hospital settings, as limited time is allowed for caregiver interaction sicker neonates and alerts are predominately responded to by healthcare providers while inpatient.

Table 4: Weighted Frequency of Alarms based on Prematurity

	Premature (≤36 weeks) (%, n)*	Mean and Median Number of Alerts	Term (≥37 weeks) (%, n)*	Mean and Median Number of Alerts	Overall (all interviews)†	Mean Number of Alerts
Daily Alarms	59% (n=34/60) (95% CI 43.2-74.1)	Mean 3.6 (95% CI 2.8-4.3) Median 2.8 (range 1-10) (95% CI 2.1-3.4)	61% (n=39/54) (95% CI 43.3-78.0)	Mean 3.8 (95% CI 3.1-4.5) Median 2.5 (range 1-9) (95% CI 1.8-3.1)	59% (n=80/126) (95% CI 48.6-70.2)	Mean 3.8 (95% CI 3.3-4.3) Median 2.8 (range 1-10 [95% CI 2.1-3.1])
Every Other Day Alarms	9% (n=4/60) (95% CI 0-19.9)	-	12% (n=4/54) (95% CI 0-24.8)	-	10% (n=9/126) (95% CI 2.2-17.9)	-
Weekly Alarms	17% (n=10/60) (95% CI 4.9-28.7)	Mean 1.7 (95% CI 1.2-2.1) Median 1.3 (range 1-2)	13% (n=5/54) (95% CI 0-26.5)	Mean 3.5 (95% CI 1.0-6.0) Median 2 (range 2-5)	15% (n=17/126) (95% CI 7.0-23.7)	Mean 2 (95% CI 1.3-2.7) Median 2 (range 1-5)
Every Other Week Alarms	6% (n=5/60) (95% CI 0.7-12.1)	-	3% (n=2/54) (95% CI 0-7.6)	-	5% (n=8/126) (95% CI 1.6-8.9)	-
Alarmed Only Once	4% (n=3/60) (95% CI 0-8.3)	-	8% (n=2/54) (95% CI 0-21.3)	-	5% (n=5/126) (95% CI 0-11.3)	-
Never Alarmed	5% (n=4/60) (95% CI 0-10.2)	-	3% (n=2/56) (95% CI 0-7.8)	-	5% (n=7/126) (95% CI 1.2-8.0)	-

*Of the caregivers whom could recall the gestational age of their infant (n=125), eleven did not give responses which could be interpreted as alarm frequencies (remaining n=114 for analysis)

†Includes all interviews with an interpretable response to questions on frequency of alarms (i.e. those that gave specific responses that could be interpreted, n=126), regardless of gestational age

Table 5: Weighted Frequency of Alarms based on Location

	Community	Mean and Median Number of Alerts	Goroka Hospital	Mean and Median Number of Alerts	POMGEN	Mean and Median Number of Alerts	Overall (all interviews)*	Mean and Median Number of Alerts
Daily Alarms	86% (n=62/72) (95% CI 78.0-94.2)	Mean 4.3 (95% CI 3.7-4.9) Median 3.3 (95% CI 2.2-4.4)	44% (n=4/9) (95% CI 11.5-77.4)	Mean 3.5 (95% CI 1.8-5.2) Median 2	31.1% (n=14/45) (95% CI 17.4-44.8)	Mean 2.3 (95% CI 1.6-3.0) Median 1.5 (95% CI 1.2-1.8)	64% (n=80/126) (95% CI 55.0-72.0)	Mean 3.8 (95% CI 3.3-4.3) Median 2.9 (95% CI 2.3-3.4)
Every Other Day Alarms	6% (n=4/72) (95% CI 0.2-10.9)	-	22% (n=2/9) (95% CI 0-49.8)	-	7% (n=3/45) (95% CI 0-14.1)	-	7% (n=9/126) (95% CI 2.6-11.7)	-
Weekly Alarms	6% (n=4/72) (95% CI 0.2-10.9)	Mean 3.5 (95% CI 1.0-6.0) Median 2	22% (n=2/9) (95% CI 0-49.8)	Mean 2 (95% CI 2.0-2.0) Median 2 (96% CI 2-2)	24% (n=11/45) (95% CI 11.7-37.2)	Mean 1.5 (95% CI 1.0-2.0) Median 1 (95% CI 0.5-1.5)	14% (n=17/126) (95% CI 7.4-19.5)	Mean 2 (95% CI 1.3-2.7) Median 1.3
Every Other Week Alarms	1% (n=1/72) (95% CI 0.0-4.1)	-	0% (n=0/9)	-	16% (n=7/45) (95% CI 4.8-26.3)	-	6% (n=8/126) (95% CI 2.0-11.7)	-
Alarmed Only Once	0% (n=0/72)	-	11% (n=1/9) (95% CI 0.0-31.9)	-	8.9% (n=4/45) (95% CI 0.5-17.3)	-	5% (n=5/126) (95% CI 0.5-7.4)	-
Never Alarmed	1% (n=1/72) (95% CI 0-4.1)	-	0% (n=0/9)	-	13% (n=6/45) (95% CI 3.3-23.4)	-	4% (n=7/126) (95% CI 1.5-9.6)	-

*Includes all interviews with an interpretable response to questions on frequency of alarms (i.e. those that gave specific responses that could be interpreted, n=126), regardless of health facility location

B. 4.2 Connectedness

Partnerships with local NGOs have largely been helpful to the program. TTU is highly praised in community and Kol Kilok device users who have VHV as counselors have had the highest rates of training (96%), recall of actions to be taken during sustained alerts (90% correct), and ability to accurately describe KMC (76%). In addition, 73% of community Kol Kilok users reported using VHV as their primary contact for Kol Kilok related questions. The VHV network also connects the program to the community, as VHV are members of communities where Kol Kilok device has been implemented, and allows for community buy-in and local advocacy of counseling topics related to Kol Kilok device and overall EENC.

Attempts are being made to link the program to government support. The program has involved EHP's governor and the national MOH, and there has been high praise for the program from these sources with discussions

ongoing regarding transitioning to government funding. However, no formal allocation has yet been made. Thus, the self-sustainability of the program is unclear as currently Kol Kilok device is entirely supported financially by UNICEF and other donors.

C. 4.3 Coherence

Village Health Volunteers (VHV) and Touching the Untouchables (TTU)

The Kol Kilok program was implemented in the community setting utilizing a network for Village Health Volunteers (VHV) through the NGO Touching the Untouchables (TTU). Prior to Kol Kilok, the network was utilized for other responsibilities (e.g. vaccination work, ANC). On average, VHV had spent three years in their current position (average 36 months; median 12 months, range 4-432) (see Table 6). Most VHV were affiliated with Komperi (41%, n=51), Henganofi (19%, n=24), Kafentina (10%, n=14), or other areas (29%, n=37).

VHV noted working an average of seven hours of work per week on routine tasks such as vaccinations and ANC (median 8, range 1-48 hours), and 11 hours per week on Bebi Kol Kilok-related activities (median 8 hours, range 0-168 hours) (see Table 7). Kol Kilok therefore doubles the work load for any VHV, but at a total of 18 hours per week. In addition, Kol Kilok counseling topics overlap with prior commitments of VHV (e.g. encouraging EENC with KMC and returns to clinic for vaccination), and most VHV reported only having an average of four Kol Kilok users over the past 6 months (median 3) (i.e. average 1 per month).

Table 6: Number of VHV and Time in Each Area

	Komperi	**Henganofi**	**Kafentina**	**Other**	**Overall (all interviews)***
Number and Percent of VHV in Area	41% (n=51)	19% (n=24)	10% (n=13)	30% (n=38)	n=127
Mean and Median time as VHV	Mean 47 months Median 48 months (range 4-432)	Mean 23 months Median 6 months (range 5-72)	Mean 42 months Median 60 months (range 4-84)	Meant 28 months Median 7 months (range 4-84)	Mean 36 months Median 12 months (range 4-432)
Average time per week working on Kol Kilok	Mean 10 hours Median 8 (range 1-48)	Mean 16 hours Median 3 (range 0-168)	Mean 7 hours Median 8 (range 3-8)	Mean 12 hours Median 8 (range 0.5-72)	Mean 11 hours Median 8 (range 0-168)
Average time per week working on other responsibilities	Mean 7 hours (n=46) Median 8 (range 1-24)	Mean 6 hours (n=23) Median 3 (range 1-48)	Mean 7 hours (n=13) Median 8 (range 2-8)	Mean 9 hours (n=27) Median 8 (range 1-48)	Mean 7.5 hours Median 8 (range 1-48)
Average Communities Served	Mean 1.5 Median 1 (range 1-5)	Mean 1.3 Median 1 (range 1-3)	Mean 1.3 Median 1 (range 1-2)	Mean 1.7 Median 1 (range 1-7)	Mean 1.5 hours Median 1 (range 1-7)
Average Kol Kilok Users	Mean 5	Mean 3	Mean 3	Mean 4	Mean 4

	Median 3 (range 0-40)	Median 2 (range 0-7)	Median 3 (range 2-4)	Median 2 (range 1-35 [n=37])	Median 3 (range 0-40)

*Includes all interviews which responded to the row's question, regardless of health facility location

Table 7: Weekly Counseling Topics Conducted by Village Health Volunteers

	Week 1	Week 2	Week 3	Week 4
Hypothermia	87%	46%	12%	9%
Kol Kilok	89%	58%	20%	8%
Response to Blue Light	91%	78%	22%	8%
Response to Orange Light	91%	80%	33%	13%
Response to Continued Alarms	92%	84%	42%	17%
KMC	94%	90%	69%	26%
KMC Diaries	77%	76%	54%	19%
Breastfeeding	86%	74%	72%	85%
Vaccines	8%	8%	8%	89%
Other	12%	10%	11%	16%

Figure 4: Weekly Kol Kilok Counseling Topics Conducted by Village Health Volunteer

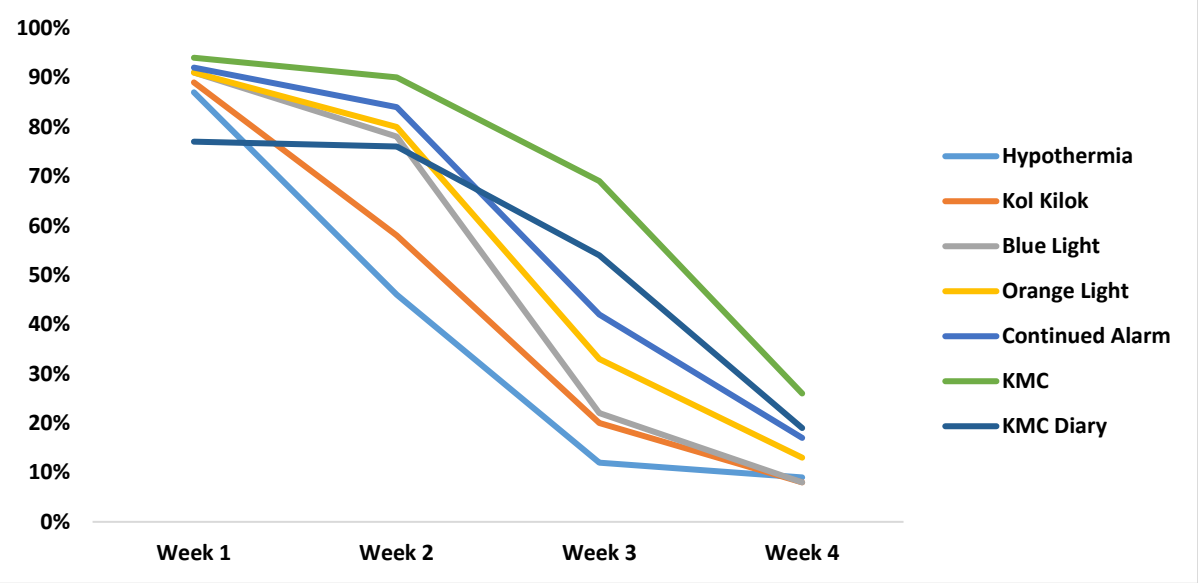
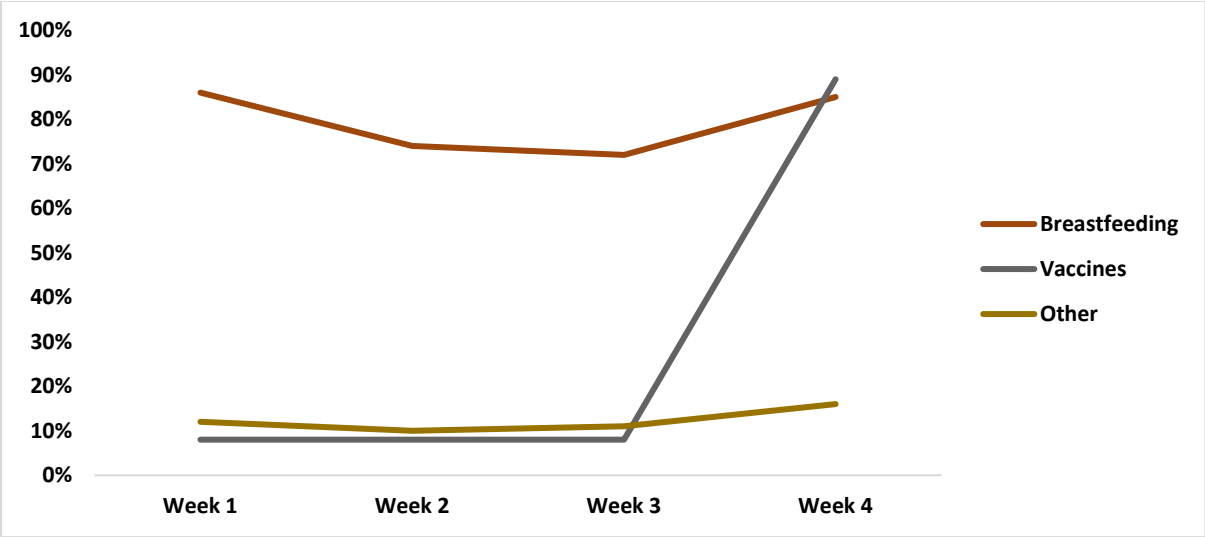


Figure 5: Weekly Kol Kilok Counseling Topics Conducted by Village Health Volunteer



Overall, VHV liked the Kol Kilok program and thought it had been well received in the communities. Specifically, VHV liked that the device detected hypothermia (97%, or n=121/125), increased KMC (91%, n=114), or was easy to use (88%, n=110). Most VHV (90%, n=113) reported caregivers also liked the device and program, and furthermore, 32 VHV noted improvement in growth in children and 11 specifically reported increased KMC from other family members (e.g. fathers).

The majority of VHV noted a major challenge with Kol Kilok was transportation (73%, n=92). Other challenges included issues with communication (59%), need for additional training (28%), or the device itself being too small for users (4%). Of note, 15 VHV reported specifically having "no issues" with Kol Kilok. Suggestions for improvement included asking for a larger band size on Kol Kilok (n=61), assistance with transportation (n=34), incentives (n=24), asking to use the device longer (n=22), and additional training (n=14).

Supplementing Early Essential Newborn Care

EENC programs in PNG have attempted to promote KMC since their implementation in January 2015.[27] To supplement EENC training, VHV and healthcare workers were provided additional training related to hypothermia and Kol Kilok through TTU and their health facilities, respectively. Overall, it appears this training was well conducted for VHV and, to a smaller extent, hospital staff**.** Overall, 98% of VHV (n=124) reported training on hypothermia compared to 70% of healthcare workers (n=35/50). In addition to hypothermia, 96% (n=121) of VHV and 80% of healthcare workers (n=39) reported training on Early Essential Newborn Care (EENC) (see Appendix 3). However, training topics covered in EENC training were mixed. Per technical leads, EENC training for VHV focused primarily on breastfeeding and KMC. However, only three VHV reported training on breastfeeding and two on KMC during their recent training.[g] Training was also mixed amongst healthcare workers with 87% (n=33) reporting training on skin-to-skin care compared to only 27% (n=13) reporting training on neonatal resuscitation (see Appendix 3).

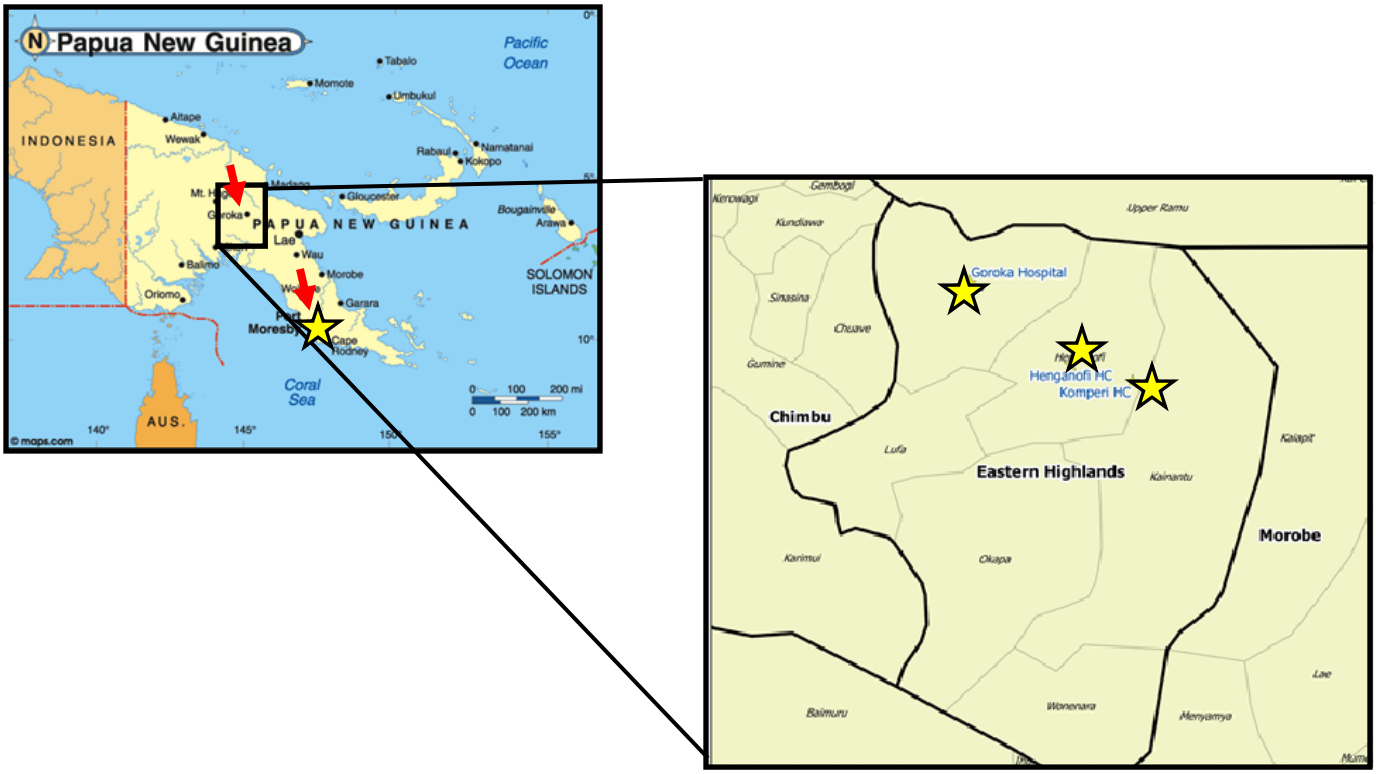
D. 4.4 Coverage

Health Facility Assessments

[g] It is possible this question was misunderstood as the majority of VHV's responded with answers focused on Kol Kilok (e.g. hospital referrals, caregiver training, documentation completion) and other questions demonstrated breastfeeding and KMC were frequently addressed in other trainings (see Figure 4, Figure 5)

Health facility assessments were implemented to assess health center's ability to respond to the needs of Kol Kilok users in their areas including neonatal resuscitation, rewarming practices and antibiotics. Overall, four facilities were available for health facility assessments (see Figure 6, Appendix 3).[h] In total, all sites had their facilities, healthcare workers, labor wards, and maternity wards available and open 24 hours a day and seven days a week (100%,n=6/6).[i] However, one site (Komperi) did not have a neonatal ward, one site (Goroka) did not have running water at all times, and two sites (Goroka and Henganofi) did not have electrical power or a functional generator at all times (see Appendix 3).

Figure 6: Map of Implementation Sites Assessed during Evaluation



For neonatal resuscitation, all sites had available mucus extractors, resuscitation masks and ventilator bags. However, several sites were missing key supplies for resuscitation. One site (Goroka) did not have a size #0 neonatal face mask for smaller infants, one site (Henganofi) did not have an endotracheal tube, and one site (Komperi) did not have a designated table for resuscitation or suction catheters. Only POMGEN (two of the three wards) had an infant laryngoscope for intubation and no sites had a foot-operated suction aspirator. Furthermore, Goroka Hospital and one ward at POMGEN noted its available equipment for resuscitation could not be reached within one minute, if necessary. No sites reported they had designated space/beds available for KMC or an available icterometer, and neither of the community health facilities (Henganofi, Komperi) reported having an available register for sick babies, radiant warmers, or incubators.

In total, 75% of sites reported performing neonatal resuscitation in the past 3 months. Of the sites who did not perform resuscitation, one (Henganofi) reported there hadn't been a case where resuscitation was necessary and the other was the labor ward at POMGEN which would refer infants to other wards for further measures

[h] Of note, Kafentina's facility was no longer operational at the time of the evaluation (due to damage during civil unrest) and was removed from analysis

[i] Due to differences in staff and equipment, three wards in POMGEN (i.e. labor ward, nursery ward and intensive care ward) were included in POMGEN's health facility assessment bringing the total number of HFA to six (n=6)

(i.e. intensive care). The same sites who noted recent neonatal resuscitation also reported administering glucocorticosteroids for pre-term labor management and antibiotics for preterm premature rupture of membranes (pPROM) (see Appendix 2). Only two sites (Komperi and all three wards in POMGEN) noted giving antibiotics for neonatal infections in the past 3 months (see Appendix 2). The other two sites (Henganofi and Goroka) noted either referring cases or not having had a case that required antibiotics. Oxygen had been administered to newborns at Goroka, Komperi and two wards of POMGEN (see Appendix 2). Finally, all sites noted KMC had been given to babies in the past 3 months.

The program of Kol Kilok was implemented with the goal of supplementing EENC practices and reducing childhood mortality through detecting early hypothermia and potential infections. The majority of health facilities reported performing neonatal resuscitation and administering antibiotics in recent months. However, community sites in particular generally lacked resuscitation equipment, warming devices for hypothermic infants and only one of these sites had administered antibiotics to an infant in the past 3 months. Thus, if the facilities near users are ill equipped to perform aspects of EENC, conduct advanced rewarming practices or address neonatal infections then the goals of Kol Kilok cannot be entirely met.

Register and KMC Diary Review

In POMGEN patient registers, a total of 2,501 neonates with a documented admission weight were reported from January 2016 to February 2018. Of these, 42% (n=1,048/2,501) were <2,500g and 50% (n=431/1048) with documented gestational age were premature.[j] In Goroka, 969 total neonates were registered from January 2017 to December 2017. Overall, 28% (n=221/777) of neonates with recorded weight were considered low birth weight and 29% (n=225/777) of those with recorded gestational age were premature.[k]

Kol Kilok and KMC had been previously studied in LBW infants and has been shown to improve mortality, weight gain and hypothermic rates in this population. However, as part of the pilot program in PNG, Kol Kilok was distributed to normal birth weight infants in EHP. This was done due to the colder climate and higher altitude in the area. However, KMC diary information from the area demonstrates that LBW infants are disproportionately under enrolled in the community. Average admission weight in hospital settings for Kol Kilok users were 1.68kg (POMGEN) and 2.15kg (Goroka), which demonstrate an average enrollment weight in hospitals of <2,500g (i.e. LBW). However, average enrollment weight in the community for Kol Kilok users were 2.98kg (Komperi) and 3.04g (Henganofi), which are normal birth weights above the 2,500g threshold.[l]

Ultimately, many caregivers of normal birth weight neonates in the community liked the device, saw its utility and believed in its benefits. Therefore, many caregivers saw the intervention as appropriate from their perspective as primary stakeholders. Furthermore, as noted in previous sections (see *Appropriateness*), Kol Kilok users in the community were *more* likely to report daily hypothermic alerts compared to hospital settings. As community users were generally higher in birth weight, compared to predominately LBW neonates in hospitals, this may represent an ongoing need for coverage in normal birth weight infants given their exceptionally higher hypothermia prevalence by proxy of alerts.

The Kol Kilok program is a pilot study by definition and does not currently have the goal of full geographic or demographic coverage within its implemented areas. If plans for scale up move forward, however, a discussion

[j] Admission weight refers to the weight of the infant upon presentation to the hospital. For hospital births, this is the infant's birth weight. For home births, this weight represents the weight upon the infants presentation – either birth weight (i.e. within hours of birth) or the weight upon the day of presentation (e.g. day 4 of life)

[k] The Kol Kilok program enrolled both LBW and normal birth weight infants.

[l] Of note, admission weights were not available from Henganofi, and therefore the first recorded weight in the program was Week 1

on the scope of Kol Kilok device distribution will be needed. EHP estimates 15,000 births per year with 38% considered LBW (i.e. 5,700 LBW births per year).[28] If the goal of the program going forward is for full coverage of those most likely to benefit from Kol Kilok and additional KMC, the focus should shift to distributing the device principally to LBW neonates until adequate coverage is attained. Otherwise, additional studies in comparable populations (i.e. *hospitalized* normal vs LBW, or *community* normal vs LBW) will be required to delineate any differences in benefits.

Village Health Volunteer (VHV) Network

In total, VHV cover 183 communities in EHP and have on average 1.5 communities for which they were responsible (median 1, range 1-7 communities). In addition, VHVs have had an average of four Kol Kilok users over the past six months.[m] House visits to Kol Kilok users were described as weekly (n=102, 81%) or daily (n=14, 11%) with multiple counseling topics regarding Kol Kilok covered during each house visits (see Appendix 3).

Geographical factors might have limited, at least in part, distribution of the device as well as postnatal follow-up for mothers and babies in the Eastern Highlands community. Almost three-fourths of caregivers reported transportation as a barrier to healthcare. In Goroka, almost half of healthcare workers reported this issue as well. VHV networks allow for distribution of the device, Maternal and Child Health (MCH)-related services and general health information to more rural areas away from health facilities. The network also facilitates increased connection to care, as VHV frequently encourage postnatal follow-up visits for mothers and babies and assist with transport/accompaniment. This mitigates, but does not eliminate, the issue of distance from health facilities and access to care with 73% (n=92) of VHV reporting transportation as a challenge. As a result, while the device may be distributed and counseling performed on KMC, its secondary intervention of encouraging referrals for ongoing alerts is not always possible.

Overall, 31 VHV (25%) had reported that they had referred a child and/or mother to the hospital, though not necessarily due to Kol Kilok alerts. Based on VHV reports, two of these referrals resulted in the death of the infant. In one unfortunate situation, a VHV reported an instance with a mother who's "Kilok remain[ed] orange, breastfeeding done, check nappy, but no change in color. [She] accompanies mother and baby to closest health facility, walking for one day, crossing a river with water reaching knees and the(n) another several hrs [sic] of walking… stillbirth [by time] reach health centre." Thus, transportation and geographical limitations affect not only access to routine ANC and maternal/neonatal PNC, but also lifesaving interventions that could limit mortality in Kol Kilok users.

E. 4.5 Efficiency

Financial Efficiency

Kol Kilok costs $20 US dollars, or $60 PNG Kina, per device. These devices are purchased through an Indian company and shipped to PNG for use. As stated previously, the device was studied primarily in LBW infants and its designed intervention (i.e. KMC) has shown primarily benefits in LBW and premature infants.[29,30,31] Thus, given the current costs of purchasing devices, prioritizing distribution to LBW neonates would likely be the most cost effective strategy during implementation. Overall, the program would benefit from a full cost effectiveness analysis comparing transportation, shipping, staff and administrative costs. However, this is beyond the scope of the current evaluation and would require evaluators with financial or accounting backgrounds.

Technical Efficiency

[m] VHV reported having a total of 513 Kol Kilok users over the past 6 months. This is higher than the number of enrolled participants, and this discrepancy potentially reflects overlap in coverage areas or recall bias on the part of VHV

Data were provided to evaluators from sensitivity and specificity studies conducted prior to program implementation. Several data sets were available, thus for analysis the first provided set was analyzed. Overall, sensitivity was 74.8% and specificity was 99.1% at POMGEN. Positive Predictive Value (PPV) was 98.3% and Negative Predictive Value (NPV) was 85.3%. This reflects similar statements made by healthcare workers. Per one interview, "with the initial phase, we've noted that temperatures 36.4^{o}C and down, up to about 35.5^{o}C, that most of them… around 35.5^{o}C it will beep. But from 35.5^{o}C up to 36.4^{o}C [it] won't pick… So a lot of them, even though the baby is around 36.3^{o}C, it was still blue." "So it really doesn't pick up mild hypothermia, but the more severe ones they will pick up."

Only 9% of caregivers (n=12) reported malfunctioning devices during their use of the device. A plurality of these users (n=5/12) reported their devices light had gone off for just a few minutes (i.e. <15 minutes). Others, noted their device had stopped working for more than one day (n=3). In addition, only four of these users (33%) reported this issue to a research assistant or healthcare provider.

If revisions are made, the device itself could also be made more efficiently. Several healthcare workers (14%, n=7) reported increased work when responding to alarms, including the dual task of responding to an alert and then measuring temperature. If device could be augmented to display temperature readings this would increase efficiency in hospitals and allow for potential outpatient or community studies on sensitivity and specificity.

Village Health Volunteer (VHV) and Research Assistants

VHV are community members who have volunteered their time to assist in community level interventions and counseling. This limits the need for travel to health facilities for select counseling and discussions. The VHV are well trained (see *below* section) and the caregivers they serve have the highest recall of counseling topics compared to hospitals (see *Effectiveness* section). This evaluation study though did not assess cost-effectiveness of the VHV model, and this could be an area for future studies to identify a scalable, effective model with a relatively low cost for sustainability.

In contrast, hospitals have utilized research assistances (RA) during implementation of Kol Kilok. This is a single person at each site, and as a result, the program relies upon the RA's presence in the facility as well as to visit homes to ensure return to clinic. While this reflects the nature of pilot program, efficiency and sustainability of the RA model was not ascertained. Per one RA "we tell the mothers to come [to weekly follow-up visits], but most of the time those mothers don't turn up… then when they don't come, I have to go and work on them. And sometimes it is very difficult to find them."

Both research assistants were interviewed and had excellent recall of Kol Kilok topics. However, while healthcare workers can ensure response to devices during hospitalization, RA's may not have the bandwidth by themselves to reliably respond to caregivers upon discharge. Thus, given these constraints, the program strategy and framework of using RA's may need to be reconsidered in the next phase of implementation.

Healthcare Worker and System Efficiency

Healthcare workers reported efficiency to be a major issue in healthcare delivery (43% at Goroka, 46% at POMGEN). However, 77% (n=33) of health providers noted an improvement in their clinical practice due to Kol Kilok and 31% (n=10) reported the device saved them time during work. When asked specifically about the positive aspects of the device, 50% (n=16) reported assistance in detecting hypothermia and 28% (n=9) noted promotion of KMC.

Conversely, when asked about challenges with the device, four providers noted Kol Kilok actually increased their workload and three noted they were too understaffed to respond to alarms. In fact, 52% of healthcare workers across multiple sites reported limited human resources at their facilities. This was particularly notable during

overnight work when one facility reported only having two staff being available to respond to alerts. Per one provider "usually the temperatures drop around 3am or 4am, and there's no way mothers sleeping in the post-natal ward will pick [the alarm] up and there's no way for our overnight health staff to pick it up." Based on temperature analysis, the majority of hypothermic readings occurred at 2am in Goroka (29%) and 4am in POMGEN (27%). Therefore, health facilities have limited capacity to respond to alerts during their peak hours. Furthermore, 16% (n=7) noted they had not had enough training around the device. Suggestions for improvement, then, focused mostly on providing additional training (24%, n=12) and more staff or space to provide KMC (10%, n=5).

Supervision

Most VHV reported supervision (96%, n=121) in either monthly (66%, n=80), weekly (23%, n=28) or quarterly (6%, n=7) intervals (see Table 8). This supervision was conducted primarily in in-person meetings (94%, n=113), but also occurred during trainings (78%, n=94) and discussions by cell phone (48%, n=58). Furthermore, some VHV noted occasional "joint home visits" with supervisors (i.e. TTU staff) as well as completing written reports to supervisors. However, data collection tools were not designed to determine the frequency or quality of these joint home visits or reports.

Table 8: Supervision Methods and Frequency in Village Health Volunteers

	Komperi	**Henganofi**	**Kafentina**	**Other**	**Overall (all interviews)***
Supervision	98% (n=50/51)	88% (n=21/24)	100% (n=13/13)	97% (n=37/38)	96% (n=121/126)
Frequency	Quarterly - 6% (n=3) Monthly - 72% (n=36) Weekly - 12% (n=6) Daily - 2% (n=1)	Quarterly - 5% (n=1) Monthly - 71% (n=15) Weekly - 24% (n=5) Daily - 0% (n=0)	Quarterly - 0% (n=0) Monthly - 92% (n=12) Weekly - 8% (n=1) Daily - 0% (n=0)	Quarterly - 8% (n=3) Monthly - 46% (n=17) Weekly - 43% (n=16) Daily - 0% (n=0)	Quarterly - 6% (n=5) Monthly - 66% (n=80) Weekly - 23% (n=28) Daily - 1% (n=1)
Contact Methods					
In Person	94% (n=46/49)	100% (n=21/21)	100% (n=13/13)	89% (n=33/37)	94% (n=113/120)
During Trainings	81% (n=40/49)	81% (n=17/21)	100% (n=13/13)	65% (n=24/37)	78% (n=94/120)
Cellphone	41% (n=20/49)	57% (n=12/21)	100% (n=13/13)	35% (n=13/37)	48% (n=58/120)
Other	20% (n=10/49)	19% (n=4/21)	0% (n=0/13)	32% (n=12/37)	22% (n=26/120)

*Includes all interviews with an answer to the row's question, regardless of location

Supervision for healthcare workers varied by location (see Table 9). Overall, 84% of healthcare workers reported supervision which was either daily (n=13), weekly (n=4) or by shift (n=3). However, some healthcare workers reported no routine supervision (n=8), and others reported their supervision was only "occasional" (n=7), monthly (n=4), quarterly (n=4) or yearly (n=3). Thus, half of healthcare workers interviewed (n=26, 50%) noted no, or infrequent, supervision. Providers in Goroka had the most frequent supervision (58% daily, see Table 9), while community health facility staff (Henganofi, Komperi) reported mostly monthly or quarterly supervision

(60% at each location). Other examples of supervision included written reports, facility inspections and educational instruction (i.e. midwifery school). Supervisor types and positions varied across sites and included clinicians, charge nurses and School of Midwifery educators.

Table 9: Healthcare Providers and Supervision at Implementation Sites

	POMGEN	Goroka	Henganofi	Komperi	School of Midwifery	Overall (all interviews)*
Percent and Number Working at Each Facility	28% (n=14)	28% (n=14)	10% (n=5)	10% (n=5)	24% (n=12)	n=51
Types of Healthcare Providers	Medical Officer – 1 Nurses – 9 Midwife – 2 CHW – 2 --	-- Nurses – 9 Midwife – 3 CHW – 2 --	-- Nurses – 1 -- CHW – 2 Extension Health Worker – 2	-- Nurses – 3 -- CHW – 2 --	-- Nurses – 5 Midwife – 7 -- --	Medical Officer – 1 Nurses – 27 Midwife – 12 CHW – 8 Extension Health Worker – 2
Average Time in Position	Mean 231 months (n=14) Median 280 (range 6-672)	Mean 98 months (n=14) Median 66 (range 3-480)	Mean 126 months (n=5) Median 72 (range 1-400)	Mean 58 months (n=5) Median 24 (range 12-204)	Mean 30 months (n=12) Median 14 (range 4-108)	Mean 117 months (n=51) Median 54 (range 1-672)
Care Provision						
Inpatient	93% (n=13)	79% (n=11)	80% (n=4)	80% (n=4)	67%) (n=8)	80% (n=40)
Intensive	71% (n=10)	79% (n=11)	40% (n=2)	20% (n=1)	17% (n=2)	52% (n=26)
Outpatient	36% (n=5)	14% (n=2)	80% (n=4)	100% (n=5)	67%) (n=8)	48% (n=24)
Other	29% (n=4)	36% (n=5)	60% (n=3)	60% (n=3)	58% (n=7)	44% (n=22)
Counseling Provided	**86% (n=12)**	**93% (n=13)**	**100% (n=5)**	**100% (n=5)**	**100% (n=12)**	**94% (n=47)**
Postnatal Infant Care	93% (n=13)	71% (n=10)	100% (n=5)	100% (n=5)	75% (n=9)	84% (n=42)
Postnatal Maternal Care	71% (n=10)	71% (n=10)	100% (n=5)	100% (n=5)	75% (n=9)	78% (n=39)
Antenatal Care	21% (n=3)	14% (n=2)	100% (n=5)	100% (n=5)	67% (n=8)	46% (n=23)
Other	43% (n=6)	71% (n=10)	80% (n=4)	100% (n=5)	67% (n=8)	66% (n=33)
Receive Supervision	71% (n=10)	86% (n=12)	100% (n=5)	100% (n=5)	83% (n=10)	84% (n=42)
Frequency of Supervision	Daily – 2 (20%)	Daily – 7 (58%)	--	--	Daily – 4 (40%)	Daily – 13 (25%)

	-- -- -- Other – 8 (80%)	Weekly – 1 (8%) -- -- Other – 4 (24%)	-- Monthly – 2 (40%) Quarterly – 1 (20%) Other – 2 (40%)	Weekly – 1 (20%) Monthly - 1 (20%) Quarterly – 2 (40%) Other - 1 (20%)	Weekly – 2 (20%) Monthly – 1 (10%) Quarterly – 1 (10%) Other – 2 (20%)	Weekly – 4 (8%) Monthly – 4 (8%) Quarterly – 4 (8%) Other – 17 (33% [includes "occasional" and "by shift"])

*Represents all interviews, regardless of stated health occupation (i.e. the total number of persons interviewed [n=51], not the total number of people with a specified healthcare occupation [n=50])

Efficiency of Training

Following training, all VHV were familiar with Kol Kilok (100%, n=125) and 94% (n=117) could correctly identify the purpose of the device (with another 4% [n=5] that were considered partially correct: e.g. "it picks up hot and cold") (see Table 10). Regarding the lights on Kol Kilok, 92% (n=115) correctly noted the meaning of the blue light (an additional 7% were partially correct), and 82% (n=125) correctly noted the meaning of the orange light (18% [n=23] partially correct [i.e. mentioning KMC, but also other incorrect interventions such as a heating lamp]). If Kol Kilok alarms continued despite KMC, 97% (n=121) of VHV correctly knew to refer a caregiver and their infant to the hospital (see Table 10). For technical issues, 99% (n=123) knew that mothers should contact VHV or be referred to a health center if the light on Kol Kilok were to stop shining. These high rates of recall allow VHV to be knowledgeable regarding Kol Kilok and efficient counselors to caregivers.

When asked to address what to do if a child continued to be cold after KMC (i.e. without mentioning Kol Kilok or its alarms), 95% (n=119) still correctly knew to take the child to the hospital. While demonstrating KMC, 90% (n=85) of VHV were able to correctly perform all actions of KMC and 10% (n=9) were considered partially correct (i.e. missing one step) (see Table 10).[n] Of the partially correct, five VHV did not mention removal of clothing for direct skin-to-skin contact and four did not mention wrapping the child and mother in a blanket. This demonstrates that the training focused on Kol Kilok and EENC has been largely understood by VHV, and potentially could contribute to future counseling surrounding these practices in non Kol Kilok users as well.

Table 10: Knowledge of Kol Kilok and Counseling Topics in VHV by Location

	Komperi	**Henganofi**	**Kafentina**	**Other**	**Overall**
Purpose of BKK	94% correct (n=46) 6% partial (n=3) --	92% correct (n=22) 4% partial (n=1) 4% incorrect (n=1)	100% correct (n=13) -- --	95% correct (n=36) 3% partial (n=1) 3% incorrect (n=1)	94% correct (n=117) 4% partial (n=5) 2% incorrect (n=1)
Blue Light	96% correct (n=48)	92% (n=22)	100% correct (n=13)	84% correct (n=32)	92% correct (n=115)

[n] Of note, 29 interviews had missing descriptions of KMC and were not analyzed

	4% partial (n=2) --	4% partial (n=1) 4% incorrect (n=1)	-- --	16% partial (n=6) --	7% partial (n=9) 1% incorrect (n=1)
Orange Light	70% correct (n=35) 30% partial (n=15)	92% (n=22) 8% partial (n=2)	77% correct (n=10) 23% partial (n=3)	92% correct (n=35) 13% partial (n=3)	82% correct (n=102) 18% partial (n=23)
Continued Alarms after KMC	98% correct (n=49) 2% incorrect (n=1)	100% (n=24) --	85% correct (n=11) 15% incorrect (n=2)	97% correct (n=37) 3% incorrect (n=1)	97% correct (n=121) 3% incorrect (n=4)
Malfunctioning Equipment	98% correct (n=49) 2% incorrect (n=1)	100% (n=24) --	100% correct (n=13) --	100% (n=38) --	99% correct (n=124) 1% incorrect (n=1)
Able to perform KMC	89% correct (n=34) 11% partial (n=4) --	87% correct (n=20) 13% partial (n=3) --	92% correct (n=12) -- 8% incorrect (n=1)	90% correct (n=19) 10% partial (n=2) --	89.5% correct (n=85) 9.5% partial (n=9) 1% incorrect (n=1)

Table 11: Hypothermia Training in Village Health Volunteers

	Komperi	**Henganofi**	**Kafentina**	**Other**	**Overall (all interviews)***
Hypothermia Training	100% (n=51/51)	100% (n=24/24)	100% (n=13/13)	95% (n=36/38)	98% (n=124/126)
Regular	86% (n=44/51)	83% (n=20/24)	100% (n=13/13)	94% (n=34/36)	90% (n=111/126)
Average Length	Mean 8 days (n=48) Median 8 days (range 1-24 days)	Mean 16 days (n=21) Median 8 days (range 2-80)	Mean 8 days (n=13) Median 8 days (range 8-8)	Mean 8.5 days (n=36) Median 8 days (range 1-35)	Mean 10 days (n=118) Median 8 days (range 1-80)
Average Time Since Last Training	Mean 38 days (n=51) Median 5 days (range 0-241)	Mean 134 days (n=22) Median 13 days (range 0-1401)	Mean 2 days (n=13) Median 2 days (range 1-2)	Mean 81 days (n=33) Median 28 days (range 2-391)	Mean 63 days (n=119) Median 7 (1-1401 days)
Training Topics					
Alert Response	98%	92%	100%	94%	96%

	(n=50)	(n=22)	(n=13)	(n=34)	(n=119/124)
Counseling	96% (n=49)	88% (n=21)	100% (n=13)	92% (n=33)	94% (n=116/124)
Referrals	84% (n=43)	83% (n=20)	100% (n=13)	86% (n=31)	86% (n=105/124)
Documentation	77% (n=39)	75% (n=18)	100% (n=13)	89% (n=32)	82% (n=100/124)
Technical Assistance	80% (n=41)	63% (n=15)	92% (n=12)	75% (n=27)	77% (n=93/124)
Other	6% (n=3)	25% (n=6)	0% (n=0)	8% (n=3)	10% (n=12/124)

*Includes all interviews with an answer to the row's question, regardless of location

Table 12: Early Essential Newborn Care Training in Village Health Volunteers

	Komperi	**Henganofi**	**Kafentina**	**Other**	**Overall (all interviews)***
ENC Training	92% (n=47/51)	100% (n=24/24)	100% (n=13/13)	97% (n=37/38)	96% (n=121/126)
Average Length	12.5 days (n=46) Median 10 days (range 1-28)	14 days (n=21) Median 10 (range 1-28)	10 (n=13) Median 10 (range 10-10)	16 days (n=37) Median 10 days (range 1-35)	14 days (n=117) Median 10 days (range 1-35)
Average Time Since Last Training	165 days (n=45) Median 167 (range 19-355)	219 days (n=22) Median 153 (range 0-1401)	107 days (n=12) Median 114 (range 84-114)	209 days (n=37) Median 218 (range 0-518)	183 days (n=116) Median 149 (range 1-1401)
Training Topics					
Breastfeeding	0% (n=0/46)	0% (n=0/23)	0% (n=0/13)	8% (n=3/37)	3% (n=3/119)
KMC	2% (n=1/46)	0% (n=0/23)	0% (n=0/13)	3% (n=1/37)	2% (n=2/119)

*Includes all interviews with an answer to the row's question, regardless of location

Healthcare workers, whose training focused more on clinical care, had moderate-to-high recall of correct clinical aspects surrounding hypothermia and EENC. Overall, 100% knew the correct way to measure temperatures in newborns (i.e. axillary), 90% (n=44) could recall the correct weight to diagnose LBW (i.e. <2,500g), 76% knew the gestational age to diagnose prematurity (i.e. <37 weeks), and 70% (n=35) the correct temperature to diagnose hypothermia (i.e. <36.5^{o} C). Regarding hypothermic care, 88% (n=44) prescribed KMC as treatment of hypothermia as well as 96% prescribing swaddling (n=48), 36% radiant warmers (n=18) and 34% application of warming pads (n=17).

Healthcare workers had mixed knowledge on EENC. Overall, 80% reported training on EENC and 84% reported recalled the need for early breastfeeding and 82% skin-to-skin immediately after birth. However, only 59% (n=29) recalled the need for Vitamin K administration after birth and 53% (n=26) recalled the need for eye antibiotics. When disaggregated by training level, lower levels of knowledge appeared to be most prominent in those without training. Those with training (n=39) routinely had higher recall of all six early interventions in

EENC compared to those without (n=10) (see Appendix 2). This illustrates the effectiveness of healthcare worker EENC training, though measures should be taken to ensure all health facility staff receive additional training.

A total of twelve midwifery students, who work with both Kol Kilok users and non users in the community, were interviewed during the evaluation. Overall, 91% (n=10/11) reported training on hypothermia with 100% reporting specific training on Kol Kilok and treatment of hypothermia. Similarly, 91% reported training on EENC with topics covered including skin-to-skin (89%), drying (78%), cord clamping (78%), breastfeeding (67%) and resuscitation (44%).

Clinical knowledge amongst these trainees was generally high. In total, 100% (n=11/11) could identify the weight for LBW (i.e. <2,500g), 100% knew the appropriate way to measure temperatures in neonates (i.e. axillary), 91% could identify the gestational age for prematurity (i.e. <37 weeks) and 82% denoted the temperature for hypothermia in neonates (<36.5° C). As per their training, when asked to identify EENC elements, a majority recalled skin-to-skin (100%), breastfeeding (91%), vitamin K administration (82%), cord clamping (64%), ophthalmic antibiotics (64%) and newborn assessments (55%). In addition, 82% (n=9) stated utilizing KMC and/or swaddling with blankets as treatment for hypothermia.

Per implementation leads at the School of Midwifery, midwives have been trained on EENC and KMC for the past several years. However, educators reported that since implementation of Kol Kilok, midwives have been carrying out this counseling more effectively with anecdotes of caregivers finally using the technique as counseled. This contrasts with anecdotes from previous years, when educators reported limited use of KMC in the community despite ongoing counseling from midwives.

F. 4.6 Effectiveness

Increased KMC

KMC diaries were introduced and developed by UNICEF (adopted from a version used in India) and given to newly enrolled caregivers of infants (i.e. both cases with devices and controls). KMC diaries consist of four sheets of colored paper with one sheet for each week enrolled in the study. Caregivers are counseled to keep an ongoing record of KMC provided each day (see Appendix 7). During weekly follow-up visits, caregivers review the weekly diary with their health provider (i.e. VHV in the community or nurses/clinicians in hospital/health facility settings). Measurements and total KMC are recorded by health providers on the diary page and submitted by VHV and research assistants for data collation. In addition, number of KMC alerts are also expected to be tallied, but none were found documented during data review.

In total, 483 KMC diaries were reviewed from POMGEN (49 cases, 51 controls), Goroka (144 cases, 55 controls), Henganofi (18 cases, 24 controls) and Komperi (95 cases, 47 controls). Overall, cases performed an average of 131.9 KMC (95% CL: 124.8-139.0) over the four weeks while controls performed an average of 70.5 (95% CL: 63.9-77.1), a statistically significant difference (p value <0.0001) (see Table 13).[o] In the first week, cases performed an average frequency of KMC of 33.8 (95% CL: 32.1-35.5) and controls performed a frequency of 18.0 (95% CL: 16.5-19.5) (p value < 0.0001). This increased to an average frequency of KMC of 37.4 (95% CL: 35.7-39.2) in cases in Week 4 and a frequency of 21.8 (95% CL: 20.1-23.4) KMC in controls (p value < 0.0001).

Kol Kilok users performed more total KMC compared to controls at all four sites (p value <0.05) (see Table 13, Table 14). When disaggregated by weekly KMC, Kol Kilok users consistently outperformed controls at three of the four facilities (i.e. POMGEN, Henganofi, Komperi [p value <0.05]). Cases performed more KMC compared to

[o] KMC diaries do not specify whether numbers recorded represent instances of KMC or hours of KMC (see *Discussion, Recommendations*)

controls at Goroka, however this was not statistically significant in select weeks (see Table 13). Overall, cases and controls at all sites gradually increased their average performance of KMC from Week 1 to Week 4 (statistically significant at POMGEN and Goroka) (see Table 13, Table 15).

A supplemental questionnaire was introduced during the evaluation addressing caregivers' average frequency of daily KMC and duration, as well as the ideal amount of daily KMC and duration they were taught to perform. Overall, caregivers performed an average of 3.8 KMC instances per day (n=19, range 1-6) while simultaneously stating an average of 5.5 instances were "ideal" (n=19, range 3-10) (see Table 16). Similarly, caregivers reported an average KMC duration of 48 minutes (n=19, range 5-120), but were taught to perform for nearly an hour (mean 58 minutes [n=18], range 30-120 minutes). Thus, only four caregivers performed their own ideal standard for KMC each day and only nine knew to perform KMC for at least sixty minutes. This questionnaire may demonstrate social desirability bias or recall bias, however, this may also occur during in person KMC diary completion. Furthermore, training materials only specify the duration of KMC (i.e. 1 hour), but vaguely encourage frequency "as many times as possible" (see Appendix 8). Thus, focus on knowledge and understanding of training, as well as differences in knowledge and practice, during follow-up visits would ensure appropriate and effective use of KMC. In addition, gaps in current KMC diary format could be amended to capture these short comings in practice.

Table 13: Case and Control Comparison of Average KMC per Week by Location

Location and Case Status		Week 1		Week 2		Week 3		Week 4	
		Mean KMC (95% CI)	P value	Mean KMC (95% CI)	P value	Mean KMC (95% CI)	P value	Mean KMC (95% CI)	P value
POMGEN*	**Case**	33.3 (29.9-36.7)	<0.0001	39.2 (35.3-43.1)	<0.0001	43.8 (39.0-48.5)	<0.0001	40.8 (33.5-48.1)	<0.0001
	Control	10.9 (8.4 - 13.4)		12.3 (9.4-15.3)		13.4 (9.7-17.0)		15.7 (9.8-21.7)	
Goroka	**Case**	22.4 (20.7-24.0)	0.0828	23.9 (22.1-25.6)	0.0244	26.1 (24.0-28.2)	0.0096	26.8 (24.7-29.0)	0.1128
	Control	19.4 (16.2-22.6)		20 (17.1-22.9)		20.7 (17.3-24.0)		23.1 (19.4-26.8)	
Henganofi*	**Case**	48.7 (41.9-55.5)	<0.0001	50.1 (43.9-56.2)	<0.0001	53.1 (48.6-57.6)	0.0494	53.4 (49.7-57.1)	<0.0001
	Control	24.1 (20.5-27.7)		24.7 (21.1-28.2)		34.5 (16.3-52.7)		26.3 (22.9-29.6)	
Komperi	**Case**	45.9 (44.8-47.0)	<0.0001	46.8 (45.9-47.7)	<0.0001	46.4 (45.4-47.4)	<0.0001	46.4 (45.4-47.4)	<0.0001
	Control	19.9 (18.0-21.7)		20.4 (18.7-22.1)		21 (19.2-22.8)		21.7 (19.8-23.6)	

*Data were not entirely normally distributed so t-test may not be the most appropriate test

Table 14: Case and Control Comparison of Total and Overall Average KMC by Location

Location and Case Status		Total (Sum of Week 1-4)†			Overall (Average of Week 1-4)†		
		Mean KMC	95% CI	P value	Mean KMC	95% CI	P value
POMGEN*	**Case**	133.1	116.0-150.2	<0.0001	38.6	34.9-42.2	<0.0001
	Control	42.6	31.1-54.0		12.6	9.7-15.4	
Goroka	**Case**	85.1	77.8-92.4	0.0022	24.4	22.8-25.9	0.0137

	Control	62.9	50.6-75.1		20.5	17.8-23.2	
Henganofi*	**Case**	199.3	172.4-226.3	<0.0001	50.2	44.0-56.4	<0.0001
	Control	109.5	88.7-130.4		27.4	22.2-32.6	
Komperi	**Case**	185.5	182.5-188.6	<0.0001	46.4	45.6-47.2	<0.0001
	Control	83	77.9-88.1		20.8	19.5-22.0	

†Includes both cases and controls

*Data were not entirely normally distributed so t-test may not be the most appropriate test

Table 15: Weekly Change in KMC Compared to Week 1

Location	**Week 2†**	**Week 3†**	**Week 4†**		**Total†**	
	KMC Change (95% CI)	**KMC Change (95% CI)**	**KMC Change (95% CI)**	**P value**	**KMC Change (95% CI)**	**P value**
POMGEN	4.2 (-0.2 - 8.5)	6.9 (2.4 - 11.5)	7.0 (1.8-12.2)	0.0089	2.6 (1.0 - 4.2)	0.0013
Goroka	1.3 (-1.0-3.5)	3.2 (0.9 -5.5)	4.5 (2.1- 6.8)	0.0009	1.5 (0.8 - 2.3)	<0.0001
Henganofi*	1.6 (-4.9 - 8.0)	6.7 (0.1 - 13.2)	3.9 (-2.6 - 10.5)	0.2098	1.7 (-0.4 - 3.8)	0.1054
Komperi	0.80 (-2.4 - 4.0)	0.8 (-2.4 - 3.9)	0.8 (-2.3 - 4.0)	0.9446	0.3 (-0.7 - 1.2)	0.6221

†Includes both cases and controls

*Data were not entirely normally distributed so t-test may not be the most appropriate test

Table 16: Ideal and Actual KMC Frequency and Duration per Caregivers

	KMC Frequency (Ideal)	**KMC Frequency (Actual)**	**KMC Duration (Ideal) (minutes)**	**KMC Duration (Actual) (minutes)**
Mean	5.5	3.8	58	48
Range	3-10	1-6	30-120	5-120

Weight Gain

Weight gain was higher amongst Kol Kilok users compared to controls. Henganofi Health Center did not have recorded admission weights, however, amongst the other sites, cases using Kol Kilok weighed on average 2,380g (95% CL 2,285-2,474g) on admission to facilities, compared to controls with an average weight of 2,467g (95% CL 2,334-2,599g) (see Figure 7, Table 17). By Week 4, cases weighed an average of 3,579g (95% CL 3,476-3,782g) and controls an average of 3,412 (95% CL 3,476-3,682g). Cases, therefore, increased by an average of 1,122g (95% CL 1066-1178g), compared to controls with an average weight gain of 653g in (95% CL 553-752g) (p value <0.0001) (see Table 18).

Figure 7: Average Weight Gain by Kol Kilok Users and Controls per Week

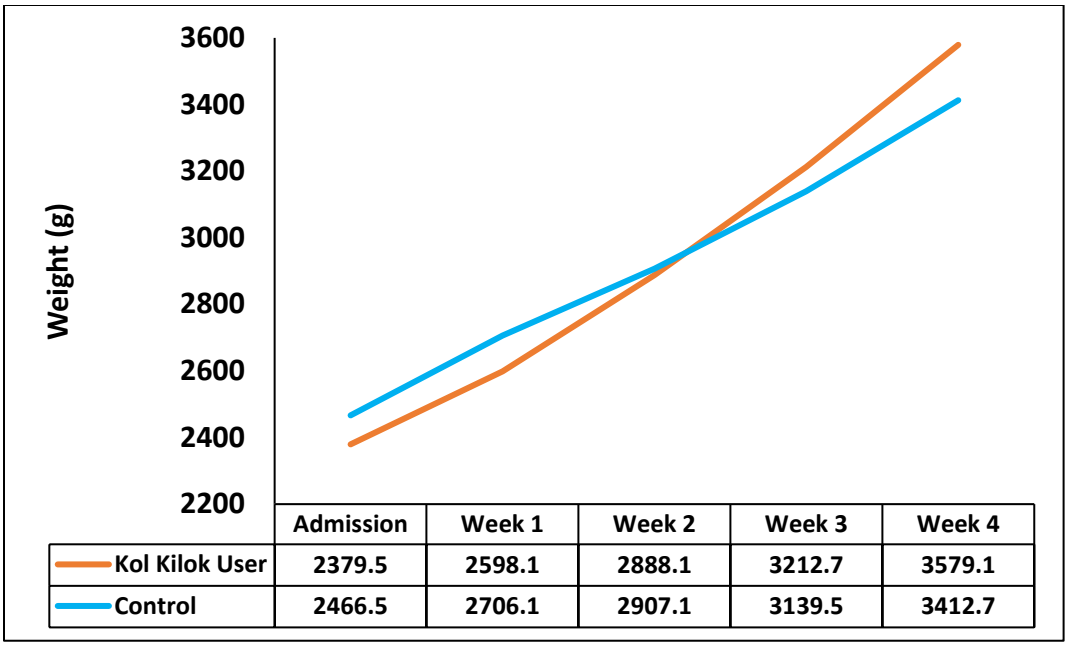


Table 17: Average Weight at Health Facilities by Kol Kilok Users and Controls per Week

Location and Case Status		Admission		Week 1		Week 2		Week 3		Week 4	
		Average Weight (g) (95% CI)	P Value	Average Weight (g) (95% CI)	P Value	Average Weight (g) (95% CI)	P Value	Average Weight (g) (95% CI)	P Value	Average Weight (g) (95% CI)	P Value
POMGEN	**Case**	1677 (1553-1801)	0.1611	1744 (1575-1914)	0.3019	1923 (1733-2113)	0.9692	2239 (2068-2409)	0.4193	2442 (2117-2706)	0.0219
	Control	1797 (1679-1915)		1853 (1730-1976)		1927 (1776-2079)		2131 (1923-2339)		2058 (1855-2262)	
Goroka	**Case**	2466 (2084-2848)	0.2944	2394 (2277-2412)	0.4500	2686 (2553-2819)	0.6061	3046 (2906-3186)	0.2609	3399 (3245-3552)	0.3423
	Control	2250.4 (2115-2386)		2313 (2132-2493)		2618 (2390-2846)		2877 (2610-3143)		3216 (2862-3571)	
Komperi	**Case**	2980 (2921-3040)	<0.0001	3137 (3052-3223)	0.0027	3437 (3343-3532)	0.108	3745 (3646-3844)	0.5155	4062 (3962-4162)	0.6079
	Control	3446 (3298-3595)		3407 (3255-3558)		3590 (3427-3752)		3807 (3644-3970)		4008 (3826-4191)	
Henganofi	**Case**	NA	NA	3039 (2846-3232)	0.0013	3333 (3174-3492)	0.1257	3488 (3299-3678)	0.2922	3682 (3445-3920)	0.8921

	Control	NA		3510 (3300-3721)		3550 (3332-3768)		3635 (3419-3852)		3660 (3422-3899)	
Total	**Case**	2379.5 (2285-2474)	0.2927	2598.1 (2511-2686)	0.1694	2888.1 (2792-2984)	0.824	3212.7 (3116-3309)	0.4022	3579.1 (3476-3682)	0.0862
	Control	2466.5 (2334-2599)		2706.1 (2571-2842)		2907.8 (2763-3053)		3139.5 (2987-3292)		3412.7 (3239-3586)	

Table 18: Average Weight Change in Kol Kilok Users and Controls by Health Facility

Location and Case Status		**Weight Change from Admission to Week 4† (g) (95% CI)**	**P Value**	**Weight Change from Week 1 to Week 4* (g) (95% CI)**	**P Value**
POMGEN	**Case**	925 (747-1103)	<0.0001	-	-
	Control	382 (233-532)		-	
Goroka	**Case**	1206 (1115-1298)	0.0632	-	-
	Control	1007 (783-1231.8)		-	
Komperi	**Case**	1085 (1016-1155)	<0.0001	-	-
	Control	562 (453-671)		-	
Henganofi	**Case**	-	-	653 (456-850)	<0.0001
	Control	-		150 (49-252)	
Total	**Case**	1122 (1066-1179)	<0.0001	1090 (1034-1145)	<0.0001
	Control	653 (553-752)		552 (463-642)	

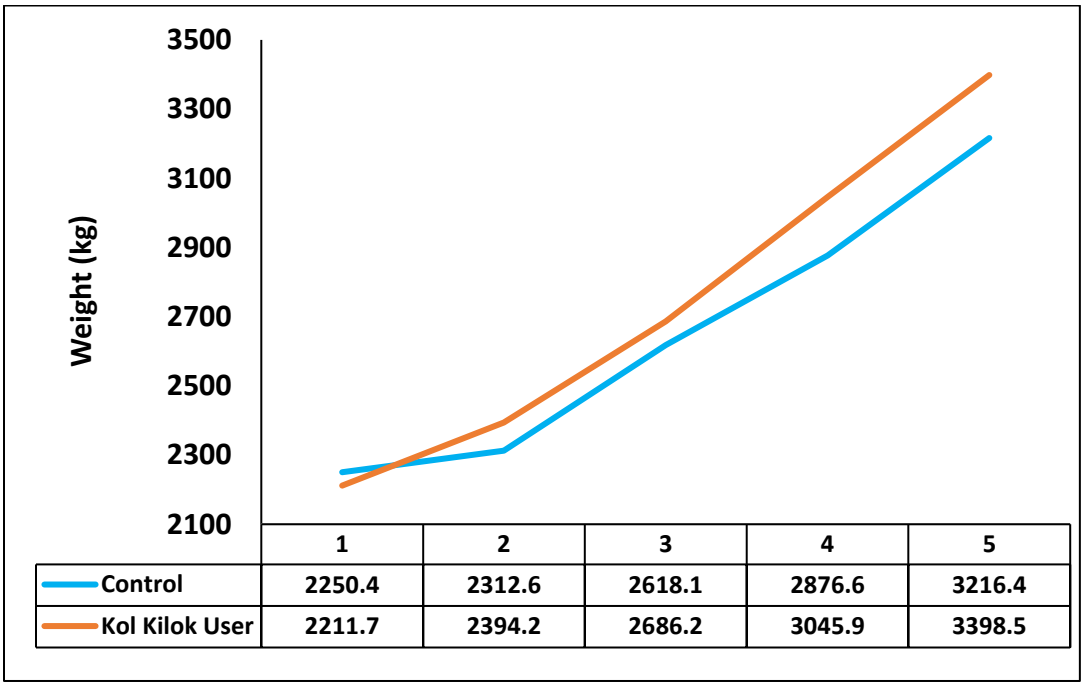
†Henganofi was missing data on "admission weight" and was therefore excluded from this column's analysis

*A separate analysis was conducted using Week 1 as a baseline. The totals in this column therefore include Henganofi

In contrast to other sites, KMC diary data from Goroka demonstrated that Kol Kilok users had approximately similar rates of weight gain as the controls (see Figure 8). Average admission weight amongst Kol Kilok users at Goroka was 2,212g (95% CL 2,066-2,358), compared to controls with an average of 2,250g (95% CL 2,115-2,386) (p value =0.6999). On discharge (Week 4), Kol Kilok users were on average 3,405g (95% CL: 3,251-3,560), compared to controls with an average weight of 3,216g (95% CL 2,862-3,571) (p value =0.2892). Overall, Kol Kilok users increased their weight by 1,206g (95% CL: 1,115-1,298) compared to 1,007g (95% CL: 783-1,232) amongst controls from admission to week 4. This demonstrates a higher weight gain amongst Kol Kilok users, but was not statistically significant (p value =0.0632).

As discussed, on average, Goroka Kol Kilok users had higher KMC than controls, but this was not statistically significant for certain weeks. In addition, Kol Kilok users at Goroka with training on the device consistently had less accurate responses to questions on the device compared to non trained users. This may correlate with the non-significant findings on weight gain at Goroka, and standardization of counseling with routine knowledge checklists may ensure uniformity across sites.

Figure 8: Weight Gain by Week in Kol Kilok Users and Controls at Goroka Hospital



	1	2	3	4	5
Control	2250.4	2312.6	2618.1	2876.6	3216.4
Kol Kilok User	2211.7	2394.2	2686.2	3045.9	3398.5

POMGEN Kol Kilok users who spent time in the hospital during the initial sensitivity and specificity trial also had the number of Kol Kilok alerts record in their charts.[p] Comparing KMC Diary data (i.e. number of KMC) to alerts recorded during the study period, 81% of Kol Kilok users performed more KMC than the number of recorded device alerts (see Table 20).[q] Of these, average weight gain from Week 1 to Week 2 to was 153.9g (95% CL: 103.4-204.3), compared to those without adequate KMC (i.e. more alerts than KMC in Week 1) with an average weight gain of 153.2g (95% CL: 48.3-258.1) (p value =0.9912). Additional hospital data (i.e. number of alerts) beyond Week 1 was limited and further analysis of KMC response to alerts and weight gain could not be conducted. It is possible that lower birth weight infants (<1,500g) received less KMC due to ward restrictions, as critically ill neonates at POMGEN are not routine given KMC, but instead are managed by nurses with radiant warmers.

Table 20: Weekly Weight Change in Kol Kilok Users with Adequate Response to Alerts

Adequacy of KMC (KMC > alerts)*	Week 1		Week 2	
	Mean Weight Change (g) (95% CI)	P value	Mean Weight Change (g) (95% CI)	P value
Adequate	1747.8 (1633.2-1862.4	0.1817	1884.6 (1751.5-2017.7)	0.2437

[p] Alerts were recorded every 6 hours and may not include alerts that occurred between recording times. Therefore, this estimate may under represent the true number of alerts per day

[q] In order to compare hospital chart data with Week 1 KMC diary data, this calculation only includes those who were hospitalized for six days or more (n=79)

Inadequate	1361.5 (767.2-1955.8)		1514.7 (856.3-2173.1)	

*Adequate frequency of KMC refers to Kol Kilok users who had more KMC in the respective week compared to number of alerts documented.

Reduction in Hypothermia

In total, 1,472 charts (1,234 at POMGEN, 238 at Goroka) were reviewed between the two hospitals with data extracted on neonatal temperatures both before and after Kol Kilok's implementation at each site. In POMGEN, percentage of temperature readings indicating hypothermia decreased from 52% (n=421/816) before Kol Kilok (January 2017 to March 2017) to 40% (n=839/2087) after the intervention (April 2017 to December 2017). However, average temperature of neonates was relatively unchanged with mean temperature of 36.5° C prior to Kol Kilok compared to 36.6° C after implementation. Furthermore, when disaggregated by Kol Kilok users and controls, there was no apparent difference in percentage of hypothermic temperatures (i.e. 40% in Kol Kilok users [n=1,140] vs. 38% in controls [n=1,016] from August to November 2017).

In Goroka, the percentage of all temperature readings indicating hypothermia (<36.5° C) decreased following the introduction of Kol Kilok from 21.3% of all temperature readings (n=324/1,521; January 2017 to June 2017) to 17.5% (n=438/2,501; July 2017 to December 2017). However, similar to POMGEN, data showed relatively no difference in mean neonatal temperature (i.e. 36.7° C prior and 36.8° C after the intervention). Due to a lack of consistent unique identifiers, data could not be disaggregated by Kol Kilok users and controls at Goroka.

Our data does not correlate the reduction in hypothermic temperatures with the introduction of Kol Kilok to select neonates, as the reduction in temperatures occurred both in cases and controls. It is unlikely hypothermia rates decreased due to environmental temperature changes, as meteorological data suggests relatively similar temperatures for both time periods (i.e. before and after implementation in their respective areas).[32] It is possible the implementation of Kol Kilok has had spillover effects into controls. Healthcare workers with additional training on hypothermia and EENC would be treating both cases and controls. Furthermore, caregivers and mothers who denied direct training on Kol Kilok still were able to report accurate descriptions of KMC, sometimes at higher percentages than those with training at select sites.[r] This could lead to additional weight gain and therefore adequate brown fat for thermoregulation. Finally, it is possible an unobserved confounder could be affecting the frequency and mean of neonatal temperatures during each of these time periods.

Understanding and use of Bebi Kol Kilok device through Counseling and Training of Caregivers

Kol Kilok users reported almost universally receiving training on their devices. Overall, 93% (n=125) reported receiving counseling on the device with topics including KMC (89%) and hypothermia (70%). However, training specific to the meaning of device's lights, guidance on continued alarms and KMC diaries was less frequently described (see Table 21). When further divided by location, training topics varied even more widely. At Goroka Hospital and the community settings 80% and 83% reported training on the meaning of the device's blue light and 80% and 91% on the meaning of the orange light, respectively. However, in POMGEN, only 44% of caregivers (n=21/48) reported training on the meaning of the blue light and 50% (n=24/48) on the orange light. Similarly, only 42% of caregivers at POMGEN reported training on what to do with continued alarms despite KMC. Both hospitals (i.e. POMGEN and Goroka) also had low levels of reported training on completing KMC diaries (23% at POMGEN, 30% at Goroka; compared to 64% in the communities).

[r] Of note, it is difficult to ensure that a caregiver's recall of having received training or not is accurate. This was subjective and has the potential for recall bias amongst both those with reported training and without

Table 21: Counseling Topics per Kol Kilok Users (Weighted) by Location

	Eastern Highlands (Community) (n=77)	95% Confidence Interval	Goroka Hospital (n=10)	95% Confidence Interval	POMGEN (n=48)	95% Confidence Interval	Overall (all interviews) (%, n)
Received Any Training	96% (n=74)	92-100%	90% (n=9)	71 -100%	88% (n=42)	78-97%	93% (n=125/135)
Kol Kilok	83% (n=64)	75-92%	90% (n=8)	55-100%	63% (n=30)	49-76%	82% (n=102/135)
Blue Light	83% (n=64)	75-92%	80% (n=8)	55-100%	44% (n=21)	30-58%	74% (n=93/135)
Orange Light	91% (n=70)	84-97%	80% (n=8)	55-100%	50% (n=24)	36-64%	82% (n=102/135)
Continued Alarms	88% (n=68)	81-96%	80% (n=8)	55-100%	42% (n=20)	28-56%	77% (n=96/135)
KMC	94% (n=65	76-93%	80% (n=8)	55-100%	79% (n=38)	68-91%	89% (n=111/135)
KMC Diaries	64% (n=49)	53-75%	30% (n=3)	1-59%	23% (n=11)	11-35%	50% (n=63/135)
Breastfeeding	52% (n=40)	41-63%	10% (n=1)	0-29 %	23% (n=11)	11-35%	39% (n=52/135)

Knowledge and Practices of Caregivers

Overall, 96% of Kol Kilok users correctly identified the meaning of the blue light on the device and 90% correctly identified the meaning of the orange light. For continued alarms after KMC, 76% (n=102) could correctly identify that the child should be brought to the hospital.[s] Mothers also were asked to perform or describe how they would routinely provide KMC. Of those with full descriptions (n=98), 48% (n=47) were described correctly, 7% (n=7) incorrectly and 45% (n=44) were deemed partially correct.[t] Of these partially correct responses, 24 did not specifically mention skin-to-skin contact between the mother and child, 21 did not mention wrapping the child in a blanket and 3 did not mention specifically placing the child in the correct area on the mother's chest.[u]

Generally, caregivers who received training on Kol Kilok were more likely to give correct answers regarding its use (see Table 22). When divided by level of training and location, community-based caregivers with training had overall higher percentages of correct answers compared to those without training (see Table 22). Similarly, caregivers at POMGEN who received training had higher overall percentages of correct answers than those without training (see Table 22).[v] By contrast, Kol Kilok users with training at Goroka Hospital did worse on questions compared to those without training. Only 50% of Kol Kilok users with training at Goroka could accurately describe the response to a blue light, 43% accurately described KMC and 25% accurately described actions to be taken during continued device alarms (i.e. compared to 100%, 50% and 50% in non-trained users,

[s] Of note, ten could "not remember" the correct response to a continued alarm after KMC (i.e. presenting to a health facility). Others mentioned continuing to provide KMC instead of brining the child to the hospital and one reported they would "remove [the] baby's clothes to reduce temperature"

[t] 38 interviews with caregivers did not have an adequate description of the process for analysis

[u] KMC has three essential steps including 1) skin-to-skin contact, 2) placement of child between breasts and 3) wrapping of KMC blanket around caregiver and child. Descriptions were designated partially correct if one of these essential steps were not described (e.g. failing to mention direct skin-to-skin contact, failing to mention the placement of the infant between breasts). This does not reflect an incorrect response, and could be representative of short hand used during interviews. However, this remains an area for further counseling to ensure all essential steps are taken during KMC

[v] The only question where users without training at POMGEN had higher percentages of correct answers was on how to perform KMC (see Table 22). While almost all respondents with training could at least partially explain how to perform KMC, only 31% of those at POMGEN with training could correctly identify each step (n=11/35)

respectively). This could be due to a lack of standardization of training across sites, or may reflect the adequacy of VHV and healthcare worker counseling at the sites with better training. In addition, recall bias on the part of caregivers could also introduce these findings (e.g. unable to recall if they had training or certain training topics).

Most Kol Kilok users reported keeping the device on at all times (86%). Of those that did not (n=19), 14 reported taking of the device during bathing, one while removing clothing, one due to the device fitting too tightly and one due to incubator use in the hospital.[w] When bathing the child, 91% (n=123) noted keeping, or attempting to keep, the device dry. The remaining 9% (n=12) indicated they kept the device dry in other ways (i.e. nine noted taking off the device). Thus, no users reported intentionally getting the device wet during bathing, however, these responses mean 25 users (19%) reported taking off the device at some point (i.e. when combining questions on device removal and bathing techniques).

Table 22: Accuracy of Question Responses (Weighted) based on Training Level and Location

Location and State of Training (%, n, 95% CI)	EHP with Training	EHP without Training	Goroka Hospital with Training	Goroka Hospital without Training	POMGEN with Training	POMGEN without training	Overall with Training	Overall without Training
How to Respond to a Blue Light	86% (n=55/64) (77-95%) [64/64 partially or entirely correct]	77% (n=10/13) (54-100%) [11/13 partially or entirely correct]	50% (n=4/8) (8-92%) [7/8 partially or entirely correct]	100% (n=2/2) (100-100%)	71% (n=15/21) (51-92%) [21/21 partially or entirely correct]	63% (n=17/27) (44-82%) [24/27 partially or entirely correct]	80% correct (19% partially correct)	66% correct (19% partially correct)
How to Respond to an Orange Light	91% (n=64/70) (85-98%) [68/70 partially or entirely correct]	86% (n=6/7) (59-100%) [6/7 partially or entirely correct]	100% (n=8/8) (100-100%)	100% (n=2/2) (100-100%)	92% (n=22/24) (80-100%) [23/24 partially or entirely correct]	83% (n=20/24) (68-99%) [22/24 partially or entirely correct]	92% correct (5% partially correct)	85% correct (6% partially correct)
How to Respond to a Continued Kol Kilok Alarm after KMC	90% (n=61/68) (82-97%)	44% (n=4/9) (11-78%)	25% (n=2/8) (0-62%)	50% (n=1/2) (0-100%)	80% (n=16/20) (62-98%)	64% (n=18/28) (46-83%)	82% correct	59% correct
How to Perform KMC	76% (n=25/33) (61-91%) [32/33 partially or entirely correct]	33% (n=3/9) (22-89%) [8/9 partially or entirely correct]	43% (n=3/7) (0-89%) [7/7 partially or entirely correct]	50% (n=1/2) (0-100%) [2/2 partially or entirely correct]	31% (n=11/35) (15-47%) [34/35 partially or entirely correct]	40% (n=4/10) (8-72%) [7/10 partially or entirely correct]	52% correct (45% partially correct)	38% correct (43% partially correct)

Perceptions of Access and Quality of Healthcare

[w] Removal time for devices were mostly <15 minutes (n=13) though four respondents could not identify how long the device had been off and one noted the device had been off for at least one day

Among the interviewed caregivers, 62% (n=88) provided specific perceptions and suggestions to improve access to healthcare (see Table 23). The majority mentioned improved access to transportation (73%), followed by supplies (43%), human resource/additional provider (41%) and family/social support (20%). There were some variations between the Eastern Highlands Province and Port Moresby – in EHP, transportation was more frequently mentioned as a barrier to care (78%), while in POMGEN more than half of caregivers (56%) reported issues with human resources or lack of additional providers.

Also, among the interviewed health workers, 88% (n=46) provided specific perceptions and suggestions to improve access to healthcare in their area (see Table 24). Most commonly, healthcare workers suggested changes to human resources/additional providers (52%) and transportation (48%). There were variations between EHP and Port Moresby – in EHP transportation was more frequently mentioned (59%), while in POMGEN, more than half (57%) reported issues with human resources or additional providers. This pattern was somewhat similar to the response from caregivers.

In regards to quality of healthcare, similarly, two-thirds of caregivers (65%, n=92) reported specific perceptions and suggestions for improvement (see Table 25). Caregiver open-ended answers were categorized in reference to the characteristics of quality of care per WHO's concept and characteristics of Quality of Care – "effective, efficient, accessible, acceptable/patient centered, equitable and safe."[33] Overall, each of the characteristics were mentioned by caregivers as issues with their quality of healthcare: safety (40%), effectiveness (34%), accessibility/timeliness (41%), efficiency (40%), equity (38%) and respect (41%). Some differences were observed between EHP and Port Moresby – in EHP, almost half of caregivers mentioned equity (48%) followed by safety (44%), timeliness (43%) and respect (43%). Alternatively, in POMGEN, almost half reported effectiveness (45%), followed by efficiency (42%), timeliness (39%) and respect (39%).

Similarly, the majority of health workers (83%, n=43) reported specific perceptions and suggestions for improvement (see Table 26). Open-ended answers were categorized based on the aforementioned six characteristics of quality of care (WHO 2006). The pattern, however, was different from that of caregivers – almost half suggested improving the effectiveness (48%) of their healthcare while only 15% suggested improvements in equity. Differences between EHP and Port Moresby were not notable – in EHP, improvements to healthcare effectiveness (43%), accessibility/timeliness (40%) and efficiency (40%) were more frequently suggested. In POMGEN, almost half reported effectiveness (45%) and efficiency (46%) as areas for improvement, while timeliness was mentioned far less often (8%).

Table 23: Perceptions and Suggestions on Access to Healthcare among Caregivers

Location	Human Resource/ Additional provider	Transportation	Supplies	Family and social support	Other
Goroka (n=54)	31% (n=17)	78% (n=42)	56% (n=30)	17% (n=9)	20% (n=11)
POMGEN (n=34)	56% (n=19)	65% (n=22)	24% (n=8)	26% (n=9)	26% (n=9)
Total (n=88)	41% (n=36)	73% (n=64)	43% (n=38)	20% (n=18)	23% (n=20)

Note: Of the respondents, 53 caregivers did not respond or mention specific suggestions and were excluded from the frequency (Goroka n=33, POMGEN n=20).

Table 24: Perceptions and Suggestions on Access to Healthcare among Health Workers

Location	Human Resource/ Additional provider	Transportation	Supplies	Family and social support	Other
Goroka (n=32)	47% (n=15)	59% (n=19)	34% (n=11)	16% (n=5)	50% (n=16)
POMGEN (n=14)	57% (n=8)	14% (n=2)	0% (n=0)	7% (n=1)	79% (n=11)
Total (n=46)	52% (n=23)	48% (n=21)	25% (n=11)	14% (n=6)	61% (n=27)

Note: Of the respondents, 6 health workers did not respond or mention specific suggestions and were excluded from the frequency (Goroka n=4, POMGEN n=2).

Table 25: Perceptions and Suggestions on Quality of Healthcare among Caregivers

Location	Safety	Effectiveness	Accessibility/ timeliness	Efficiency	Equity	People-centered/ respect	Other
Goroka (n=54)	44% (n=24)	34% (n=31)	41% (n=38)	40% (n=37)	38% (n=35)	41% (n=38)	24% (n=22)
POMGEN (n=38)	34% (n=13)	26% (n=14)	43% (n=23)	39% (n=21)	48% (n=26)	43% (n=23)	19% (n=10)
Total (n=92)	40% (n=37)	45% (n=17)	39% (n=15)	42% (n=16)	24% (n=9)	39% (n=15)	32% (n=12)

Note: Of the respondents, 49 caregivers did not respond or mention specific suggestions and were excluded from the frequency (Goroka n=33, POMGEN n=16).

Table 26: Perceptions and Suggestions on Quality of Healthcare among Health Workers

Location	Safety	Effectiveness	Accessibility/ timeliness	Efficiency	Equity	People-centered/ respect	Other
Goroka (n=30)	43% (n=13)	43% (n=13)	47% (n=14)	43% (n=13)	17% (n=5)	33% (n=10)	30% (n=9)
POMGEN (n=13)	8% (n=1)	54% (n=7)	8% (n=1)	46% (n=6)	8% (n=1)	23% (n=3)	92% (n=12)
Total (n=43)	34% (n=14)	49% (n=20)	37% (n=15)	46% (n=19)	15% (n=6)	31% (n=13)	51% (n=21)

Note: Of the respondents, 9 health workers did not respond or mention specific suggestions and were excluded from the frequency (Goroka n=6, POMGEN n=3).

Knowledge, Attitudes and Practices among Non Kol Kilok Users

A total of ten caregivers were interviewed in the catchment of health centers in Eastern Highland province (over two separate Focus Group Discussions) and seven in POMGEN (over two separate FGDs). In addition, two FGDs were held with approximately forty mothers in the community setting (i.e. Saviza village) in EHP. Overall knowledge, attitudes and practices concerning the prevention and management of hypothermia among the non device users were found to be relatively lower or less accurate than the users. However, some reported

awareness and positive experience of Kangaroo Mother Care as a spillover in the both intervention sites (see Appendix 8 for FGD questions).[x]

Attitudes on newborn health and sickness of their own babies: The majority of caregivers considered their baby as healthy. In POMGEN, all interviewed mothers/caregivers who had LBW babies (less than 2,000g) described their babies as "a bit tiny" or "healthy". Of note, per one implementation lead, this may reflect the traditional, local cutoff point of less than 2,000g as LBW.

> *"Yes [my baby is] healthy."* (Majority of caregivers in the both sites, in response to the introductory interview question: *"Would you consider your baby/child healthy?"*)
> *"A bit worry [about my baby's health] as my baby is tiny."* (POMGEN)
> *"My babies are well."* (Mother of twin LBW babies less than 2,000g, POMGEN)

Knowledge and attitudes on general newborn health, sickness and hypothermia: In Goroka, while the increasing use of postnatal care at health centers were reported, the perceived risk of hypothermia was low and that a cold baby was recognized as "normal in the cold environment." In contrast, fever was described as a "cause of sickness." Similarly, the perceived risk of LBW baby was observed as low, notably in POMGEN per the above quotes, and awareness and knowledge on hypothermia were also limited.

> *"Fever is a cause of sickness, but cold baby is normal in the cold environment."* (Eastern Highland Province)
> *"Cold baby/hypothermia is a new idea/knowledge."* (Eastern Highland Province)
> *"I do not know [about hypothermia/cold baby]."* (Postnatal ward, POMGEN)
> *"I have not heard about it [i.e. hypothermia/cold baby]."* (Postnatal ward, POMGEN)
> *"No info/counseling received [about hypothermia]."* (Postnatal ward, POMGEN)

Knowledge, attitudes and practice on KMC and skin-to-skin: These were reported as increasing in the both sites, although variations were observed across wards in POMGEN. Positive experiences and attitudes towards KMC were commonly reported in the both sites, such as physical and emotional benefits for babies and mothers/caregivers (e.g. growth, bonding between mothers and babies, emotional benefits). Spillover effects of KMC practice were reported in the Neonatal Intensive Care Unit (NICU), where non-device users reported observing, learning and attempting KMC with reportedly positive experiences. However, the understanding of each individual practice – KMC and skin-to-skin – was not evident. Mothers reported "no difference" between the two concepts of KMC and skin-to-skin, and described them in the same term in the local language of Pidgin English creole. In addition, in POMGEN variations of each practice were observed in several wards (i.e. NICU, the postnatal ward).

> *"I do not know/heard about it [KMC]."* (Postnatal ward, POMGEN)
> *"No info/counseling received [about KMC]."* (Postnatal ward, POMGEN)
> *"My last baby [who received KMC] is healthier than the second last born [who did not receive KMC]."* (Eastern Highland Province)
> *"Babies [who received KMC] grow quick and gain weight."* (Eastern Highland Province)
> *"I am happy to put my baby on the chest and see the baby growing."* (Eastern Highland Province)
> *"[KMC and skin-to-skin are] the same for sick newborn and healthy baby."* (Eastern Highland Province)
> *"I saw other mothers doing KMC [while staying at the Neonatal Intensive Care Unit] and I also attempted. I felt nice expressing my love to my baby. My baby also feels comfortable."* (NICU, POMGEN)

[x] FGDs were recorded with a voice recorder, yet transcripts, translations and final reports by field note takers were not shared with the study leads, resulting in FGD data entirely consisting of draft field notes (see *4.9 Results Limitations*)

Attitudes and practice of early initiation of breastfeeding: Early initiation of breastfeeding was reportedly limited at both hospital sites. In Goroka, it was common practice for babies delivered at night to normally receive their first breastfeeding the following morning. This was cited as a common practice to prioritize a mother's recovery and rest. In POMGEN, various disabling factors were reported as a barrier to early initiation of breastfeeding such as lactation problems, separations of mothers from babies, relevant restrictions in the hospital setting, and limited counseling during ANC. Of note, regulated and limited entry to NICUs was also reported during the caregiver interview, per the hospital policy both in the national and provincial hospitals (i.e. POMGEN and Goroka).

> *"If delivered at night, the baby receives the first breastfeeding the following morning for mothers to recover first [as a common practice]."* (Eastern Highland Province)
> *"My baby was taken to nursery and I gave my first breastfeeding 28h after delivery."* (POMGEN)
> *"I was not allowed to enter [nursery]."* (POMGEN)
> *"I had problems with lactation/nipples."* (POMGEN)
> *"I did not receive counseling/advice on breastfeeding during antenatal visits."* (POMGEN)

Perceptions and opinions of VHVs and community support for newborn care: Overall, FGD caregivers described mixed perceptions and opinions concerning community support. However, in EHP in particular, VHVs were highly recognized for their role and activities in the community. Increasing use of postnatal care was reported in the EHP community in general, and the contributions of VHV's counseling and KMC kit distribution (i.e. procured through TTU) were explicitly acknowledged by caregivers. In addition to VHV's current activities, some caregivers requested expanding VHV functions, such as training them to become birth attendants at community birth centers due to the distance from existing health centers.

> *"[Several caregivers mentioned that] VHVs taught us on how to take care of babies and they are helpful. We trust them."* (Eastern Highland Province)
> *"We received KMC kit and liked it."* (Eastern Highland Province)
> *"We want them to provide more services in the community, like birth assistance at birth centers, as HCs are far."* (Eastern Highland Province)

Perceptions and opinions of husbands' and family support for newborn care: Perceptions of husband and family support were mixed at the both hospital sites. Husbands' engagement and support were considered enabling by some caregivers, while others reported their husbands had been antagonistic to their childcare. Some caregivers reported husbands complained about mothers' increased time and attention to babies while providing KMC, restricted to accessing health care for a child, denied providing mothers with needed funding, or enacted "penalties" – which are understood as violence in the local context according to the local facilitators – when taking a child to health facility.

> *"They [husbands] are supportive for KMC."* (Eastern Highland Province)
> *"Some husbands complain that mothers [who provide KMC] take more time and pay attention to babies."* (Eastern Highland Province)
> *"Family support is needed for seeking facility care."* (POMGEN)
> *"Some husbands/families do not support mothers to take a child to clinic. Some husbands/breadwinners even give penalties [if taking a child to clinic]."* (POMGEN)

Perceptions and opinions of access and quality of care for mothers and babies: A number of enabling and disabling factors were reported regarding the access and quality of care for mothers and babies. In both Port Moresby and EHP, geographic barriers and transportation issues were commonly reported as a major challenge

to accessing healthcare (i.e. per the quotes above and below). In EHP, VHVs were well recognized and trusted by caregivers, with some mothers reporting trust in VHVs, rather than health facility staff. In POMGEN, mothers highlighted their dependency on husband and family support for accessing healthcare. Of note, perceptions and suggestions on access and quality of care showed similar patterns among the Kol Kilok device users and non-users. At the both sites, the perceived quality of care was mixed. Overall, both caregiver interview and FGDs highlighted requests for more respectful and friendly services to mothers, in particular among young, expectant mothers. It should be noted that four of six FGDs were held in health facilities, which might have prevented frank discussions on this topic.

> *"Transport is a challenge [in accessing care]."* (POMGEN)
> *"Bus fare is a problem."* (POMGEN)
> *"I have no bus fare."* (POMGEN)
> *"[The quality of care is] OK."* (POMGEN)
> *"It is timely [in NICU]."* (POMGEN)
> *"No [and silence, to the interview question about quality of care at health center, after probing on friendliness and respect]."* (Eastern Highland Province)
> *"[Some caregivers mentioned that] we do not go there [i.e. the health center] because we hear negative experience."* (Eastern Highland Province)

Mortality Rate and Verbal Autopsies

In POMGEN neonatal registers, 22% (n=260/1182) of infants with a documented outcome died from January 2016 to February 2018.[y] Prior to Kol Kilok, 30% (n=141/464) of neonates with outcome data died during the evaluation period, compared to 17% (n=119/718) after implementation of the device. However, no data were available to delineate mortality in Kol Kilok users compared to controls.[z] In Goroka, 12% (n=114/969) of neonates with outcome data died from January 2017 to December 2017. Of those in Goroka with data from the Kol Kilok program, 8% (n=11/144) of registered Kol Kilok users and 15% (n=8/54) controls died during their enrollment, with one control dying one week after discharging from the study. However, these differences were not statistically significant (p value =0.1268). At both sites, limited register data were available to ascertain cause of death which limited further analysis on casual factors for changes in mortality.

Verbal autopsies were conducted with caregivers of three caregivers at POMGEN and four in Eastern Highlands Province.[aa] Most infants who died were premature (57.1%, n=4/7) with an average birth weight of 1678g (median 1630g, range 1200 to 2200g). Two infants (28.6%, n=2/7) were noted to have congenital abnormalities at birth, though no specific details on the abnormalities were provided, and three mothers (42.9%, n=3/7) reported complications during labor. Two caregivers had the neonate's death certificate available for review. One infant was listed as dying from "prematurity & low birth weight" and the other infant from "Aspirated [sic] Pneumonia." All but one of those interviewed were Kol Kilok users (n=5/6). Two mothers recalled their device alarmed prior to the infants' death with one mother reporting the device alarmed for four hours prior to the infant's death (of note, the mother reported this infant did not feel cold to touch and did not receive treatment prior to death).

[y] Register data did not delineate when neonates died and it was not possible to differentiate deaths at birth, during hospitalization or upon return to facilities after discharge
[z] POMEGN Kol Kilok and control mortality could not be calculated due to a lack of unique identifiers to connect POMGEN register data with KMC diary information
[aa] Multiple verbal autopsy interviews could not be conducted due to lack of follow-up, inability to find caregivers, or refusal by the caregiver or family members. In addition, two verbal autopsies were interrupted, with only one completed at another date (i.e. the other could not be completed due to a violent family member)

Limited data on causes of death, a lack of consistent identifiers for cases and controls, and the inability to conduct adequate verbal autopsies limited analysis on mortality in neonates seen at implementation sites or enrolled in the Kol Kilok study. Due to the methodology employed for this evaluation study, additional analysis on the direct contribution of the Kol Kilok program to newborn mortality reduction, or the causal link between the intervention and newborn mortality, could not be assessed.

G. 4.7 Coordination

Monitoring, Evaluation, Data Management and Quality Assurance Mechanisms

Kol Kilok data are regularly recorded in paper-based KMC diaries which are sent to TTU and Goroka Hospital for collation. These data are collated in Microsoft Excel for future analyses, however, several limitations exist due to poor data management. First, unique identifiers are inconsistently recorded on the Kol Kilok dataset. In addition, unique identifiers are not provided to health facilities in order to routinely link KMC diary data to facility chart and register data. Similarly, health facilities do not routinely upload chart and register data into electronic formats, and analysis alongside Kol Kilok data is not possible for additional studies or routine monitoring.

Second, KMC diaries do not record the number of Kol Kilok alerts and therefore this data are not recorded in the electronic dataset. Third, neonatal weight is not always recorded on the day a device is received, and the date of discharge on KMC diaries does not always differentiate discharge from a health facility and discharge from the Kol Kilok program.

Fourth, the number of KMC on diaries does not differentiate between instances of KMC and duration of KMC (e.g. if KMC is listed as “five” for one day, it is unclear if this reflects five instances of KMC or five hours). Finally, numerical data and categorical data are recorded simultaneously in the dataset, increasing the need for data cleaning and limiting frequent analyses (e.g. recording “Weight” as “2.7kg” instead of “Weight (kg)” and “2.7” for ease of analysis).

Finally, the Kol Kilok program routinely collects data from KMC diaries on users’ weight, head circumference and length, and enters these data into electronic systems (i.e. Excel). Currently, EENC reports are not captured by routine HMIS reports. Thus, this data could contribute to public health surveillance in implemented areas with some augmentations. In addition, the network used for routine data collection (i.e. VHV) could be used for other surveys or measurements of public health practices.

H. 4.8 Impact

Social

Caregivers overwhelmingly had positive responses to the Kol Kilok program. In particular, some caregivers reported increased bonding with their neonates. In addition, 61% (n=80) of caregivers reported male involvement in the neonate’s care (e.g. father, uncle, brother). This differs from reports from implementation leads, who reported male involvement in childcare was infrequent in areas of PNG. This may reflect a shift in perceived gender roles or behaviors. In addition, increased family assistance has a potential to allow mothers increased time away from direct childcare for other opportunities. This contrasts with focus group discussions with non users, with several caregivers reporting insufficient support from their own and others’ husbands, such as husbands complaining about the time and attention KMC required and husbands restricting access to health services for mothers and children.

Per caregivers and VHV, changes in community behaviors pertaining to health have begun to occur since Kol Kilok’s implementation. In particular, there was understanding of the risk of hypothermia and KMC. During questions that focused only on hypothermia (i.e. without mention of Kol Kilok) caregivers and VHV continued to

demonstrate appropriate recall of actions to be taken during continued hypothermia (i.e. KMC, taking neonate to health facility). This contrasts with the findings from focus group discussions with non Kol Kilok users (see *Effectiveness* section). Without this additional counseling, Kol Kilok users may have had some misconceptions surrounding hypothermia and KMC as demonstrated by focus group discussants and would have continued similar reported inappropriate practices.

The Kol Kilok program may also be leading to unintended spillover of newborn health information into the uncounseled or non user community. As mentioned previously, both caregivers and healthcare workers without reported training were still able to describe some aspects of KMC and Kol Kilok despite inaccuracies. This may be due to communication between fellow caregivers and healthcare providers or simply reflect an aspect of recall bias (e.g. forgetting the training they received). However, during focus group discussions with non users, some reported watching Kol Kilok users in their communities and attempting KMC themselves. Thus, non users have the potential to learn from Kol Kilok users and promote positive newborn health information and practices themselves as well as wider health topics.

The intervention may also increase the visibility of VHV for other counseling topics, as well as increase connection to healthcare services for other family members who attend these visits. The program may also contribute to building trust in the community to facilitate additional interventions or increased linkage to healthcare, healthcare providers and VHV.

Subjective reports from VHV and healthcare worker interviews noted increased follow-up for one month neonatal visits following Kol Kilok's implementation. This allows for one month vaccinations (i.e. Hepatitis B) and additional postnatal and neonatal counseling. Papua New Guinea remains below targets for vaccination coverage, and if these reports are verified, the program appears to have encouraged healthcare follow-up which could indirectly assist in providing vaccinations and additional health counseling.

While caregivers liked many aspects of the device, several statements raised concerns for elevated expectations. Several statements made by caregivers appeared unrealistic, such as "[it/Kol Kilok device] will save my baby" or "it will help to save his life." It is possible these are paraphrased or misinterpreted, however, several promotional materials for the program also appear to conflate its benefits (see Appendix 5). Posters for Kol Kilok claim that "nearly half of… babies can be saved by continuously monitoring their temperature." This is difficult to justify based on current scientific evidence, and over promising the device can betray trust in the community should adverse health events occur in users.

Economic and Financial

Questions remain regarding the sustainability and cost effectiveness of the Kol Kilok program, particularly the Kol Kilok device. Financial support is entirely dependent on donors, and PNG's financial situation remains strained with limited funds available to supplement programs. It is possible the device is cost effective and that its utility in improving KMC or adjuvant EENC programs would improve neonatal health to the point of benefit over cost. However, additional studies are needed before conclusive evidence can be provided.

Recommendations for improvements from caregivers and staff focused on improving transportation access in EHP. Currently, Goroka Hospital promotes a free service for emergency medical transportation. The expansion of the transportation service by health facilities and/or public transportation services would have the added benefit of improving access to care as well as financial opportunities in the city of Goroka in a long term.

Finally, this pilot project's monetary assistance and healthcare assistance could also be driving increased KMC reporting and returns to clinic. The project provides study participants with KMC kits when caregivers return to health facilities after delivery (at the value of $8 US dollars) and intermittent monetary compensation for PNC

visits (at the value of $10 PNG kina). It is unclear if this was randomized or unintentionally incentivized cases over controls. Therefore, it is unclear if the benefits and attitudes outlined in previous sections are directly from the Kol Kilok program or from additional monetary incentive/support.

Technical

The use of Kol Kilok has introduced a new technology in implementation hospitals and communities. It is unclear if the long-term impact of this change will be beneficial. When asked for details some workers thought the device "saves time," but others reported it may negate the need for regular temperature checks or encourage less frequent checks. If the technology truly encourages healthcare workers to decrease the frequency of temperature checks this provides less opportunities to detect hyperthermic events as well.

The use of this hypothermia alert device and its technology also triggered discussions from implementation leads on how such alert functions could be adapted in other devices and project areas (e.g. immunization reminders per the recommended schedule). Given the reception and positive feedback seen in communities, similar uses of alert device technologies may be feasible in these areas and could use lessons learned from Kol Kilok for implementation.

Environmental

Upon completion of the program, 91% (n=60/66 of previous users) noted they returned their device while 9% (n=6) kept their device at home. The Kol Kilok device is made from rubber and stainless steel, and there is a risk for an indirect, detrimental environmental impact should it be discarded in the community. Currently, this does not appear to be the routine practice, though additional measures should be taken to incentivize returning the device after one month.

I. 4.9 Limitations in Findings

Our findings were subject to several limitations. First, translations from English to Pidgin (English creole) were delayed and therefore back translation did not occur until after the evaluation. This led to two questions being removed from analysis due to mistranslation concerns. Second, due to limitations in human resources, supervisors and upper level staff were utilized as enumerators in several situations. Thus, the project staff/implementers, health providers and VHV assisted with interviews, which may have led to social desirability bias amongst both interviewees and interviewers when asked directly about the quality of healthcare services, competencies of health workers (e.g. knowledge, practice) and caregiver's practice.

Third, per anecdotes from UNICEF staff, cultural aspects may have limited the response to of open ended questions. In certain cultures, open ended questions are difficult to answer. This may have limited open ended question response or encouraged unintentional prompting to ascertain answers. Fourth, refusal and unavailable family members led to limited numbers of verbal autopsies. Fifth, we were unable to perform a planned evaluation of the Kafentina Health Facility due to destruction of the facility during civil unrest.[bb]

Sixth, no chart or register data were available in community health facilities (i.e. Henganofi, Komperi) for review. When these routine data (e.g. charts, registers) were available, limited information was available on newborn care due to the incompleteness and lack of clarity of data entry (e.g. missing admission weight, poor handwriting). Seventh, no KMC diaries had data on the number of alerts seen by caregivers and we could not calculate the ratio of KMC to alerts form the community. KMC diaries recorded "KMC session (per day)" yet did

[bb] Of note, evaluators were able to interview VHV and caregivers from Kafentina in the community and other locations. However, no chart/register review, health provider interviews or HFA were conducted at Kafentina due to destruction

not specify if this meant “instances of KMC (per day)” or “duration/hours (of each session)” resulting in ambiguity when attempting to understand the reality of KMC practice and limitations in analysis.

Eighth, alerts recorded in hospital settings (POMGEN only) were recorded every 6 hours during the study period and may not reflect the true number of alerts seen over the course of a day. In addition, previously collected data listing alert color and temperature at 6 hour intervals had discrepancies (e.g. one Excel sheet noting the color was blue, another Excel sheet noting orange). Ninth, documentation issues occasionally led to missing data such as missing dates of birth, hospital numbers, weights, or gestational ages. Other issues with documentation included illegibility, inclusion of categories in numerical areas (e.g. use of the word “term” instead of gestational age in weeks), and discordant categorical and numerical classifications (e.g. a 32 week infant referred to as “term”).

Tenth, data collection tools were not designed to determine the frequency or quality of joint home visits or reports from VHV for supervision. Eleventh, FGDs were also recorded with a voice recorder, yet transcripts, translations and final reports by the field note takers were not shared with the study leads resulting in FGD data entirely consisting of draft field notes and limited examples of direct quotes from caregivers. Twelfth, outcome data in registers were limited regarding cause of death and KMC diary data could not be linked to most health facility data for further analysis. Finally, data quality review and assurance mechanisms have not yet been established for data collection under the pilot project bilaterally (e.g. frequency of KMC practice, Kol Kilok alert). In addition, these mechanisms have not yet been integrated into the routine systems (e.g. facility registers, HMIS), leading to some uncertainty of data quality.

5. CONCLUSIONS

Overall, the Kol Kilok program has been very well received by caregivers of infants, VHV and healthcare workers. Caregivers liked the device and cited subjective increased in bonding and growth along with decreased instances of illness. VHV had high praise for the device and believed it was well received in their communities, citing its detection of hypothermia, increased KMC and ease of use. A majority of healthcare workers reported an improvement in their clinical practice due to the use of the device.

General knowledge surrounding Kol Kilok device was high, though highlighted several areas for improvement and additional training. Caregivers reported very few issues, though occasionally would report the device was "too small" or having issues with transportation to health facilities. Village health volunteers were knowledgeable and well educated on use of the device. Specifically, every VHV knew the correct measures for alarms on Kol Kilok and almost all VHV knew to refer infants to health facilities for continued alarms. However, VHV reported challenges within referring cases to health facilities during continued alarms. In addition, training around community EENC is a part of the modules yet VHV's knowledge appeared limited. Healthcare workers had a high knowledge of ways to diagnose hypothermia, appropriate treatment for mild-moderate hypothermia and definitions of low birth weight. They also were highly educated on the purpose of Kol Kilok and had reported recent training on hypothermia. Healthcare workers identified a limitation in space for providing KMC during hospitalization and limited man power to respond to alerts. In addition, they highlighted the need for additional training on Kol Kilok (e.g. technical assistance).

Increase in knowledge and attitudes around KMC and hypothermia among caregivers has also been reported, followed by initiation of KMC practice. Focus group discussions highlighted misconceptions about childcare and hypothermia (e.g. "*cold baby is normal in the cold environment*"). By contrast, Kol Kilok users recognized the need for KMC during these periods and indirect questions regarding cold infants (i.e. specifically without mentioning Kol Kilok) yielded similar responses. Comparable responses were found during interviews with VHV, with almost all VHV reporting the need to bring a consistently cold infant to a health facility for evaluation (i.e. without mentioning Kol Kilok alarms). Thus, the primary intervention of the Kol Kilok program appears to have promoted knowledge and attitudes – the importance of recognizing and taking care of cold infants. KMC has been increasingly been initiated compared to controls. However, caregivers infrequently perform the prescribed duration or frequency due to challenges with continuation and/or insufficient knowledge and attitudes.

Additional conclusions are organized per the WHO Health System Blocks as below (see Appendix 10):

Health Services Delivery

Health facility assessments demonstrated all sites evaluated were open daily for 24 hours with available healthcare workers, labor wards and maternity wards. In addition, when a case presented, most sites reported having conducted neonatal resuscitation, provided KMC or administered antibiotics. However, select facilities were missing key areas (i.e. neonatal ward in Komperi), accessible or functional resuscitation supplies, or infrastructure such as running water or consistent power. Furthermore, neither community centers had available registers specifically for sick neonates or therapeutic devices for moderate-severe hypothermia (i.e. warmers). The lack of this equipment and devices demonstrates that, while health facilities have attempted resuscitation and select interventions, the documentation and quality of these services may be limited by available resources. This effects the feasibility of implementing Kol Kilok in health facility settings, as referrals for continued alerts may not be documented or may not receive adequate secondary interventions given limited resources.

Furthermore, caregivers of sick newborns reported that a hospital policy restricted entrance to nursery (e.g. the number of times and timing to enter nursery, duration of stay) and frequently cited this restriction as an impeding factor for providing breastfeeding and KMC to sick newborns. Healthcare workers also identified a lack of space for providing KMC during hospitalization and highlighted the need for additional training on hypothermia and EENC. Health facility assessments echoed these reports, as administrators reported limited space and records on KMC at all facilities. Without areas or opportunities to promote KMC during hospitalization, this limits the overall feasibility of utilizing the device in hospitals. Policy changes and allocations for KMC spaces could mitigate this limitation, however, and would promote practices that could improve overall weight gain, bonding and breastfeeding during inpatient stays.

By contrast, VHV were highly praised by community caregivers and focus groups as improving access to care. Many EHP caregivers reported that distance from health centers limited their access to care and specifically highlighted the need for improved access to transportation in order to access services at health centers. Thus, caregivers routinely cited VHV as their primary point of contact for healthcare-related questions and focus groups cited VHV as providing additional access to postnatal care. Furthermore, some caregivers hoped for an expanded role of VHV with additional services provided to the community. Ultimately, it appears the VHV network was vital to the implementation of the Kol Kilok program and overall healthcare delivery in community settings, though limited transportation affects the feasibility of referrals for continued alerts in these areas.

Focus Group Discussions (FGDs) underscored some misconceptions and myths surrounding hypothermia and essential newborn care among caregivers in general, hence the importance of health promotion, education and counseling in the community and health facility settings, particularly with mothers/caregivers who have limited access to facilities. Further, a lack of family support was cited as a barrier to care (e.g. husband's/family's consent, geographic and financial barriers for transportation, respectful care etc.), suggesting the critical role of husband and family support as well as the need for quality improvement with dignity and equity. Given the constrained practice of some EENC (e.g. early initiation of breastfeeding), the quality of ANC counseling and proceeding counseling during postnatal period was not evident, suggesting the need of strengthening health promotion activities through health professionals at health facility and VHV.

Health Workforce

Health facilities all reported having staff available 24 hours and 7 days a week. However, healthcare providers occasionally reported being understaffed and some noted this limited their ability to respond to Kol Kilok alarms. Caregivers themselves also highlighted the need for additional supplies and human resources at several facilities. In contrast, VHV noted spending limited time on additional tasks and reported only having an average of one Kol Kilok user per month. Therefore the possibility of task shifting, such as linking CHW to health facilities, or expanding VHV roles in the community, could be studied and considered which may have the twofold benefit of improving quality and access to care as well as decreasing the work burden of healthcare workers. This would fulfill community requests for expanded roles of VHV and improve access to healthcare interventions in the community (e.g. birth attendants).

The effectiveness of training for providers appeared to be mixed. Healthcare workers at hospitals infrequently recalled training on hypothermia, EENC or Kol Kilok. Correlatively, very few healthcare workers could recall all aspects of EENC. In some locations, healthcare workers with reported training in these areas would score worse on general knowledge questions than those without. This highlights the need for not only increased quantity of healthcare providers, but also increased quality and frequency of training and supportive supervision amongst providers. Similarly, while VHV were lauded by caregivers in their communities, interviews with VHV demonstrated that training around community EENC was insufficient. VHV almost universally recalled receiving

training on EENC; however, almost none could recall all topics covered in EENC training. Thus, while caregivers rely on VHV in remote areas, they may not be getting the full benefit from EENC as limited training may affect the quality of VHV counseling services.

HMIS and Surveillance

Data collected under the Kol Kilok program (e.g. KMC frequency, weight gain) is not yet incorporated into health facility HMIS, does not contribute to implementation area surveillance, and does not produce regular reports. This lack of integration with existing health information systems highlights the limited connection the program has to existing public health infrastructure. However, the cross sectional, epidemiologic findings from this evaluation were entirely derived from data routinely collected by the Kol Kilok program (e.g. hypothermia prevalence, weight gains), and with modifications and/or incorporation to existing data collection tools (e.g. KMC diaries, MCH booklets), some aspects or methods of the evaluation could be adopted/adapted into HMIS for routine surveillance and monitoring of indicators in the areas implemented.

The prevalence of hypothermia at Goroka demonstrated nearly three-in-four LBW, premature or deceased neonates experienced hypothermia. However, it was difficult to connect chart, register and Kol Kilok data as neonates lack a unifying unique ID. This led to many users not being linked with hospital data, and at POMGEN in particular, linking Kol Kilok and hospital data was not even possible. This limitation may contribute to the Kol Kilok program's lack of regular reporting on device user temperature data or instances of infection during, or requiring, hospitalization. Adjustments to the program could allow for routine reporting of this information back to health facilities for quality improvement as well as provide Ministry of Health, local government, and other regional or national public health officials additional data for forthcoming programmatic planning (see *Recommendations*).

Medical Product and Technology

Kol Kilok appears to be a complimentary utility for promoting KMC and weight gain, though its exclusive effect is difficult to delineate. KMC diary information revealed that, on average, Kol Kilok users had higher KMC per week and overall weight gain compared to controls. However, at Goroka provincial hospital in particular, there was no significant differences between cases and controls. This could be due to limited recall of Kol Kilok training at the site, non-significant increases in KMC or differences in enrollment weights. By contrast, POMGEN users more frequently recalled training topics, had higher KMC and were more severely underweight compared to Goroka. LBW could have benefited more from the additional KMC they received, as the weight gain benefits of KMC have been primarily demonstrated in lower birth weight infants.

Chart data from hospitals showed the percentage of temperatures indicating hypothermia decreased after implementation of Kol Kilok. However, when disaggregated by Kol Kilok users and non users at Goroka, both groups appeared to have similar percentages of hypothermia after the intervention (i.e. 40% in cases, 38% in controls). It is difficult to define the reasons for this outcome based on the data available. As previously discussed, Goroka provincial hospital was the only health facility where differences in KMC and weight gain were not significant between cases and controls. Both groups, therefore, may have had the same benefit from additional KMC, though no data are available on baseline rates of this practice in each group prior to implementation. In addition, a spillover effect in management of hypothermia may have occurred, as the same healthcare workers who were trained to provide care for Kol Kilok users would also respond to low temperatures in controls. Alternatively, effect size may also be affected by sample size as only 58 charts were available at this site for data extraction during the evaluation period.

The influence of the Kol Kilok device on KMC has been studied and shown to benefit LBW infants elsewhere, and the PNG program has largely re-demonstrated these findings.[34] However, it remains unclear if it is appropriate to use Kol Kilok in normal birth weight infants. While the frequency of Kol Kilok alarms in normal birth weight infants in community settings is concerning, a clear benefit of using the device in this group has not been demonstrated. On average, normal birth weight Kol Kilok users gained more weight than controls in community settings, however cases were nearly 0.5g smaller than controls upon enrollment and both groups had similar, statistically insignificant differences in weights upon discharge from the program. This may represent a lack of complete randomization in the community arm, however, these findings do not conclusively demonstrate a reason to use the device in non-LBW or non premature infants. Therefore, priority should be given to LBW and premature infants for enrollment in Kol Kilok. Then, if additional resources become available, all infants could be included in the program along with additional outcome studies in normal birth weight population.

Furthermore, the device has been primarily studied in hospital settings and no community-based studies have been conducted utilizing Kol Kilok. However, community-based KMC programs have been tested, piloted and implemented in other countries and self-reported data from KMC diaries demonstrates a significant increase in Kol Kilok user KMC initiation compared to controls. Therefore, it is possible this program can show the relevance of use of technology in communities towards weight gain and increased KMC. However, so far, the findings are mixed and potential confounders remain present in these settings given their higher overall enrollment weights (see prior paragraph).

The need for additional training on the use of the device was also frequently cited as an issue by interviewees. Caregivers, for example, would routinely miss critical steps in describing how to respond to alerts, continued alerts and how to perform KMC. Amongst caregiver having had received the reported trainings, a fourth could not identify the appropriate next steps when Kol Kilok continued to alarm after KMC (i.e. hospital referral). In addition, half of caregivers with training could only partially describe or demonstrate KMC. This does not mean these mothers did not know these steps for KMC, nor that they had not been trained. This could be due to limited descriptions during interviews, and may not necessarily reflect a lack of knowledge or practice. However, per caregivers own requests for additional training, these steps could be reinforced during counseling sessions to ensure KMC is done correctly.

Overall, one Kol Kilok device costs $20 US dollars (around $60 PNG Kina). Per local estimates, EHP has 15,000 live births per year. If there are plans to scale up use of Kol Kilok, and assuming full coverage, it would cost $300,000 US dollars to procure devices for all live births. This does not include overhead costs, training, recruitment or transportation. Alternatively, Kol Kilok was primarily designed for and demonstrated efficacy in LBW children. Thus, coverage of only LBW births (estimated 38% of live births in EHP) would reduce the cost for full geographic coverage to $114,000 US dollars. A full cost-benefit analysis should be considered prior to expanded use of the product. Furthermore, efforts to limit the cost of the device should be pursued. This will ensure efficient use of resources and ensure that the device is distributed equitably to those most in need of its benefits.

Financing and Resources

As discussed previously, health facilities where Kol Kilok has been implemented have had mixed resources. When the Kol Kilok program and Early Essential Newborn Care (EENC) are introduced, facilities need to be equipped to treat both hypothermia and identified infections among other newborn sickness. As a result, many healthcare providers and caregivers requested additional space to perform KMC. Furthermore, as mentioned previously (see *Health Workforce*), a lack of human resources at many sites limits response to Kol Kilok alerts. Overall, these limitations of resource decrease the availability and quality of care provided at these facilities and

could be an area the program could supplement by regularly reviewing available resources of management of hypothermia and EENC and allocating necessary resources for systems strengthening.

Caregivers, VHV, and healthcare workers all cited limited transportation resources as a major barrier to healthcare access. Per implementation leads, Goroka has an emergency service for referrals in remote areas. However, this system could be expanded to ensure consistent coverage. Furthermore, larger transportation options (e.g. buses), when viable, could be utilized for weekly referrals. Besides the free MCH service policy and financing, PNG government's planned policy and financial allocation to reduce transportation costs and demand side financial barriers are well acknowledged, as several other countries in Asia and the Pacific are also considering, consulting and/or piloting similar programs. In addition to the service provision in health facility settings, the need for additional financial allocation was noted for community-based service provision, health promotion activities, and training for health professionals and lay workers. These PHC services and systems strengthening should be recognized and prioritized in the ongoing government effort for universal health coverage.

Leadership and Governance

Implementation leads highlighted general support from government officials for the Kol Kilok program. Representatives from EHP's Governor and PNG's Minister of Health both expressed support for the program during post-evaluation discussions. However, additional funding and financial support would be needed. Papua New Guinea has committed to the promotion of EENC, and the leadership of MOH should be acknowledged for its progress and scale up of EENC implementation. In addition, PNG utilizes Regional EENC Guidelines and training materials developed jointly by WHO and UNICEF. However, given the mixed results from VHV and healthcare providers on EENC, additional promotion of training should be encouraged from not only health facilities, but educational, ministerial and non-governmental organizations.

Standardized EENC training modules exist for facility-based service and community-based EENC training modules have been developed and implemented in the project sites. However, the Kol Kilok program lacks a standardized training module or guidelines for implementation areas. As discussed, both VHV and healthcare workers frequently requested additional training. Community-based EENC is a part of the training module for VHVs/Village Birth Attendants (VBAs) as developed by TTU, yet this is not routinely practiced in other sites/regions where various modules have been introduced and implemented by different projects. Standardization of training, particularly on EENC in community settings, would ensure consistent counseling and practices across geographic areas and health facility types (i.e. hospital, community health center). Furthermore, distribution of WHO treatment guidelines during trainings would also assist VHV and healthcare providers through use of algorithms or step-by-step procedures for addressing specific health events (e.g. refractory hypothermia).

Supervision was mixed amongst providers and more frequent supportive supervision was requested specifically in EHP. While the majority of healthcare providers and VHV reported regular and frequent supervision, healthcare providers in community health facilities reported less frequent supervision (i.e. monthly, quarterly). Furthermore, neither healthcare provider nor VHV supervision is standardized and most supervision was reportedly "ad hoc" or as needed. More standardization or routine mechanisms of supportive supervision could assist the program and newborn health interventions by ensuring consistent reviews, guidance and responses are being taken across different sites

Successful models from implementation sites could be utilized across all intervention areas. A recent hospital-based initiative in POMGEN encouraged regular, supportive supervision as well as routine quality review and improvement. This initiative included EENC team meetings, periodic feedback sessions, and quality review and

improvement cycles across different wards. Given the differences in supervision reported at POMGEN compared to community settings this model could be adopted or adapted to advance supportive supervision and quality improvement at peripheral sites.

6. RECOMMENDATIONS

- *Health Services Delivery*
    - Per the EENC guidelines, scale up quality healthcare delivery services and ensure health centers where the Kol Kilok program has been implemented have appropriate materials/equipment/supplies
        - E.g. resuscitation masks for LBW infants, designated areas for resuscitation, antibiotics, referrals systems to higher levels of care
    - Designate areas/spaces for KMC in implementation facilities, including health centers where appropriate and feasible, to allow VHV or caregivers to respond to Kol Kilok alerts and provide routine KMC. An enabling hospital policy is needed for mothers to be able to provide KMC to sick newborns, given reported policies and restrictions for mother to enter a nursery.
    - Expand use of VHV in some of the EENC delivery and consider expansion of their roles per requests in the community (e.g. assistance/support for delivery care)
    - Study use of device (e.g. to controls) and changes in relevant infant and child care, such as vaccination rates (e.g. Hepatitis B vaccinations)
    - Update and revise counseling and health promotion materials (e.g. posters, flyers) and consider use of electronic media devices for health education and promotion to be used by VHVs and CHWs
        - Modify posters and flyers to include up-to-date information and remove language that exaggerates hypothermia data or Kol Kilok's impact (e.g. will save half of neonates)
- *Health Workforce*
    - Study and consider task shift in hospital/health facility settings to allow caregivers to respond to device alerts through use of designated KMC space, as well as other newborn care
        - E.g. study and consider positioning CHW in rural health facilities to respond to Kol Kilok alerts and provide additional KMC when mothers are unavailable
    - Provide additional, standardized training to healthcare providers/VHV and counseling related to Kol Kilok device and EENC to caregivers, with routine recording and self-monitoring systems
        - Update counseling check list with area to verify to all items are completely understood or second set of boxes to confirm a topic has been learned (e.g. using teach back method) (see Appendix 2)
        - Example:
            - *"Explain the meaning of the Blue Light"*
            - Specifically clarify contacting a provider/VHV or presenting to a health facility for continued alarms

Counseling Given	**Caregiver Able to Recall Counseling**
X	X

    - Provide additional, refresher trainings on EENC and hypothermia to healthcare providers and VHV
        - Repeat and/or provide refresher training for all EENC core interventions in healthcare providers in the facility and emphasize the two primary EENC counseling components for VHV working in the community (e.g. breastfeeding, KMC)
        - Review diagnostic cut off of hypothermia (36.5 C) as well as temperature testing frequency based on term and birth weight (i.e. LBW, VLBW, ELBW)
            - Distribute guidelines as well as diagnostic and treatment protocols for hypothermia to providers in health facilities (e.g. WHO Clinical Guidelines for

Hypothermia; distribute algorithms or protocol for treatment based on hypothermia severity)

- *HMIS and Surveillance*
    - Continue lobbying and supporting for the inclusion of EENC indicators in the routine HMIS systems to ensure regular reporting and analysis of relevant indicators
    - Create an analysis-ready dataset containing temperature data from hospitalized infants
    - Add unique ID's that are shared across health facilities and Kol Kilok program documents (e.g. same register, chart and Kol Kilok diary ID)
    - During future pilot and implementation studies of Kol Kilok programs, ensure variables exist for specifying cases and controls
    - Use monthly reports/excel sheets from facilities to create a monthly report from Kol Kilok program
        - In the future, the methods used to compile reports (e.g. KMC diary data) can be used by local health authorities for local surveillance on neonatal morbidity
    - Ensure neonate weight and appropriate term is recorded on the day a user receives the device
        - Include the date the neonate was discharged from a health facility (record as NA is not applicable) and the date the neonate stopped using the device
    - Standardize KMC Diaries and provide additional training regarding how to complete the form
        - Include areas on KMC diary for both device alerts and corresponding KMC to be able to differentiate alerts from KMC during data collection (e.g. side by side columns for alarm and corresponding KMC) (see below for example)
        - For the sake of recoding KMC practice with sufficient clarity, KMC diary format and elements should be revised and caregivers trained to complete the form both with "instances" per day and "hours" per session (e.g. on average) (e.g. 2 instances of KMC per day, with "2 hours" per session on average)
            - Allows for quality checks on counseling to ensure the frequency and duration of KMC is appropriate, as well as ongoing analysis of outcomes based on KMC instances/time
        - VHV should be trained on ways to limit "prompting" and not lead mothers with example of answers
        - Ensure "discharge weight" is consistently used across sites (e.g. discharge from hospital vs discharge from Kol Kilok program)
        - Modify KMC diary pages to ensure proper completion by illiterate individuals
            - Example:

From:

1	2	3
4	5	6
7	8	9

To:

	KMC	Alarm
		

1	X	X
2	X	
3		X
4	X	X
5	X	X
6	X	
7		X

    - Improve data management of neonatal health data collected by the program
        - Standardize Excel sheet use and KMC diary data collection
            - Ensure only text is used in Excel-based categorical variables (e.g. male, female)
            - Remove text from numerical variables (e.g. change Excel cells with '10cm' to '10' with 'cm' in column's header [length in 'cm'])
            - Incorporate use of code for missing data (e.g. using clear, outlier numbers such as "99" for unknown numerical values [or alternatively "999" whenever 99 is a possible data value])
    - Information/data recorded in the KMC diary could be integrated into the existing MCH handbook, an existing home-based record which could be periodically updated and reviewed
    - Update register and charts to capture essential services and counseling and ensure standardization across the facility under the ministry's leadership
        - Provide standard patient registers from the ministry to ensure the same information is collected at each site
        - Introduce procedures for periodic upload of paper based register and chart data into electronic formats (i.e. Excel) for newborn health
- *Medical Product and Technology*
    - Prioritize allocation of devices to neonates who meet the criteria for LBW (<2,500g) or premature (<37 weeks) to ensure inclusion of the most vulnerable infants
        - If devices and resources are available, can consider expanding to normal birth weight and/or term infants
    - Provide additional counseling to caregivers to ensure proper use of the technology
        - Ensure caregiver counseling covers all major steps in KMC (e.g. skin-to-skin, proper positioning, use of KMC wrap) as well as proper response to continue alerts after KMC (e.g. referrals to health facilities)
        - Incorporate "teach back" method to ensure all participants understand the technique and need for referral during continued alarms
    - Update and modify use of the device to increase sensitivity, feasibility and overall device cost
        - In an effort to reduce the cost, reconsider procurement approaches and introduce bidding from multiple suppliers/companies
        - Consider adding temperature reading device (if no added cost) to allow for healthcare workers to immediately measure temperature during alert
        - If plan for use in normal birth weight or term neonates, consider enlarging band to ensure fit
- *Financing and Resources*
    - Expand use of Goroka's emergency services for referrals in remote areas and ensure routine maintenance of vehicles

        - Consider larger transportation options for remote caregivers in order to ensure consistent postnatal clinic follow-ups (e.g. buses)
    - With the government's planned policy and financial allocation to reduce transportation and demand side financial barriers, H6 partners could consider strengthening support for health financing and relevant advocacy targeting the Ministry of Finance in Universal Health Coverage efforts
- *Leadership and Governance*
    - In addition to use of standardized EENC modules/guidelines in health facilities, program leaders should orient and ensure healthcare provider use of existing EENC guidelines; and develop standardized training for VHV which include select core EENC interventions (e.g. KMC, breastfeeding) in the community including hypothermia care
    - Given restriction for mothers on time allowed in nurseries, guidance should be issued from MOH to hospitals to develop a supportive hospital policy for mothers to provide KMC for sick newborns
    - Establish routine mechanisms for quality improvement and supportive supervision with scheduled timing (e.g. monthly) using POMGEN as a model (e.g. EENC team and beyond)
        - Healthcare workers should have scheduled times to review and discuss quality of care, which may include performance and feedback, review recent issues, shortage of resources, and technical problems with Kol Kilok
        - VHV supervisors should ensure standardized routine mechanisms such as the use of checklists during joint field visits to allows for quantification and tracking of VHV performance
    - Encourage continued advocacy to government leaders for commitments to long term funding of program (i.e. sustainability)
    - Acknowledge the provincial leadership and coordination mechanism in the EHP as an excellent model, such sub-national model could be replicated in other provinces.
    - Conduct additional studies on the effectiveness and cost effectiveness of community based newborn health intervention, as a part of wider community health systems, to identify a scalable model
        - E.g. Case-control study of normal and LBW neonates to demonstrate definite benefits in both groups in this setting
        - E.g. Cost analysis of Kol Kilok program to ensure appropriate allocation of device to those most in need (i.e. LBW, premature)

7. LESSONS LEARNED

General Knowledge

To our knowledge, no prior studies have been conducted on the prevalence of neonatal hypothermia in Papua New Guinea. Prior studies in multiple settings have documented the prevalence of hypothermia in vulnerable populations such as premature or LBW neonates.[37] Our findings contribute to other studies on the morbidity experienced by newborns as well as country-specific data for Papua New Guinea in two areas of differing climate, elevation, urbanization and socioeconomic statuses.

The evaluation was able to calculate the number of LBW and premature infants born at POMGEN (PNG's national hospital) as well as one other provincial hospital (Goroka). In addition, neonatal morbidity (e.g. infections, jaundice) and mortality as well as limited maternal complications were documented for each of these locations. These findings will provide PNG, UNICEF and other NGO/IGOs with additional data for other neonatal and maternal health programs beyond the Kol Kilok program.

The Kol Kilok device was previously studied only in hospital settings and in low birth weight infants.[38] Prior studies demonstrated high sensitivity and specificity (98.6% and 95%, respectively), increased weight gain and positive attitudes through use of the device. Our data corroborates the two later studies, but conflicts with the former on sensitivity and specificity. The findings from this evaluation thus contribute to the body of knowledge surrounding the use of the device. In addition, our evaluation findings expands research on the device/program to feasibility, acceptability and outcomes in community settings as well as normal birth weight infants.

Our findings conflict with prior studies demonstrating no correlation between increased KMC and increased weight gain. A recent meta-analysis of 124 KMC studies, demonstrated no significant association between KMC in weight gain or body length.[39] Our evaluation, however, noted a significant, exposure-response association between increased KMC and higher weight gain compared to controls with lower rates of KMC. The same meta-analysis noted decreased risk of hypothermia in KMC users (RR 0.22, 95% CI 0.12, 0.41). Our findings noted no difference in hypothermic episodes in cases with higher KMC and controls. However, controls could have benefited from low levels of KMC, which may demonstrate how even low frequencies of KMC use could potentially be thermally protective.[cc]

Application

The findings from this evaluation provide Papua New Guinea's MOH and stakeholders with additional data on neonatal hypothermia prevalence, neonatal morbidity and mortality, and knowledge, attitudes and practices on EENC programs. This data will provide PNG with additional data for its other neonatal and maternal health programs. In addition, the prevalence of neonatal health concerns can be used to inform policy makers and donors for future interventions.

New evidence has been introduced which reflect on the utility of the Kol Kilok device. First, the device's sensitivity and specificity was previously demonstrated to be >95%; the findings from this assessment conflict with these prior studies and call for additional studies into the accuracy of the device or changes in its design. Second, healthcare workers requested the ability to see the temperature the device detected to ease their use of Kol Kilok in their clinical practice. Finally, users with normal birth weight infants requested a larger band size for their neonates.

[cc] Of note, our findings compared two populations both performing KMC. In contrast, the meta-analysis used studies comparing KMC use to controls not utilizing KMC. Thus, the reduction of hypothermia may be intrinsic to use of KMC rather than scale with increased frequency of KMC.

Evidential Limitations

Our findings are subject to several limitations. First, our evaluation was specific to four facility locations and catchment areas: POMGEN, Goroka Hospital, Komperi Health Center and Henganofi Health Center. This represents only three districts in Papua New Guinea and only two provinces, thus data from these findings may be specific to only the study locations and are not generalizable to other contexts. Second, due to relatively low numbers of Kol Kilok users, sample size was calculated using a lower precision (i.e. 10%) and the evaluation was limited to convenience sampling at health facilities. Third, multiple confounders could be present within our data, including monetary support through the Kol Kilok program and geographic distance from healthcare services or counseling.

Fourth, the internal and external validity of our data is subject to several biases including recall, sponsor and social desirability bias on the part of the interviewed; interviewer bias amongst enumerators; and selection and culture bias intrinsic to the study design. On the later point (i.e. culture bias), several questions were asked in open question format. Per local implementation leads, however, some communities do not respond well to this communication style and prefer multiple choice. Finally, qualitative data from focus group interviews were incomplete (see *Findings, Limitations* subheading) which limits the quality of this data and analysis.

8. APPENDICES

A. Appendix 1: Terms of Reference for Program Evaluation

1. Overview

1.1. Intervention Title

Evaluation of Bebi Kol Kilok Implementation in Papua New Guinea: Feasibility and Utility of Implementing Bebi Kol Kilok Medical Device for Detection of Hypothermia

1.2. Investigation Summary

The purpose of this evaluation is to assess the use of Bebi Kol Kilok and associated essential newborn care techniques in addressing neonatal hypothermia in hospital and community-based settings in Papua New Guinea. The evaluation has 3 specific objectives:

- To assess the feasibility and acceptability of implementing Bebi Kol Kilok in hospital and community settings;
- To assesses potential strengths and challenges of the program and its implementation;
- To evaluate the utility of Bebi Kol Kilok as an alert device to improve newborn care management associated with hypothermia, including KMC, in facility and home-based settings

The evaluation will be conducted in two hospitals (Port Moresby General Hospital and Goroka Hospital) and three health centers in Goroka and Henganofi districts where Kol Kilok has been distributed and utilized at the community level. This evaluation will inform the Ministry of Health and other stakeholders of the feasibility and acceptability of implementing smart devices to detect hypothermia and encourage management of hypothermia through kangaroo mother care (KMC).

1.3. Investigators/Collaborators:

- Papua New Guinea (PNG) Ministry of Health (MOH)
- Pediatric Association of PNG
- Port Moresby General Hospital
- University of Papua New Guinea School of Medicine and Health Services
- University of Goroka
- United Nations Children's' Fund (UNICEF)
- Center for Disease Control and Prevention (CDC) Emergency Response and Recovery Branch (ERRB)

2. Introduction and Background

2.2. Background

In recent decades, mortality for children under five has been reduced by almost 50%.[1] However, mortality amongst neonates has not declined as rapidly. As progress has been made in addressing childhood illnesses, newborn death now accounts for 44% of all deaths among children less than 5 years of age. In low-resource settings and developing nations, neonatal hypothermia represents a significant contributor to newborn morbidity and mortality. Although the true prevalence of hypothermia in developing countries is unknown, previous studies have estimated that prevalence of hypothermia could range from 11% to as much as 95% of all neonates in community settings.[2,3]

Hypothermia is often associated with high mortality, and prolonged hypothermia can lead to additional complications in newborns such as hypoglycemia, kernicterus, and brain damage.[4] In addition, in a Nigerian

study, hypothermic infants had a two-fold increase in case fatality rates upon admission to the hospital.[5] Given the morbidity and mortality associated with neonatal hypothermia in developing nations, reducing neonatal hypothermia would contribute to the reduction of childhood mortality worldwide. Morbidities and mortality related to hypothermia can largely be prevented by performing regular kangaroo maternal care (KMC).[6] However, hypothermia remains a challenging issue to recognize and manage outside of highly-resourced hospital settings.

Developed in India in 2013 under the original name "Bempu," Bebi Kol Kilok (a name derived from local languages in PNG) is a medical device used to detect neonatal hypothermia. The device is applied to a newborn's wrist and continuously monitors the child's temperature during the first month of life. Whenever the temperature decreases to <36.5°C, an alarm will begin to sound and an orange light will flash, prompting the caregiver to warm the neonate via KMC. If the alarm and orange light continue despite warming techniques, this could indicate hypothermia due to a more systemic process such as sepsis. At these times, caregivers are encouraged to present with their children to health facilities for further care. Studies following Bempu's implementation in India have shown the device is generally well received by caregivers, demonstrates high sensitivity and specificity, and has increased KMC during early weeks of life.[7]

Kol Kilok was piloted in Papua New Guinea beginning in June 16th, 2017 with additional sensitivity and specificity studies currently underway. As of January 15, 2018, a total of 170 neonates have been enrolled in the study in community settings with an additional 310 in the two hospitals. After nearly a year of use in Papua New Guinea, an evaluation of the Kol Kilok program is necessary to assess best practices and challenges of implementation, its feasibility in low-resource settings, and utility in improving care services to address hypothermia in neonates.

2.3. Evaluation Justification

Kol Kilok is a medical device used to detect neonatal hypothermia. The device was introduced in Papua New Guinea by UNICEF in June 2017, and has been implemented in two hospital settings as well as at the community level through three rural health centers. However, after nearly a year since implementation, the device's utility and feasibility for detecting newborn hypothermia in Papua New Guinea has not been fully assessed. Thus, an evaluation of the program is necessary to ensure efficient and effective use of this technology. The findings of this evaluation will go on to inform and improve use of Kol Kilok in Papua New Guinea to better serve caregivers and healthcare providers using its technology.

2.4. Evaluation Location

This evaluation will be conducted at two hospitals and three community health centers where Kol Kilok has been utilized. The facilities are as follows:

1. Port Moresby General Hospital
2. Goroka Hospital
3. Henganofi Health Center
4. Komperi Health Center
5. Kafentina Health Center

2.5. Intended/Potential Uses of Evaluation

The purpose of this evaluation is to assist UNICEF in assessing whether Kol Kilok is appropriately detecting and encouraging early interventions for neonatal hypothermia in Papua New Guinea. The evaluation will identify strengths and challenges of implementing the medical device in both hospital and community

settings, and provide recommendations for improving the program. The results will be used to improve the Kol Kilok program and refine interventions in this population.

2.6. Goals and Objectives

The goal of this evaluation is to assess the use of Bebi Kol Kilok and other essential newborn care techniques in addressing neonatal hypothermia in hospital and community-based settings in selected areas in Papua New Guinea.

Objectives include:

- To assess the feasibility and acceptability of implementing Bebi Kol Kilok in hospital and community settings;
- To assesses potential strengths and challenges of program implementation;
- To evaluate the utility of Bebi Kol Kilok as an alert device to improve newborn care management associated with hypothermia, including KMC, in facility and home-based settings

2.7. Timing of Evaluation

The evaluation will take place between February 23nd and April 30th, 2018. Evaluators will depart on March 15th, 2018 while additional data collection will continue through the end of April.

3. Methods

5.1. Evaluation Design

The evaluation will utilize mixed methods with multiple data sources, both prospective and retrospective, to assess the implementation of Bebi Kol Kilok and provision of essential newborn care. Caregiver satisfaction interviews, health care provider interviews, health facility assessments, and chart reviews will be conducted at the two health facilities (Port Moresby General Hospital and Goroka Hospital). Village health volunteer, focus groups, and household caregiver interviews will be conducted at Henganofi, Komperi, and Kafentina health centers and the communities within their catchment areas. All interviews will be conducted using electronic tablets utilizing open data kit (ODK) software (KoBo Toolbox).

The data collection methods and data sources include:

a) Health facility assessments (HFA) to assess facility readiness and provider capacity for delivering essential newborn care related to neonatal hypothermia and other newborn complications;
b) Review of facility registers and clinic patient records to assess hypothermia prevalence and mortality in the year preceeding, and following, the intervention. A second, sub-analysis will be conducted of the register and related charts documenting the outcomes of all babies receiving the Kol Kilok device;
c) Health provider interviews to assess clinicial knowledge regarding the detection and management of hypothermia, as well as provider satisfaction with use of Kol Kilok device;
d) Caregiver satisfaction surveys administered to caregivers after receving and using Bebi Kol Kilok both prospectively in the facility setting and retrospectively in the community setting;
e) Focus groups of caregivers in the community settings who did not receive the Kol Kilok device to assess opinions and perceived barriers for hypothermia care;
f) Review and data abstraction from KMC diary provided to the caregivers during use of Kol Kilok in the community setting;
g) Village health volunteer (VHV) interviews to assess general knowledge regarding the use of Kol Kilok, appropriate techniques for intervening in the case of alerts, and community satisfaction with use of the device.

h) One-on-one interviews among select implementation leads in order to assess challenges and strengths of the implementation process

Two hospitals and three community health centers who received the pilot intervention will be assessed using the facility asssement tools for newborn care services. This assessment will determine the capacity of facilities at any level to provide essential newborn care. In addition, this will assess the capacity of facilities to utilize Bebi Kol Kilok as an alert device in detecting and supporting the management of hypothermia.

Key inputs and outputs to be tracked from the HFA include the following fields:

Input	Proccess
Human resources, equipment and supplies	Number and quality
Provision of Emergency Newborn Signal Function	Newborn resuscitation • Antenatal corticosteroid • Antibiotics for pPROM • Antibiotics for neonatal infection • Kangaroo Mother Care • Administratio of oxygen • Administration of IV fluids

Health Provider readiness knowledge assessment and implement	• Essential Newborn care
	  • Care of the baby at the time of birth
	  • Examination of the newborn baby
	  • Care of the newborn baby until discharge
	  • Special situation
	• Management of newborn resuscitation and birth asphyxia
	• Diagnosis and treatment of newborn infection
	• Management of complications of prematurity and low birth weight (LBW) children including hypothermia and Kangaroo mother care (KMC)
	• Other special training

A data collection team will be trained on the use of the standardized and validated data collection tools. Chart review will then be conducted at each health facility, reviewing neonatal registers and patient charts to extract information on care provided to newborns and their respective outcomes one year prior to the implementation of Bebi Kol Kilok (i.e. 2016). Data will be collected from all available registers at pilot facilities to ascertain baseline morbidity and mortality data, including hypothermia prevalence. A second exhaustive chart review will be conducted of 2018 data to determine if there were changes in neonatal morbidity and mortality.

A second, separate analysis of charts and registers from those babies given the Kol Kilok device will be conducted where data are available. The review will include extraction of temperature data of neonates who received the intervention to identify the incidence of hypothermia in this population, as well as to assess the subsequent response from health providers, including whether or not KMC was performed by caregivers or whether other clinical interventions were needed.

Selection for Interviews: For those segments where participants for interviews will be selected, selection will occur in the following manner:

Health provider interviews will be administered to all consenting providers who provide neonatal care at each facility. Verbal and written consent will be obtained from all participating providers. Providers include nurses, doctors, and midwives. This questionnaire will assess whether training of lower level care providers has been completed, provider understanding of Bebi Kol Kilok, knowledge of best practices for detecting/managing hypothermia, and changes in clinical care due to use of the device.

Caregiver satisfaction surveys will be administered to caregivers to assess level of knowledge and satisfaction surrounding the use of Bebi Kol Kilok. These interviews will be collected separately among caregivers seeking facility based care and those using the Kol Kilok device in their own homes. In the two selected hospitals (Port Moresby and Goroka) satisfaction and knowledge interviews will be conducted prospectively among all caregivers of newborns who receive a Bebi Kol Kilok device during the evaluation peroid as well as those presenting for their follow-up visits, having received Kol Kilok 7-21 days prior.

In the community setting, retrospective study methods will be used to select 107 pariticpants who received Bebi Kol Kilok between June 2017 and January 2018. All interviews will be conducted in-home by trained interviewers. Interviews will focus on the use of Kol Kilok and overall opinions regarding the device. In order to assess adherence to KMC practices associated with the device, log books kept by the mothers will be reviewed and data extracted regarding the number of alerts seen per week and whether or not KMC was given following alerts. Verbal Autopsy will be conducted for the newborns who died during the intervention of Bebi Kol Kilok to determine cause of death and lessons learned. Verbal autopsy (VA) is a technique used to determine the cause of death by asking caregivers, friends, or family members about signs and symptoms exhibited by the deceased in the period before death.[8]

Interviews will be conducted with 107 VHVs, and will focus on the volunteer's level of comfort and knowledge in providing Bebi Kol Kilok services and interventions for neonatal hypothermia. Interviews will also review VHV opinions of the device, perceived benefits, challenges, and recommendations.

One-on-one interviews will be held with key implementation leads to assess how Bebi Kol Kilok was implemented in Papua New Guinea. Interviews will focus on implementation timeliness, difficulties, successes and resource requirements. Suggestions for future implementations and lessons learned will be reviewed.

Focus groups will be conducted with caregivers in community settings who did not receive the Kol Kilok device. Focus groups will assess knowledge and opinions regarding neonatal hypothermia as well as care associated with addressing hypothermia. The focus group will also address perceived barriers to care in these settings.

Summary of participants, methodology and outcome assessment

Participants	Methodology	Outcome
Hospital, Health centers	Health Facility Assessment Registers review, Chart review	Facility readiness for management newborn hypothermia and other complication, Neonatal Mortality rate, LBW and other neonatal morbidity condition rate, Hypothermia Incident Rate, KMC management and other specific response
Health providers	Knowledge, practical skills, and opinion interview	Human resource capacity for quality of newborn care,

		knowledge and opinions regarding use of Kol Kilok
Caregiver Interviews	Satisfaction interviews at the facility and the community level, focus groups with non-Kol Kilok caregivers, logbook review	Satisfaction with use of Bebi Kol Kilok, understanding of medical device; concerns and opinions of non-Kol Kilok users; KMC use response rate with Kol Kilok
Village Health volunteers	Knowledge and opinion interview	Human resource capacity at community level to provide guidance and monitoring, identification of challenges and recommendations for the program
Implementation lead including the MOH	One-on-one interviews	Implementation timeliness, difficulties, successes, resource requirements and lessons learned

3.2. Sample Size and Justification

For the outcome of assessing acceptability via interviews in the community setting, sample sizes were calculated assuming a conservative prevalence of 50% acceptance of the device, a desired precision of 10% and 95% confidence interval, yielding a desired sample size of 107 interviews.

In the facility, prospective data analysis will occur, and thus sample size will be limited by the number of patients presenting for care who receive, or have received, the Bebi Kol Kilok device during the evaluation period. All consenting caregivers will be interviewed if they receive Bebi Kol Kilok following birth or had received a Kol Kilok device in the preceding 7 to 21 days prior to the facility follow-up visit.

For the outcome of assessing knowledge of best practices and opinion of the Bebi Kol Kilok among VHVs, two different samples sizes were calculated. For the outcome of assessing knowledge of best practices, twenty yes or no questions will be asked of the VHV to determine whether correct action would be taken. Assuming a mean overall score on the 20 questions of 0.75 and a conservative standard deviation of 0.2, a sample size of 62 observations was calculated to produce an estimate with ±5% standard error around the mean estimate. Assuming 10% non-response or non-participation, 69 VHVs would need to be interviewed to achieve adequate precision. For the outcome of determining opinions on whether the Bebi Kol Kilok was found to be useful and was liked, we assumed a conservative 50% of VHVs would find the device useful. Assuming a 95% Confidence Interval and 10% non-response, a sample size of 107 VHVs was found to be necessary in order to achieve a precision of ±10% around the prevalence. Given that we will need 107 interviews for the outcome assessing utility and acceptability, we suggest asking the knowledge questionnaire of each of the 107 VHVs for ease of implementation.

3.3. Data Analysis Plan

Data from the health facility assessment will be summarized using Excel and SAS to provide descriptive statistics on the availability of equipment, adequacy of newborn care given, and management of clinical conditions. Data from the two hospitals and three health centers will be assessed separately and jointly to determine differences in care and readiness.

Data obtained from the exhaustive chart review will be analyzed using SAS version 9.4. Chart data will be weighted by the observed number of births per site. Complex survey frequency and means procedures will

be used to assess the proportion of cases who received adequate care in the facility, the mean number of births observed, and, if possible, hospital mortality rates among newborns. Kol Kilok data will be summarized using complex survey procedures to determine the total and mean number of alerts, the proportion acted upon, the estimated and reported levels of missing data, and the sensitivity and specificity of the Kol Kilok in detecting hypothermia.

Health provider interviews will be analyzed using SAS version 9.4. Since this sample will be exhaustive, complex sampling procedures are not necessary for analysis and no survey weights will be used. Basic descriptive statistics will be provided on the knowledge of practices for managing hypothermia and degree of training of hypothermic response. If the study size allows, these analyses will be stratified by type of provider (e.g. doctor, nurse, etc.).

Analysis of the patient satisfaction surveys and village health volunteer (VHV) surveys will be conducted using complex survey procedures in SAS 9.4 to account for variability caused by the sampling strategy. One the main study objectives of assessing acceptability of the Kol Kilok device will be calculated individually for community and for facility interviews using the SurveyFreq procedure in SAS, as well as for the VHVs. A second objective of the caregiver interviews is to measure utility of the device for caregivers in responding to hypothermia alerts. To assess this measurement, the percentage of alerts that were responded to appropriately will be calculated from data extracted by caregiver logbooks. Using the Surveymeans procedure in SAS, the mean response percentage among all community users will be calculated. For the VHV interviews, a second objective is to assess the mean knowledge score across twenty questions for all VHV. Using the Surveymeans procedure in SAS, the mean score will be calculated and variability will be recorded.

Qualitative data obtained from one-on-one implementation lead interviews and focus group discussions among community members who did not receive the Bebi Kol Kilok device will be analyzed in Excel to examine common responses and trends across various participants.

3.4. Dissemination Plan

The dissemination will have several components including local dissemination:

a) Presentation of the preliminary findings in Port Moresby to Ministry of Health and stakeholders including UNICEF and other United States government partners
b) Review of the assessment data to advocate for public health action
c) Global level dissemination including analysis of data, presentation of data at conferences, and manuscript write up for publication.

4. Ethical Considerations

Data collector training will include justification for the purpose of the investigation, inclusion and exclusion criteria, and the informed consent process.

Health service providers that work at those selected facilities and are directly involved in the provision of the newborn care and the project will be approached and asked if they are willing to participate in the investigation, and those that consent will be included in the provider competency assessment and key informant interviews. These interviews will be coded with unique identifiers to de-identify the data for analysis.

Caregivers presenting to the facilities for delivery or care who meet inclusion criteria for the evaluation will be approached and consent will be attained prior to interviews. As the investigation is based at local health

facilities, the setting is expected to provide sufficient privacy to minimalize any risk associated with the recruitment. The data related to the main objective is not expected to be sensitive or stigmatizing. Further, through use of gender-sensitive interview methods and having female interviewers, any sensitivity associated with the investigation process will be minimized

Interviews conducted in the community will be conducted in the caregivers' homes, having been identified by VHVs. Only VHVs will have records of the names and addresses of the caregivers; all interviews will have unique identifiers to match the logbook information to the caregiver satisfaction data.

Interviews with VHVs and key implementers will also be de-identified with consent obtained prior to interviews. For focus group discussions, no individual names or identifiers will be recorded, only the focus group number identifying the date and time of the discussion.

Data collected will be stored and maintained in secure networks to ensure participant privacy. Data analyzed and reported for the purposes of dissemination will be de-identified to ensure confidentiality. The data collector will read the consent form script in the local language to the participants and ask if they wish to provide their consent and participate in the investigation. Awareness of confidentiality of responses and the ability to opt-out at any stage of the investigation will be ensured.

5. Data Security and Sharing

The data will be stored at the MOH and UNICEF PNG office. The investigator coordinator will be primarily responsible for the security of the paper form of data. The data will be gathered on tablets which will require a password to access, and sent to a secure database through KoBo Toolbox. De-identified data will be shared with the coordinator, principal investigator, and data analysis team.

6. Evaluation Management

6.1. Timeline

	Activity	January	February	March	April
Protocol development and review	Protocol development	**X**			
	NRD submission and review	**X**	**X**		
	Data collection tool refinement	**X**	**X**		
Field evaluation	Planning and meeting		**X**	**X**	
	Data collection training		**X**		
	Site Evaluations		**X**	**X**	
	Document Review, Interviews		**X**	**X**	
	Draft Presentation of preliminary findings and results			**X**	
Data analysis and review	Analyze Data			**X**	**X**
	First Draft of Report			**X**	**X**
	Dissemination of Final Report				**X**

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B. Appendix 2: Results Framework and Additional Tables of Findings

i. Health Facility Assessment Findings

Location			Goroka (n=1) n (%)	Henganofi (n=1) n (%)	Komperi (n=1) n (%)	PMGH (n=3) n (%)	Overall (n=6) n (%)
Facility Infrastructure		Health worker available 24/7	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Facility Open 24/7	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		There is a labor ward	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		The labor ward is open	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		There is a maternity ward	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		There is a neonatal ward	1 (100.0%)	1 (100.0%)	0 (0.0%)	3 (100.0%)	5 (83.3%)
		There is running water 24/7	0 (0.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	5 (83.3%)
		There is a generator / power 24/7	0 (0.0%)	0 (0.0%)	1 (100.0%)	3 (100.0%)	4 (66.7%)
Neonatal resuscitation pack:	The facility has the following:	Newborn resuscitation table	1 (100.0%)	1 (100.0%)	0 (0.0%)	2 (66.7%)	4 (66.7%)
		Mucus extractor/simple suction	1 (100.0%)	1 (100.0%)	1 (100.0%)	2 (66.7%)	5 (83.3%)
		Neonatal face mask, size 0	0 (0.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	5 (83.3%)
		Neonatal face mask, size 1	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Neonatal size ambu (ventilator) bag	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Suction catheter, 10, 12 Ch	1 (100.0%)	1 (100.0%)	0 (0.0%)	3 (100.0%)	5 (83.3%)
		Infant laryngoscope with spare bulb and batteries	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)	2 (33.3%)
		Endotracheal 3.5, 3.0	1 (100.0%)	0 (0.0%)	1 (100.0%)	1 (33.3%)	3 (50.0%)
		Suction aspirator (operated by foot or electrically)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Mucus trap for suction	0 (0.0%)	0 (0.0%)	1 (100.0%)	2 (66.7%)	3 (50.0%)
		Anatomical model (for practice)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	1 (16.7%)
	The following are functional: (% among those that exist in facility)	Newborn resuscitation table	1 (100.0%)	1 (100.0%)	NA	2 (100%)	4 (100.0%)
		Mucus extractor/simple suction	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (50%)	4 (80.0%)
		Neonatal face mask, size 0	NA	1 (100.0%)	1 (100.0%)	3 (100.0%)	5 (100.0%)
		Neonatal face mask, size 1	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Neonatal size ambu (ventilator) bag	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Suction catheter, 10, 12 Ch	1 (100.0%)	0 (0.0%)	NA	3 (100.0%)	4 (80.0%)
		Infant laryngoscope with spare bulb and batteries	NA	NA	NA	2 (100.0%)	2 (100.0%)
		Endotracheal 3.5, 3.0	1 (100.0%)	NA	1 (100.0%)	1 (100.0%)	3 (100.0%)

		Suction aspirator (operated by foot or electrically)	NA	NA	NA	NA	NA
		Mucus trap for suction	NA	NA	1 (100.0%)	2 (100.0%)	3 (100.0%)
		Anatomical model (for practice)	NA	NA	NA	1 (100.0%)	1 (100.0%)
Resuscitation equipment within 1 minute			0 (0.0%)	1 (100.0%)	1 (100.0%)	2 (66.7%)	4 (66.7%)
Small or sick newborn care	**The facility has the following:**	**Register for sick babies**	1 (100.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)	3 (50.0%)
		Daily patient chart	1 (100.0%)	0 (0.0%)	1 (100.0%)	3 (100.0%)	5 (83.3%)
		IV fluid (neonatal giving) set/umbilical catheter	1 (100.0%)	0 (0.0%)	1 (100.0%)	3 (100.0%)	5 (83.3%)
		Syringes (0.5, 1.ml)	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Radiant warmer	1 (100.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)	3 (50.0%)
		Incubator	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	2 (33.3%)
		Designated space or beds for kangaroo mother care	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		KMC register	0 (0.0%)	1 (100.0%)	1 (100.0%)	2 (66.7%)	4 (66.7%)
		Nasogastric feeding tube	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Cup and spoon for infant feeding	0 (0.0%)	1 (100.0%)	0 (0.0%)	2 (66.7%)	3 (50.0%)
		Small cup for breast milk expression	0 (0.0%)	1 (100.0%)	0 (0.0%)	2 (66.7%)	3 (50.0%)
		Icterometer	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Fluorescent tubes for phototherapy to treat jaundice	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	2 (33.3%)
	The following are functional: (% among those that exist in facility)	**Register for sick babies**	1 (100.0%)	NA	NA	2 (100.0%)	3 (100.0%)
		Daily patient chart	1 (100.0%)	NA	1 (100.0%)	3 (100.0%)	5 (100.0%)
		IV fluid (neonatal giving) set/umbilical catheter	1 (100.0%)	NA	1 (100.0%)	3 (100.0%)	5 (100.0%)
		Syringes (0.5, 1.ml)	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Radiant warmer	1 (100.0%)	NA	NA	2 (100.0%)	3 (100.0%)
		Incubator	1 (100.0%)	NA	NA	1 (100.0%)	2 (100.0%)
		Designated space or beds for kangaroo mother care	NA	NA	NA	NA	NA
		KMC register	NA	1 (100.0%)	1 (100.0%)	2 (100.0%)	4 (100.0%)
		Nasogastric feeding tube	1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100.0%)
		Cup and spoon for infant feeding	NA	1 (100.0%)	NA	2 (100.0%)	3 (100.0%)
		Small cup for breast milk expression	NA	1 (100.0%)	NA	2 (100.0%)	3 (100.0%)
		Icterometer	NA	NA	NA	NA	NA

		Fluorescent tubes for phototherapy to treat jaundice	1 (100.0%)	NA	NA	1 (100.0%)	2 (100.0%)
Newborn resuscitation with bag and mask been performed within the past 3 months			1 (100.0%)	0 (0.0%)	1 (100.0%)	2 (66.7%)	4 (66.7%)
The following health worker provided neonatal resuscitation (% among those that said yes above)		**Doctor (GP)**	1 (100.0%)	NA	0 (0.0%)	1 (50.0%)	2 (50.0%)
		Pediatrician	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Neonatologist	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
		OB/GYN	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Associate Clinician	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Midwife	1 (100.0%)	NA	1 (100.0%)	1 (50.0%)	3 (75.0%)
		Nurse	0 (0.0%)	NA	1 (100.0%)	1 (50.0%)	2 (50.0%)
		CHW	0 (0.0%)	NA	1 (100.0%)	1 (50.0%)	2 (50.0%)
		Health Extension Officer	1 (100.0%)	NA	0 (0.0%)	0 (0.0%)	1 (25.0%)
Why newborn resuscitation with bag and mask was not performed within the past 3 months		**Lack of human resources**	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		Training needed	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		Lack of supplies/equipment/drugs	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		Weak management	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		Unsupportive or no policy	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		No indication	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		In Labour Ward	NA	0 (0.0%)	NA	1 (100.0%)	1 (50.0%)
		No need	NA	1 (100.0%)	NA	0 (0.0%)	1 (50.0%)
Antenatal Corticosteroids have been provided to manage pre-term labor in the past 3 months			1 (100.0%)	0 (0.0%)	1 (100.0%)	2 (66.7%)	4 (66.7%)
The following health worker provided antenatal corticosteroids (% among those that said yes above)		**Doctor (GP)**	1 (100.0%)	NA	0 (0.0%)	1 (50.0%)	2 (50.0%)
		Pediatrician	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Neonatologist	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
		OB/GYN	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Associate Clinician	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Midwife	1 (100.0%)	NA	1 (100.0%)	1 (50.0%)	3 (75.0%)
		Nurse	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
Why antenatal corticosteroids for pre-term labor were not provided within the past 3 months		**Lack of human resources**	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		Training needed	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		Lack of supplies/equipment/drugs	NA	1 (100.0%)	NA	0 (0.0%)	1 (50.0%)
		Weak management	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		Unsupportive or no policy	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		No indication	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
		In Labour Ward	NA	0 (0.0%)	NA	1 (100.0%)	1 (50.0%)
Antibiotics have been provided for preterm premature rupture of membranes (pPROM) in the past 3 months			1 (100.0%)	0 (0.0%)	1 (100.0%)	2 (66.7%)	4 (66.7%)

The following health worker provided antibiotics for pPROM (% among those that said yes above)	**Doctor (GP)**	0 (0.0%)	NA	0 (0.0%)	1 (50.0%)	1 (25.0%)
	Pediatrician	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Neonatologist	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	OB/GYN	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Associate Clinician	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Midwife	1 (100.0%)	NA	1 (100.0%)	1 (50.0%)	3 (75.0%)
	Nurse	0 (0.0%)	NA	0 (0.0%)	1 (50.0%)	1 (25.0%)
	Community Health Worker	1 (100.0%)	NA	0 (0.0%)	1 (50.0%)	2 (50.0%)
Why antibiotics for pPROM were not provided within the past 3 months	**Lack of human resources**	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	Training needed	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	Lack of supplies/equipment/drugs	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	Weak management	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	Unsupportive or no policy	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	No indication	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	In Labour ward	NA	0 (0.0%)	NA	1 (100.0%)	1 (50.0%)
	Case was referred, given penicillin	NA	1 (100.0%)	NA	0 (0.0%)	1 (50.0%)
Antibiotics have been provided for neonatal infections in the past 3 months		0 (0.0%)	0 (0.0%)	1 (100.0%)	3 (100.0%)	4 (66.7%)
The following health worker provided antibiotics for neonatal infections (% among those that said yes above)	**Doctor (GP)**	NA	NA	0 (0.0%)	1 (33.3%)	1 (25.0%)
	Pediatrician	NA	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Neonatologist	NA	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	OB/GYN	NA	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Associate Clinician	NA	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Midwife	NA	NA	1 (100.0%)	1 (33.3%)	2 (50.0%)
	Nurse	NA	NA	0 (0.0%)	3 (100.0%)	3 (75.0%)
	CHW	NA	NA	0 (0.0%)	1 (33.3%)	1 (25.0%)
Why antibiotics for neonatal infections were not provided within the past 3 months	**Lack of human resources**	0 (0.0%)	0 (0.0%)	NA	NA	0 (0.0%)
	Training needed	0 (0.0%)	0 (0.0%)	NA	NA	0 (0.0%)
	Lack of supplies/equipment/drugs	0 (0.0%)	0 (0.0%)	NA	NA	0 (0.0%)
	Weak management	0 (0.0%)	0 (0.0%)	NA	NA	0 (0.0%)
	Unsupportive or no policy	0 (0.0%)	0 (0.0%)	NA	NA	0 (0.0%)
	No indication	0 (0.0%)	0 (0.0%)	NA	NA	0 (0.0%)
	No Cases, but stock for sepsis	0 (0.0%)	1 (100.0%)	NA	NA	1 (50.0%)
	Referred to neonatal ward	1 (100.0%)	0 (0.0%)	NA	NA	1 (50.0%)
KMC has been given to very small babies in the past 3 months		1 (100.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	6 (100%)
The following health worker provided KMC in past 3 months (% among	**Doctor (GP)**	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100.0%)	3 (50.0%)
	Pediatrician	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Neonatologist	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

those that said yes above)	**OB/GYN**	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Associate Clinician	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Midwife	1 (100.0%)	0 (0.0%)	1 (100.0%)	1 (33.3%)	3 (50.0%)
	Nurse	0 (0.0%)	1 (100.0%)	1 (100.0%)	3 (100.0%)	5 (83.3%)
	Community Health Worker	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	3 (50.0%)
Oxygen has been administered to newborn in the past 3 months		1 (100.0%)	0 (0.0%)	1 (100.0%)	2 (66.7%)	4 (66.7%)
The following health worker administered oxygen in past 3 months (% among those that said yes above)	**Doctor (GP)**	0 (0.0%)	NA	0 (0.0%)	2 (100.0%)	2 (50.0%)
	Pediatrician	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Neonatologist	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	OB/GYN	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Associate Clinician	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Midwife	1 (100.0%)	NA	1 (100.0%)	1 (50.0%)	3 (75.0%)
	Nurse	0 (0.0%)	NA	0 (0.0%)	1 (50.0%)	1 (25.0%)
	Auxiliary Nurse	0 (0.0%)	NA	1 (100.0%)	0 (0.0%)	1 (25.0%)
	Community Health Worker	1 (100.0%)	NA	0 (0.0%)	0 (0.0%)	1 (25.0%)
Oxygen was monitored by pulse oximetry		0 (0.0%)	NA	0 (0.0%)	1 (50.0%)	1 (25.0%)
Why oxygen for newborns was not provided within the past 3 months	**Lack of human resources**	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	Training needed	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	Lack of supplies/equipment/drugs	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	Weak management	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	Unsupportive or no policy	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	No indication	NA	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)
	In Nursery	NA	0 (0.0%)	NA	1 (100.0%)	1 (25.0%)
	No Cases	NA	1 (100.0%)	NA	0 (0.0%)	1 (25.0%)

ii. Number and Percent of Premature and Low Birth Weight Infants at Hospital Admission

POMGEN			
Birth weight*	**Premature®**	**Full Term**	**Overall (all interviews)†**
ELBW (<1,000 g)	52 (12%)	3 (1%)	59 (5%)
VLBW (<1,500g)	116 (27%)	20 (5%)	154 (13%)
LBW (<2,500 g)	241 (58%)	332 (77%)	835 (73%)
Normal (2,500g or more)	17 (4%)	74 (17%)	91 (9%)
Total	426	429	1,139

Goroka Hospital			
Birth weight*	**Premature®**	**Full Term**	**Overall (all interviews)†**
ELBW (<1,000 g)	7 (4%)	0 (0%)	7 (1%)
VLBW (<1,500g)	30 (16%)	1 (0.2%)	35 (5%)
LBW (<2,500 g)	93 (50%)	62 (14%)	179 (23%)
Normal (2,500g or more)	55 (30%)	392 (86%)	556 (72%)
Total	185	455	777

*LBW in this table excludes VLBW and ELBW, and VLBW excludes ELBW for the purposes of comparison

®Preterm is calculated based on recorded gestational age

†Overall includes all reviewed infants with a recorded weight, regardless of whether gestational age was recorded

iii. Register Review Findings by Health Facility

Location		**POMGEN (n=2501)**		**Goroka Hospital (neonatal register only) (n=969)**	
		Mean (SD) or n (%)	**Min/ Max (for continuous variables)**	**Mean n (%)**	**Min/ Max (for continuous variables)**
Admission Weight (g)*†		1999.3 (SD 549.4)	520 / 4600	2794 (SD 821)	640 / 5610
Birth Weight (g)*		-	-	2834 (median 3000) (SD 784)	500 / 5700
Discharge Weight (g)*		1881.9 (SD 608.9)	485/4870	2788 (SD 777)	640 / 5360
Admission Weight (g) among those with recorded Discharge Weight*		1926.2 (SD 599.8)	520 / 4600	2802.8 (SD 814.1)	640 / 5610
Discharge Weight (g) among those with recorded Admission Weight*		1885.9 (SD 614.1)	485 / 4870	2785.3 (SD 777.5)	640 / 5360
Weight Change (g) (discharge - admission)		-40.3 - (SD 272.8)	-1400 / 3210	-17.4 (median -30) (SD 258)	- 2290 / 1060
Low Birth Weight*	**No**	99 (9%)		556 (72%)	
	Yes	1048 (91%)		221 (28%)	
	ELBW (<1,000 g)	59 (5%)		7 (1%)	

Birth Weight Category*	**VLBW (<1,500g)**	154 (13%)		35 (5%)	
	LBW (<2,500 g)	835 (73%)		179 (23%)	
	Normal (2,500g or more)	99 (9%)		556 (72%)	
Outcome	**Absconded**	27 (2%)		158 (16%)	
	Death	260 (22%)		114 (12%)	
	Discharged/Alive	735 (62%)		652 (67%)	
	Discharged, but died later	1 (0.1%)		-	
	LHAOR	16 (1%)		11 (1%)	
	Transferred out	103 (9%)		15 (2%)	
Gestational Age (in weeks)		36.0 (SD 3.6)	24 / 43	38.2 (median 39) (SD 3.6)	22 / 46
Prematurity*	**No**	434 (50%)		86 (45%)	
	Yes	431 (50%)		105 (55%)	
Premature Infants by Birth Weight Category	**ELBW (<1,000 g)**	52 (12%)		7 (4%)	
	VLBW (<1,500g)	116 (27%)		30 (16%)	
	LBW (<2,500 g)	241 (58%)		93 (50%)	
	Normal (2,500g or more)	17 (4%)		55 (30%)	
Term Infants by Birth Weight Category	**ELBW (<1,000 g)**	3 (1%)		0 (0%)	
	VLBW (<1,500g)	20 (5%)		1 (0.2%)	
	LBW (<2,500 g)	332 (77%)		62 (14%)	
	Normal (2,500g or more)	74 (17%)		392 (86%)	
Age at admission* (in days)		0.70 - (SD 3.84)	0 / 70	2.7 (median 0) (SD 5.4)	455
Length Stay (in days)		7.5 - (SD 9.8)	0 / 111	6.0 (median 3) (SD 9.8)	0 / 78
Complications	**No**	1337 (53.5%)		-	
	Yes	1164 (46.5%)		-	
Specific complications (among those with recorded complications)	**BBA**	66 (6%)		121 (13%)	
	PT	452 (39%)		133 (14%)	
	Hypothermia	4 (0.3%)		1 (0.1%)	
	IUGR	53 (5%)		30 (3%)	
	MEC	22 (2%)		310 (32%)	
	NNJ	29 (2.5%)		53 (6%)	
	NNS	102 (9%)		247 (25.5%)	
	PROM	69 (6%)		175 (18%)	
	RDS	43 (4%)		12 (1%)	
	RVI	3 (0.3%)		-	

Type of Delivery	**Normal Vaginal Delivery**	n/a		733 (76%)	
	Cesarean	-		92 (10%)	
	Vacuum-Assisted	-		38 (4%)	
	Breech	-		5 (1%)	
	Missing	-		101 (10%)	
Place of Birth	**General Hospital**	-		740 (77%)	
	Home	-		127 (13%)	
	Health center or aid post	-		32 (3%)	
	Rural hospital	-		26 (3%)	
	Missing information	-		44 (5%)	
	Born before arrival (BBA)	-		121 (13%)	

*Reflects register entries with the available information (e.g. percent of those who are premature only includes those with a recorded gestational age)

†Admission weight reflects the recorded weight of the infant upon presentation to the hospital (e.g. synonymous with birth weight for hospital births, but may reflect a later age weight if presenting after home births).

iv. Findings from Maternal Registers at Goroka

Birth Outcomes Recorded in Maternal Register – January—May 2017

Month	Total births	Live N (%)	FSB N (%)	MSB N (%)	Unspecified SB N (%)	Perinatal death N (%)
Jan	344	338 (98%)	4 (1%)	2 (1%)	-	-
Feb	334	323 (97%)	7 (2%)	3 (1%)	-	1 (0.3%)
Mar	374	357 (96%)	5 (1%)	8 (2%)	4 (1%)	-
Apr	377	362 (96%)	3 (1%)	6 (2%)	4 (1%)	2 (0.5%)
May	406	393 (97%)	6 (2%)	5 (1%)	-	2 (0.5%)
Total	1835	1774 (97%)	25 (1%)	24 (1%)	8 (0.4%)	5 (0.3%)

Maternal Characteristics for Neonates Born at Goroka Provincial Hospital

	Mean	Median	Range (Min/Max)
Maternal age (years)	24.9	23	14 / 46
Para	1.1	0	0 / 7
Gravida	2.2	1	1 / 8

Labor and Delivery Findings from Goroka Hospital

Details	Total N (%)
Membrane rupture	252

Spontaneous	152 (60%)
Artificial	100 (40%)
Labor	257
Spontaneous	166 (65%)
Augmented	77 (30%)
Induced	12 (5%)
Not in labor	2 (0.8%)
Amniotic liquid	228
Clear	132 (58%)
Meconium stained	96 (42%)
Presentation	265
Cephalic	241 (91%)
Breech	11 (4%)
Transverse	4 (2%)
Other (e.g., foot, arm, etc.)	9 (3%)
Partograph	264
Complete	176 (67%)
Not done	88 (33%)

Provisional and Final Diagnoses in Mothers in Goroka Hospital

Code	Provisional N (%)	Final N (%)
M1: Complications of placenta, cord and membranes	0 (0%)	2 (0.7%)
M2: Maternal complications of pregnancy	240 (82%)	226 (84%)
M3: Other complications of labor and delivery	1 (0.3%)	0 (0%)
M4: Maternal medical and surgical conditions	52 (18%)	42 (16%)
Total	293	270

v. Primary Contacts of Kol Kilok Users in Implementation Areas

Primary Contact	Eastern Highland Province (Community) (n=77)	95% Confidence Interval	Goroka Hospital (n=10)	95% Confidence Interval	POMGEN (n=48)	95% Confidence Interval	Overall (all interviews) (n=135)
VHV	73% (n=56)	63-83%	0% (n=0)	0%	2% (n=1)	0-6%	42% (n=57)
Health Provider	40% (n=31)	29-51%	0% (n=0)	0%	77% (n=37)	65-89%	50% (n=68)
Other User	1% (n=1)	0-4%	0% (n=0)	0%	0% (n=0)	0%	1% (n=1)
Other Person	8% (n=6)	2-14%	100% (n=10*)	100-100%	27% (n=13)	14-40%	22% (n=29)

*Of note, 6/10 reported contacting their research assistant at Goroka

vi. Healthcare Providers at Implementation Sites

	POMGEN	Goroka	Henganofi	Komperi	School of Midwifery	Overall (all interviews)*
Percent and Number Working at Each Facility	28% (n=14)	28% (n=14)	10% (n=5)	10% (n=5)	24% (n=12)	n=51
Types of Healthcare Providers	Medical Officer – 1 Nurses – 9 Midwife – 2 CHW – 2 --	-- Nurses – 9 Midwife – 3 CHW – 2 --	-- Nurses – 1 -- CHW – 2 Extension Health Worker – 2	-- Nurses – 3 -- CHW – 2 --	-- Nurses – 5 Midwife – 7 -- --	Medical Officer – 1 Nurses – 27 Midwife – 12 CHW – 8 Extension Health Worker – 2
Average Time in Position	Mean 231 months (n=14) Median 280 (range 6-672)	Mean 98 months (n=14) Median 66 (range 3-480)	Mean 126 months (n=5) Median 72 (range 1-400)	Mean 58 months (n=5) Median 24 (range 12-204)	Mean 30 months (n=12) Median 14 (range 4-108)	Mean 117 months (n=51) Median 54 (range 1-672)
Care Provision	-	-	-	-	-	-
Inpatient	93% (n=13)	79% (n=11)	80% (n=4)	80% (n=4)	67%) (n=8)	80% (n=40)
Intensive	71% (n=10)	79% (n=11)	40% (n=2)	20% (n=1)	17% (n=2)	52% (n=26)
Outpatient	36% (n=5)	14% (n=2)	80% (n=4)	100% (n=5)	67%) (n=8)	48% (n=24)
Other	29% (n=4)	36% (n=5)	60% (n=3)	60% (n=3)	58% (n=7)	44% (n=22)
Counseling	**86% (n=12)**	**93% (n=13)**	**100% (n=5)**	**100% (n=5)**	**100% (n=12)**	**94% (n=47)**
Postnatal Infant Care	93% (n=13)	71% (n=10)	100% (n=5)	100% (n=5)	75% (n=9)	84% (n=42)
Postnatal Maternal Care	71% (n=10)	71% (n=10)	100% (n=5)	100% (n=5)	75% (n=9)	78% (n=39)
Antenatal Care	21% (n=3)	14% (n=2)	100% (n=5)	100% (n=5)	67% (n=8)	46% (n=23)
Other	43% (n=6)	71% (n=10)	80% (n=4)	100% (n=5)	67% (n=8)	66% (n=33)
Receive Supervision	71% (n=10)	86% (n=12)	100% (n=5)	100% (n=5)	83% (n=10)	84% (n=42)
Frequency of Supervision	Daily – 2 (20%) -- --	Daily – 7 (58%) Weekly – 1 (8%) --	-- -- Monthly – 2 (40%)	-- Weekly – 1 (20%) Monthly - 1 (20%)	Daily – 4 (40%) Weekly – 2 (20%) Monthly – 1 (10%)	Daily – 13 (25%) Weekly – 4 (8%) Monthly – 4 (8%)

	-- Other – 8 (80%)	-- Other – 4 (24%)	Quarterly – 1 (20%) Other – 2 (40%)	Quarterly – 2 (40%) Other - 1 (20%)	Quarterly – 1 (10%) Other – 2 (20%)	Quarterly – 4 (8%) Other – 17 (33% [includes "occasional" and "by shift"])

*Represents all interviews, regardless of stated health occupation (e.g. the total number of persons interviewed [n=51], not the total number of people with a specified healthcare occupation [n=50]).

vii. Training on Hypothermia and Early Essential Newborn Care based on Facility Location

	POMGEN	**Goroka**	**Henganofi**	**Komperi**	**School of Midwifery**	**Overall (all interviews)***
Hypothermia Training	57% (n=8/14)	43% (n=6/14)	100% (n=5/5)	100% (n=5/5)	91% (n=10/11)	70% (n=35/50)
Time Since Last Training	Mean 207 days Median 206 (range 24-365 days)	Mean 155 days Median 173 (range 0-365 days)	Mean 102 days Median 151 (range 7-168 days)	Mean 74 days Median 41 (range 20-245 days)	Mean 165 days Median 105 (range 14-699 days)	Mean 152 days Median 138 (range 0-699 days)
Length of Training	Mean 1.5 days Median 1 (range 0.75-3.0)	Mean 2.6 days Median 2 (range 1.0-7.0)	Mean 1.6 days Median 1 (range 1.0-3.0)	Mean 1.2 days Median 1 (range 0.02-2.0)	Mean 1.9 days Median 1 (range 0.5-5.)	Mean 1.9 days Median 1 (range 0.02-7.0 days)
Topics Covered During Training (of those with training)	-	-	-	-	-	-
Kol Kilok	63% (n=5/8)	67% (n=4/6)	100% (n=5/5)	80% (n=4/5)	100% (n=10/10)	82% (n=28/34)
Treatment of Hypothermia	50% (n=4/8)	67% (n=4/6)	80% (n=4/5)	80% (n=4/5)	100% (n=10/10)	77% (n=26/34)
Diagnosis of Hypothermia	50% (n=4/8)	67% (n=4/6)	80% (n=4/5)	80% (n=4/5)	90% (n=9/10)	74% (n=25/34)
Counseling	25% (n=2/8)	33% (n=2/6)	80% (n=4/5)	80% (n=4/5)	70% (n=7/10)	56% (n=19/34)
Documentation	25% (n=2/8)	50% (n=3/6)	80% (n=4/5)	60% (n=3/5)	10% (n=1/10)	62% (n=13/34)
Essential Newborn Care Training (EENC)	64% (n=9/14)	79% (n=11/14)	100% (n=5/5)	80% (n=4/5)	91% (n=10/11)	80% (n=39/49)
Time Since Last Training	Mean 588 days	Mean 317 days	Mean 217 days	Mean 222 days	Mean 83 days	Mean 303 days

	Median 669 (range 27-943 days)	Median 111 (range 0-1096 days)	Median 184 (range 32-365 days)	Median 195 (range 141-356 days)	Median 14 (range 0-287 days)	Median 191 (range 0-1096 days)
Length of Training	Mean 4.7 days Median 2 (range 1-17)	Mean 2.9 days Median 3 (range 1-5)	Mean 4.0 days Median 3 (range 2-10)	Mean 2.0 days Median 2 (range 2-2)	Mean 5.6 days Median 2 (range 1-28)	Mean 4 days Median 2 (range 1-28 days)
Topics Covered During Training (of those with training)	-	-	-	-	-	-
Drying of Newborn	44% (n=4/9)	73% (n=8/11)	100% (n=5/5)	100% (n=4/4)	78% (n=7/9)	74% (n=28/38)
Cord Clamping	44% (n=4/9)	73% (n=8/11)	100% (n=5/5)	100% (n=4/4)	78% (n=7/9)	74% (n=28/38)
Skin-to-Skin	67% (n=6/9)	91% (n=10/11)	100% (n=5/5)	100% (n=4/4)	89% (n=8/9)	87% (n=33/38)
Breastfeeding	56% (n=5/9)	64% (n=7/11)	100% (n=5/5)	100% (n=4/4)	67% (n=6/9)	71% (n=27/38)
Resuscitation	44% (n=4/9)	46% (n=5/11)	0% (n=0/5)	0% (n=0/4)	44% (n=4/9)	27% (n=13/38)
Other†	33% (n=3/9)	9% (n=1/11)	40% (n=2/5)	75% (n=3/4)	33% (n=3/9)	32% (n=12/38)

*Represents answers from all interviews, regardless of stated health facility location

†"Other" responses include emergency care, eye antibiotics, family planning, hypothermia, follow-up visits, KMC, LBW, oxytocin, bathing and vaccinations

viii. Clinical Knowledge by Health Facility Location

Clinical Knowledge	POMGEN	Goroka	Henganofi	Komperi	School of Midwifery	Overall (all interviews)*
Prematurity (<37 weeks)	43% (n=6/14)	79% (n=11/14)	100% (n=5/5)	100% (n=5/5)	91% (n=10/11)	76% (n=37/49)
Low Birth Weight (<2500g)	78% (n=11/14)	86% (n=12/14)	100% (n=5/5)	100% (n=5/5)	100% (n=11/11)	90% (n=44/49)
Hypothermia Diagnosis (<36.5^{O} C)	57% (n=8/14)	50% (n=7/14)	100% (n=5/5)	100% (n=5/5)	82% (n=9/11)	70% (n=35/50)
Temperature Measurement Method in Newborn	7% Sublingual (n=1/14) 7% Tympanic (n=1/14) 14% Rectal (n=2/14) 100% Axillary (n=14/14)	-- -- -- 100% Axillary (n=14/14)	-- -- 20% Rectal (n=1/50 100% Axillary (n=5/5)	-- -- -- 100% Axillary (n=5/5)	-- -- -- 100% Axillary (n=11/11)	2% Sublingual (n=1/49) 2% Tympanic (n=1/49 6% Rectal (n=3/49) 100% Axillary (n=49/49)

	29% Other (n=4/14)	--	20% Other (n=1/5)	--	9% Other (n=1/11)	12% Other (n=6/49)
Temperature Measurement Frequency in Healthy Newborn	--	--	--	--	9% - Once (n=1/11)	2% - Once (n=1/49)
	--	--	--	20% - Every 15 minutes (n=1/5)	9% - Every 15 minutes (n=1/11)	4% - Every 15 minutes (n=2/49)
	14% - Every 30 minutes (n=2/14)	--	--	--	--	4% - Every 30 minutes (n=2/49)
	--	--	20% - Every 1 hour (n=1/5)	40% - Every 1 hour (n=2/5)	9% - Every 1 hour (n=1/11)	8% - Every 1 hour (n=4/49)
	36% - Every 6 hours (n=5/14)	50% - Every 6 hours (n=7/14)	60% - Every 6 hours (n=3/5)	20% - Every 6 hours (n=1/5)	18% - Every 6 hours (n=2/11)	37% - Every 6 hours (n=18/49)
	50% - Other frequencies (n=7/14)	50% - Other frequencies (n=7/14)	20% - Other frequencies (n=1/5)	20% - Other frequencies (n=1/5)	55% - Other frequencies (n=6/11)	45% - Other frequencies (n=22/49)
Temperature Measurement Frequency in Premature Newborn	--	--	--	--	--	0% - Once (n=0/49)
	14% - Every 15 minutes (n=2/14)	--	20% - Every 15 minutes (n=1/5)	40% - Every 15 minutes (n=2/5)	9% - Every 15 minutes (n=1/11)	12% - Every 15 minutes (n=6/49)
	14% - Every 30 minutes (n=2/14)	14% - Every 30 minutes (n=2/14)	20% - Every 30 minutes (n=1/5)	40% - Every 30 minutes (n=2/5)	9% - Every 30 minutes (n=1/11)	12% - Every 30 minutes (n=6/49)
	--	14% - Every 1 hour (n=2/14)	20% - Every 1 hour (n=1/5)	40% - Every 1 hour (n=2/5)	27% - Every 1 hour (n=3/11)	16% - Every 1 hour (n=8/49)
	36% - Every 6 hours (n=5/14)	50% - Every 6 hours (n=7/14)	--	--	36% - Every 6 hours (n=4/11)	33% - Every 6 hours (n=16/49)
	36% - Other frequencies (n=5/14)	21% - Other frequencies (n=3/14)	40% - Other frequencies (n=2/5)	20% - Other frequencies (n=1/5)	18% - Other frequencies (n=2/11)	27% - Other frequencies (n=13/49)
Newborn Care to be taken after birth	-	-	-	-	-	-
Cord Clamping	29% (n=4/14)	79% (n=11/14)	100% (n=5/5)	100% (n=5/5)	64% (n=7/11)	65% (n=32/49)
Skin-to-Skin	43% (n=6/14)	93% (n=13/14)	100% (n=5/5)	100% (n=5/5)	100% (n=11/11)	82% (n=40/49)
Breastfeeding	57% (n=8/14)	93% (n=13/14)	100% (n=5/5)	100% (n=5/5)	91% (n=10/11)	84% (n=41/49)
Newborn Assessment	64% (n=9/14)	100% (n=14/14)	100% (n=5/5)	100% (n=5/5)	55% (n=6/11)	80% (n=39/49)
Eye Antibiotics	21% (n=3/14)	57% (n=8/14)	80% (n=4/5)	80% (n=4/5)	64% (n=7/11)	53% (n=26/49)

Vitamin K	21% (n=3/14)	57% (n=8/14)	80% (n=4/5)	100% (n=5/5)	82% (n=9/11)	59% (n=29/49)
Treatment of Hypothermia	-	-	-	-	-	-
KMC	79% (n=11/14)	100% (n=14/14)	100% (n=5/5)	100% (n=5/5)	82% (n=9/11)	88% (n=44/50)
Swaddling or Blankets	100% (n=14/14)	100% (n=14/14)	100% (n=5/5)	100% (n=5/5)	82% (n=9/11)	96% (n=48/50)
Radiant Warmer	93% (n=13/14)	29% (n=4/14)	0% (n=0/5)	0% (n=0/5)	9% (n=1/11)	36% (n=18/50)
Warming Pad	7% (n=1/14)	71% (n=10/14)	20% (n=1/5)	20% (n=1/5)	36% (n=4/11)	34% (n=17/50)
Clothing	43% (n=6/14)	0% (n=0/14)	0% (n=0/5)	20% (n=1/5)	9% (n=1/11)	16% (n=8/50)
Incubator	7% (n=1/14)	7% (n=1/14)	0% (n=0/5)	0% (n=0/5)	9% (n=1/11)	6% (n=3/50)
Hospital Stay Length after Healthy Birth	--	--	20% - 12 hours (n=1)	--	--	12 hours - 2% (n=1)
	24 hours - 50% (n=7/14)	24 hours - 64% (n=9/14)	--	--	24 hours - 18% (n=2/11)	24 hours -37% (n=18/49)
	--	--	--	--	36 hours - 9% (n=1/11)	36 hours - 2% (n=1/49)
	48 hours - 7% (n=1/14)	48 hours - 36% (n=5/14)	48 hours - 60% (n=3/5)	48 hours - 100% (n=5/5)	48 hours - 27% (n=3/11)	48 hours - 35% (n=17/49)
	--	--	--	--	72 hours - 27% (n=3/11)	72 hours - 6% (n=3/49)
	Other - 43% (n=6/14)	--	Other - 20% (n=1/5)	--	Other - 22% (n=2/11)	Other - 18% (n=9/49)

*Represents answers from all interviews, regardless of stated health facility location

ix. Care Provided, Counseling Topics and Clinical Knowledge by Health Provider Type

	Medical Officers (n=1)	**Nurses (n= 27)®†**	**Midwives (n=10)**	**Community Health Workers (n=8)**	**Health Extension Officers (n=2)**	**Overall (all interviews)***
Care Provided (n=50)	-	-	-	-	-	-
Outpatient	100% (n=1)	41% (n=11)	40% (n=4)	50% (n=4)	100% (n=2)	80% (n=40)
Inpatient	100% (n=1)	78% (n=21)	80% (n=8)	75% (n=6)	100% (n=2)	52% (n=26)
Intensive (ICU)	100% (n=1)	52% (n=14)	50% (n=5)	38% (n=3)	100% (n=2)	48% (n=24)
Counseling Topics	-	-	-	-	-	-

Antenatal	0% (n=0)	33% (n=9)	50% (n=5)	63% (n=5)	100% (n=2)	46% (n=23)
Postnatal Maternal	0% (n=0)	78% (n=21)	70% (n=7)	88% (n=7)	100% (n=2)	78% (n=39)
Postnatal Infant	100% (n=1)	82% (n=22)	70% (n=7)	100% (n=8)	100% (n=2)	84% (n=42)
Clinical Knowledge	-	-	-	-	-	-
Prematurity (<37 weeks)	100% (n=1)	82% (n=22)	44% (n=4/9)	75% (n=6)	100% (n=2)	76% (n=37/49)
Low Birth Weight (<2500g)	100% (n=1)	93% (n=25)	78% (n=7)	88% (n=7)	100% (n=2)	90% (n=44/49)
Hypothermia Diagnosis (<36.5^{O} C)	0% (n=0)	70% (n=19/27)	44% (n=4)	88% (n=7)	100% (n=2)	70% (n=35/50)
Temperature Measurement Method in Newborn	-- -- -- 100% Axillary (n=1) 100% Other (n=1)	4% Sublingual (n=1/27) 4% Tympanic (n=1/27) 7% Rectal (n=3/41) 100% Axillary (n=27) 11% Other (n=3/27)	-- -- -- 100% Axillary (n=9) 15% Other (n=6/41)	-- -- -- 100% Axillary (n=8) 25% Other (n=2)	-- -- 50% Rectal (n=1) 100% Axillary (n=2) --	2% Sublingual (n=1/49) 2% Tympanic (n=1/49 6% Rectal (n=3/49) 100% Axillary (n=49/49) 12% Other (n=6/49)
Temperature Measurement Frequency in Healthy Newborn	-- -- -- -- 100% - Other frequencies (n=1)	4% - Once (n=1) 4% - Every 15 minutes (n=1) 4% - Every 30 minutes (n=1) 4% - Every 1 hour (n=1) 41% - Every 6 hours (n=11) 4% - Other frequencies (n=1)	-- 11% - Every 15 minutes (n=1) -- -- 22% - Every 6 hours (n=2) 67% - Other frequencies (n=6)	-- -- 13% - Every 30 minutes (n=1) 38% - Every 1 hour (n=3) 25% - Every 6 hours (n=2) 25% - Other frequencies (n=2)	-- -- -- -- 100% - Every 6 hours (n=2) --	2% - Once (n=1/49) 4% - Every 15 minutes (n=2/49) 4% - Every 30 minutes (n=2/49) 8% - Every 1 hour (n=4/49) 37% - Every 6 hours (n=18/49) 45% - Other frequencies (n=22/49)
Temperature Measurement Frequency in	--	--	--	--	--	0% - Once (n=0/49)

Premature Newborn	100% - Every 15 minutes (n=1) -- -- -- --	4% - Every 15 minutes (n=1) 7% - Every 30 minutes (n=2) 19% - Every 1 hour (n=5) 19% - Every 6 hours (n=5) 30% - Other frequencies (n=8)	11% - Every 15 minutes (n=1) 11% - Every 30 minutes (n=1) -- 44% - Every 6 hours (n=4) 33% - Other frequencies (n=3)	25% - Every 15 minutes (n=2) 25% - Every 30 minutes (n=2) 13% - Every 1 hour (n=1) 13% - Every 6 hours (n=1) 25% - Other frequencies (n=2)	50% - Every 15 minutes (n=1) -- 50% - Every 1 hour (n=1) -- --	12% - Every 15 minutes (n=6/49) 12% - Every 30 minutes (n=6/49) 16% - Every 1 hour (n=8/49) 33% - Every 6 hours (n=16/49) 27% - Other frequencies (n=13/49)
Care to be taken after birth (n=47)	-	-	-	-	-	-
Cord Clamping	0% (n=0)	63% (n=17)	56% (n=5/9)	75% (n=6)	100% (n=2)	65% (n=32/49)
Skin-to-Skin	100% (n=1)	74% (n=20)	89% (n=8)	88% (n=7)	100% (n=2)	82% (n=40/49)
Breastfeeding	100% (n=1)	74% (n=20)	100% (n=9)	88% (n=7)	100% (n=2)	84% (n=41/49)
Newborn Assessment	0% (n=0)	82% (n=22)	67% (n=6)	88% (n=7)	100% (n=2)	80% (n=39/49)
Eye Antibiotics	0% (n=0)	48% (n=13)	56% (n=5)	63% (n=5)	100% (n=2)	53% (n=26/49)
Vitamin K	0% (n=0)	52% (n=14)	67% (n=6)	63% (n=5)	100% (n=2)	59% (n=29/49)
Treatment of Hypothermia (n=47)	-	-	-	-	-	-
KMC	100% (n=1)	85% (n=23)	89% (n=8/9)	100% (n=8)	100% (n=2)	88% (n=44/50)
Swaddling or Blankets	100% (n=1)	100% (n=27)	78% (n=7)	100% (n=8)	100% (n=2)	96% (n=48/50)
Radiant Warmer	100% (n=1)	44% (n=12)	22% (n=2)	38% (n=3)	0% (n=0)	36% (n=18/50)
Warming Pad	0% (n=1)	41% (n=11)	33% (n=3)	13% (n=1)	50% (n=1)	34% (n=17/50)
Clothing	0% (n=0)	15% (n=4)	22% (n=2)	25% (n=2)	0% (n=0)	16% (n=8/50)
Incubator	0% (n=0)	11% (n=3)	0% (n=0)	0% (n=0)	0% (n=0)	6% (n=3/50)
Hospital Stay Length after Healthy Birth	--	--	--	--	12 hours (n=1) --	12 hours - 2% (n=1)

	24 hours (n=1) -- -- -- --	24 hours (n=11) 36 hours (n=1) 48 hours (n=8) 72 hours (n=1) Other (n=6)	24 hours (55%, n=9) -- 48 hours (n=1) 72 hours (n=1) Other (n=2)	24 hours (n=1) -- 48 hours (n=6) -- Other (n=1)	 -- 48 hours (n=1) -- --	24 hours - 37% (n=18/49) 36 hours - 2% (n=1/49) 48 hours - 35% (n=17/49) 72 hours - 6% (n=3/49) Other - 18% (n=9/49)

*Represents answers from all interviews, regardless of stated health facility location

®Includes 1 nurse administrator

†Includes 3 nurses with midwifery training

x. Clinical Knowledge based on Provider Care Provision

Clinical Knowledge	Post Natal Infant Care (n=41)	Post Natal Maternal Care (n=38)	Antenatal Care (n=23)	Overall (all interviews)* (n=51)
Prematurity (<37 weeks)	73% (n=30/41)	76% (n=29/38)	87% (n=20/23)	76% (n=37/49)
Low Birth Weight (2500g)	90% (n=37/41)	90% (n=34/38)	100% (n=23/23)	90% (n=44/49)
Hypothermia Diagnosis (<36.5^{O} C)	73% (n=29/41)	71% (n=27/38)	87% (n=20/23)	70% (n=35/50)
Temperature Measurement Method in Newborn	2% Sublingual (n=1/41) 2% Tympanic (n=1/41) 7% Rectal (n=3/41) 100% Axillary (n=41/41) 15% Other (n=6/41)	3% Sublingual (n=1/38) 3% Tympanic (n=1/38) 5% Rectal (n=2/38) 100% Axillary (n=38/38) 8% Other (n=3/38)	0% Sublingual (n=0/23) -- 9% Rectal (n=2/23) 100% Axillary (n=23/23) 17% Other (n=4/23)	2% Sublingual (n=1/49) 2% Tympanic (n=1/49 6% Rectal (n=3/49) 100% Axillary (n=49/49) 12% Other (n=6/49)
Temperature Measurement Frequency in Healthy Newborn	2% - Once (n=1) 5% - Every 15 minutes (n=2) 5% - Every 30 minutes (n=2) 10% - Every 1 hour (n=4) 34% - Every 6 hours (n=14)	3% - Once (n=1) 5% - Every 15 minutes (n=2) 5% - Every 30 minutes (n=2) 11% - Every 1 hour (n=4) 37% - Every 6 hours (n=14)	4% - Once (n=1) 9% - Every 15 minutes (n=2) 4% - Every 30 minutes (n=1) 13% - Every 1 hour (n=3) 30% - Every 6 hours (n=7)	2% - Once (n=1/49) 4% - Every 15 minutes (n=2/49) 4% - Every 30 minutes (n=2/49) 8% - Every 1 hour (n=4/49) 37% - Every 6 hours (n=18/49)

	44% - Other frequencies (n=18)	40% - Other frequencies (n=15)	39% - Other frequencies (n=9)	45% - Other frequencies (n=22/49)
Temperature Measurement Frequency in Premature Newborn	-- 15% - Every 15 minutes (n=6) 15% - Every 30 minutes (n=6) 20% - Every 1 hour (n=8) 27% - Every 6 hours (n=11) 24% - Other frequencies (n=10)	-- 13% - Every 15 minutes (n=5) 13% - Every 30 minutes (n=5) 21% - Every 1 hour (n=8) 29% - Every 6 hours (n=11) 24% - Other frequencies (n=9)	-- 22% - Every 15 minutes (n=5) 13% - Every 30 minutes (n=3) 22% - Every 1 hour (n=5) 22% - Every 6 hours (n=5) 22% - Other frequencies (n=5)	0% - Once (n=0/49) 12% - Every 15 minutes (n=6/49) 12% - Every 30 minutes (n=6/49) 16% - Every 1 hour (n=8/49) 33% - Every 6 hours (n=16/49) 27% - Other frequencies (n=13/49)
Care to be taken After Birth (n=49)	-	-	-	-
Cord Clamping	63% (n=26/41)	66% (n=25/38)	87% (n=20/23)	65% (n=32/49)
Skin-to-Skin	78% (n=32/41)	79% (n=30/38)	96% (n=22/23)	82% (n=40/49)
Breastfeeding	81% (n=33/41)	82% (n=31/38)	91% (n=21/23)	84% (n=41/49)
Newborn Assessment	81% (n=33/41)	84% (n=32/38)	78% (n=18/23)	80% (n=39/49)
Eye Antibiotics	51% (n=21/41)	55% (n=21/38)	70% (n=16/23)	53% (n=26/49)
Vitamin K	59% (n=24/41)	63% (n=24/38)	83% (n=19/23)	59% (n=29/49)
Treatment of Hypothermia (n=50)	-	-	-	-
KMC	90% (n=37/41)	90% (n=34/38)	100% (n=23/23)	88% (n=44/50)
Swaddling or Blankets	98% (n=40/41)	97% (n=37/38)	96% (n=22/23)	96% (n=48/50)
Radiant Warmer	37% (n=15/41)	32% (n=12/38)	13% (n=3/23)	36% (n=18/50)
Warming Pad	29% (n=12/41)	32% (n=12/38)	30% (n=7/23)	34% (n=17/50)
Clothing	22% (n=9/41)	18% (n=7/38)	17% (n=4/23)	16% (n=8/50)
Incubator	5% (n=2/41)	5% (n=2/38)	4% (n=1/23)	6% (n=3/50)

Hospital Stay Length after Healthy Birth	12 hours - 2% (n=1) 24 hours - 32% (n=13) 36 hours - 2% (n=1) 48 hours - 37% (n=15) 72 hours - 7% (n=3) Other - 20% (n=8)	12 hours - 3% (n=1) 24 hours - 29% (n=11) 36 hours - 3% (n=1) 48 hours - 40% (n=15) 72 hours - 8% (n=3) Other - 18% (n=7)	12 hours - 4% (n=1) 24 hours - 17% (n=4) 36 hours - 4% (n=1) 48 hours - 48% (n=11) 72 hours - 6% (n=3) Other - 13% (n=3)	12 hours - 2% (n=1) 24 hours -37% (n=18/49) 36 hours - 2% (n=1/49) 48 hours - 35% (n=17/49) 72 hours - 6% (n=3/49) Other - 18% (n=9/49)

*Represents answers from all interviews, regardless of stated health facility location

xi. Knowledge of Kol Kilok, After Birth Care and Treatment of Hypothermia based on Training Level

	With Training+	**Without Training**	**Overall (all interviews)***
Prematurity (<37 weeks) [EENC Training®]	72% (n=28/39)	90% (n=9/10)	76% (n=37/49)
Low Birth Weight (<2500g) [EENC Training®]	87% (n=34/39)	100% (n=10/10)	90% (n=44/49)
Hypothermia Diagnosis (<36.5^{O} C) [Hypothermia Diagnostic Training®]	88% (n=22/25)	50% (n=12/24)	70% (n=35/50)
Temperature Measurement Method in Newborn [Hypothermia Diagnostic Training®]	-- -- 4% Rectal (n=1/25) 100% Axillary (n=25/25) 8% Other (n=2/25)	4% Sublingual (n=1/24) 4% Tympanic (n=1/24) 8% Rectal (n=2/24) 100% Axillary (n=24/24) 17% Other (n=4/24)	2% Sublingual (n=1/49) 2% Tympanic (n=1/49 6% Rectal (n=3/49) 100% Axillary (n=49/49) 12% Other (n=6/49)
Temperature Measurement Frequency in Healthy Newborn [Hypothermia Diagnostic Training®]	-- 8% - Every 15 minutes (n=2) 4% - Every 30 minutes (n=1) 16% - Every 1 hour (n=4) 36% - Every 6 hours (n=9) 36% - Other frequencies (n=9)	4% - Once (n=1) -- 4% - Every 30 minutes (n=1) -- 38% - Every 6 hours (n=9) 54% - Other frequencies (n=13)	2% - Once (n=1/49) 4% - Every 15 minutes (n=2/49) 4% - Every 30 minutes (n=2/49) 8% - Every 1 hour (n=4/49) 37% - Every 6 hours (n=18/49) 45% - Other frequencies (n=22/49)

Temperature Measurement Frequency in Premature Newborn [Hypothermia Diagnostic Training®]	-- 20% - Every 15 minutes (n=5) 8% - Every 30 minutes (n=2) 32% - Every 1 hour (n=8) 24% - Every 6 hours (n=6) 16% - Other frequencies (n=4)	-- 4% - Every 15 minutes (n=1) 17% - Every 30 minutes (n=4) -- 42% - Every 6 hours (n=10) 38% - Other frequencies (n=9)	0% - Once (n=0/49) 12% - Every 15 minutes (n=6/49) 12% - Every 30 minutes (n=6/49) 16% - Every 1 hour (n=8/49) 33% - Every 6 hours (n=16/49) 27% - Other frequencies (n=13/49)
Essential Newborn Care (EENC Training®)	-	-	-
Cord Clamping®	74% (n=23/28)	26% (n=8/20)	65% (n=32/49)
Skin-to-Skin®	91% (n=30/33)	60% (n=9/15)	82% (n=40/49)
Breastfeeding®	96% (n=26/27)	71% (n=15/21)	84% (n=41/49)
Newborn Assessment	80% (n=31/39)	80% (n=8/10)	80% (n=39/49)
Eye Antibiotics	56% (n=22/39)	40% (n=4/10)	53% (n=26/49)
Vitamin K	64% (n=25/39)	40% (n=4/10)	59% (n=29/49)
Treatment of Hypothermia (Hypothermia Treatment Training®)	-	-	-
KMC	92% (n=24/26)	87% (n=20/23)	88% (n=44/50)
Swaddling or Blankets	96% (n=25/26)	96% (n=22/23)	96% (n=48/50)
Radiant Warmer	19% (n=5/26)	56% (n=13/23)	36% (n=18/50)
Warming Pad	39% (n=10/26)	30% (n=7/23)	34% (n=17/50)
Clothing	15% (n=4/26)	17% (n=4/23)	16% (n=8/50)
Incubator	4% (n=1/26)	9% (n=2/23)	6% (n=3/50)
Kol Kilok (Hypothermia Training specific to Kol Kilok®) [only includes those "familiar with Kol Kilok"]	-	-	-
Blue Light	78% correct (n=21/27) 11% partial	81% correct (n=13/16) 6% partial	79% correct (n=34/43) 9% partial

	(n=3) 11% incorrect (n=3)	(n=1/16) 13% incorrect (n=2/16)	(n=4/43) 12% incorrect (n=5/43)
Orange Light	85% correct (n=23/27) 7% partial (n=2/27) 7% incorrect (n=2/27)	81% correct (n=13/16) 13% partial (n=2/16) 6% incorrect (n=1/16)	84% correct (n=36/43) 9% partial (n=4/43) 7% incorrect (n=3/43)
Continued Alarms	93% correct (n=25/27) -- 7% incorrect (n=2/27)	81% correct (n=13/16) 6% partial (n=1/16) 13% incorrect (n=2/16)	88% correct (n=38/43) 2% partial (n=1/43) 9% incorrect (n=4/43)
No light	63% correct (n=17/27) 15% incorrect (n=4/27) 22% unclear (n=6/27)	63% correct (n=10/16) 25% incorrect (n=4/16) 13% unclear (n=2/16)	63% correct (n=27/43) 19% incorrect (n=8/43) 19% unclear (n=8/43)

*Represents answers from all interviews, regardless of training level

[+]Training on specific topic – either Kol Kilok, ENC or treatment of hypothermia (all subtopics indicated by [*] were specifically asked whether training had occurred)

[®]Specifically asked if training had been conducted on this topic

C. Appendix 3: Evaluation Questions and Matrix

Evaluation Question	Data Collection Tool	Source(s)	Purpose	Indicator	Criteria
Has the device been well accepted by the target population and involved health workers/VHV?	**-Caregiver Interview** **-Health Provider Interview** **-VHV Interview**	Individual interview(s)	Assess caregiver, health worker and VHV satisfaction, opinions, and perceived beliefs on use of Kol Kilok	- Percentage of caregivers, health workers, and VHV who liked the Kol Kilok device and program (%) - Percentage of caregivers, health workers and VHV with challenges surrounding use of the device or program (%)	- Relevance, effectiveness, efficiency
			Evaluate reception to training and counseling on Kol Kilok, EENC and hypothermia amongst participants	- Percentage of caregivers who received counseling on Kol Kilok (%) - Percentage of health workers and VHV who reported training on Kol Kilok, EENC and hypothermia (%)	
Has the device's implementation been feasible in community settings?	**-Caregiver Interview** **-VHV Interview** **-Health Facility Assessment** **-Impl. Leads**	Individual interview(s)	Assess the ease of accessing and providing Kol Kilok to caregivers and neonates in non hospital and community settings	- Attitudes and opinions of caregivers observing Kol Kilok users in community settings - Reported process and observations of VHV distribution to and enrollment of participants - Percentage of caregivers reporting issues with access to health centers and contact with VHV (%)	- Relevance, coherence, connectedness, coverage, effectiveness, efficiency

			Evaluate challenges and concerns surrounding Kol Kilok and EENC in village health volunteer (VHV) network	- Percentage of caregivers with identified challenges within the program - Percentage of VHV with identified challenges of the program (%) - Percentage of caregivers with a reported malfunctioning device (%)	
			Assess frequency of visits and time involved in Kol Kilok activities (i.e. VHV)	- Frequency of VHV visits and counseling (#) - Average, median and range of VHV time spent working on Kol Kilok and other activities (#)	
			Evaluate capacity and accessibility of local health centers for referrals of and management of continued alerts	- Percentage of caregivers/VHV with identified issues surrounding access to healthcare (%) - Percent and number of community health centers with accessible, operational and staffed facilities for neonatal care (%) - Percentage and number of community health centers with available/functional equipment to respond to hypothermia, infections and neonatal resuscitation (%)	

			Assess how often the device is removed or not used	- Percentage of caregivers who removed the device (%)	
			Ascertain return rate of device	- Percentage of caregivers who kept the device at home after four weeks of use (%)	
Has the device's implementation been feasible for high risk newborns in hospital settings?	**-Caregiver Interview** **-Healthcare Worker Interview** **-Health Facility Assessment** **-Impl. Lead Interview** **-Chart and Register Review** **-KMC Diary Review**	Individual Interview(s) Document Review	Assess the ease of providing Kol Kilok to caregivers and high risk neonates in hospital settings	- Attitudes and opinions of caregivers observing Kol Kilok users in hospital settings - Reported process and observations of device distribution to and enrollment of participants - Percentage of caregivers reporting issues with access to health centers and contact with VHV (%)	- Relevance, coherence, connectedness, coverage, effectiveness, efficiency
			Evaluate challenges and concerns surrounding Kol Kilok and EENC in hospital healthcare workers	- Percentage of caregivers with identified challenges within the program - Percentage of healthcare workers with identified challenges of the program (%) - Percentage of caregivers with a reported malfunctioning device (%)	

			Evaluate capacity and accessibility of hospitals for referrals of and management of continued alerts	- Percentage and number of hospitals with accessible, operational and staffed facilities for neonatal care (%) - Percentage and number of hospitals with available/functional equipment to respond to hypothermia, infections and neonatal resuscitation (%)	
			Assess how often the device is removed or not used	- Percentage of caregivers who removed the device (%)	
What health outcomes have been observed in Kol Kilok users compared to controls?	**-Caregiver Interview** **-Focus Group Discussions** **-Chart and Register Review** **-KMC Diary Review** **-Verbal Autopsy**	Individual Interview(s) Focus Group Discussion Document Review	Review of KMC diary data on weekly changes in weight and KMC in both Kol Kilok users and controls	- Weekly weight gain amongst Kol Kilok users compared to controls - KMC frequency amongst Kol Kilok users compared to controls (#)	- Relevance, effectiveness, efficiency
			Assess for differences in hypothermia in Kol Kilok users compared to controls	- Mean recorded temperature in Kol Kilok users and controls before and after the intervention - Percentage of hypothermic temperatures in Kol Kilok users compared to controls	
			Evaluate differences in outcomes in Kol Kilok users compared to controls	- Percentage of adverse health outcomes reported in Kol Kilok users compared to controls (e.g. infections)	

			Assess for differences in mortality in Kol Kilok users compared to controls	- Mortality rates of Kol Kilok users compared to controls	
Has the program increased use of Early Essential Newborn Care components? (i.e. Specifically KMC)	-**Caregiver Interview** -**Healthcare Worker Interview** **-VHV Interview** -**KMC Diary Review**	Individual interview(s) Document Review	Assess opinions and beliefs of caregivers, healthcare workers and VHV regarding EENC	- Kol Kilok user practices and beliefs around EENC compared to non users in focus groups - Healthcare worker and VHV practices and beliefs around EENC	- Coordination, connectedness, coherence, efficiency, impact
			Assess clinical knowledge regarding EENC and efficacy of training	- Caregiver, healthcare worker, and medical knowledge accuracy surrounding EENC (%) - Caregiver, healthcare worker and VHV knowledge on EENC accuracy compared to those without training (%) - Changes in healthcare worker practice due to device use (e.g. improvement or worsening)	
			Ascertain human resource capacity for implementation and programmatic operations	- Number of healthcare workers and quality of counseling provided on EENC (#,%) - Number of VHV and quality of counseling provided on EENC (#,%)	

			Review of KMC diary data on weekly changes in KMC in both Kol Kilok users and controls	- KMC frequency amongst Kol Kilok users compared to controls (#)	
Has the program increased early referral and recognition of hypothermia?	**-Caregiver Interview** **-Healthcare Worker Interview** **-VHV Interview** **-Focus Group Discussions** **-Chart and Register Review** **-KMC diary review**	Individual Interview(s) Focus Group Discussions Document Review	Assess opinions and beliefs of caregivers, healthcare workers and VHV regarding hypothermia	- Kol Kilok user practices and beliefs around hypothermia compared to non users in focus groups - Healthcare worker and VHV practices and beliefs around hypothermia	- Coordination, connectedness, coherence, efficiency, impact
			Assess clinical knowledge regarding detection and management of hypothermia	- Caregiver, healthcare worker, and medical knowledge accuracy surrounding hypothermia (%) - Caregiver, healthcare worker and VHV knowledge on hypothermia accuracy compared to those without training (%) - Changes in healthcare worker practice due to device use (e.g. improvement or worsening)	
			Evaluate caregiver and health worker/VHV recognition of hypothermia	- Number of hypothermic alerts compared to number of recorded KMC in the first week of hospitalization	

			Ascertain human resource capacity for implementation and programmatic operations (hospital setting)	- Number of healthcare workers and quality of counseling provided on hypothermia (#, %) - Number of VHV and quality of counseling provided on hypothermia (#, %)	
			Assess the frequency of hypothermia detection by Kol Kilok devices and users	- Percentage of Kol Kilok users who report daily or weekly alarms (%) - Frequency of daily and/or weekly alarms amongst Kol Kilok users	
Has the program increased health seeking behaviors or interventions?	**-Caregiver Interview** **-Healthcare Worker Interview** **-VHV Interview**	Individual interview(s)	Ascertain barriers and beliefs regarding healthcare access	- Percentage of caregivers, healthcare workers and VHV with identified problems regarding access to health centers and hospitals (%)	- Coherence, relevance, coverage, effectiveness, efficiency, impact
			Evaluate knowledge and practices of caregivers and VHV surrounding referrals to health facilities	- Percentage and number of Kol Kilok users with knowledge of need for referral (%) - Percentage of Kol Kilok users who referred their neonate to a health facility for continued alarms (%) - Percentage of VHV who referred a Kol Kilok user to a health facility for continued alarms (%) - Outcomes and description of referrals to health	

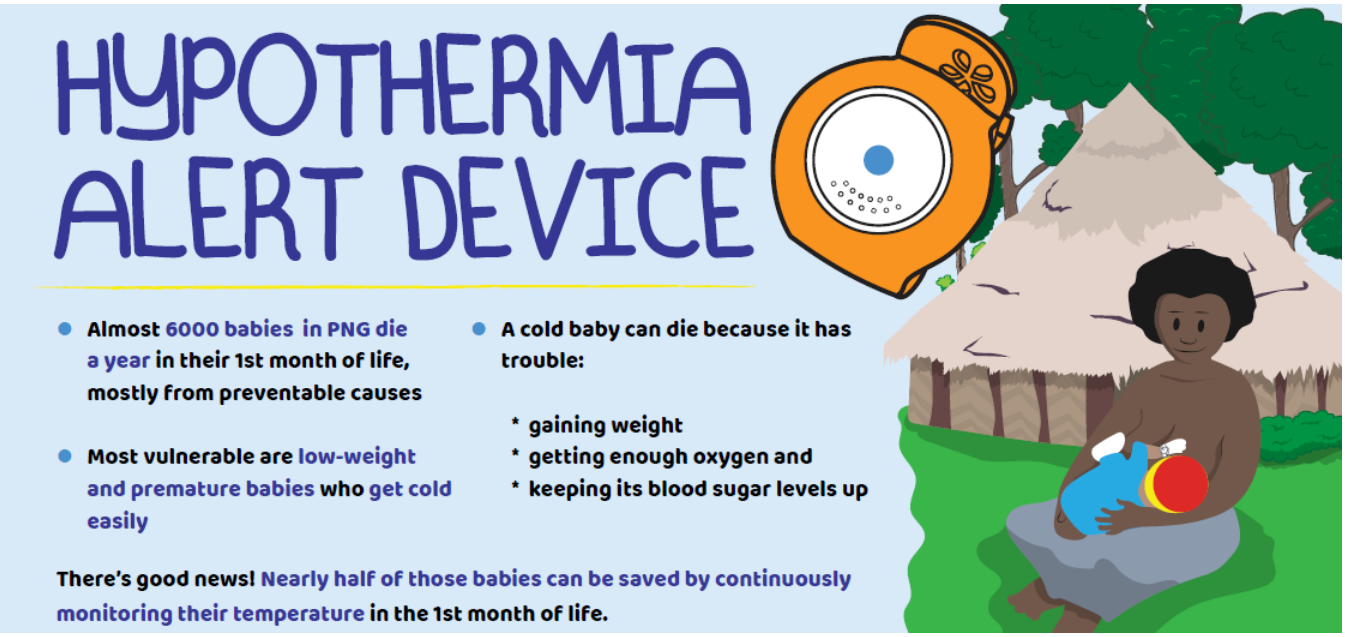
				facilities for continued alarms	
What are barriers to implementation of Kol Kilok in selected areas?	**-Caregiver interview** **-Healthcare Workers Interview** **-VHV Interview** **-Impl. lead Interview**	Individual interview(s)	Assess attitudes of leadership, caregivers, healthcare workers and community members towards hypothermia and neonatal care	- Extent to which program and government leadership identifies hypothermia and neonatal health as a priority (*Political)* - Extent to which caregivers identify hypothermia and neonatal health is a priority - Percent of healthcare workers/VHV who see Kol Kilok as impeding their current work (%)	- Coherence, coordination, efficiency, impact
			Evaluate changes in healthcare worker and VHV practices	- Percent of healthcare workers/VHV who consider Kol Kilok useful or improve their current work (%)	
			Evaluate training level of caregivers, healthcare workers and VHV (i.e. acceptability of training)	- Percent of trained caregivers, healthcare workers, and VHV (%) - Percentage of recalled topics covered during training of caregivers, healthcare workers and VHV (%)	

D. Appendix 4: Kol Kilok Program Checklist for Counseling of Caregivers

Checklist for Nurses to train Mothers

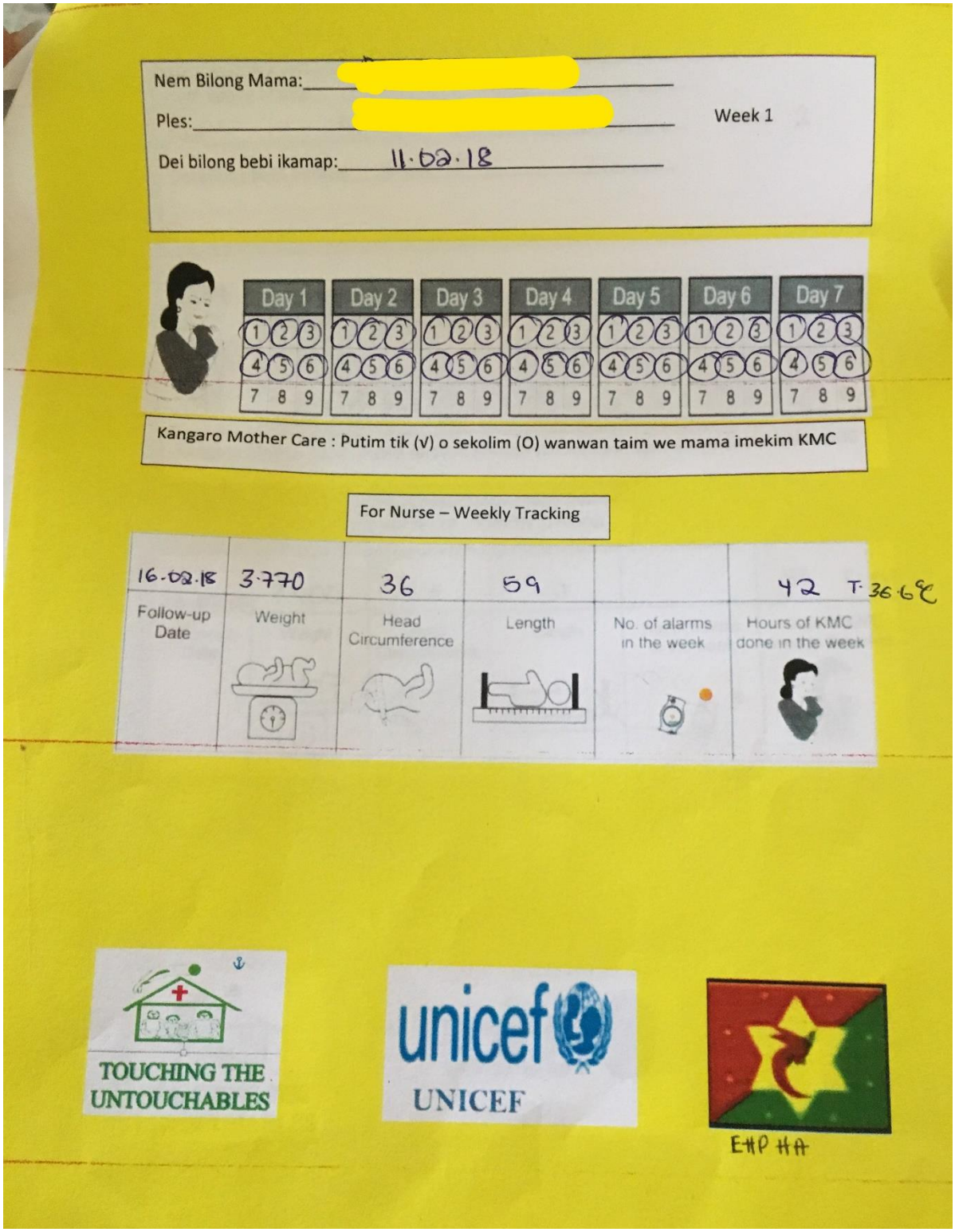
- ☐ 1. Explain about hypothermia
- ☐ 2. Explain how to use Hypothermia Kol Kilok - Refer poster
- ☐ 3. Explain the meaning of Blue light
- ☐ 4. Explain the meaning of beep and orange light
- ☐ 5. Explain to mother what she should do when Kol Kilok beeps or shows orange light
- ☐ 6. Teach Kangaroo Mother Care
- ☐ 7. Instruct how to fill the KMC tracking chart

E. Appendix 5: Excerpt from Promotional Poster for Kol Kilok Program



F. Appendix 6: Photograph of Kol Kilok Device

G. Appendix 7: Example of KMC Diary Entry



H. Appendix 8: Focus Group Discussion (FGD) Question Summary

A Background Information

1. Can each of you introduce yourself, tell us your age and how many weeks were the mother pregnant at the time of the baby's last birth?
2. Are any of you not this child's mother?

B History pregnancy and delivery, and postnatal care

3. While you are pregnant did you visit a health provider, or clinic to received pregnancy check up?
4. Where you deliver the baby? Who help you when you deliver the baby?
5. After giving birth to baby, did you seek postnatal care/check up for the baby?

C Newborn health

6. In your opinion, would you consider your baby/child healthy?
7. Was your baby born too early or too thin?

D Hypothermia

8. Have you ever heard about Hypothermia? If yes, what is "Hypothermia"?
9. What do you think about hypothermia?
10. If your baby were to get cold, how would you warm them?
11. Have you ever noticed your child is too cold? If yes, how did you notice? What did you do?

E Kangaroo Mother Care

12. Have you ever heard about "Kangaroo Mother Care/Skin to-Skin"? If yes, what is "Kangaroo Mother Care (KMC)"? What is it specifically for 1) sick babies; and 2) healthy newborns?
13. What do you think about KMC?
14. Have you ever received any information and counseling on KMC? If yes, where and who provided? What specific information/knowledge you learned?
15. Have you ever practiced KMC for your baby? If yes, can you show and explain how? What happened after you provided KMC? If any, were there any challenges?

F Early Initiation of Breastfeeding

16. After the delivery of your baby, when did you first initiated breast feeding to your baby?
17. What are the benefits of early initiation of breastfeeding?

G Suggestion

18. From your experience that you baby became cold, what you think could have been helpful in order to: 1) prevent babies become cold; 2) check the baby's temperature; and 3) recover cold babies to become healthy?
19. From your experience, what can be improved to make it easier for you to access healthcare?
20. From your experience, what can be improved regarding the quality of health care services or counseling to you as a mother?

I. Appendix 9: OECD-DAC Criteria

Organization for Economic Cooperation and Development - Development Assistance Committee (OECD-DAC) Criteria for Evaluating Humanitarian Action

- **Relevance** is concerned with assessing whether the project is in line with local needs and priorities (as well as donor policy).
- **Appropriateness** is the tailoring of humanitarian activities to local needs, increasing ownership, accountability and cost-effectiveness accordingly.
- **Connectedness** refers to the need to ensure that activities of a short-term emergency nature are carried out in a context that takes longer-term and interconnected problems into account.
- **Coherence** refers to the need to assess security, developmental, trade and military policies, as well as humanitarian policies, to ensure that there is consistency and, in particular, that all policies take into account humanitarian and human-rights considerations.
- **Coverage** is the need to reach major population groups facing life-threatening risk wherever they are.
- **Efficiency** measures the outputs – qualitative and quantitative – achieved as a result of inputs. This generally requires comparing alternative approaches to achieving an output, to see whether the most efficient approach has been used.
- **Coordination** is the systematic use of policy instruments to deliver humanitarian assistance in a cohesive and effective manner. Such instruments include strategic planning, gathering data and managing information, mobilising resources and ensuring accountability, orchestrating a functional division of labour, negotiating and maintaining a serviceable framework with host political authorities and providing leadership.
- **Impact** looks at the wider effects of the project – social, economic, technical, environmental – on individuals, gender- and age-groups, communities and institutions. Impacts can be intended and unintended, positive and negative, macro (sector) and micro (household).

J. Appendix 10: WHO Health System Blocks

- **Health Services Delivery:** "Good health services are those which deliver effective, safe, quality personal and non-personal health interventions to those who need them, when and where needed, with minimum waste of resources."
- **Health Workforce:** "A well-performing health workforce is one which works in ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances. I.e. There are sufficient numbers and mix of staff, fairly distributed; they are competent, responsive and productive."
- **HMIS and Surveillance:** "A well-functioning health information system is one that ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health systems performance and health status."
- **Medical Product and Technology:** "A well-functioning health system ensures equitable access to essential medical products , vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use."
- **Finances and Resourcing:** "A good health financing system raises adequate funds for health, in ways that ensure people can use needed services, and are protected from financial catastrophe or impoverishment associated with having to pay for them."
- **Leadership and Governance:** "Leadership and governance involves ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, the provision of appropriate regulations and incentives, attention to system-design, and accountability."

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