SAFER BIRTES

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A Research and Development Project to Save Lives at Birth

2019 UPDATE

KEY ACHIEVEMENTS

- Sustained improvement in newborn outcome, with two extra lives saved per midwife per year over the project period.
- Institutionalized simulation-based, low-dose, high-frequency training and quality improvement, creating a culture of excellence.
- Developed research tools that were transformed to and validated as life-saving medical devices in the hands of the Tanzanian midwives.
- Observed and collected data from over 23,000 consecutive deliveries and 1,600 resuscitation cases, making this the largest study on newborn resuscitation ever.
- Increased knowledge on fetal heart rate, transition of newborns at birth and newborn resuscitation that will improve international guidelines.
- Engaged 11 PhD fellows, including four from Tanzania, who together have published 40 papers with 50 more to come.
- Presented over 90 Safer Births abstracts at leading international conferences with many more to come.









Two more lives saved per midwife per year

Multiple new innovations introduced

23,000 births observed and analyzed

1,600 resuscitations recorded

Seven years ago, Danieli was born with meconium, not breathing. With the newly implemented Safer Births project, the young nurse at Haydom Hospital was trained in Helping Babies Breathe. She dried the baby, suctioned and stimulated him. Still he was not breathing, so she started ventilations. After some minutes of continuous ventilation, Danieli became the first baby successfully resuscitated in the Safer Births project - He survived.



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Paving the way forward for better outcomes Fetal heart rate monitoring and obstetric care Newborn resuscitation

Foreword

WE WANTED TO MAKE A DIFFERENCE

Every birth-related death is a tragedy, and on a global scale, too many babies continue to die due to lack of proper care. We wanted to make a difference, so we initiated the Safer Births project to establish better knowledge and develop products for improved training and treatment. We were convinced that systematic, simulation-based training would transform into better clinical care, increase perinatal survival, and at the end of the day, contribute to safer births.

It was extremely important for us to address critical needs and not burden the health providers and health systems in Tanzania. Our research tools, training, and new innovations should make the work easier for the providers, and facilitate optimal care for every mother and newborn. With this in mind, each training, research protocol, and new piece of equipment was developed collaboratively with the users. The overarching goal was to foster confidence, competence, capacity and commitment for everyone involved.

Through the Safer Births project, we obtained new important knowledge about newborns as they transitioned from their intrauterine to extrauterine lives, developed more efficient training methods, and implemented affordable, adaptable and user-friendly training and therapy equipment. When implemented properly as a Safer Births bundle, the project proved that the innovations have the potential to create impact and improve perinatal survival on a global scale.

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DR. HEGE L. ERSDAL External Principal Investigator

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DR. EMANUEL Q. NUWASS Director at Haydom Lutheran Hospital

Responding to the challenge

A JOURNEY TO SAFER BIRTHS

Births are still not safe. Worldwide, 3 million newborns die and another 2.6 million are stillborn. 99% of these deaths happen in low- and middle-income countries. We, a team of health workers, researchers, innovators and developers in Tanzania and Norway wanted to change this. It was time to make every birth safer.

MORE EVIDENCE

In order to support safer births, we needed to build evidence on quality of care in the settings with the highest burden. We needed to collect data on every birth to understand newborn responses and outcomes during labour and delivery, as well as during resuscitation. No such data collection tools existed, so we made them.

HELPING EVEN MORE BABIES BREATHE

Safer Births and its team of birth attendants saw an urgent need to improve quality of care at birth. We wanted to support sustainability of the remarkable achievements of the Helping Babies Breathe program, which showed a 47% reduction in early newborn mortality and a 24% reduction in fresh stillbirths.³⁵ In addition, we needed to tackle the remaining 60-80% mortality related to birth asphyxia.¹¹ The ambitious goal of the safer births project was to develop and implement new innovations fit for resource-poor settings that could detect labor and birth abnormalities early on, provide feedback, support retention of skills and at the same time reduce the workload of birth attendants.

A MASSIVE TEAM EFFORT

The Safer Births project started in 2012 when Haydom and Muhimbili hospitals in Tanzania and Stavanger University Hospital in Norway joined forces with Laerdal Global Health. Today it is a multidisciplinary team made up of over 100 researchers, research staff and engineers, represented by 12 international institutions. The researchers, many of whom are based in Tanzania, include 11 PhD fellows, 13 Master students, and 25 supervisors with PhDs.

Baby Eliwaza did not breathe at birth. Luckily, Midwife Sabrina had been trained in Helping Babies Breathe, and as part of the Safer Births project, regularly practices newborn resuscitation. Sabrina detected a slow heart rate and immediately started ventilating. Like many other babies in Haydom, Eliwaza survived.



PRIMARY OBJECTIVE

Improve perinatal outcomes by supporting the prevention, detection and management of birth asphyxia through sustainable, feasible and adaptable training and therapy solutions.

SECONDARY OBJECTIVES

Collect data to better understand the relationships between fetal heart rate, newborn heart rate, bagmask ventilation treatment, newborn response and newborn outcomes.

Establish new training strategies and develop durable, affordable and adaptable equipment to bridge the knowledge/skill-do gaps identified in practice within fetal heart rate monitoring and newborn resuscitation.

Compare the new fetal heart rate monitoring and newborn bagmask ventilation equipment to the existing and available equipment to determine if they lead to better treatment and improved outcomes.

Perform qualitative and quantitative evaluations on the feasibility, acceptability and user-friendliness of the solutions developed.

The Safer Births approach

LEARNING FROM EVERY BIRTH, SUPPORTING EVERY MIDWIFE

In order to improve birth outcomes, it was necessary to first understand what happens at birth. Collecting reliable data was crucial, and it had to be done in a way that supported the health providers rather than adding a burden.

The first initiative of the Safer Births project was to collect information on every baby born and objective data on those who needed ventilation. To support this, a dedicated research device ---the Resuscitation Monitor--- was developed. The monitor collected objective data on newborn heart rate and health worker's performance during newborn ventilation. This information was coupled with video recordings and data collected by trained observers, which included the time of birth, the condition of the baby at birth and the outcome of the baby.

SAFER BIRTHS DATA

1,600 3,700 episodes of newborn resuscitation

and analyzed

continuous fetal episodes with heart heart rate recorded rate and ventilation and analyzed

23,000 13,000 deliveries observed in-situ trainings using

NeoNatalie Live

Resuscitation monitor Each monitor was connected to an ECG-based heart rate sensor, as well as a sensorenhanced bag-mask that provided objective information around applied pressure, volume, flow, mask leakage and gas exchange while resuscitating newborns.

The data highlighted the challenges faced during newborn resuscitation: babies were being ventilated too late, and not effectively. With an aim to better understand why, focus group discussions and interviews were held with the Tanzanian midwives. The findings helped develop tools to support improved care during newborn resuscitation, including an upright bagmask and a 'smart' newborn ventilation training manikin.



SAMPLE OF HAYDOM RESUSCITATION DATA — JANUARY 2014





Ventilation

efforts

paused

Newborn heart rate 0 BPM at the bottom to 200 BPM at the top

Newborn normal

Newborn admitted

Newborn deceased



The Safer Births approach

PREVENTING THE NEED FOR TREATMENT

One of the early findings from the Safer Births research showed that absent or abnormal fetal heart rate is associated with increased labour complications and perinatal deaths (fresh stillbirth and early neonatal death). The goal of fetal heart rate monitoring is early detection of a fetus at risk so that timely, life-saving action can be taken. In low-resource settings, however, there is often neither sufficient staff nor equipment to monitor fetal heart rate according to guidelines. One of the aims of the Safer Births Project was to develop a tool to support improved care during labour management and fetal heart rate monitoring in low-resource settings.

DETECTING AND TREATING **BIRTH ASPHYXIA**

Through the data collected, the Safer Births project was able to understand and support health care providers needs in detecting, preventing and treating birth asphysia through improved training and therapy tools for fetal heart rate monitoring and newborn resuscitation.

"In low-resource settings, fresh stillbirth may be prevented by using a combined strategy of clinical risk identification, early detection of abnormal fetal heart rate, and expedited delivery."

The Multi-Crystal Fetal Heart Rate Doppler — Moyo was designed to support fetal heart rate monitoring in facilities where there is high patient to provider ratio. The monitor detects fetal heart rate within seconds and can be used intermittently or continuously. Studies were performed to compare the efficacy and feasibility of Moyo compared to existing fetal heart rate devices.

The 'Smart' Traning Manikin — NeoNatalie Live was designed to improve health care provider confidence and competence in newborn ventilation. Connected to a tablet application and online web log, the manikin enabled low-dose-high-frequency training and continuous improvement through objective feedback. The project evaluated the impact of the solution on health care provider's skills and clinical performance.

The Ergonomic Bag-Mask with PEEP — Upright was designed with improved ergonomics to make it easier for health care providers to obtain mask seal and provide effective ventilations. A positive-end-expiratorypressure (PEEP) valve added to the bag-mask provided an affordable and simple solution to state-of-the-art ventilation in low-resource settings. Studies were performed to compare the upright bag-mask to the standard bag-mask.

Hussein Kidanto. Internal Principal Investigator, Safer Births Project







The sites

FOUR HOSPITALS 35,000 BIRTHS PERYEAR



"Every baby should survive. Every mother should survive. Every life is important"

Monica Tippe, Head of Labour ward at Haydom Hospital

DONGOBESH RURAL HEALTH CENTER **400** deliveries/year

Situated in rural Tanzania, Haydom offers a unique research infrastructure with experience from major studies like the Bill and Melinda Gates Foundation funded MALED study on malnutrition. It was also one of the Helping Babies Breathe study sites, and thus had the necessary expertise and resources, and an extensive database of observed births that could be built upon for further studies.







Collaboration

A GLOBAL EFFORT TO HELP SAVE LIVES

The project was possible thanks to an impressive collaboration involving 12 Tanzanian, Norwegian and other international institutions, conducting research and developing solutions.

The Safer Births Project was organized with one research arm under the leadership of Stavanger University Hospital, focused on establishing new knowledge within fetal heart rate monitoring and newborn transition and resuscitation; and one development arm, under the leadership of Laerdal Global Health, focused on improving perinatal outcomes by supporting the detection, prevention and management of birth asphyxia through sustainable, feasible and adaptable training and therapy solutions.

FOUNDING PARTNERS

Haydom Institute for **Global Health, Haydom** Lutheran Hospital

Research staff and infrastructure for Haydom and Dongobesh; user feedback for product development

Muhimbili National Hospital

Conceptualized,

coordinated the

implementation

of the project

designed and

Research staff and infrastructure for Temeke and Muhimbili; user feedback for product development

Laerdal Global Health

Product development and industrialization; admin and coordination support

SAFER Foundation

Infrastructure and training strategies

Stavanger University Hospital Scientific project leadership

KEY RESEARCH PARTNERS

University of Stavanger Biomedical signals research and statistical assistance

University of Oslo Resuscitation science research

Weill Cornell Research on newborns in Tanzania

Østfold University Hospital Newborn resuscitation research

Folkehelseinstituttet Newborn resuscitation research

PRODUCT

Supported product development with relevant expertise

Hosted and

expertise in

relevant areas

supervised PhD fellows with

DEVELOPMENT

Trinity College Biomedical instrumentation and applications

Laerdal Medical Mechanical, electronic and software engineering

FUNDING SUPPORT

- GLOBVAC, Norwegian Research Council
- Laerdal Foundation
- Skattefunn
- Visjon 2030 Innovation Norway
- Saving lives at birth, USAID
- Norwegian Ministry of Education
- Stavanger University Hospital
- The Southern and Eastern Regional Health Trust in Norway

Invested over 12 million USD in the Safer Births project

TRADITIONAL TOOLS

SAFER BIRTHS BUNDLE

NeoNatalie Live Newborn Resuscitation Simulator

A smart manikin that provides feedback on key elements that providers often have difficulties with during newborn resuscitation

- multiple cases

Moyo Fetal Heart Rate Monitor

Moyo is an affordable fetal heart rate monitor designed for intermittent and prolonged monitoring. It detects abnormal fetal heart rate more quickly and easily, enabling appropriate and timely decision-making

- Lightweight, portable and reusable

NeoBeat Newborn Heart Rate Meter

An easy-to-use heart rate meter that provides an accurate and continuous display of newborn heart rate. It takes seconds to place on a baby, and the instantaneous heart rate can help guide neonatal resuscitation

- Reusable and consumable-free

Upright Newborn Bag-Mask with PEEP

A self-inflating, manual and reusable bag-mask for newborns and infants who require respiratory support with positive end-expiratory pressure (PEEP)

Evidence-based innovations

THE SAFER **BIRTHS BUNDLE**

The Safer Births Bundle is a collection of training and therapy tools that supports health care workers to prevent, detect, and/or treat birth asphyxia.

These tools were used during the project as subjects for research and were validated as effective solutions for training and care. They address many of the barriers to quality care - lack of resources (staff and equipment), low provider confidence and competence, low motivation for training, and lack of culture of quality improvement.

The innovations are designed to support Helping Babies Breathe, reduce the workload and better utilize human resources, support feedback-based training and treatment, require no extra skills for use or maintenance, and adapt to harsh environments with scarce power supply.











- Varying lung compliance and initial heart rates for practice on

- Targeted and objective feedback enables self-training - Training logs on frequency and resuscitation competency to track progress

- 30-minute histogram display of the fetal heart rate, as well as an audio-visual alarm if abnormal fetal heart rate is detected - Both intermittent and continuous monitoring

- ECG-based signal following ILCOR 2015 guidelines - Accurate, fast and easy to use by a single provider - Practical charging stand for quick access

- The upright design and redesigned mask help support a better seal - PEEP can help prevent repeated lung collapse, recruit lung volume more efficiently, clear fluid from the lungs and reduce damage to the lung tissue during ventilation



Activities and impact

INTERVENTIONS THAT GENERATED KNOWLEDGE AND SAVED LIVES

					NeoBeat											
	2018													20	19	
ICY TRAINING																
TH P	EEP															
cus Group Discussion 📃 🕨 Tool											intro	oduc	ed			

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IMPROVING PERINATAL OUTCOMES

Helping Babies Breathe and the Safer Births implementation study – resulted in a steady improvement in perinatal survival at Haydom Hospital, the main research site in Tanzania. One study showed that the implementation of these two interventions resulted in two extra newborns lives saved per midwife per year.^{31,36}

Two additional newborn lives saved per midwife per year

New knowledge

NORMAL TRANSITION AT BIRTH

Resuscitation monitor's heart rate sensor made it possible to record newborn heart rate immediately at birth and during resuscitation. The data collected by NeoBeat showed the connection between newborn heart rate and outcomes.

• Newborn heart rate increases from 120-150 beats/minute during the first 45 seconds after birth, stabilizing around 155 beats/minute at 2 minutes.²³

• Median time to start spontaneous breathing is 5 seconds after birth. Over 90% of babies who will breathe without additional interventions will start breathing by 30 seconds.¹²

• Out of 12,800 normal/healthy newborns, the risk of death/admission decreased by 20% for every 10-second delay in cord clamping after breathing started.¹⁶

For every 10-second delay in cord clamping, the risk of death/ admission decreases by 20%





NEWBORN RESUSCITATION

1,582 resuscitations were captured using the Resuscitation Monitor. This data showed effects of bag-mask ventilation on newborn heart rate and outcomes.

• Fresh stillbirths and severely asphyxiated newborns share the same hypoxic-ischemic pathway.²⁴ Distinguishing fresh stillbirths from severely asphyxiated newborns is clinically difficult and likely influences estimated global perinatal mortality rates.²⁴

 During newborn bag-mask ventilation, higher tidal volumes than the recommended levels in international guidelines lead to a rapid increase in newborn heart rate.²⁷ This rapid increase in heart rate has shown to benefit newborn outcomes.^{28,33} Newborn heart rate and delivered tidal volume with continuous ventilation are important predictors of newborn outcomes.^{27,28,33}

• The initial newborn heartrate is distributed into two peaks, with an initial heart rate above 100 bpm noted in about 50% of the population of non-breathing newborns after stimulation.27, 32 Application of bag-mask ventilation is associated with an increase in heart rate in most neonates, producing a single peak distribution of heart rate values above 100 bpm.^{27,32}

 Initial and final heart rate have a significant association with outcome — higher heart rates predicted a better prognosis.^{15, 19, 28, 33}

It is clinicaly difficult to tell fresh stillbirth apart from early neonatal death. This influences estimated global perinatal mortality rates

The optimal tidal volume during bag-mask ventilation of newborns is higher than previously believed

Higher initial newborn heart rate is correlated with better **post-resuscitation** outcomes



The Upright

delivers higher

bag-mask

outcomes

• The optimal timing of cord clamping in non-breathing newborns in need of resuscitation remains unclear. Research did not demonstrate a relationship between time to cord clamping and onset of breathing (after stimulation/suction) or initiation of ventilation and 24-hour outcomes.⁴³ However, there was a significant increase in risk of death/admission (12%-16%) for every 30-second delay in initiation of bag-mask ventilation.^{12,43}

• Presumed causes of death (within 7 days after birth) among admitted newborns at Haydom were birth asphyxia (60%), prematurity (15%), sepsis (15%) and congenital abnormalities (11%).^{11,44} Hypothermia (<36 °C) on admission is very common and a major contributor to morbidity and mortality. 44

• The use of the Upright bag-mask without PEEP, compared to standard bag-masks, resulted in slightly increased tidal volumes,³⁰ which is needed to rapidly increase newborn heart rate and to improve outcomes.^{27, 28,} ³³ More babies were classified as normal 30 minutes after birth if ventilated with the Upright bag-mask, as compared to standard bag-mask.³⁰ Data from a subsequent RCT, comparing the Upright bag-masks with and without PEEP, is under analysis.

tidal volumes, compared to standard bagmasks, which leads to better



Newborn deaths at Haydom



FETAL HEART RATE MONITORING

There is often insufficient staff and equipment to monitor fetal heart rate according to guidelines. Moyo fetal heart rate monitor was developed and compared to existing fetal heart rate monitoring tools for efficacy and feasibility of use in low-resource settings. Over 3,700 episodes of continuous fetal heart rate cases were recorded and analyzed.

Before the introduction of Moyo, randomized control trials (RCT) were conducted in Haydom and Muhimbili hospitals in order to compare the effectiveness and preferences of available fetal heart rate monitoring devices.

• At Haydom, there were no differences in detection or outcomes between Pinard Fetoscope and single-crystal Doppler,⁵ but the providers preferred to use the Pinard.⁸ Abnormal fetal heart rate was detected much more frequently with Moyo compared to the Pinard (8.1% versus 3.0%).⁴ Intrauterine resuscitation and cesarean section were performed more often when Moyo was used, with a non-significant trend towards better perinatal outcomes, compared to when the Pinard was used.⁴

• At Muhimbili, the use of single-crystal Doppler led to more abnormal fetal heart rate detections and better perinatal outcomes compared to the Pinard fetoscope.⁶ Abnormal fetal heart rate was detected more frequently with Moyo compared to the single-crystal Doppler (13.3% versus 9.8%). Abnormalities were detected earlier, but time from detection to delivery was longer.³

Abnormal fetal НАҮДОМ PINARD heart rate was detected more frequently in MUHIMBILI DOPPLER the Moyo arm compared to the Pinard and the 1 1 1 1 1 single-crystal 0% 5% 10% Doppler arm Rate of abnormal fetal heart rate detection

comparing Moyo and existing fetal heart rate monitoring devices

Moyo was also introduced at Temeke Hospital in a before-after implementation study. Implementation of Moyo improved midwifery practice: there were lower rates of undocumented fetal heart rate post versus pre implementation (2.2% versus 45.7%), increased detection of abnormal fetal heart rates post versus pre implementation (8.0% versus 1.6%), more and timelier obstetric responses and cesarean sections, and reduced number of newborns in need of resuscitation, compared to intermittent assessments using Pinard.¹⁰

Fetal heart rate abnormalities were strongly associated with fresh stillbirths and birth asphyxia.^{1, 2, 24, 28, 33} Strategies to improve fetal heart rate monitoring to facilitate awareness of fetal distress, decision-making and timely obstetric actions are needed.



Before-after implementation study of Moyo in Temeke Hospita

Fetal heart rate abnormalities are associated with perinatal deaths and early detection and action can help survival

Moyo provided improved detection of fetal heart rate abnormalities and resulted in more frequent and timelier responses compared to existing fetal heart rate monitoring devices







Upright bag-mask was more easily handled and accepted by untrained personnel, compared to the standard bag-mask

Low-dose high-frequency ventilation training, preparation for birth and heart rate feedback are important factors for improving care during resuscitation

New knowledge

THE HEALTH CARE PROVIDER'S PERSPECTIVE

Focus group discussions and interviews were also performed to understand midwives' perspectives on the research interventions.

• Focus group discussions and interviews led to important insights around resuscitation. Midwives expressed that frequent ventilation training and "being prepared" are critical factors to improve clinical practice.³⁴ They also felt newborn heart rate provided useful feedback during resuscitation.³⁴

• Midwives preferred the Upright design compared to the standard bag-mask. Before the Upright was used in the RCT in Haydom, it was introduced using the Neo-Natalie Live newborn simulator. Simulation tests showed that the Upright was more easily handled and accepted by untrained personnel, compared to the standard bagmask,²⁰ and providers managed to provide adequate PEEP.⁴⁶

• High staff turn-over was considered a huge challenge. As trained personnel left, providers needed frequent training sessions to feel prepared.^{9,34}

• Moyo was perceived a useful tool that let them adequately monitor and care for several laboring women at the same time and respond faster.⁴⁹

• Midwives expressed fear of being blamed for negative outcomes and a lack of clarity about when Moyo should be used in a continuous manner.⁹ They felt that the Moyo training was useful but asked for additional training in basic labor monitoring and management.⁹

New Knowledge

THE MOTHER'S PERSPECTIVE

Focus group discussions with mothers on whom Moyo was used showed that the use of Moyo positively affected the mothers' birth experience, provided reassurance of the child's wellbeing, and increased the midwives' communication and attention.⁷



"I was relieved to know that my baby was safe"

Mother on Moyo

FURTHER UNDERSTANDING TO IMPROVE SURVIVAL

The Safer Births research findings stress the importance of reliable fetal heart rate monitoring during labour and providing effective ventilation following birth to enhance survival. The risk of death in apneic newborns can be predicted by the fetal heart rate, initial newborn heart rate and the heart rate response during ventilation.

Studies in progress are investigating the predictive value of end-expiratory CO_2 levels, the importance of gasping, the establishment of functional residual capacity during initial ventilation, lung compliance during ventilation, the use of PEEP in resuscitations, newborn heart rate distribution and changes during ventilation, ECG-signals in fresh stillbirths, the reliability of Apgar scoring, the effects of suctioning, head positions and hand-grips during ventilation, Helping Babies Breathe adherence in clinical practice, and further effects of trainings on clinical practice and newborn outcomes.

Research focused on building knowledge around labor management and fetal heart rate monitoring is also underway. Fetal heart rate recordings using Moyo have been collected from 3,711 deliveries at Muhimbili, Temeke and Haydom hospitals. They are currently being analyzed to better understand different fetal heart rate patterns, alarm settings, and optimal frequencies of intermittent assessments in different stages of labor in relation to perinatal outcomes. Find updates at saferbirths.com



Looking forward

SCALING AND EXPANDING



THE SUSTAIN PROJECT IN NEPAL

HBB, Quality Improvement and scaling up the Safer Births Bundle

In collaboration with Golden Community and the Ministry of Health in Nepal, Funding from Grand Challenges Canada and Innovation Norway has been secured to implement the Safer Births Bundle in 9 high-delivery hospitals in Nepal. We expect to observe and record over 100,000 deliveries throughout the project period, during which the Safer Births innovations (Moyo, NeoBeat, Upright and NeoNatalie Live) will be used. The purpose of the study is to build extensive evidence on the Safer Births products in improving the quality of care and outcomes of newborns in various regions across Nepal.







Data collecting devices NeoBeat, Movo and

versions are clinical tools

that collect and connect

data from a patient and

Upright in their "live"

health care provider



Supported training and clinical practice

THE LIVEBORN PROJECT

A development initiative by Laerdal to support care during day of birth

Liveborn is a bundle of user-oriented, 'smart' products and services to support health care workers and health systems globally to deliver better quality care at birth, with increased efficiency and accountability. The project will digitize and connect innovations that have already demonstrated acceptability and effectiveness through the Safer Births Project. The Liveborn initiative builds on the experiences gained from Tanzania around local quality improvement and aims to take advantage of new partnerships in Nepal and the Democratic Republic of Congo. The bundle has four pillars: 1) data-driven training to close gaps in skill, knowledge, and teamwork; 2) technology support during labor management to better prevent birth asphyxia; 3) technology support during newborn resuscitation to better manage birth asphysia and 4) data-driven quality improvement and data management systems to drive local quality improvement initiatives. By creating the Liveborn system, it will be possible for the first time to link training with patient care and use gaps in patient care to change training locally.





HEART-GUIDED HELPING BABIES BREATHE IN DRC

Testing of NeoBeat by AAP with Funding from Saving Lives at Birth (SL@B)

The American Academy of Pediatrics received funding from USAID Saving Lives at Birth in 2017 to test NeoBeat and an adapted heart rate guided Helping Babies Breathe program in the Democratic Republic of Congo. The aim of the study is to test the acceptability and efficacy of including heart rate as a more prominent component of Helping Babies Breathe, in line with 2015 ILCOR recommendations. The hypothesis is that assessing heart rate will ensure live-born non-breathing babies are not misclassified as stillborn and will receive effective resuscitation, and that during assisted ventilation, heart rate provides vital information about the effectiveness of the ventilation and the need for additional corrective measures.

The study will test whether having heart rate information impacts the decision-making and care of health care providers, and ultimately the outcome of newborns.







SAFER HAYDOM IN TANZANIA

Expanding best practices to the wider community

Good research fosters excellence, new research questions and hypotheses. This is also the case with the Safer Births project. The new SAFER Haydom project will continue to collect data, now with a stronger emphasis on how simulation-based learning could improve monitoring of fetal heart rate, as well as improve newborn resuscitation. It will also follow-up on the resuscitated newborns to study and address possible issues of long-term neurological disabilities. Building on Safer Births activities, SAFER Haydom wants to expand on the simulation-based training approach to establish a Center for Excellence in Education. It will also implement the approach in the schools, pediatric and surgery departments, and at surrounding referring health centers. Personnel that have been key over the last decade will continue their work at Haydom, take new responsibilities and make the proposed development possible together with essential Norwegian partners.

FROM EAST AFRICA TO WEST NORWAY

Implementation of the Safer Births Bundle in Stavanger University Hospital (SUS)

Training and therapy solutions that have proven to be effective in low-resource settings, have also shown success in high-resource settings. Having first hand experience of this success through utilizing the simulation-based Helping Mothers Survive training program developed for low-resource settings, Stavanger University Hospital in Norway aims to implement the Safer Births bundle in their maternity ward. They will initiate low-dose, high-frequency training using NeoNatalie Live, and implement the use of Upright and NeoBeat during clinical care. Using the Resuscitation Monitor to collect objective birth data, SUS will determine the effects of the interventions on the quality of care and outcomes.



Research publications

PAVING THE WAY FORWARD FOR BETTER OUTCOMES

The Safer Births Project engaged 11 PhD fellows including four from Tanzania, who together have published over 40 papers with 50 more to come.

The following pages provide a brief description of the papers that have been published so far in the Safer Births Project within fetal heart rate monitoring and obstetrics care, and newborn resuscitation. These papers have been accepted in reputable journals including the International Journal of Gynecology & Obstetrics, PLOS One, Pediatrics, Neonatology, Resuscitation and BMC Pregnancy and Childbirth.



Research publications

FETAL HEART RATE MONITORING AND OBSTETRIC CARE

Visit saferbirths.com for the latest bibliography, and click on the titles to view the articles online.

1 Ersdal H et al. 2012

Intermittent Detection of Fetal Heart Rate Abnormalities Identify Infants at Greatest Risk for Fresh Stillbirths, Birth Asphyxia, Neonatal Resuscitation, and Early Neonatal Deaths in a Limited-Resource Setting. Neonatology. 102:235-42 ->

The objective of this study was to determine whether specific medical conditions and/or fetal compromise during labor are associated with fresh stillbirth (FSB). Of over 15,000 deliveries, approximately 500 ended in stillbirth. These cases were reviewed and the research found that stillbirth was more likely in cases where there was maternal transfer, absent fetal heart rate before delivery, uterine rupture, placental abruption, cord prolapse and prematurity. In low-resource settings, FSB may be prevented by using a combined strategy of clinical risk identification, early detection of abnormal fetal heart rate, and expedited delivery.

to improve perinatal outcomes.

A randomized controlled trial was conducted at Haydom Hospital where Moyo was tested against the Pinard fetoscope. The study results showed that abnormal fetal heart rate was detected much more frequently in the Moyo arm compared to the Pinard arm (8.1% versus 3.0%). Intrauterine resuscitation and cesarean section were also performed more often in the Moyo arm, with a non-significant trend towards better perinatal outcomes.

2 Kidanto H et al. 2015 Predisposing Factors Associated with Stillbirths in Tanzania - Opportunities for Prevention. Int | Gynaecol Obstet. 130:70-73 →

3 Kamala B. et al. 2018 Effectiveness of a novel strap-on automatic Doppler (Moyo) versus intermittent Doppler in intrapartum detection of abnormal foetal heart rate: A randomized controlled study in Tanzania. Int | Environ Res Public Health. 16:315 \rightarrow

4 Mdoe P et al. 2018 Fetal heart rate monitoring in a lowresource setting; continuous Doppler versus intermittent fetoscope - A randomized controlled study. Int | Gynaecol Obstet. 143(3):344-350 →

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The objective of this observational study was to determine the value of routine intermittent fetal heart rate monitoring during labor in the detection of fetal heart rate abnormalities. Authors observed and recorded labor information for 10,271 deliveries at Haydom Lutheran Hospital in Tanzania. Assessments showed that intermittent detection of an absent or abnormal fetal heart rate using a fetal stethoscope is associated with fresh stillbirth, increased need for resuscitation, birth asphyxia and neonatal death in a limited-resource setting. This supports the well-established hypothesis that an abnormal fetal heart rate is an important indicator of fetal compromise. Moreover, the findings indicate a significant association between an abnormal fetal heart rate and labor complications.

A randomized controlled trial was conducted at Muhimbili Hospital where Moyo was tested against the single-crystal Doppler. The results showed that abnormal fetal heart rate was detected more frequently in the Moyo arm compared to the single-crystal Doppler arm (13.3% versus 9.8%). Abnormalities were detected earlier, but time from detection to delivery was longer. Timely response to interventions following early detection is needed

5 Mdoe P et al. 2018

Intermittent Fetal Heart Rate Monitoring using Fetoscope or Hand held Doppler in Rural Tanzania: a Randomized Controlled Trial. BMC Pregnancy and Childbirth. 18:134 →

6 Kamala B et al. 2018

Intrapartum fetal heart rate monitoring using a hand-held Doppler versus Pinard stethoscope:A randomized controlled study in Dar es Salaam. Int J Women's Health. 10:341-48 →

7 Lafontan S et al. 2018

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Midwives' perceptions on using a fetoscope and Doppler for fetal heart rate assessments during labor: A qualitative study in rural Tanzania. BMC Pregnancy and Childbirth. 18:103 →

9 Lafontan S et al. 2018

Acquiring knowledge about the use of a newly developed electronic fetal heart rate monitor: A qualitative study among birth attendants in Tanzania. Int J Environ Res Public Health 15:E2863 →

10 Kamala B. et al. 2018

Implementation of a Novel Continuous Fetal Doppler (Moyo) Improves Quality of Intrapartum Fetal Heart Rate Monitoring in a Resource-Limited Tertiary Hospital in Tanzania:An Observational Study. Plos One. 13(10) → In order to compare the effectiveness and preferences of available fetal heart rate monitoring devices at Haydom Hospital, a randomized control trial was conducted. The trial failed to demonstrate a statistically significant difference in the detection of abnormal fetal heart rate between intermittently used Doppler and fetoscope and adverse perinatal outcomes. Regardless of the device used, fetal heart rate measurements were not performed as often as recommended by international guidelines.

In order to compare the effectiveness of available fetal heart rate monitoring devices at Muhimbili Hospital, a randomized control trial was conducted. Intermittent fetal heart rate monitoring using hand-held, single-crystal Doppler was associated with an increased detection of abnormal fetal heart rate compared to Pinard fetoscope in a low-risk population (6.0% vs 3.9%). Additionally, perinatal outcomes were better among vaginally delivered newborns with detected abnormal fetal heart rate in the Doppler arm. In both arms, time intervals from abnormal fetal heart rate detection to delivery were longer than recommended.

A qualitative study was done to explore the attitudes and perceptions of women who had worn Moyo continuously during their most recent delivery. The results indicated that the use of Moyo positively affected the women's birth experience. It provided much-needed reassurance about the wellbeing of the child and the women felt that wearing Moyo improved care due to an increase in communication and attention from birth attendants. However, the women did not fully understand the purpose and function of the device and overestimated its capabilities. This highlights the need to improve how and when information is conveyed to women in labor:

The Doppler was thought to be more comfortable and effective compared to the fetoscope for assessing fetal heart rate during labor. However, midwives in Haydom Hospital who had easy access to both devices mostly used fetoscope. This study explored midwives' perception of factors influencing their preference for using either a Pinard fetoscope or a handheld, single-crystal Doppler for intermittent fetal heart rate monitoring. The results showed that midwives' choices were influenced by the level of training, experience with using a device, reliability of measurements, and convenience and comfort during use.

A qualitative study was done to explore skilled birth attendants' perceptions and experiences acquiring and transferring knowledge about the use of Moyo. Focus group discussions and interviews revealed that participants experienced the training on Moyo as useful but inadequate. The study highlighted the need for frequent training sessions over time with more focus on increasing overall knowledge in labor management to ensure optimal use of the monitor over time.

A pre- and post-observational study was conducted at Temeke Hospital, during which time Moyo was introduced. Compared to intermittent monitoring with Pinard fetoscope, Moyo was associated with greater detection of abnormal fetal heart rate (1.6% vs 8.0%) and higher rates of assessment and documentation of fetal heart rate. Implementation of Moyo was associated with improved quality of intrapartum care and partograph use. Rates of interventions (cesarean section and vacuum-assisted delivery) also increased with use of Moyo. Larger scale studies are needed to determine differences in perinatal outcomes.

Research publications

NEWBORN RESUSCITATION

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11 Ersdal H et al. 2012 Birth Asphyxia: A Major Cause of Early Neonatal Mortality in a Tanzanian Rural Hospital. Pediatrics. 129:1238-43 → Global estimates on the presumed causes of neonatal deaths have remain unchanged over the past decade, so the objective of this study was to determine the presumed causes of neonatal death within the first 24 hours in a rural hospital in northern Tanzania. Over one year, 4,720 infants were born and evaluated. Observational findings indicate that most cases of early neonatal mortality were related to birth asphyxia (BA), and the 5-minute Apgar score is a poor surrogate of BA. Reducing perinatal mortality requires a multifaceted approach with attention to issues related to BA, prematurity and low birth weight.

12 Ersdal H et al. 2012

Early initiation of basic resuscitation interventions including face mask ventilation may reduce birth asphyxia related mortality in lowincome countries. Resuscitation. $83:869-73 \rightarrow$

13 Ersdal H et al. 2013

A one-day "Helping Babies Breathe" course improves simulated performance but not clinical management of neonates. Resuscitation. 84:1422-1427 →

14 Vossius C et al. 2014 Cost-Effectiveness of the "Helping Babies Breathe" Program in a Missionary Hospital in Rural Tanzania. Plos One 9(7): e102080 → This report documents the long-term impact of a one-day HBB training on practical skills and management strategies among providers in a rural Tanzanian hospital. When providers simulated "Routine Care" and "Neonatal Resuscitation" seven months after HBB training, skills and performance were significantly better. By contrast, neonatal management in the delivery room during the corresponding time period did not improve and in fact worsened. Thus, less newborn infants were stimulated and the time to initiate face mask ventilation was longer. Subsequently, measures were taken (short HBB re-trainings delivered regularly and frequently with local mentoring) to improve the transfer of acquired knowledge and skills into clinical practice. Further research is necessary to explore the impact of these measures on performance and patient outcome. More focus on early stimulation and discussions around local implementation should be prioritized during HBB training.

Authors analyzed the cost effectiveness of HBB at Haydom Hospital in rural Tanzania. Costs per life saved were USD 233, while they were USD 4.21 per life year gained. Costs for maintaining the program were USD 80 per life saved and USD 1.44 per life year gained. Authors conclude that HBB is a low-cost intervention, and implementation in Haydom Hospital has been highly cost-effective. To facilitate further global implementation of HBB, a cost-effectiveness analysis including government, urban hospitals and district facilities is necessary.

The objectives of this observational study at a rural hospital in Tanzania were to describe normal transitional respiratory adaption at birth and to assess the importance of initiating basic resuscitation within the first minutes after birth as it relates to neonatal outcome. Results demonstrated that the majority of lifeless babies were in primary apnea and responded to stimulation/suctioning and/or bag-mask ventilation (BMV). Infants who required BMV were more likely to die particularly when ventilation was delayed or prolonged.

15 Vu H et al. 2014

Exploratory Analysis of Heart Rate Changes in Newborns to Investigate the Effectiveness of Bag-Mask Ventilation. Computing in Cardiology. 41: 457-460 →

16 Ersdal H et al. 2014

Outcome Following Cord Clamping After Onset of Spontaneous Respiration. Pediatrics. 134:265-72

17 Mduma E et al. 2015

Frequent brief on-site simulation training and reduction in 24-h neonatal mortality - An educational intervention study. Resuscitation. 93:1-7 →

18 Vu H et al. 2015

Exploratory Analysis of Ventilation Signals from Resuscitation Data of Newborns. Conference: International Conference on Bio-inspired Systems and Signal Processing. $12-20 \rightarrow$

19 Vu H et al. 2015

Exploring the relationship between characteristics of ventilation performance and response of newborns during resuscitation. **Conference:** Communication in Computer and Information Science. 574. 275-290 →

Currently, an increase in heart rate is thought to be the most important indicator of successful bag-mask ventilation. In this study, ECG and ventilation signals were parameterized into relevant information to propose a data analysis approach to identify the relationships between these signal characteristics and heart rate changes. Several associations between characteristics of ventilation parameters and changes in heart rate were identified.

Evolving data indicates that delayed cord clamping (CC) after birth is beneficial for all infants. including babies that require ventilation. The objective of this study was to describe the relationship between time to CC, onset of spontaneous respirations (SR), and 24-hr neonatal outcome. Over 15,000 babies born at Haydom Hospital were included. Results showed that the risk of death/admission was consistently higher if CC occurred before SR, infants with low birthweight were more likely to die or be admitted, and the risk of death/admission decreased by 20% for every 10-second delay in CC after SR, regardless of birthweight.

The objective was to assess the impact of frequent brief (3-5 min weekly) on-site HBB simulation training on newborn resuscitation practices in the delivery room and the potential impact on 24-h neonatal mortality. A newborn simulator was placed in the labor ward and frequent brief HBB simulation training was implemented on-site; 3-min of weekly paired practice, assisted by local trainers. Local trainers also facilitated 40-min monthly re-trainings. The researchers reported that the number of neonates receiving stimulation increased, as did those who received suctioning. Neonates receiving bag-mask ventilation decreased as did 24-hour mortality. The study concludes that on-site, brief and frequent HBB simulation training appears to facilitate transfer of new knowledge and skills into clinical practice and is accompanied by a decrease in neonatal mortality

Information extracted from ventilation signals might give a good indication of the effectiveness of therapy. A framework for exploratory data analysis was developed facilitating the development of signal parameters to identify the relationships between certain signal characteristics and various outcome groups.

Non-breathing newborns should be ventilated within the first minute after birth. In this study, ventilation signals were evaluated and parameterized to reflect the characteristics of the provided ventilation. The effectiveness of ventilation was characterized by changes in Apgar score and heart rate. A framework for exploring the association between ventilation parameters and the effectiveness of ventilation showed possible correlation between the corresponding ventilation parameters and the outcome of the treatment.

20 Thallinger M et al. 2015 Manikin ventilation comparing new upright neonatal resuscitator to standard equipment. Arch Dis Child Fetal Neonatal. 0:F1-F5 ->

21 Vu H et al. 2016

Automatic Detection and Parameterization of Manual bagmask ventilation of Newborns. I of Biomedical and Health Informatics. $10 \rightarrow$

22 Vu H et al. 2015

Detection of Activities during Newborn Resuscitation Based on Short-Time Energy of Acceleration Signal. Image and Signal Processing. 9680:262-270 →

23 Linde J et al. 2016

Normal Newborn Heart Rate in the First Five Minutes of Life Assessed by Dry-Electrode Electrocardiography. Neonatology. $110:231-237 \rightarrow$

24 Ersdal H et al. 2017

Fresh Stillbirths and Severely Asphyxiated Neonates Represent a Common Hypoxic-ischemic Pathway. Int | Gynaecol Obstet. 141:171- $180 \rightarrow$

The objective of this study was to compare ventilation properties and user preferences of Upright bag-mask with standard bag-mask, 87 Tanzanian and Norwegian nursing and medical students with no prior training in newborn resuscitation were included, and a manikin that could simulate normal and low lung compliance was used. The results showed that Upright provided significantly higher lung volume and lower rates of mask leakage, and was preferred by the students.

The outcome of resuscitation is influenced by not only ventilation, but also other therapeutics activities such as drying, stimulating, suctioning etc. This paper illustrates the detection of activities based on information from acceleration signals. The results show that the signal-based algorithm was able to accurately detect the existence of an activity 90% of the time (sensitivity), and non- existence of an activity 80% of the time (specificity). This validates the possibility to use acceleration signals to detect the presence of various activities during resuscitation.

In this study, ventilation and ECG signals were recorded during neonatal resuscitation and stored in Resuscitation Monitors at Haydom Hospital. Perinatal events were observed and recorded by research assistants. Results from 215 newborns showed there was a non-linear relationship between delivered tidal volume (TV) and heart rate (HR) increase. TV of 9.3 ml/kg produced the largest increase in HR during bag mask ventilation (BMV). Frequent interruptions of BMV sequences to provide stimulation/suctioning occurred in all cases and were associated with further HR increases, especially for newborns with initial HR < 100beats/minute.

The purpose of this paper was to illustrate the processing and parameterization of ventilation signals recorded from the newborn resuscitation monitor into meaningful data. The study results showed that different types of events can be detected and parameterized to describe the characteristics of ventilation procedure. Efficient detection algorithms as well as parameterization of ventilation events could be useful for retrospective analysis of resuscitation data. This could also potentially be useful during a resuscitation situation by giving immediate feedback to the health care provider.

The objective of this study was to help characterize non-breathing newborns as fresh stillbirth (FSB) or early neonatal death (END) based on immediate heart rate and responses to ventilation. The results showed that while more ENDs responded to ventilation with increasing heart rates, progression to FSB or END after intrapartum hypoxia is likely part of the same circulatory end process. Distinguishing FSB from severely asphyxiated newborns is clinically difficult and probably influences estimated global perinatal mortality rates.

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26 Urdal J et al. 2017

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27 Linde J et al. 2017

The relation between given volume and heart rate during newborn resuscitation. Resuscitation. 11:80- $86 \rightarrow$

28 Linde J et al. 2017

Predictors of 24-hour outcome in newborns needing positive pressure ventilation at birth in a low-resource setting. Resuscitation. 129:1-5 \rightarrow

29 Linde J et al. 2017

Feasibility of a prototype Newborn Resuscitation Monitor measuring heart rate and ventilator parameters. Resuscitation. 116:66-72 \rightarrow

Information learned from ventilation and other treatment could help increase survival rate of newborns in need of resuscitation. This paper aimed to classify resuscitation activities using information from acceleration and ECG signals. A machine learning algorithm was trained using 30 manually annotated resuscitation videos. The results showed that that the algorithm was able to classify resuscitation activities with an accuracy of 79%. This indicates that it is possible to use ECG and acceleration signals to automatically derive useful information regarding resuscitation activities.

Using a machine learning framework, factors including the initial condition of the newborn, the treatment given, and early heart rate response from bag-mask ventilation were identified and investigated for their role in determining newborn outcomes. The results showed that the factors had an identification rate of 89% for the normal group and 74% for the group that ended in death. This points to the direction of identifying important factors for newborn survival.

The objectives of this study were to determine (i) the relationship between a given tidal volume (TV) during initial ventilation and heart rate (HR) responses of asphyxiated newborns, and (ii) the optimal delivered TV associated with a rapid increase in HR. The results showed that there was a consistent positive relationship between HR increase and delivered TV. Surprisingly, ventilation pauses to provide stimulation/suction resulted in further increase in HR. This suggests that most newborns were in primary rather than secondary apnea.

The objective of this study was to describe the relationship between initial heart rate (HR) in non-breathing newborns, HR responses to ventilation and 24-hour survival or death. The results suggest that the risk of death in non-breathing newborns can be predicted by the fetal HR (absent or abnormal), initial newborn HR (bradycardia), and the HR response to ventilation. These findings stress the importance of reliable fetal HR monitoring during labor and providing effective ventilation following birth to enhance survival.

The aim of this preclinical study was to describe the abilities of a prototype newborn resuscitation monitor to measure ventilation and heart rate parameters against pathophysiological responses to different induced conditions in a piglet. The results showed that the monitor was capable of continuously displaying heart rate and detecting inflicted changes in ventilation and compliance of piglets - it could measure inflated and exhaled volume, the pressure of the ventilations and also the end tidal CO₂. Since piglets have similar tidal volumes as human newborns, the monitor could also be used in clinical studies to collect objective feedback and generate new knowledge on newborn transition and resuscitation.

30 Thallinger M et al. 2017 Born not breathing: A randomised trial comparing two self-inflating bagmasks during newborn resuscitation in Tanzania. Int J Qual Health Care. 30(4):271-275 →

31 Mduma E et al. 2018

Using statistical process control methods to trace small changes in perinatal mortality after a training program in a low-resource setting. Int | Qual Health Care. 30(4):271-275 →

32 Eilevstjønn J et al. 2018

Distribution of initial heart rate and responses to resuscitation related to outcome among 1053 apneic neonates at birth. Conference Abstract: PAS 2018

33 Moshiro R et al. 2018

Newborn Resuscitation in a Rural Tanzanian Hospital: Quality of Positive Pressure Ventilation of Admitted Newborns and Outcome within 7 days. Plos One $13(8) \rightarrow$

34 Moshiro R et al. 2018 Factors affecting effective ventilation during newborn resuscitation: A qualitative study among midwives in rural Tanzania. Global Health Actions. 11(1):1423862 →

Effective ventilation is crucial to save non-breathing newborns. The objective of this study was to compare standard equipment for newborn resuscitation to the Upright bag-mask. Of 6.110 babies born at Haydom hospital, 330 newborns requiring resuscitation were randomized. The study results showed that the Upright bag-mask provided higher expired tidal volume, mean airway and peak inspiratory pressures, and early expired CO₂ compared to the standard bag. Clinical outcome differed at 30 min, but not at 24 h.

Heart rate (HR) response to bag-mask ventilation (BMV) is an important indicator of effectiveness. The aim of this study was to determine the relationship between initial newborn HR and the response to BMV and newborn outcomes through the first seven days. The results of the study showed that performing BMV was associated with an increase in HR in most newborns, and that initial and final HR had a significant association with outcome, where higher HR predicted better prognosis.

The objective of this study was to determine the perinatal predictors of death including the quality of ventilation provided to admitted newborns. Asphyxiated newborns who died showed delayed heart rate responses compared to survivors. This may be due to prolonged abnormal fetal heart rate during labor management or delay in initiating adequate ventilation. Improving fetal heart rate monitoring to identify fetuses at risk for expedited delivery, coupled with optimizing delivery room ventilation might decrease mortality in this setting.

Interviews with eight midwives in Tanzania were analyzed to provide insight on barriers and facilitators to effective Bag-mask ventilation. Based on the midwives' experiences, improvement efforts should focus on labor monitoring, birth preparedness, accurate assessment and high-quality and frequent simulation training.

The aim of this study was to retrospectively apply cumulative sum (CUSUM) chart and variable life-adjusted display (VLAD) plots on a validated labor database to monitor changes in early perinatal mortality over a 5-year period. The results demonstrated that steady improvement in perinatal survival were detected, and the variations in improvement were sometimes linked to specific interventions and events. This method (use of VLAD and CUSUM charts) can be used to monitor impact and sustainability of interventions like the Helping Babies Breathe program, as well as facilitate the early detection of negative trends.

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When Baby Gloria was born in Haydom, she did not breathe. And then Mama Regina also needed help – parts of her placenta were retained and Regina was bleeding heavily. Luckily her midwife knew how to help both mother and baby. Regina lived to see to see Gloria grow up.



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