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Implementation of ThermoSpots in low-resource settings: a caregiver centred approach to decrease neonatal hypothermia

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To my great grandmother Dr. med. Marianne Wulkop

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List of Abbreviations

BW.....Birthweight
Chichewa.....Next to English Malawi's official language
CoM..... College of Medicine, University of Malawi
comp.....comparable
COMREC.....College of Medicine Research Ethics Committee
CPAP.....Continuous Positive Airway Pressure
CPR..... Cardio Pulmonary Resuscitation
g.. ..... grams
GA .....Gestational Age
HIE .....Hypoxic Ischaemic Encephalopathy
HT..... Hypothermia
Int .....Intervention
KCH.....Kamuzu Central Hospital
KMC.....Kangaroo Mother Care
LBW..... Low Birth Weight
LMU .....Ludwig Maximilians University
LW .....Labour Ward
MDGs .....Millennium Development Goals
MWK.....Malawian Kwacha
O_2 ..... Oxygen
OR ..... Operation Room
Pre .....Pre-Intervention
Prem.....Premature
RDS.....Respiratory Distress Syndrom
SGA.....Small for Gestational Age
temp.....Temperature
TS.....ThermoSpot
WG ..... Weight Group
WHO..... World Health Organisation

1 Introduction

1.1 Global and Local Mortality of Children and Newborns

7.4 million child- and youth deaths (under 25 years) occurred worldwide in 2019 (1). 70% of those were younger than five years, from which 47% died in the neonatal period, defined as the first 28 days of life (1). Most of those deaths resulted from preventable causes (1). There were large regional differences in child mortality: the highest incidence of under-five (53%) and neonatal deaths (42%) worldwide was in sub-Saharan Africa (1). Through the expected increasing birth rates in that region, neonatal deaths might even increase in the coming years (1).

The MDGs (Millennium Development Goals) of the United Nations for 2015 included the decrease of child mortality. The worldwide under-five mortality was reduced over more than half between 1990-2015 (2). The consecutive goals of the Agenda for Sustainable Development for 2030 include the reduction of neonatal mortality to 12 of 1000 live births worldwide (3). The United Nations Children's Fund claims for life saving interventions in the newborn period, concentrating on the most fragile regions (1). The Every Newborn Study Group set the goal to reduce the neonatal mortality rate to even ≤ 10 deaths per 1000 newborns until 2035 and recommends focussing on Africa (4).

Malawi is a country in sub-Saharan Africa. It was the country with the fastest progress in sub-Saharan Africa towards the MDG to decrease child mortality from 1990-2012 (4). Still, one out of 37 live-born newborns in Malawi died in the neonatal period between 2010-2015/16 (5). The under-5 mortality in Malawi was reduced by 73% from 1992 to 2015/16 while the neonatal mortality decreased only 34% (1, 5). Rates of the under-five mortality are highest in rural areas and the central region of the country (5).

1.2 Neonatal Hypothermia – Pathophysiology and Consequences

The WHO (World Health Organisation) defines hypothermia as a body core temperature equal or less than 36.5°C, classified into mild hypothermia (36.0-36.4°C), moderate hypothermia (32.0-35.9°C) and severe hypothermia (<32.0°C) (6).

Heat loss in neonates happens through radiation, conduction, convection and evaporation (7). Newborns lose heat mostly through evaporation in the first 15 minutes of life, where amniotic fluid vaporizes from the skin (7-9). In term newborns (gestational

age ≥ 37 weeks) older than 15 minutes the largest amount of heat is lost through radiation, a transfer of heat from the body to surrounding cold surfaces (7, 8, 10). Via conduction, heat is lost to surfaces that are colder than the body and in direct contact with the newborn (7). Convection leads to a heat transfer from the newborn's body to moving air (7).

Neonates lose heat easily because the relation of their body surface compared to their weight is large (7, 11, 12). In addition, they have less subcutaneous fat for isolation (11-13). Heat loss in newborns is four times greater compared to adults while their basal heat production per body surface unit is lower (12, 14). Therefore, newborns need higher room temperatures (32-33°C) for thermoneutrality (14). Prematurity (gestational age < 37 weeks) and low birth weight (birthweight < 2500g) are great risk factors for neonatal heat loss (12, 15, 16). The body surface - weight ratio in those newborns is even larger and subcutaneous fat even less (12). They do not manage sufficient heat production to keep a stable body temperature until they reach a normal weight (12). In addition to that, preterm newborns have higher evaporation rates due to high transepidermal water diffusion through immature skin (8, 17-19).

Newborns produce heat by increased metabolic activity (non-shivering thermogenesis) (11). The non-shivering thermogenesis emerges in brown adipose tissue, which newborns show in various body regions (11). Brown adipose tissue is highly vascularized and innervated and contains plenty mitochondria (11). Noradrenaline and thyroid-stimulating hormone are mediators that are released when a newborn is exposed to a cold environment and introduce thermogenesis through ß-oxidation of brown fat tissue (20-22). Especially in the first hours of life, this heat production is not sufficient to make up for the enormous heat loss (23).

Temperature regulation is high stress for a newborn's body and metabolic system (14). Neonatal hypothermia leads to an alteration of oxygen consumption, to acidotic conditions and to low blood sugar levels as well as to peripheral vasoconstriction (6-8, 23-26). The cardiac output decreases, and the renal excretion of water and solutes increases (8, 26, 27). It also evokes electrolyte shifts in the serum (26). Bradycardia and apnoea are typical consequences of hypothermia in newborns (6). Hypothermic newborns are at increased risk for infections and haemorrhagic manifestations through coagulation disorders (6, 24, 28-30). The weight gain decreases with temperature decrease (31). Better growth in extremely low birthweight newborns during

hospitalisation has been found to have a positive long-term impact on the neurodevelopment and growth (32, 33) .

It is long known that neonatal hypothermia through the mentioned issues increases the risk for neonatal morbidity and mortality worldwide (6, 34-41). Therefore, the WHO defined thermal control as one of the essential components of newborn-care to reduce neonatal mortality and improve neonatal health (42).

1.3 Prevention of Neonatal Hypothermia

The WHO claims for continuity in maintaining the “Warm Chain”, which contains practices that should be followed to prevent neonatal hypothermia (6). The difference between body- and room temperature should be kept as low as possible and radiation should be prevented by averting e.g. close cold walls in the surrounding, especially tiles (43, 44). Skin to skin contact as well as breast feeding have shown to be excellent methods to prevent and cure hypothermia and can be done without any further equipment (15, 45, 46). Early bathing of the newborn is not necessary and leads to heat loss; it should be postponed to day two or three of life (6, 47). Newborns should be dried thoroughly and covered well by clothes or linen and, especially in the first hours of life, wear a hat to maintain heat (6, 48-50). Incubators, radiant heaters and heated mattresses have also proven as useful in the prevention of neonatal hypothermia (6, 51, 52).

The importance of health worker awareness of neonatal hypothermia and maternal involvement in thermo-surveillance of newborns has been emphasised for high-resource settings long ago and continues to be emphasised repeatedly for low-resource settings today (6, 24, 28, 53, 54).

1.4 Neonatal Hypothermia in Low-Resource Settings

Hypothermia in neonates occurs frequently in low-resource settings, even in warm countries like in sub-Saharan Africa, including Malawi (6, 34, 38, 39, 44, 55-57). One reason for the high incidence is that 91% of all newborns with low birthweight are born in low- and middle-income countries - in 2015, sub-Saharan Africa was the place with the worldwide second-highest incidence of low birthweight (58). Also, preterm births are most often in sub-Saharan Africa and Malawi is the country that had the highest premature birth rate worldwide (18%) in 2010; this rate was reaffirmed in a study between 2012-2015 (4, 42, 59).

Further factors that lead to the high incidence of neonatal hypothermia in low-resource settings are: often cold delivery rooms (60-62), frequently no sufficient drying and wrapping of the child (60, 63, 64), not much skin to skin contact and delayed breastfeeding (57, 61, 63, 65), early and frequent bathing of the newborn (61, 63, 66-69) and only sporadic body temperature measurements of neonates in health facilities (39, 61).

High percentages of home deliveries are performed with traditional procedures with cultural beliefs that often do not consider neonatal hypothermia to be harmful, sometimes leaving the newborn exposed on the floor until the placenta is delivered (64, 67-71). Mothers and even health workers often do not know enough about the definition of hypothermia, the methods of correct temperature measurement, the physiology of thermoregulation in newborns and about the prevention, management and risks of neonatal hypothermia: even simple ways to keep the newborn warm are not used and the need for education on this topic is high (6, 54, 56, 60, 61, 72). The absence of shivering and the facial erythema during hypothermia in neonates can be misleading without a proper knowledge and hinder its recognition (24, 73). Experts think that hypothermia in low-resource settings is not due to a lack of material but solely due to insufficient knowledge of health workers and mothers (74).

Still, even with sufficient knowledge, the prevention and treatment of hypothermia is not always performed as expected and lack of care has been shown in several studies (15, 61, 75). An explanation for this might be the simple lack of resources: shortage of thermometers, functioning incubators and clean/warm linen could lead to a minimisation of possibilities to detect, prevent and react to hypothermia (72). Human touch is the only available method in many places to measure a body temperature particularly for mothers and is not accurate for detecting especially mild and moderate hypothermia (76, 77). A shortage of staff leading to overworked health personal, which in turn leads to under-documentation of body temperatures and a lack of diagnosing hypothermia might also play an important role (40, 78).

Many sources call up for the implementation of education and training on neonatal hypothermia in the newborn care in low-resource settings to improve its prevention and management (39, 55, 56, 69, 73, 79).

An investigation carried out in 1988 in one of our study sites (KCH; “Kamuzu Central Hospital”) already reported a high incidence of neonatal hypothermia and the

impression that it was associated with high mortality, thus the authors asked for the development of interventions (44). Although the problem is known at least since then, in 2013/2014, the body temperature was checked within the first two days of life in only 64% of the births in Malawi (5).

In the Malawian hospitals known to us, thermometers are not always available and temperature checks are not regularly performed. In the wards we often saw newborns in the cot not having been touched for hours and many times too cold to establish a physiological circulation and metabolic level. Similar circumstances have been reported in the study from 1988, where the authors described placing of newborns into a cot immediately after birth and mothers who did not hold the newborn until after the transfer to the postnatal ward approximately one hour later (44).

Due to above reasons, mothers and health workers might not perceive this behaviour as harmful and, therefore, Malawi has a high incidence of insufficient continuity in keeping newborns warm according to international standards and guidelines (6). This is the point we planned an intervention to reduce neonatal hypothermia by teaching mothers and health workers about the topic and on the use of a simple hypothermia detecting device (ThermoSpot).

2 Study Objective

Only sporadic data about the prevalence of neonatal hypothermia in Malawi exist to our knowledge (5, 44). Investigations about the accuracy of ThermoSpots have been realised but to our knowledge no studies about their impact on the frequency of hypothermia and patient health exist (80-83). The acceptance of mothers has been analysed only focusing on malnourished children and in a study involving ten newborns but no studies with a bigger sample size of newborns have been conducted to our knowledge (80, 84).

Our study aimed to examine if ThermoSpots could be introduced to the caregivers of newborns and improve health outcomes in a low-resource setting (Malawi). The attempt was to enhance the awareness about and the monitoring of neonatal hypothermia as well as to cause behavioural change regarding hypothermia, focussing on the newborns' guardians. The hypothesis was that this would reduce hypothermia and improve health outcomes in terms of mortality, inpatient times, weight gain and secondary coinfections of hospitalized newborns.

The goals of this study were to:

- describe the surveillance of newborns regarding hypothermia in Malawi
- identify gaps in surveillance regarding neonatal hypothermia in Malawi
- compare the incidence of neonatal hypothermia in Malawi to a German obstetric/neonatal care provider at a University hospital
- assess if a simple, caregiver centred device could be introduced in Malawi
- assess if the implementation of caregiver based continuous temperature surveillance had a positive impact on the incidence of neonatal hypothermia rates in Malawi
- assess if a hypothermia centred approach in surveillance enhanced patient care and is sustainable in Malawi
- assess if continuous temperature surveillance affected the duration of stay, weight gain, coinfections and mortality
- assess if the approach altered caretaker behaviour with beneficial effects on health understanding, caretaking and seeking of support
- assess the acceptance and opinion of guardians about the use of ThermoSpots
- compare the findings between rural hospitals and the central hospital in Malawi

3 Methodology

3.1 Ethical and Legal Issues

The study was approved by the ethical review committee of the LMU and by COMREC (College of Medicine Research Ethics Committee, Malawi). It was performed in conformity with the current Declaration of Helsinki (2013). The guardians of the newborns, who participated in the intervention, signed a consent form (Appendix: p. 77, p.80) in Chichewa (next to English Malawi's official language). In case of illiterate guardians, consent was confirmed with a thumbprint after explaining the content.

3.1.1 Data Security

Personalised data of patients was anonymised. Only persons directly involved in the data collection had access to the confidential data, in which patients were named, within the framework of the appropriate statutory provision. These persons underlie professional discretion and must respect privacy protection. Other parties did not have access to the original patient files. Patient records were entered anonymised into data tables. Thus, tracing the patient to the study number is impossible after the completion of data collection. No circulation of data took place. The procession and publication of the data include only anonymised data without naming or inference to patients.

3.2 Study Design

3.2.1 Design Type

Experimental intervention study with a prospective control group. Qualitative components in form of focus group discussions and personal interviews.

3.2.2 Hypothermia Indicator ThermoSpot

A ThermoSpot (CE No. 0434) is a non-invasive, liquid crystal temperature indicator (85). It is an adherent, round device (12 mm diameter) that is stuck onto the skin and placed in the axilla, in the epigastrium above the liver or in the jugular fossa; the sites are equivalent (72, 85). The ThermoSpots' colour changes with the body temperature. With a normothermic body temperature of 36.5-37.5°C, it is bright green and has a smiling face (85). With a decreasing body temperature, it first turns to yellow/pale green and then to red/brown (85). With a body temperature of <35.5°C the colour changes to black and the smiling face disappears (85). A ThermoSpot can also detect fever and

turns blue at a body temperature of ≥39°C (86). The accuracy tolerance of the device is ± 0.5°C (85).

ThermoSpots were included into the WHO compendium of innovative health technologies for low-resource settings 2012 (85). They are a cost-effective solution for hypothermia which is easily introduced and already exists, thus they meet the criteria "Safe the Children" claimed for in 2001 (74). The accuracy of liquid crystal temperature indicators like ThermoSpots has been verified in several studies (80-83). The understanding of ThermoSpots and reactions against hypothermia as well as the acceptability amongst mothers in Malawi has been studied in ten newborns and 162 malnourished children and resulted to be high (80, 84).

Image 1: ThermoSpot

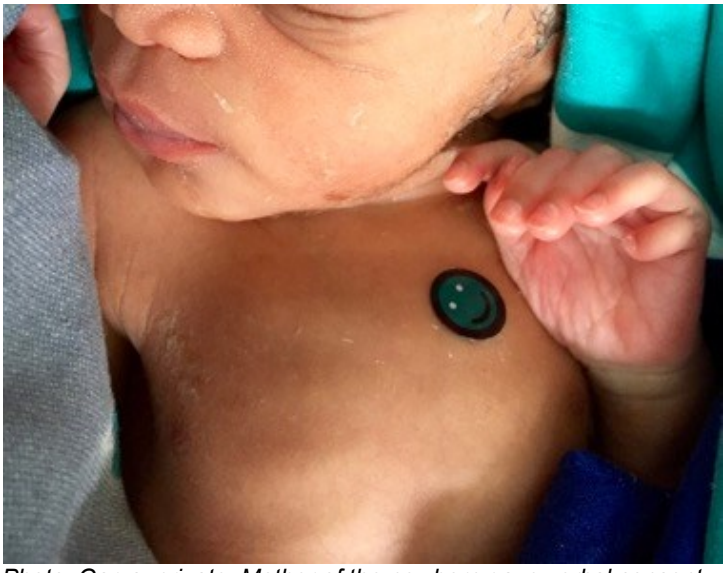


Photo: Garvs, private. Mother of the newborn gave verbal consent.

3.2.3 Locations of Research

The investigation took place in the nurseries and the associated KMC (Kangaroo Mother Care) = skin to skin care units of the central hospital and two district hospitals in the central region of Malawi:

- **Kamuzu Central Hospital (KCH), Lilongwe**

  The KCH is a referral hospital in Lilongwe, Malawi's capital. Patients that cannot get the necessary treatment in other hospitals are referred here. The neonatology unit contains 70 beds. It is divided into a high-risk area, corresponding to an intensive care unit, a low-risk area for sick but stable neonates, and an isolation area for neonates admitted from home. More newborns are placed in the unit, if

needed. Guardians are allowed to visit for feeding every two hours. A KMC ward (13 beds) for guardians and their healthy newborns with too low body weight (discharged when a weight of ≥ 1500g is reached) also belongs to the nursery. The total nursing staff in the neonatal ward consists of seven nurses taking shifts; usually four nurses per day- and three per night shift. Sometimes nursing students help with tasks during their internships. One clinical officer and one physician work in the nursery as permanent staff. Interns rotate for two weeks duration into the neonatal ward and are sometimes present. There is no air-conditioning and the windows are mostly open. Therefore, the ward is as warm as the outside temperature (average temperatures during months of the study period: 13-26 °C) with a certain amount of air circulation or even warmer if radiant heaters are used (87).

- **Dedza District Hospital**

  The Dedza District Hospital is a rural hospital about 100 kilometres south of Lilongwe. The structure of the neonatal ward is similar to KCH, but only 18 beds in the nursery and nine beds for KMC are provided, and just one nurse per shift is responsible for the neonatal patients. No paediatrician works at the hospital. During our study, three students of the bachelor's program "Paediatrics and Child Health" of the CoM (College of Medicine) were in charge of all paediatric wards in Dedza. As Dedza is located about 1600 meters above sea level, the climate can get cold (average temperatures in the months of the study period: 13-27°C) (88).

- **Salima District Hospital**

  The Salima District Hospital is a rural hospital about 100 kilometres east of Lilongwe. The structure of the nursery and KMC of the neonatal ward is the same as in Dedza, but just ten beds in the nursery and four beds for KMC are provided and guardians are allowed in the ward around the clock. In Salima, also, three students of the bachelor's program "Paediatrics and Child Health" of the CoM were in charge of all paediatric wards during the period of data collection. The climate in Salima is warmer than in the other study sites (average temperatures in the months of the study period: 21-27 °C) (89).

The sites were chosen for their urban and rural locations and differences in altitude and climate to compare whether these had an impact on the outcome. For

comparisons between Malawian and German hospitals, the database of both neonatology departments of the **LMU** (Ludwig Maximilians University), a maximum care provider in Munich, Germany, was used.

3.2.4 Duration of Research

The study included the collection of basic data for the control group during the pre-intervention period and the collection of data in the intervention period.

- KCH Pre-intervention Period: December 2017 - February 2018
  Intervention Period: March 2018 – May 2018
- District Hospitals Pre-intervention Period: January 2018 - February 2018
  Intervention Period: March 2018 – April 2018
- LMU March 2018 – June 2018

3.2.5 Description of the Intervention

The intervention for each participating newborn started on the admission and ended at discharge or death. Every newborn admitted to the nurseries of one of the study locations during the intervention period participated, provided the guardian agreed. Newborns who participated in the intervention got a ThermoSpot stuck to the skin. The health workers of the nurseries and the guardians of the participating newborns were trained on the use of ThermoSpots in a conducive environment. The training for the staff was held in English or Chichewa by students of the CoM or J. Garvs, LMU. Guardians were trained in Chichewa and other native languages by the vital signs assistant (KCH; see below), students of the CoM, or nurses (night and weekends).

Content of Training:

Health workers were taught about neonatal hypothermia and its consequences to refresh and expand their knowledge. Guardians were also taught about the meaning of neonatal hypothermia and its importance for the outcome of their sick newborns. Health workers were trained on localizing and fixing ThermoSpots. They were instructed to stick a ThermoSpot on every participating newborn on admission and fix the device with transparent medical tape (Leukoflex®) if a ThermoSpot came loose. As ThermoSpots are reusable, they were also instructed to disinfect the devices professionally to reuse them. We explained and demonstrated how to interpret the colour of a ThermoSpot by cutting off the bottom of a plastic bottle to create a bowl

and sticking a ThermoSpot on the outside. The bowl was filled with cold water, and hot water was slowly added to see the device's colour and face change.

Image 2: Training of Guardians with Plastic Bottles

Photos: Garvs, private. Verbal consent was given by all pictured women

The suggested options how to react to a hypothermia indicating ThermoSpot were:

- Providing skin to skin care
- Wrapping the newborn
- Changing wet diapers of the newborn
- Using a heating lamp
- Closing open windows
- Putting a hat on the newborn's head
- Guardians: Asking another guardian for help
- Guardians: Calling a nurse or clinician for help

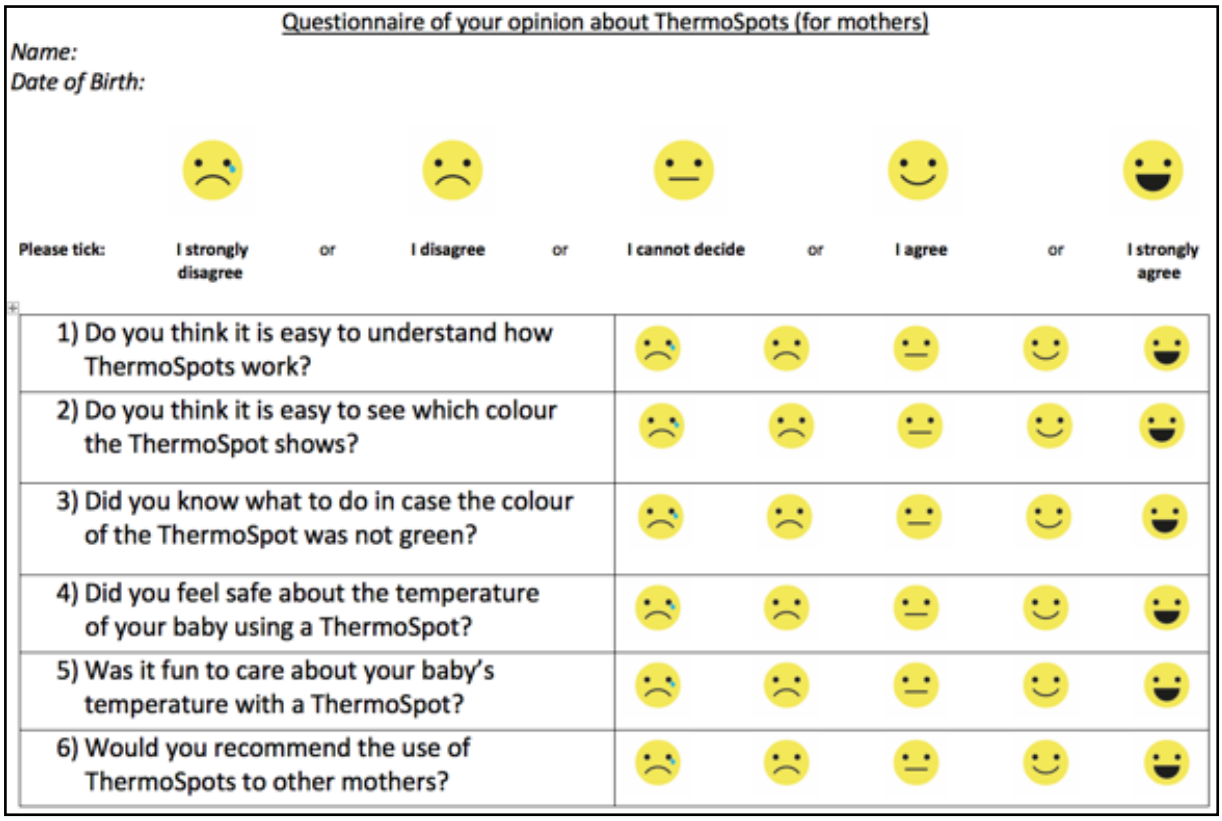
We explained that in case of hypothermia the ThermoSpot should be controlled after 30 minutes and that steps to warm up the newborn should be continued until the device turned green. We also sensitized all participants not to overheat the newborn. The guardians at KCH and Dedza were allowed to see their newborns only every two hours so that they could provide care as instructed only partially. They were instructed to ask a nurse to continue the steps.

A sheet in Chichewa was placed at the bed of participating newborns (Appendix, p.84) where the guardian was supposed to document by ticking boxes the colour of the ThermoSpot and their action in case of hypothermia each time they saw the newborn. Pens were available in several places on the ward. The use of bedside

sheets was explained, and illiterate guardians were briefed to notify a staff member or another guardian with writing skills to get help with writing down their reactions. Instructions with intuitive illustrations in English and Chichewa were hung out on various, easily accessible, and well visible places in the nurseries (English: Image 4, Chichewa: Appendix, p.83).

At the end of the hospital stay, each participating guardian in the intervention completed a questionnaire with six questions on a Likert scale (English: Image 3, Chichewa: Appendix, p.85) about the experience with ThermoSpots. The discharging person was in charge of making sure the ThermoSpot was returned.

Image 3: Questionnaire for Guardians



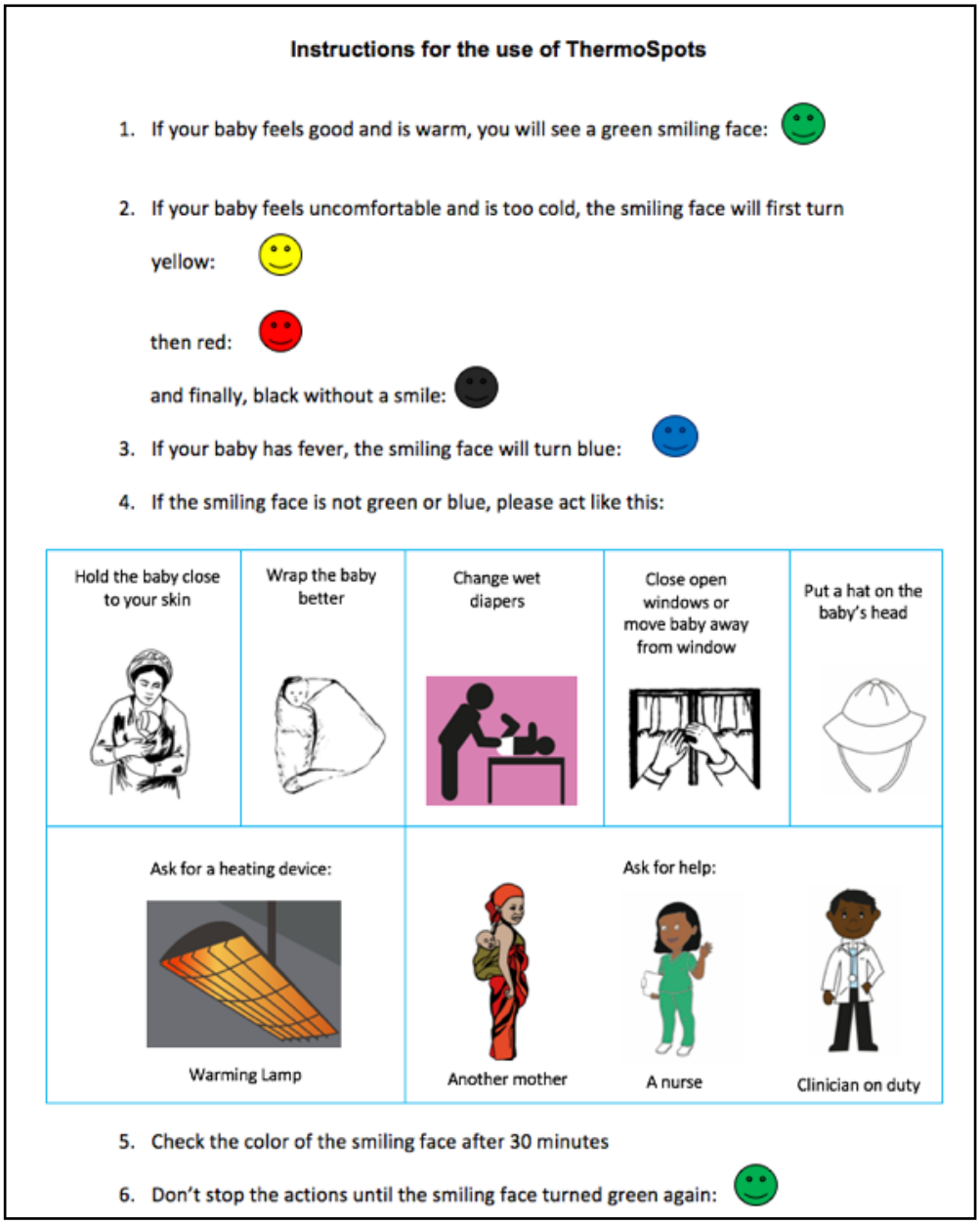
Questionnaire of your opinion about ThermoSpots (for mothers)

Name:
Date of Birth:

Please tick:	I strongly disagree	or	I disagree	or	I cannot decide	or	I agree	or	I strongly agree
1) Do you think it is easy to understand how ThermoSpots work?									
2) Do you think it is easy to see which colour the ThermoSpot shows?									
3) Did you know what to do in case the colour of the ThermoSpot was not green?									
4) Did you feel safe about the temperature of your baby using a ThermoSpot?									
5) Was it fun to care about your baby's temperature with a ThermoSpot?									
6) Would you recommend the use of ThermoSpots to other mothers?									

Illustrations: Luise Wuestling©. Modified after QuestionPro. Bipolare Likert-Skala Dallas; 2018 [retrieved 5th January 2018]. Available from: https://www.questionpro.com/blog/wp-content/uploads/2016/06/Bipolare-Likert-Skala.jpg.

Image 4: Instructions for ThermoSpots



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3.2.6 Methods of Data Collection

3.2.6.1 Quantitative Data

Quantitative data were collected using the patient files after their discharge or death. Intervention data were additionally collected evaluating the bedside sheets and questionnaires. Data was listed in Excel tables. The first twelve days of hospitalisation were documented and analysed. The study supervisors of each hospital and study period were responsible for making sure that usable data were recorded in the patient files. J. Garvs, LMU, visited all study sites at least once a week during the intervention period and linked the study locations.

KCH: In cooperation with the KCH and the Baylor College of Medicine, Texas, USA, prospective data were collected. The Baylor College of Medicine created a database for neonates at KCH in general (not hypothermia focused). We expected that the data would underline the need for improvement of the thermal care of neonates in Malawi. We helped the Baylor College of Medicine collect the data and therefore were allowed to use hypothermia related data.

A vital signs assistant worked in the nursery during the data collection to measure detailed hypothermia-related data (body- and room temperatures and weights) and to help to conduct the study. Body- (axillar and in-ear) and room temperatures were supposed to be taken four times daily per child, weights once per day. Admission temperatures were measured additionally. On weekends, the nurse on duty was asked to fulfil those tasks as well as the briefing of guardians. The nurses were paid for their extra work (MWK=Malawian Kwacha; 1 Euro ≈ 950 MWK (90)): (500 MWK for briefing the guardian of a new admission, 300 MWK for completing the questionnaire and collecting the ThermoSpot on discharge). J. Garvs, LMU, supervised the collection of the quantitative intervention data.

Every two weeks, a meeting of the KCH study group, consisting of Dr. med. A. Schultz (paediatrician) as chairman, the clinical officer and nurse in charge of the study, the vital signs assistant, and J. Garvs, LMU, was held to evaluate the study's progress and the data collection.

District Hospitals: In cooperation with the CoM, University of Malawi, students of the bachelor's program "Paediatrics and Child Health" were in charge of collecting hypothermia related data and conducting the intervention. Body temperatures (axillar) were supposed to be taken three times daily per child, room temperature and weight

once daily. The admission temperature was included in the three daily temperatures on the first day of stay. Room thermometers were available only for the intervention period. During the intervention, J. Garvs, LMU, supervised the data collection through weekly visits to each district. Once a month, Dr. med. A. Schultz joined the visit and led a meeting with all the involved staff.

LMU: The digital database of the neonatology departments of the LMU was used. Rectal body temperatures on admission were recorded.

3.2.6.2 Qualitative Data (Only KCH)

A focus group discussion led by Dr. med. A. Schultz was held with twelve guardians (mostly mothers, some grandmothers) of the KMC ward to analyse their acceptance and opinions about ThermoSpots. The vital signs assistant was present for translating from English to Chichewa, and J. Garvs, LMU, wrote the protocol. The discussion was realised in the setting of a circle of chairs at the nursery's reception, the guardians having their newborns in KMC position.

After an introduction of the participants and staff, the aim of the discussion was explained. We emphasised that the discussion would represent the opinion of all guardians who participated in the study. The participants were informed that contents of the discussion might be part of a publication that might have impact on the general use of ThermoSpots and that no names or personal details would be registered. The leading questions of the discussion were:

- Does your newborn still have a ThermoSpot?
- What do you think the ThermoSpot is for?
- Who briefed you on the use of ThermoSpots?
- Were you afraid to use your ThermoSpot, when you first got briefed about it? Did you understand immediately?
- What do you do in case the ThermoSpot falls off? Where is it positioned?
- When do you look at your ThermoSpot?
- Did you ever see a not-green ThermoSpot?
- Do you like the use of ThermoSpots? If yes, why?
- What were the problems you faced while using ThermoSpots?
- Would you buy a ThermoSpot for your next baby if it costed 240 MWK?

- When you first came into the nursery and saw that other newborns had a ThermoSpot, were you interested in using one, too?
- Would you rather trust a ThermoSpot or a nurse measuring by thermometer regarding the temperature of your newborn?
- Do you have a better idea than ticking on bedside sheets for the documentation of colours?
- Did you always know where to make a tick on the bedside sheet?
- Did you have problems differentiating between the colours?
- If you would take the ThermoSpot home and it falls off, what would you do?
- Is there anything else you would like to comment on about ThermoSpots?

Another focus group discussion, led by Dr. med. A. Schultz, was realised with the KCH study group at the end of the intervention period to reflect the study methods and limitations. The leading questions were:

- What could we have done better?
- Which problems did occur?
- Would it make sense to establish ThermoSpots in clinical standards?
- Is there anything else, you would like to state about the study?

J. Garvs, LMU, held interviews with nurses of the neonatal ward to evaluate their opinion about ThermoSpots and gather information about the system and working conditions. She held the interviews in the ward in a surrounding with as much privacy as possible. The nurses were informed that the answers would be anonymised.

3.3 Patient Cohort

3.3.1 Inclusion and Exclusion Criteria

Inclusion: Patients in the neonatal period (< 29 days), including SGA (small for gestational age) and preterm newborns, admitted during the study period.

Exclusion:

Table 1: Number and Reason of Newborns excluded – Malawian Hospitals

Reason	KCH		Dedza		Salima	
	Pre (N=573)	Int (N=582)	Pre (N=156)	Int (N=121)	Pre (N=157)	Int (N=82)
Gestational age < 28 weeks	18	17	1	2	0	1
Birthweight < 1000 g	10	7	2	2	1	0
Severe diagnosis*	12	16	0	0	0	0
Age on admission > 28 days	2	10	3	1	1	2
Missing files	0	8	0	0	0	0
No ThermoSpot used	--	46	--	0	--	0

N=initial sample size
Int=Intervention; Pre=Pre-Intervention
** gastroschisis, omphalocele and prune belly syndrome*
Note: Newborns who did not participate in the intervention due to decline of the guardian were included in the group "No ThermoSpot used". No detailed documentation about the use of ThermoSpots exists for the district hospitals; all newborns in the intervention period were assumed to have had one.

At LMU, the data of two newborns were excluded because they died in the delivery room, 16 newborns due to a gestational age of < 28 weeks and five newborns because of a birth weight of < 1000g.

3.3.2 Sample Size

Table 2: Newborns per Study Site Malawian Hospitals

	KCH	Dedza	Salima	Total
Pre-Intervention	531	150	155	836
Intervention	478	116	79	673
Total	1009	266	234	1509

The sample size of newborns from LMU is 366.

3.3.2.1 Differing Sample Sizes

The quality of documentation of many variables was insufficient due to implausible and missing values. Therefore, not the total sample sizes but adjusted ones were used in many cases for analyses. Exact information about the criteria to consider values implausible can be found in the Appendix, p. 86-94. In some cases, values were corrected retrospectively according to those criteria. The quality of documentation for each variable can be found in the Appendix, p. 95-104. The quality of documentation of body temperatures is part of the primary outcomes. If a variable was unknown in > 50% of the expected values, it was not analysed. Exceptions from this rule are marked

as such. If the sample size for a calculation differs from the total sample size, the used sample size is indicated in the respective analysis results.

3.4 Biases

3.4.1 General Limitations

Sample Sizes

We would have expected equal proportions of sample sizes in each hospital in both study periods. However, the sample sizes in the district hospitals were smaller during the intervention. An explanation for this might be that the data-entering students were in their examination period during the intervention period and not all files were entered into the database. In addition, another data collection was running simultaneously, which might have led to missing files as other researchers may have been using the files.

Excluded Newborns

KCH, reported some newborns who had no ThermoSpot and were excluded. These cases occurred mainly in the beginning of the intervention when health workers were not used to ThermoSpots, or when a newborn died soon after arrival. Only few guardians declined to participate in the study. Unfortunately, we did not count those cases.

Time of ThermoSpot Application

Only KCH data exist. Only 63% of the newborns received their ThermoSpot on their admission day. As many nurses did not collaborate (see discussion), newborns who were admitted during nights or weekends often received the device with delay. This biased the data as hypothermia occurs most often in the first hours after birth and many of such incidents may have been missed (79).

Information about Prematurity

If information about the maturity of a newborn was missing but a birth weight of <2000g was documented, the newborn was assumed to have been preterm (two times at KCH Pre). This biased the data as we did not consider the possibility of those newborns to be SGA.

3.4.2 Limitations of Data Collection

Due to the shortage of staff and the nurses' lack of time and motivation (see Discussion), many data are missing or implausible. This led to difficulties analysing the data and incongruent sample sizes. For further studies, it might be helpful to arrange more assistants for a better documentation on patient files. However, additional staff as the vital signs assistant who was present during both study periods at KCH and bachelor students who were present during the intervention period in the district hospitals to support the health personnel bring a certain bias as the everyday situation in the wards is interrupted.

The precise biases of the data collection of specific variables are mentioned in the discussion of the affected result.

3.4.3 Limitations of the Intervention Design

The limitations of the intervention design are discussed in 5.2.

3.5 Analysis

3.5.1 Definition of Hypothermia

Hypothermia was defined following the WHO definition (6): Body temperature 36.0-36.4°C: mild hypothermia, body temperature 32.0-35.9°C: moderate hypothermia, body temperature <32.0°C: severe hypothermia.

3.5.2 Statistical Methods

The data were evaluated using GraphPad Prism version 8.4.3 (471) for Mac OS X, GraphPad Software, San Diego, California, USA, and Microsoft Excel version 16.16.27 (202012) for Mac, Microsoft Corporation, Redmond, Washington, USA. Statistical advice was provided by the "Institut für Medizinische Informationsverarbeitung Biometrie und Epidemiologie" of the LMU.

Descriptive analyses of pre-intervention and intervention data were realised using absolute and relative frequencies as well as geometric means, medians, geometric standard deviation factors, and 25%- and 75% quartiles. Crosstables were used to determine the relative frequency of possible factors influencing the different variables with special consideration given to stratifications by admission weight, places admitted from, maturity, outcome, and age on admission in certain calculations. If the

difference between the pre-intervention and intervention period was not significant, the descriptive data from both periods are presented in one, except for the primary and secondary outcomes. Significances between the hospitals were analysed by summarizing the study periods if the difference between them was not significant.

Bivariate nonparametric analyses for unpaired groups were carried out to compare the pre-intervention and intervention data as well as the different hospitals, using the Mann-Whitney-U test, as, in all comparisons, at least one data set was not normally distributed. Bivariate Chi Square tests were used to compare categorical data. Correlation analyses were conducted by bivariate Spearman nonparametric correlation. The strength of the correlation was evaluated using the Evans (1996) guidelines.

The “D’Agostino & Pearson” normality test “omnibus K2” was used to determine Gaussian distributions. The level of significance was determined as 0.05; 5%. For multiple testing, we used Bonferroni correction.

Qualitative data about the acceptance of ThermoSpots of the guardians and health workers were analysed descriptively.

3.5.3 Exclusion from Discussion

Descriptive Data: If the pre-intervention and intervention period differed significantly, but the variable could not have been influenced by the intervention (e.g., admission temperature), the difference was described but not discussed. Missing data at LMU were not included into the discussion. They were assumed to be missing because of insufficient transcription from the files to the database, not due to insufficient documentation in the nursery.

Room Temperatures: Data are shown in the results but were not discussed.

4 Results

4.1 Descriptive Data

Table 3 describes the sample characteristics. Additional characteristics (gestational age, maternal risk factors, mode of delivery, multiple births, Apgar scores, treatment immediately after birth, birth weight, application of vitamin K, sex, presumptive diagnoses, mode of transport to the hospital, origin of families, age of mothers, respiratory support during hospitalisation, methods of feeding, presumptive causes of death) are described in the Appendix, p.105-115.

Table 3: Sample Characteristics – Percentages of Newborns per Study Site

Variable		KCH	Dedza		Salima		LMU	Difference between Study Periods*	Difference between Hospitals*
Admission Weight (in %) *Quality of Documentation: p. 100*	Study Period	Both	Both		Both		--	Not significant	KCH admitted significantly more newborns ≤1500 g than Salima/LMU. LMU admitted significantly more newborns >2500 g and significantly less newborns in the two lower weight groups than Dedza *(KCH-Salima: p=0.0001; KCH-LMU: p<0.0001; Dedza-LMU: p=0.0003)*
	N	901	192		142		364		
	1000-1500 g	18.8	11.5		6.3		2.7		
	1501-2500 g	32.6	30.7		26.1		27.8		
	> 2500 g	48.6	57.8		67.6		69.5		
Age on Admission (in %) *Quality of Documentation: p. 98*	Study Period	Both	Both		Both		--	Not significant	Newborns at KCH were significantly younger on admission than newborns in the districts. Newborns at LMU were significantly younger on admission than newborns in Malawi *(KCH-Dedza: p=0.001; rest: p<0.0001)*
	N	1003	264		232		364		
	1 day	70.4	59.1		49.6		94.3		
	2 days	9.7	14.0		17.7		1.9		
	3 days	4.9	6.4		4.7		0.5		
	4 days	2.6	3.0		4.3		0.8		
	> 4 days	12.4	17.5		23.7		2.5		
Place admitted from (in %) *Quality of Documentation: p.98*	Study Period	Both	Pre	Int	Pre	Int	No comp data	**During Intervention:** In Dedza, significantly more newborns came from home and less from the same facility/as referrals. In Salima, significantly less newborns came from home and more from the same facility/as referrals *(Dedza: p=0.003; Salima: p=0.05)*	Not tested due to unequal distribution in the study periods in the districts
	N	1009	145	115	155	79			
	Home	5.0	5.5	19.1	20.0	7.6			
	Referred	26.2	20.0	16.5	18.1	22.8			
	This Facility	68.8	74.5	64.4	61.9	69.6			
Department admitted from (in %)	Study Period	Both	No comparable data		No comparable data		No comp data	Not tested	No comparable data
	N	694							
	Delivery Room	70.2							
	OR	20.3							
	Postnatal Ward	9.5							

Variable		KCH		Dedza		Salima		LMU	Difference between Study Periods*	Difference between Hospitals*
Admission Temperature (in %) All Admission Weights *Quality of Documentation:* *p.* 26, p. 98, p. 100	Study Period	Pre	Int	Pre	Int	Pre	Int	--	Significantly more newborns in Salima were moderately hypothermic and significantly less were hyperthermic during the intervention period *(p=0.01)*	**KCH:** significantly more normothermia than Dedza; significantly less normothermia than LMU, significantly more mild HT than Dedza/Salima; significantly more moderate HT than Salima/LMU; significantly less hyperthermia than Dedza/Salima. **Dedza:** significantly less normothermia than LMU, significantly more mild HT than Salima; significantly more moderate HT than Salima/LMU; significantly more hyperthermia than LMU **Salima:** significantly less mild HT than LMU; significantly more moderate HT/ hyperthermia than LMU *(KCH-Dedza: p=0.0004; rest: p<0.0001)*
	N	491	452	133	115	95	76	359		
	Normothermia	23.6	21.5	21.1	11.3	24.2	28.9	71.3		
	Mild HT	21.4	16.8	9.0	14.8	4.2	6.6	16.7		
	Moderate HT	37.7	46.0	43.6	46.1	10.5	26.3	4.7		
	Severe HT	0.2	0.0	0.0	0.0	0.0	0.0	0.0		
	Hyperthermia	17.1	15.7	26.3	27.8	61.1	38.2	7.3		
Admission Temperature*[1] (in %) Admission Weight 1000-1500 g	Study Period	Pre	Int	Pre	Int	Pre	Int	--	Not significant	Not tested due to small sample sizes
	N	88	72	11	8	2	3	10		
	Normothermia	9.2	15.3	9.1	0.0	0.0	0.0	80.0		
	Mild HT	13.6	13.9	0.0	25	0.0	33.3	10.0		
	Moderate HT	65.9	66.6	90.9	62.5	50.0	66.7	0.0		
	Severe HT	1.1	0.0	0.0	0.0	0.0	0.0	0.0		
	Hyperthermia	10.2	4.2	0.0	12.5	50.0	0.0	10.0		

Variable		KCH		Dedza		Salima		LMU	Difference between Study Periods*	Difference between Hospitals*
Admission Temperature*[1] (in %) Admission Weight 1501-2500 g	Study Period	Pre	Int	Pre	Int	Pre	Int	--	Significantly more hypothermic admission temperatures during the intervention at KCH *(p=0.02)*	At KCH and Dedza significantly more hypothermia on admission than at LMU *(p<0.0001)*
	N	144	131	26	31	10	19	101		
	Normothermia	25.0	15.3	19.2	6.4	20.0	36.8	66.3		
	Mild HT	22.2	18.3	19.2	19.4	10.0	5.3	20.8		
	Moderate HT	41.0	58.0	46.2	64.5	20.0	21.1	6.9		
	Severe HT	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
	Hyperthermia	11.8	8.4	15.4	9.7	50.0	36.8	6.0		
Admission Temperature*[1] (in %) Admission Weight >2500 g	Study Period	Pre	Int	Pre	Int	Pre	Int	--	Significantly more hypothermic admission temperatures during the intervention in Dedza *(p=0.01)*	Significantly more hypothermia on admission at KCH than in Salima. Significantly more hypothermia on admission at KCH and Dedza than at LMU *(Dedza-LMU: p=0.001; rest: p<0.0001)*
	N	214	195	48	61	37	42	248		
	Normothermia	29.4	27.7	31.2	12.1	21.6	28.6	73.0		
	Mild HT	24.3	19.0	6.3	12.1	2.7	4.8	15.3		
	Moderate HT	26.2	31.8	18.8	36.2	16.3	19.0	4.0		
	Severe HT	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
	Hyperthermia	20.1	21.5	43.7	39.6	59.4	47.6	7.7		
Admission Temperature*[2] (in %) Referred	Study Period	Both		Both		Both		No comp data	**KCH:** Significantly more hypothermic admission temperatures of newborns admitted from within the hospital than referred/admitted from home and of referred newborns than admitted from home *(Referred-Home: p=0.02; rest: p<0.0001)* **Dedza:** Significantly more hypothermic admission temperatures of newborns admitted from within the hospital/referred than admitted from home *(p<0.0001)*	Referred newborns were significantly less times hypothermic on admission in Salima than in the other hospitals *(KCH-Salima: p=0.002; Dedza-Salima: p<0.0001)*
	N	250		25		42				
	Normothermia	27.2		28.0		31.0				
	Mild HT	14.4		16.0		14.3				
	Moderate HT	34.8		40.0		7.1				
	Severe HT	0.0		0.0		0.0				
	Hyperthermia	23.6		16.0		47.6				

Variable		KCH		Dedza	Salima	LMU	Difference between Study Periods*	Difference between Hospitals*
Admission Temperature*[2] (in %) Home	Study Period	Both		Both	Both	No comp data	**KCH:** Significantly more hypothermic admission temperatures of newborns admitted from within the hospital than referred/admitted from home and of referred newborns than admitted from home *(Referred-Home: p=0.02; rest: p<0.0001)* **Dedza:** Significantly more hypothermic admission temperatures of newborns admitted from within the hospital/referred than admitted from home *(p<0.0001)*	Not significant
	N	45		30	22			
	Normothermia	42.2		36.7	13.6			
	Mild HT	13.4		3.3	0.0			
	Moderate HT	13.3		13.3	9.1			
	Severe HT	0.0		0.0	0.0			
	Hyperthermia	31.1		46.7	77.3			
Admission Temperature*[2] (in %) Same Facility*[3]	Study Period	Both		Both	Both	No comp data	**KCH:** Significantly more hypothermic admission temperatures of newborns admitted from within the hospital than referred/admitted from home (*p<0.0001)* **Dedza:** Significantly more hypothermic admission temperatures of newborns admitted from within the hospital/referred than admitted from home *(p<0.0001)*	Newborns admitted from the same facility were significantly less times hypothermic on admission in Salima than in the other hospitals *(p<0.0001)*
	N	647		168	107			
	Normothermia	19.4		11.9	27.1			
	Mild HT	21.5		11.3	2.8			
	Moderate HT	46.2		51.2	23.4			
	Severe HT	0.2		0.0	0.0			
	Hyperthermia	12.7		25.6	46.7			
Room Temperatures*[4] (in °C) *Quality of Documentation: p.104*	Study Period	Pre	Int	Int	Int	No comp data	At KCH, the room temperatures were significantly colder during the intervention *(p<0.0001)*	In the districts, room temperatures during the intervention period were significantly colder than at KCH. Room temperatures in Dedza were significantly lower than in Salima *(p<0.0001)*
	N	2973	3199	237	213			
	Minimum	27	24	23	21			
	25% Percentile	33	33	26	29			
	Median	36	35	28	29			
	75% Percentile	38	37	29	30			
	Maximum	41	42	37	33			

Variable		KCH		Dedza	Salima	LMU	Difference between Study Periods*	Difference between Hospitals*
KMC*[5] *Quality of Documentation: p.103*	Study Period	Pre	Int	Both	Both	No comp data	Significantly more KMC was implemented at KCH during intervention *(p=0.003)*	Significantly more KMC was implemented in Dedza compared to Salima *(p=0.02)*
	N	528	476	266	233			
	% KMC applied	17	25	15	8.2			
KMC per WG	Study Period	Pre	Int	Sample size too small	Sample size too small	No comp data	At KCH, significantly more newborns with admission weight ≤ 2500 g received KMC during the intervention *(≤1500g: p=0.009; 1501-2500g: p=0.02)*	No comparable data
1000-1500 g	N	93	75					
	% KMC applied	45.2	65.3					
1501-2500 g	N	154	138					
	% KMC applied	24.0	36.9					
≥ 2500 g	N	232	205					
	% KMC applied	0.9	1.0					
Time of ThermoSpot Application (Days of hospital stay in %) *Quality of Documentation: p.104*	Study Period	Int		No comparable data	No comparable data	No comp data	No comparable data	No comparable data
	N	467						
	Day 1	62.7						
	Day 2	27.8						
	Day 3	4.1						
	Day 4	2.4						
	Day 5	1.7						
	> Day 5	1.3						

**:* *Not specifically mentioned differences are not significant*

**[1]:* *Ns for admission temperature per admission weight group: number of newborns in the specific weight group and known admission temperature. Significance was only tested for sample sizes >10. For testing, temperatures were grouped into hypotherm – not hypotherm. Admission weights were used to classify the newborns for interpretation of temperatures despite >50% unknown values in Salima Pre.*

**[2]:* *Ns for admission temperature per place, admitted from: number of newborns from the specific place, admitted from and known admission temperature. For testing, temperatures were grouped into hypotherm – not hypotherm. First significance column not comparing study periods but places admitted from*

**[3]:* *For detailed data of departments admitted from at KCH see Appendix, p. 105*

**[4]:* *Ns for room temperatures: number of documented room temperatures. The room temperatures are biased (*see 5.1.4).

**[5]:* *Ns for KMC: Number of newborns with known admission weight and KMC data. For testing between hospitals, KCH Pre/ Int were combined. The KMC data are biased (5.1.9).*

Abbreviations: Pre=Pre-Intervention; Int=Intervention; KMC=Kangaroo Mother Care; WG=Weight Group; OR=Operating Room; comp=comparable; HT=Hypothermia

Note: If the differences between the study periods were not significant, the values are given combined for both periods. If not indicated otherwise, values are given as absolute numbers (Ns) and percentages (rest)

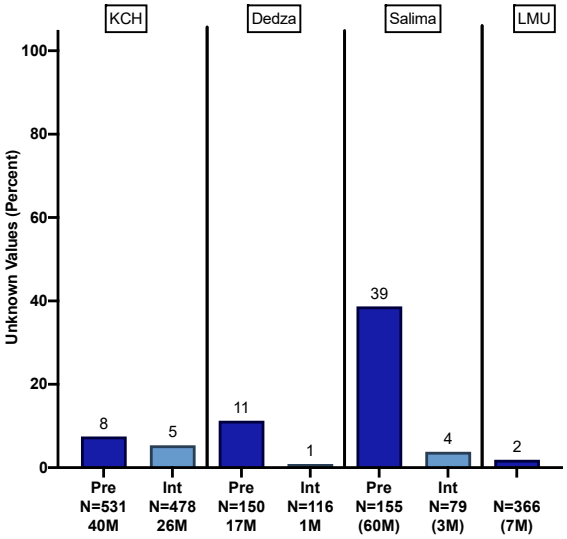
4.2 Primary Outcomes

4.2.1 Body Temperatures

4.2.1.1 Quality of Documentation

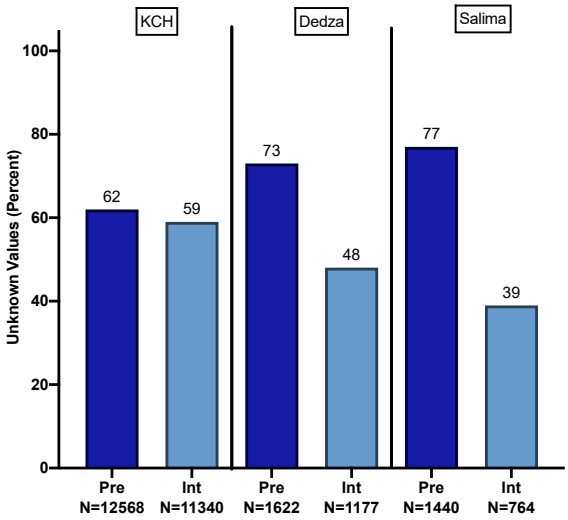
These data are biased (see 5.1.4).

Figure 1: Quality of Documentation Admission Temperature



Pre=Pre-Intervention; Int=Intervention
M=Missing

Figure 2: Quality of Documentation Temperatures after Admission



Pre=Pre-Intervention; Int=Intervention
N=Number of expected temperatures

Figure 1 and Figure 2 show that in all study periods and hospitals more admission- and in-ward temperatures were taken during the intervention. This difference was significant for admission temperatures in the districts and for temperatures after admission in all hospitals ($p<0.0001$). For exact daily percentages and proportions of missing and implausible values of temperatures after admission see Appendix, p.102. At LMU, no temperatures during the in-hospital time were documented in the virtual database besides the admission temperature.

Table 4 shows the central tendencies of the frequencies of temperature measurements per newborn per day.

Table 4: Temperatures per Newborn per Day

	KCH Pre N=520	KCH Int N=461	Dedza Pre N=124	Dedza Int N=107	Salima Pre N=120	Salima Int N=67
Minimum	0.0	0.0	0.0	0.5	0.0	0.0
25% Percentile	0.8	1.0	0.7	1.0	0.3	1.5
Median	1.3	1.6	1.0	1.8	0.7	2.3
75% Percentile	2.0	2.3	1.2	1.8	0.7	2.3
Maximum	4.0	4.0	3.0	2.5	2.6	3.3

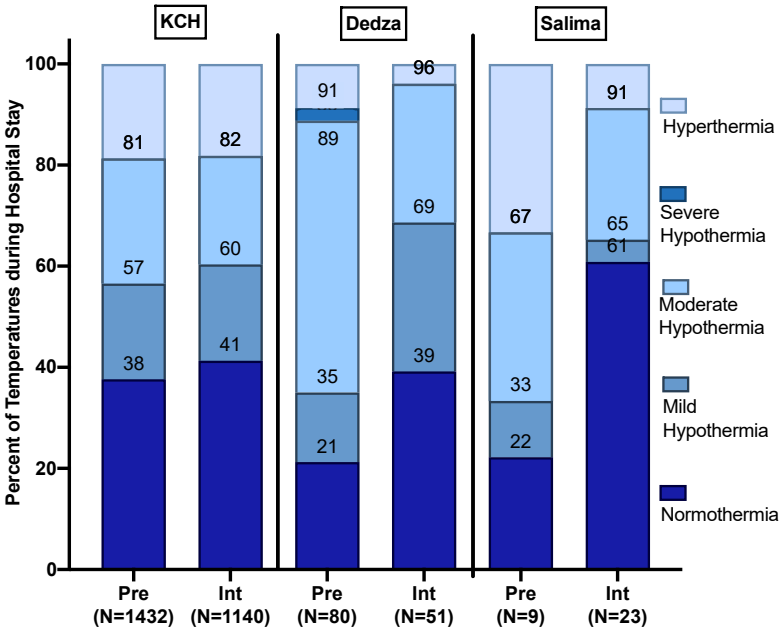
N=Newborns with known length of stay
Pre=Pre-Intervention; Int=Intervention

4.2.1.2 Body Temperatures during Hospital Stay

Quality of Documentation: p. 26, p. 100, p. 103
The documentation of body temperatures was <50% of the expected measures in most hospitals and periods. The temperatures were analysed despite this. Admission weights were used to classify the newborns despite >50% unknown values in Salima pre-intervention.

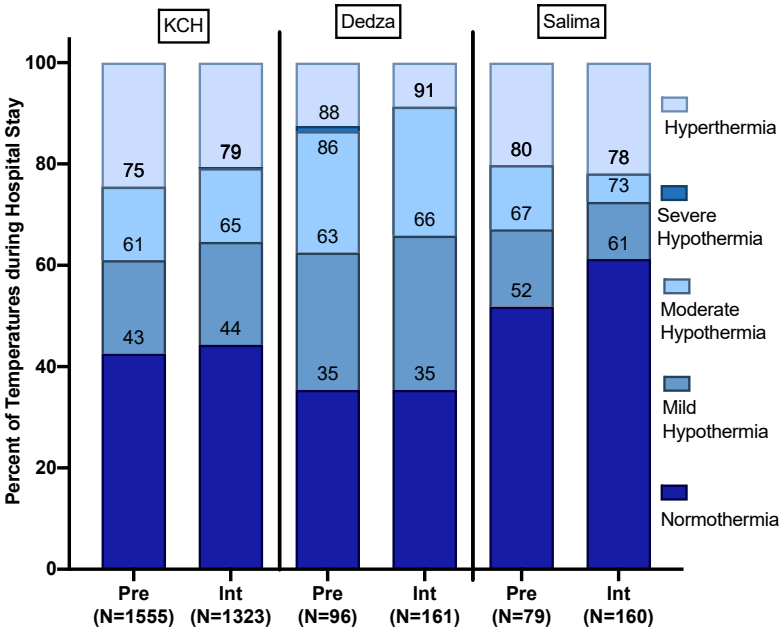
Frequency of Temperature Ranges

Figure 3: Temperatures during Hospital Stay
Admission Weight ≤1500 g



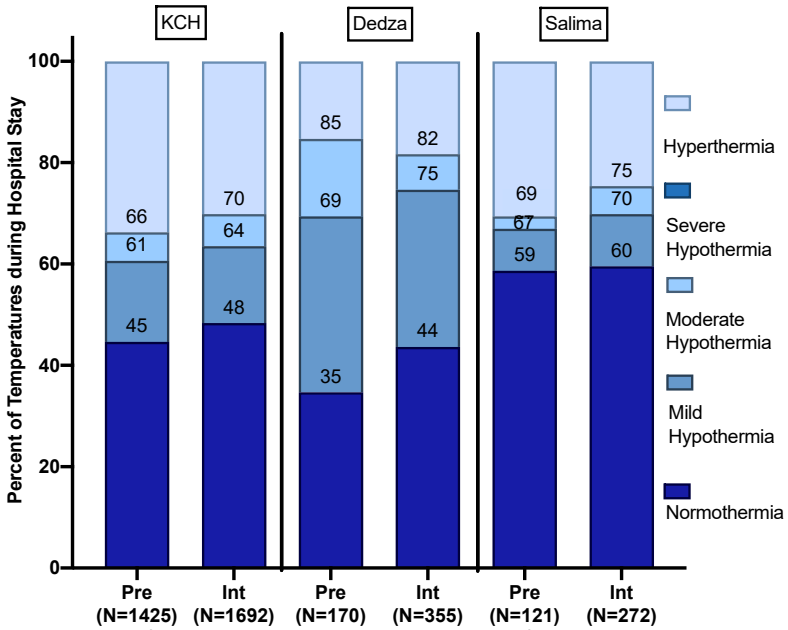
N=number of recorded temperatures during hospital stay of newborns with admission weight ≤1500g
Pre=Pre-Intervention; Int=Intervention

Figure 4: Temperatures during Hospital Stay
Admission Weight 1501-2500 g



N=number of recorded temperatures during hospital stay of newborns with admission weight 1501-2500g
Pre=Pre-Intervention; Int=Intervention

Figure 5: Temperatures during Hospital Stay
Admission Weight >2500 g



N=number of recorded temperatures during hospital stay of newborns with admission weight >2500g
Pre=Pre-Intervention; Int=Intervention

Figure 3, Figure 4 and Figure 5 show the proportions of the temperature ranges of all documented temperatures after admission. The frequency of measurements for the individual newborns varied widely – some newborns contributed more data than others.

Newborns with severe hypothermia were excluded for statistic tests due to small sample sizes. For the other temperature ranges (normothermia, mild and moderate hypothermia, hyperthermia), there was no significant difference at KCH in the distribution of recorded temperatures between the study periods and no statistical test for Salima was conducted due to the small sample size for newborns with admission weight **≤1500g**. In Dedza, significantly more normothermic and mildly hypothermic and less moderately hypothermic temperatures were reported during the intervention (p=0.004). Newborns with admission weight **1501-2500g** did not show significant differences in any hospital. In newborns with admission weight **>2500g**, no significant difference was shown at KCH and Salima. However, in Dedza, moderately hypothermia was reported significantly less often during the intervention (p=0.01).

Newborns with at least one hypothermic event after admission

Table 5 shows the percentages of newborns with at least one hypothermic event after admission. The study periods were not significantly different at Salima and Dedza. At KCH, newborns with admission weight **>2500g** had at least one reported measurement of a hypothermic temperature significantly more often during the intervention (p=0.004). The other weight groups showed no significant difference.

Table 5: Percentages of Newborns with at least one hypothermic event after Admission

Weight	KCH Pre	KCH Int	Dedza Pre	Dedza Int	Salima Pre	Salima Int
≤1500 g	91 (N=90)	96 (N=75)	91 (N=12)	100 (N=5)	50 (N=2)	100 (N=3)
1501-2500 g	81 (N=148)	85 (N=136)	86 (N=21)	89 (N=28)	82 (N=11)	63 (N=16)
> 2500 g	61 (N=219)	74 (N=200)	88 (N=43)	80 (N=54)	35 (N=31)	55 (N=42)

N=number of newborns with known admission weight and at least one documented temperature after admission

4.2.1.3 Correlation between Body- and Room Temperature

Spearman's correlation coefficient showed no significant correlation between body- and room temperature (KCH: r=0.008, N=718; Dedza Int: r=-0.02, N=78; Salima Int: r=-0.02, N=59).

4.2.1.4 Hypothermia as a Diagnosis and a Symptom

Quality of Documentation: All newborns in the Malawian hospitals had documented information about if hypothermia was literally named in their file as symptom or diagnosis. Diagnoses at LMU were reported differently.

Hypothermia as a symptom or a diagnosis was written down in the patient files significantly more often during intervention at KCH (Pre: 2.6%, N=531; Int: 5.4%, N=478; p=0.02). In the districts, the difference between the study periods was not significant (Dedza: 1.3% Pre, N=150; 4.3% Int, N=110. Salima: 7.7% Pre, N=155; 15% Int, N=79).

4.2.2 Case Fatality Rate

Quality of Documentation: p. 103
The data were not compared to LMU as the survival rates are higher in Germany through many factors. Admission weights were used to classify the newborns despite >50% unknown values in Salima pre-intervention. Newborns with not tracked outcome were excluded.

Table 6 shows the percentages of newborns who were discharged alive in each study period and hospital. Significance tests were conducted only for sample sizes >10. The survival did not differ significantly between the study periods in any hospital.

Table 6: Percentages of Surviving Newborns

Weight Group	KCH Pre	KCH Int	Dedza Pre	Dedza Int	Salima Pre	Salima Int
≤1500 g	59 (N=93)	52 (N=73)	77 (N=13)	33 (N=9)	20 (N=5)	50 (N=4)
1501-2500 g	85 (N=152)	84 (N=135)	78 (N=23)	83 (N=29)	80 (N=15)	88 (N=17)
>2500 g	88 (N=229)	88 (N=200)	85 (N=47)	85 (N=55)	82 (N=45)	86 (N=36)
All Newborns	82 (N=520)	81 (N=463)	72 (N=130)	80 (N=107)	85 (N=122)	84 (N=67)
Admission temperature not normothermic*	80 (N=370)	80 (N=347)	73 (N=91)	79 (N=94)	86 (N=86)	80 (N=45)

N=number of known outcomes in the specific group
Pre=Pre-Intervention; Int=Intervention
**: N=number of newborns with hypo-/hyperthermic admission temperature and tracked/known outcome*

4.3 Secondary Outcomes

4.3.1 Weight Trend

Quality of Documentation: p. 100, p. 97
In Dedza and Salima, high percentages of weights are unknown. Only KCH and LMU were analysed. Admission weights were used to classify the newborns despite >50% unknown values in Salima pre-intervention. Considering the physiologic weight loss until day six of life, the samples were divided by the last weight measurement before and after six days. To avoid the bias of comparing newborns of different ages, only newborns, admitted on their first day of life were included.
At LMU, only two weights per newborn were documented. The daily weight trend was analysed only for KCH.

Weight Trend Admission Weight – Last Weight

In Table 7, the admission weights are compared to the weights that were recorded last by building the geometric mean of the percental weight trend per day.

Newborns with admission weight **>2500g** with the last weight measurement **before day six** at KCH lost significantly less weight during the intervention (p=0.02). The weight trend of all other groups did not change significantly.

Table 7: Weight Trend Admission Weight-Last Weight

	KCH Pre	KCH Int	LMU
Admission Weight ≤1500 g			
Last Weight Day 1-6	N=20	N=25	N=2
Mean weight gain per day in %	-1.4	-0.8	-0.2
Last Weight Day 7-12	N= 45	N= 34	N=0
Mean weight gain per day in %	-0.8	-0.6	--
Admission Weight 1501-2500 g			
Last Weight Day 1-6	N=65	N=69	N=26
Mean weight gain per day in %	-2.3	-2.3	-0.8
Last Weight Day 7-12	N= 44	N= 34	N= 33
Mean weight gain per day in %	-1.1	-1.3	0.1
Admission Weight >2500 g			
Last Weight Day 1-6	N=92	N=93	N= 60
Mean weight gain per day in %	-2.3	-1.7	-0.7
Last Weight Day 7-12	N=27	N=23	N=51
Mean weight gain per day in %	-0.7	-0.9	0.0

N=newborns with known admission weight, at least one weight during stay and age of one day on admission
Mean=geometric mean of weight gain per day
Pre=Pre-Intervention, Int=Intervention

Table 8: Percentages of Newborns with Pathologic Weight Loss KCH

	≤1500g	1501-2500g	>2500g
	Last Weight Day 1-6		
Pre	51 (N=65)	65 (N=108)	35 (N=115)
Int	40 (N=63)	51 (N=103)	34 (N=116)
	Last Weight Day 7-12		
Pre	59 (N=44)	83 (N=42)	27 (N=26)
Int	42 (N=38)	71 (N=34)	61 (N=23)

Pre=Pre-Intervention, Int=Intervention

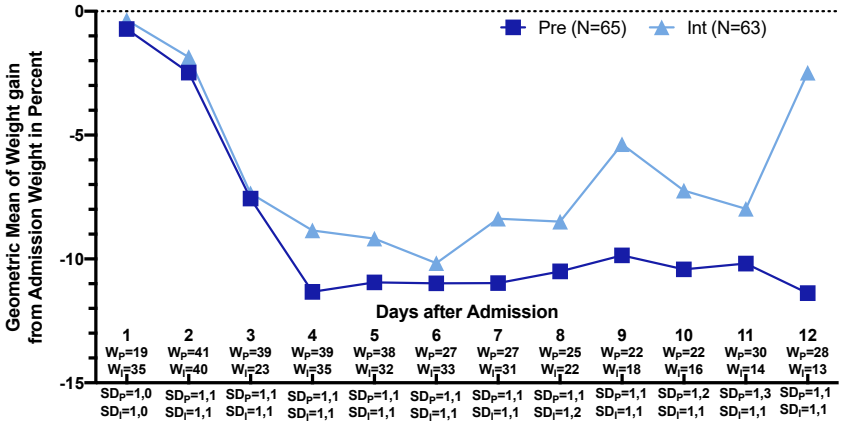
Physiologic and Pathologic Weight Loss KCH

Table 8 shows the percentages of newborns with a pathologic weight loss (defined as a weight loss of >10% from the admission weight on at least one day). Newborns of **1501-2500g** admission weight with their last weight measurement **before day six** lost more than 10% of their admission weight significantly less often during the intervention (p=0.04). Newborns of **>2500g** admission weight with their last weight measurement **after day six** lost more than 10% of their admission weight significantly more often during intervention (p=0.02).

Daily Weight Trend KCH

Figure 6, Figure 7 and Figure 8 show the geometric means of the daily weight trend per admission weight group. In newborns with admission weight **≤1500g** and **1501-2500g**, the weight gain from the admission weight was significantly higher in intervention period on day twelve (p=0.03). In the weight group of >2500g, the weight gain from the admission weight was significantly higher in intervention period on the first day (p=0.008). All other days in all weight groups did not change significantly.

Figure 6: Daily Weight Trend: Admission Weight ≤1500 g

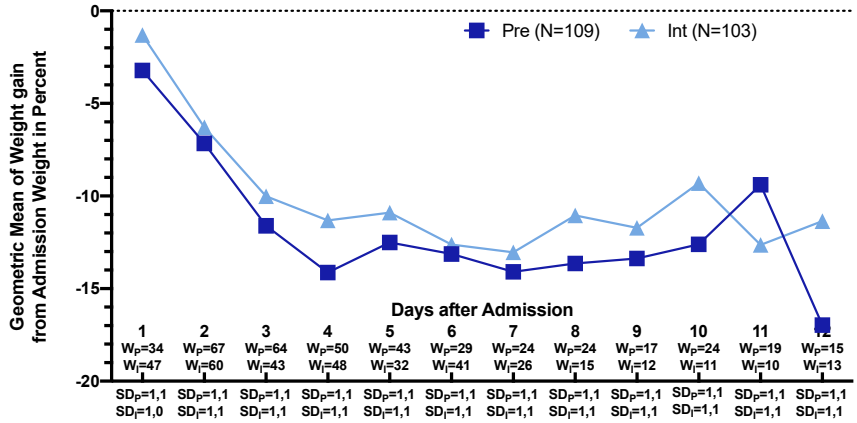


N=number of newborns with known admission weight and at least one recorded weight after admission

W_P/W_I=number of weights, recorded on that day preintervention/intervention

SD_P/SD_I=geometric standard deviation factor that day preintervention/intervention

Figure 7: Daily Weight Trend: Admission Weight 1501-2500 g

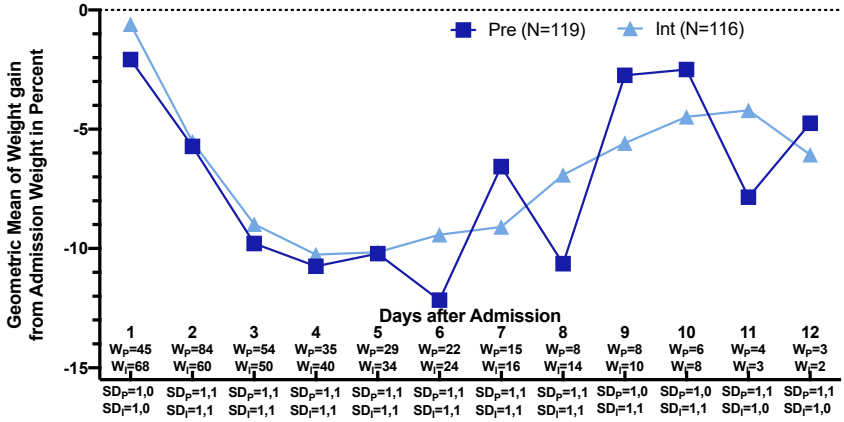


N=number of newborns with known admission weight and at least one recorded weight after admission

W_P/W_I=number of weights, recorded on that day preintervention/intervention

SD_P/SD_I=geometric standard deviation factor that day preintervention/intervention

Figure 8: Daily Weight Trend Admission Weight >2500 g



N=number of newborns with known admission weight and at least one recorded weight after admission

W_P/W_I=number of weights, recorded on that day preintervention/intervention

SD_P/SD_I=geometric standard deviation factor that day preintervention/intervention

4.3.2 Hospitalisation Time

Quality of Documentation: p. 100, p. 103
Admission weights were used to classify the newborns despite >50% unknown values in Salima pre-intervention. The data of Dedza are biased (see 3.4.2).

Table 9 shows the medians of the hospitalisation time of surviving newborns. The median of the length of stay decreased or stayed the same in all hospitals and weight groups. Newborns with admission weight **<1500g** at KCH had significantly shorter hospital stays during the intervention (p=0.007), while newborns with admission weight **1501-2500g** had significantly shorter hospital stays in Dedza (p=0.04) and Salima (p=0.01). All other weight groups did not show significant differences between the study periods; sample sizes <10 were not tested.

Table 9: Length of Stay in Days

Admission Weight Group	KCH		Dedza		Salima		LMU
	Pre	Int	Pre	Int	Pre	Int	--
≤1500 g	N=55	N=37	N=10	N=2	N=1	N=2	N=20
Minimum	1	2	0	3	10	3	4
25%Percentile	15	9	4	3	10	3	6
Median	23	15	7	7	10	6	29
75%Percentile	35	26	23	11	10	8	43
Maximum	72	40	36	11	10	8	66
1501-2500 g	N=128	N=113	N=17	N=25	N=13	N=15	N=92
Minimum	0	0	1	1	0	2	2
25%Percentile	3	2	4	1	5	3	6
Median	5	5	4	2	6	3	10
75%Percentile	10	9	6	5	7	5	18
Maximum	32	25	18	8	11	6	83
>2500 g	N=198	N=175	N=37	N=46	N=36	N=31	N=250
Minimum	0	0	0	0	0	2	0
25%Percentile	2	1	3	2	2	2	4
Median	4	4	4	4	3	2	5
75%Percentile	6	6	5	4	4	3	7
Maximum	41	24	8	8	10	9	92

Unit: days
N=number of newborns, who survived with known length of stay and known admission weight
Pre=Pre-Intervention, Int=Intervention

4.3.3 Coinfections

Quality of Documentation: 103
The data of Dedza are biased (see 5.1.8).

Table 10 shows the percentages of newborns with antibiotic treatment. At KCH and Dedza, significantly less newborns received antibiotics during the intervention (KCH: p=0.001; Dedza: p=0.006). The other hospitals did not show significant differences of antibiotic-prescription between the study periods.

Table 10: Prescribed Antibiotics

	KCH		Dedza		Salima		LMU
	Pre (N=529)	Int (N=477)	Pre (N=150)	Int (N=116)	Pre (N=153)	Int (N=79)	(N=316)
Newborns with antibiotic treatment (%)	85	77	77	61	97	94	49

N=Number of newborns with known data about use of antibiotics
Pre=Pre-Intervention, Int=Intervention

4.3.4 Surveillance

Documentation of ThermoSpot Colours by Guardians

Table 11: Quality of Documentation – Bedside Sheets

	KCH	Dedza	Salima
Day 1	**52** (N=458,194M,44I)	**14** (N=107, 15I)	**4.5** (N=67, 2M, 1I)
Day 2	**33** (N=425,78M,63I)	**13** (N=91, 2M, 10I)	**4.7** (N=63, 2M, 1I)
Day 3	**29** (N=340,51M,46I)	**17** (N=71, 1M, 11I)	**9.4** (N=53, 3M, 2I)
Day 4	**27** (N=299,35M,46I)	**24** (N=55, 4M, 9I)	**13** (N=31, 2M, 2I)
Day 5	**30** (N=267,42M,37I)	**19** (N=37, 3M, 4I)	**29** (N=17, 5M)
Day 6	**28** (N=225,30M,34I)	**19** (N=21, 1M, 3I)	**13** (N=8, 1M)
Day 7	**26** (N=184,20M,27I)	**8.3** (N=12, 1M)	**60** (N=5, 3M)
Day 8	**31** (N=146,24M,21I)	**38** (N=8, 3M)	**75** (N=4, 3M)
Day 9	**44** (N=115,34M,16I)	**67** (N=3, 2M)	**67** (N=3, 2M)
Day 10	**45** (N=97,31M, 13I)	**100** (N=2, 2M)	-
Day 11	**38** (N=88,22M,11I)	**100** (N=2, 2M)	-
Day 12	**36** (N=75,18M,9I)	**100** (N=1, 1M)	-

Value in front of parenthesis: percentage of not or wrongly used bedside sheets
M=Missing, I=Implausible
N = Newborns that were still in hospitalised that day

Table 11 shows the percentage of correctly used bedside sheets per day. The sheet was interpreted as used with at least one tick per day. The calculated percentages are biased (see 5.1.9 and 5.2.)

Improvement of Temperature Surveillance through ThermoSpots

Quality of Documentation: p. 34
Only data from the intervention were used. Newborns, who stayed less than 24 hours, were counted as if they stayed a whole day. These data are biased (see 5.1.9 and 5.2).

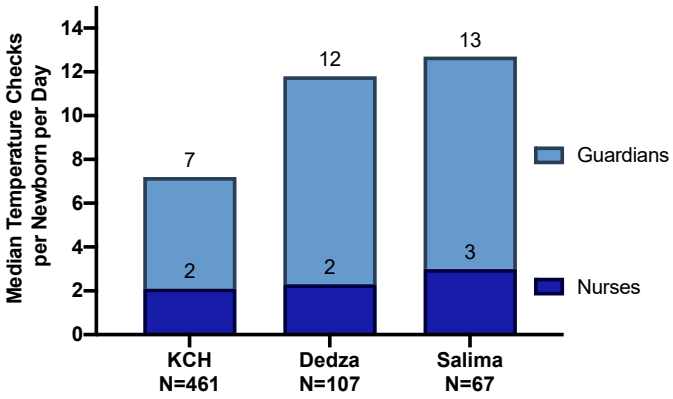
Figure 9 shows the improvement of the newborns' temperature surveillance through ThermoSpots. It shows the number of measured temperatures by nurses and the times the guardian plausibly reported a temperature on the bedside sheet. Implausible values of the nurses' measurements were counted (we assume that the temperature was checked but wrongly recorded). Significantly more newborns were monitored as often as they were supposed to be (4 times daily at KCH, 3 times daily in the districts) when summarising the monitoring of nurses and guardians ($p < 0.0001$).

Correctness of ThermoSpot Utilisation by Guardians

Calculations are based on days with at least a tick per bedside sheet. The data are biased (5.1.9, 5.2).

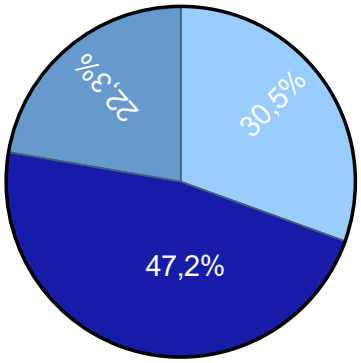
Figure 10, Figure 12 and Figure 11 show the percentages of days, the colours on the bedside sheet were indicated correctly and incorrectly.

Figure 9: Temperature Surveillance



N=number of newborns with known lenght of stay

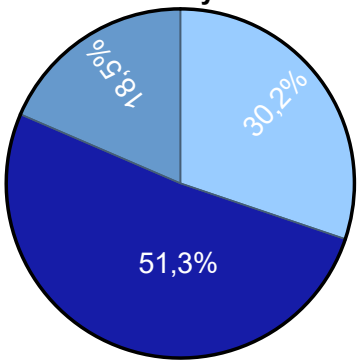
Figure 10: Correctness of Temperature Documentation by Guardians KCH



N=2244 documented days on bedside sheets

Right *Wrong* *Unknown*

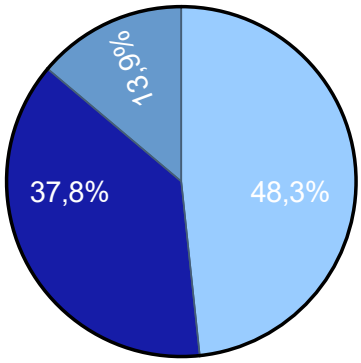
Figure 11: Correctness of Temperature Documentation by Guardians Dedza



N=421 documented days on bedside sheets

Right *Wrong* *Unknown*

Figure 12: Correctness of Temperature Documentation by Guardians Salima



N=267 documented days on bedside sheets

Right *Wrong* *Unknown*

Table 12 shows the percentages of guardians who reported a reaction to hypo-/hyperthermia indicating ThermoSpots.

Table 12: Guardians' Reactions on Hypo-/ Hyperthermia indicating ThermoSpots

	KCH (N=1860)	Dedza (N=365)	Salima (N=261)
Percentage of days with hypothermic ticks	14	21	7.6
Percentage of hypothermic ticks with according reaction	64	96	95
Percentage of days with hyperthermic ticks	15	13	22
Percentage of hyperthermic ticks with according reaction	51	77	65
Percentage of days with inappropriate reactions to ticked colours*	0.6	2.2	0.0

N=number of days of basically correctly completed bedside sheets (no implausible days); number of reactions on not correctly completed bedside sheets: KCH:123; Dedza:13; Salima:0
**Newborns with > one day with inappropriate reactions counted once*

Table 13 lists details about the guardians' ticks and reactions that were noted on specific bedside sheets when entering the data. The option to record such information was only used at KCH.

Table 13: Notes about ticks on bedside sheets

Details of specific bedside sheets
• Vital signs assistant reacted
• ThermoSpot was green, although the newborn had fever (documented by vital signs assistant)
• First days questionably filled in correctly, but mother seems to have understood after a few days
• Mother commented her actions by herself, understood the system
• Mother documented time when the ThermoSpot was checked
• Guardian reacted on her own
• Guardian improvised when bedside sheet was full
• Guardian commented "Temperature fine" when seeing a green ThermoSpot
• Guardian commented "Baby is fine, no linen added, has jaundice"
• Guardian commented "The baby was feeling cold, so the baby was wrapped"
• Guardian commented "Baby is fine"
• Guardian commented "My babies' colour is green, I did not add linen"

4.3.5 Acceptance of ThermoSpots

4.3.5.1 Guardians' Questionnaire

Quality of Documentation: p. 104

Table 14: Evaluation of Guardians' Questionnaire – Percentages of Answers

	KCH						Dedza						Salima					
	N	0	1	2	3	4	N	0	1	2	3	4	N	0	1	2	3	4
Do you think it is easy to understand how ThermoSpots work?	372	0.0	0.0	1.3	30	69	115	0.0	0.0	0.9	30	69	59	0.0	0.0	0.0	14	86
Do you think it is easy to see which colour the ThermoSpot shows?	372	0.0	0.0	1.9	33	65	115	0.0	0.0	0.9	30	69	59	0.0	0.0	0.0	6.8	93
Did you know what to do in case the colour of the ThermoSpot was not green?	372	0.0	0.0	2.7	34	64	115	0.0	0.0	1.7	29	70	59	0.0	0.0	1.7	12	86
Did you feel safe about the temperatures of your baby using a ThermoSpot?	371	0.0	0.0	2.2	30	68	114	0.0	0.0	0.9	32	68	59	0.0	0.0	0.0	6.8	93
Was it fun to care about your baby's temperature with a ThermoSpot?	372	0.0	0.3	1.1	25	74	115	0.0	0.0	0.0	32	68	59	0.0	0.0	0.0	6.8	93
Would you recommend the use of ThermoSpots to other mothers?	371	0.0	0.0	1.6	27	71	115	0.0	0.0	0.0	18	82	59	0.0	0.0	0.0	6.8	93

Legend: 0: I strongly disagree, :1 I disagree, :2 I cannot decide, 3: I agree, 4: I strongly agree

Only one guardian at KCH used the option to make a separate comment. The comment was: "I had difficulties to differentiate blue and green and asked another mother for help.

4.3.5.2 Focus Group Discussion with Guardians

For the description of the setting see 3.2.6.2

The following boxes summarise the contents of the focus group discussion with guardians at KCH.

Procedures around the use of ThermoSpots

- All of the participating guardians stated that they still had a ThermoSpot and did not lose it
- All of the participating guardians stated having been briefed by the vital sings assistant on admission, not by a nurse
- None of the guardians positioned the device in the jugular fossa, all stated having to unwrap the newborn for checking the ThermoSpots' colour
- In the case that a ThermoSpot came lose, the guardians stated that they did not replace it as they did not have medical transparent tape, but asked a nurse or the vital signs assistant; until that, they "just kept the spot"
- The guardians stated that they looked at the device to check the colour while breastfeeding, when they changed diapers and sometimes in between
- About the imaginary case, that the participants would have taken the ThermoSpot home and it would have come loose, they stated: "I would just keep it" and "I would bring it to the review appointment in the nursery and ask to get it repositioned"
- If the guardians could not distinguish between two colours, they stated that they asked another guardian or a nurse for help

Understanding of the Device

- The guardians stated that they knew that ThermoSpots were visualising the temperatures of their newborns
- The guardians were aware that a ThermoSpot can be positioned on the abdomen of the newborns
- The question, if the participants always knew which box to tick, was answered by "Yes, I know where the green box is and always tick that box"; after asking again, the guardians stated, that they also knew, where the boxes of the other colours were

Occurring Problems while using ThermoSpots

- The guardians brought up the point that the ThermoSpots turned blue while doing KMC as the body temperature of the guardian also affected the device
- It was mentioned that it was difficult to differentiate between green and blue

Reactions in the case of non-green ThermoSpots

The guardians gave some examples for this situation:

- The ThermoSpot changed to black when the newborn was still in the high-risk area- the guardian wrapped the baby and rechecked the ThermoSpot at the next feeding time, where it had changed to green
- The ThermoSpot turned black in the KMC ward and the guardian notified a nurse, who told her to take the newborn back to the high-risk area
- The ThermoSpot turned blue and the guardian called a nurse, who told her to expose the baby
- The ThermoSpot turned blue and the guardian exposed the newborn by herself
- If a guardian could not distinguish between two colours, she asked another guardian or a nurse for help

Feelings about the use of ThermoSpots

- If the guardians were interested in using the device when they first came into the ward and saw other newborns with ThermoSpots was answered with: 1. “I did not see/did not pay attention to the other babies”, 2. “I was interested to have a ThermoSpot”
- The guardians stated that they were not afraid to use the device as they were encouraged by the vital signs assistant on how to take care of their newborns
- Statements about the reasons for positive mindsets about the use of ThermoSpots were: “I was able to know more things about the temperature of my baby”, “I knew what I was supposed to do”, and “I was happy because it was taken good care of my baby”
- The guardians stated they would buy a ThermoSpot for their next newborn if it costed 240 MWK, the mentioned reason was “Because we know how good it is”
- The guardians were asked if they would rather trust the opinion of a nurse or a ThermoSpot about the temperature of their newborns. The guardians stated that they would be angry with the nurse and would still have wrapped their baby in the case that the Spot showed hypothermia
- When the moderator asked about the ticking for documentation of the temperatures, the participants stated that they liked the ticking and did not have a better idea for the documentation
- The guardians were “thankful for being able to take care of our babies because the ThermoSpot is so good”

4.3.6 Health Workers' Experiences with and Opinions about ThermoSpots

For the description of the setting see 3.2.6.2

Statements about ThermoSpots of the KCH study team in a focus group discussion and of nurses in personal interviews are summarised in the following boxes.

Occurring Problems

Guardians' Ticking on Bedside Sheets

- Many cases of wrong ticking occurred (e.g. ticking all the colours at once, not understanding the dates, filling the whole box with ticks, ticking more than once at the same time, continuing with a box of another colour after filling the box for green)
- Sometimes the briefing by nurses was not done in an understandable way, which led to wrong ticking. This was noted when the vital signs assistant came back after a weekend and the ticking got better because she explained the approach again
- Some guardians did not understand how to tick even after various explanations
- The correctness of ticking was also depending on the educational background of the guardian

Reactions on non-green ThermoSpots

- Some guardians were too shy to ask a nurse if they could come back after feeding time to bring more linen and warm their newborn up (also depending on nurse on duty)
- As many staff members in the nursery were rotating, not all of them were known by the guardians and they did not ask for help

Technical Issues

- ThermoSpots that were used many times developed a hardly removable glue layer on the sticking side and changed the colour differently ("they were yellow in normothermic babies or always blue")

Guardians' Questionnaires

- The guardians were interviewed by the discharging nurse. Nearly all of them answered in a positive way. The answers might be biased because there is a chance that the guardians were afraid of being readmitted because they "had to understand first" so they answered as if they understood and liked ThermoSpots. Also, the happiness about being sent home might have influenced the mood of the guardians and they said that everything was fine
- The guardians of some newborns who deceased did not answer the questions because of their emotional situation

Setting of the use of ThermoSpots

- The guardians had to share the pens for ticking on the bedside sheets which made them talk about the device and compare the colours of their newborns' ThermoSpots
- When the guardians of newly admitted newborns noticed that other newborns had ThermoSpots and that their guardians were ticking, they wanted to participate also – everyone was open for the device
- The longer the device had been implemented, the more guardians were experienced in the use of ThermoSpots and could help each other
- The actions that were used most by the guardians were: putting a hat, changing diapers and adding linen
- The most important point was a good briefing of each guardian to make him/her understand the idea of ThermoSpots

Idea of implementing ThermoSpots into the daily routine

- It would make sense to establish ThermoSpots as clinical standard: "It helped me to see very fast of which baby I had to take care in terms of thermoregulation when I was working alone, for example on weekends."; "Through a shortage of staff we have an undermanagement of the ward. With ThermoSpots, mothers could help with a task."; "We don't have time [...] this is why we have to rely on the guardians to alert us if something is wrong with their baby. We explain them, in which cases they have to alert us […]. But it is hard to tell about the temperature by just touching the infant. With ThermoSpots, the guardians were able to tell […] just by looking at the device."
- The required time for explaining ThermoSpots to each guardian would be justifiable also in the clinical routine. It could be included in the orientation that each guardian is given on the admission day. As without an investigation, no consent forms, bedside sheets and questionnaires would have to be filled out or explained, the briefing about ThermoSpots could be done quickly
- Many guardians did understand how ThermoSpots worked. Many problems were caused by difficulties with the ticking on bedside sheets
- The guardians reported and intervened against hypothermia
- Some guardians did come to nurses and told them e.g. "I added linen, but the Spot remains yellow" to get help
- Some guardians were asking the nurses for permission to come back after feeding time to bring their newborn with a non-green ThermoSpot more linen
- Hypothermia was not erased but the device helped to react much faster
- The sustainability of ThermoSpots might be a problem as mothers might take the spot home

5 Discussion

5.1 Discussion of Results

5.1.1 Neonatal Temperature Surveillance in Malawi

Admission Temperatures

In both study periods at KCH and at LMU, admission temperatures were reported reliably in over 90% of the newborns. In the districts, the documentation was unreliable during the pre-intervention period. Only sporadically taken admission temperatures were also reported by Manji et al. in Tanzania and Fulton in Ethiopia in studies on newborns (39, 91). As Kwansah et al. reported in a study in rural Ghana, a low satisfaction of nurses through high workload and lack of equipment and education possibilities compared to urban workplaces might be a reason for this unreliability (92). In addition, a better knowledge and working attitude of the nurses and a lower workload at KCH might have caused the difference to the district hospitals.

Significantly more admission temperatures were documented in the districts in the intervention period. This could have emerged through higher educated bachelor students present in that period or be attributed to a higher awareness of health workers of the importance of body temperatures through the intervention.

Temperatures during Hospitalisation

High percentages of body-temperature measurements during hospitalisation were missing in all Malawian hospitals in both study periods. The observation of a low compliance with hospital guidelines regarding the frequency of body temperature measurement was also made in Ethiopia (91). Nahimana et al. accordingly found a poor adherence to guidelines (CPAP) by nurses in Rwanda (93).

We cannot attribute the lack of documented temperatures singularly to poor knowledge of nurses, as (I) admission temperatures were recorded more frequently and (II) the vital signs assistant was focussed only on this task and trained on its importance. It is more likely that a lack of staff and thermometers led to poor documentation, as a nurse in an interview explained: “We only take vitals (vital signs) of the sickest babies […]. This is due to a shortage of staff. We have sometimes 70 babies in the ward and only one nurse – if I would take all these vitals, I couldn’t complete the rest of my work”. We know from the head nurse at KCH that usually four nurses per shift should be present in the neonatal department. However, as the stock of nurses is too small, only one to two nurses take a shift. No thermometers are

provided by the hospital and only nurses who have their own thermometer can measure temperatures. A study with Malawian nurses in 2015 accordingly reported that nearly all nurses were suffering from a high workload through a shortage of staff and lack of supplies (94). A shortage of staff and supplies, specifically thermometers, was similarly reported in several trials in Zimbabwe, Ethiopia, Rwanda and Ghana (72, 78, 91, 92, 95). The WHO described that per 10.000 population in Malawi only 4.4 nurses or midwifes existed from 2010-2018 (for comparison: in Germany, 132.4 nurses per 10.000 population) (96).

Buerhaus et al. showed that nurses in the USA perceived a shortage of staff to lead to significantly lower health care quality, efficiency, effectiveness and patient security through, for instance, a delay in detecting complications (97).

Although the incidence of measured hypothermia was high, it was not often reported as an issue in the patient files. The percentage of newborns at KCH with “hypothermia” written in their file increased significantly in the intervention period. The increased rate could be attributed to an advanced awareness about the issue through the implementation of ThermoSpots.

The findings show that the lack of staff and equipment should be improved for better thermo-surveillance in newborns in Malawi. Additionally, awareness-rising for the topic and better educated health workers specifically in rural hospitals might potentially increase the recognition rate of body temperatures.

5.1.2 Incidence of Hypothermia on Admission

Hypothermic body-temperature measurements on admission occurred frequently in the Malawian hospitals. This is confirmed by many studies, identifying a high incidence of neonatal hypothermia in low-resource settings (6, 34, 38, 39, 44, 55-57).

Within the weight group of admission weight **≤1500g**, all Malawian hospitals admitted significantly more hypothermic newborns than LMU, suggesting a more appropriate handling of very low birthweight newborns before admission to the neonatal ward in high-resource settings. As a referral hospital, KCH should be prepared better than district hospitals for risk deliveries. However, there was no significant difference between the three Malawian hospitals.

Within the weight group of admission weights of **1501-2500g** and **>2500g**, KCH and Dedza reported significantly more hypothermic newborns on admission than LMU. Within the weight group of admission weight of **1501-2500g**, KCH reported significantly more newborns with hypothermia than Salima. These findings could be attributed to a warmer climate in Salima (89) and to the higher incidence of neonatal hypothermia in low-resource settings compared to high-resource settings.

At KCH and in Dedza, newborns who were admitted from the same facility were hypothermic significantly more often than newborns who came from home. At KCH, newborns who were admitted from the same facility were also hypothermic significantly more often than referred newborns. This is contrary to other studies (39, 79), where externally born newborns were hypothermic equally or more frequent. Referred newborns were significantly more often hypothermic than newborns who were admitted from home at KCH and Dedza. This speaks for inadequate thermal care during transport of a referred newborns, like previously reported from a low-resource setting (38).

At KCH, when comparing the inborn newborns, the hypothermia rate of newborns coming from the labour ward and OR was significantly higher than from the postnatal ward. This might be a result of older newborns being admitted from the latter.

According to scholars, the higher incidence of neonatal hypothermia in low-resource settings could result from a lack of staff (94, 98), cold delivery rooms (61), lack of knowledge (54), inadequate transportation of newborns (38, 39), and in the case of home deliveries, traditional beliefs and practices (70, 71).

Our findings demand to start interventions directly after delivery and keep the warm chain during the hospitalisation of newborns. Furthermore, they suggest an improved handling of very low and low birthweight infants in terms of thermal care before admission to a nursery. Additionally, the thermal care while transporting newborns should be improved.

5.1.3 Incidence of Hypothermia during the Hospital Stay

As discussed in 5.1.4, a large number of temperature measurements during hospitalisation is missing. The discussed temperatures reflect only a small proportion.

High percentages of the measured temperatures were hypothermic; in the weight group of **≤1500g** up to 68% of all temperatures in a hospital, in the weight group of **1501-2500g** up to 56%, and in the weight group of **>2500g** up to 50%. Except for the weight group of >2500g in Salima, more than half of the newborns had at least one documented hypothermic temperature in all weight groups and hospitals in both study periods. The findings confirm many studies that showed high incidences of neonatal hypothermia in low-resource settings and underline the problem of neonatal hypothermia in Malawi not only on admission but also during the hospital stay. (6, 34, 38, 39, 44, 55-57).

Hypothermia rates during the intervention period decreased significantly only in Dedza in two weight groups. In both groups, only the rates of moderate hypothermia decreased significantly. Dedza had the highest incidence of moderate hypothermia during the pre-intervention period in all weight groups. Additionally, the weight group without significant difference between the study periods had the lowest incidence of moderate hypothermia during the pre-intervention. This could mean that our intervention only decreased hypothermia rates significantly if a high percentage of the hypothermic temperatures was in the range of moderate hypothermia (<36.0°C).

The percentages of newborns with at least one hypothermic measurement during their hospital stay did not decrease significantly in any weight group or hospital during the intervention. At KCH, the percentage of newborns with at least one hypothermic measurement even increased significantly.

To our knowledge, this is the first study that not only assessed the accuracy and feasibility of ThermoSpots (80, 84), but also examined their impact on body temperatures. Our findings might indicate an improvement of the thermo-surveillance through the intervention that then led to less moderate hypothermia. However, further studies in a more suitable setting and with more frequent temperature measurements would be needed to proof this and although the frequency of moderate hypothermia was reduced in Dedza, hypothermia itself was not prevented.

A possible reason that may have led to a decrease of only moderate hypothermia might be a differing clarity of the ThermoSpots' colours. Our findings suggest that mild

hypothermia might be harder to distinguish from normothermia, while moderate hypothermia is better visible.

5.1.4 Limitations of Data about Body Temperatures

Body temperatures in Malawi were measured axillary while at LMU rectal measurement was used. Studies have shown that axillar and rectal measurements in newborns are comparable (6, 51, 99-101).

Temperatures were not taken regularly on weekends and during night shifts, and we started to pay nurses at KCH for temperature measurements to achieve sufficient data. Despite this, many measurements are missing, and we observed in one occasion that a nurse did make up temperatures without actually measuring them to receive the incentive. All nurses assured that this happened only once, but we cannot be sure about this.

In addition to difficulties and issues with nurses, also the data transcription and calculations contain biases. The admission and discharge dates counted as whole days, expecting all temperatures to be taken, although the newborns might not have stayed in the ward the whole day. In the calculations of frequencies of measured temperature ranges, the temperatures per newborn ranged from zero to 42 values and some newborns were weighed more than others. In the transcription of hypothermia as a diagnosis, the whole file of the newborns in the districts but only the admission at KCH sheet was reviewed.

Through the mentioned circumstances, the body temperatures of newborns we analysed might be highly biased.

The correlation between room- and body temperatures was not significant. However, to calculate a reliable correlation, it would have been necessary to take a room temperature with each body temperature measurement also in the districts (as at KCH). Each pair of body- and room temperature would, in addition, have had to be transferred linked to each other into the database. Through the inaccuracy of the obtained data for the correlation analyses, the weather and room temperatures probably affected body temperatures, although no correlation was found.

At KCH, room temperatures were significantly higher during the pre-intervention compared to the intervention and compared to the districts. The median of the room

temperature was lowest in Dedza, where the weather was colder and fewer radiant heaters were available (88). Salima had the hottest weather, and we expected the highest room temperatures (89), however, no working radiant heaters were available, and the windows of the nursery were broken. These might be reasons for lower room temperatures than at KCH. Differing room temperatures are likely to have biased the body temperatures.

5.1.5 Case Fatality Rate

The case fatality rates were recorded reliably. As mortality rates in Germany are known to be much lower due to many factors, LMU data were not analysed (1).

Between 72% and 85% of the newborns survived in the different study periods and hospitals. Survival rates rose with higher admission weights. No significant differences were found between pre-intervention and intervention periods.

It was a primary objective to reduce the neonatal mortality through (I) reducing hypothermia rates and (II) achieving an improvement of patient care. However, this objective was not achieved in any hospital, not even in the two weight groups in Dedza, in which moderate hypothermia decreased significantly. The decrease of hypothermia probably anyway affects mortality rates, as many studies have shown (6, 34-40). Furthermore, hypothermia was analysed as a cause of morbidity, neglecting that also morbidity can cause hypothermia, and our sample size might have been too small to show significant differences (56).

Besides not achieving a decrease in overall mortality, newborns, who were admitted with hypo- or hyperthermia did not reach significantly lower mortality rates during the intervention. We expected that the concentration on and awareness about body temperature on admission through the introduction of ThermoSpots would lead to immediate interventions and decrease the mortality rates of this cohort of newborns. However, admission hypothermia might have been caused by the underlying disease and therefore a change of the surveillance system was probably not enough. A change of the surveillance system does logically not treat an already underlying illness.

Our findings are probably attributed to biased and incomplete data about hypothermia and a most likely incorrect implementation of ThermoSpots (see 5.1.9). Therefore, we still believe that a well settled intervention that leads to decreased neonatal hypothermia could reduce mortality rates.

5.1.6 Weight Gain

The weight gain was only analysed for KCH and LMU because the majority of measurements in the districts is missing.

When comparing the admission weight to the last weight of their hospitalisation, newborns at KCH lost significantly less weight during the intervention in the weight group of **>2500g with the last measurement before day six**. As the body temperatures in this group did not differ significantly, this finding is not associated with reduced hypothermia rates. It could, however, be attributed to an improvement of care through our intervention. Similarly, a study by Azad et al. showed that a hypothermia indicating bracelet for newborns had a significantly positive effect on the weight gain of newborns, although it did not affect hypothermia rates (102).

The fact that only the heaviest newborns showed a significantly increased weight gain could be attributed to more severely ill newborns in the lower weight groups. In severely ill newborns, solely a better care might not be enough to achieve a better growth. The finding that the weight gain of the heaviest newborns only increased significantly in those, whose last weight was recorded on the first six days of life, could be related to the physiologically increased weight stability reached after six days (103).

The weight gain between the first and last day of hospitalisation at LMU was significantly higher than at KCH (except for the weight group ≤1500g; however, the sample size of this group is too small to interpret this finding). This outcome claims for a strengthening of weight development interventions in hospitalised newborns in Malawi.

The mean of the daily weight development at KCH was negative on all days and in all weight groups. In the weight groups of **≤1500g** and **1501-2500g**, the mean weight loss during the intervention was significantly lower on the twelfth day. However, as the sample sizes on the twelfth day are small and we did not collect data on the following days, more studies with longer observation periods and greater sample sizes are needed to verify this finding.

In the weight group of **>2500g**, the weight loss on the first day was significantly lower during the intervention. As the following days did not show significant differences, this finding cannot be clearly attributed to the intervention.

At KCH, up to 71% of the newborns per weight group showed a weight loss of >10% on at least one day. Significantly less newborns showed a weight loss of >10% in the group of **1501-2500g before day six** during the intervention. Contrary, significantly more newborns showed weight loss of >10% in the group of **>2500g after day six** during the intervention. The finding that the newborns in the most stable weight- and age group showed a pathological weight loss more frequently during the intervention is difficult to explain. Probably, this finding is attributed to the small sample size through a high number of missing values in this group. As only one group showed the aimed outcome of less weight loss, we cannot attribute this finding to the intervention and further studies with reliable weight measurements are needed.

In order to achieve an improved weight development of hospitalised newborns in Malawi, various aspects need improvement, and neonatal hypothermia is one of them. The data show that an improved care might be a central point to achieve significantly better weight gain, specifically in heavier and healthier children and maybe even more after a longer hospital stay. However, further investigations with reliable daily weight measurements are essential to examine this aspect.

Limitations of Body Weight Measures

Although scales were available in all study sites, body weights, including birth-admission and daily weight, were reported unreliably. This could be related to overworked nurses and insufficient knowledge about the importance of a controlled weight development of newborns. In the district hospitals, weights were documented more frequently in the intervention period, while bachelor students were present.

Admission weights were used to group the newborns in many calculations and the weight development was one of our secondary objectives, therefore, the low documentation rate decreases the quality of the data.

5.1.7 Hospitalisation Time

Neonatal hypothermia is a risk factor for morbidity and can lead to longer hospitalisation times (6, 39, 104). A study in Ghana showed that hypothermic admission temperatures in newborns led to longer hospital stays and a study of Cattaneo et al. showed significantly shorter hospital stays in newborns with KMC application (39, 105). As our primary objective was to decrease hypothermia rates and

KMC was one of the reactions to hypothermia we suggested, we hoped to achieve shorter hospital stays.

The data from Dedza are biased (see below) and therefore not discussed. The medians of the hospitalisation time in the different weight groups in Malawi ranged from 2 to 23 days, while the medians at LMU ranged from 5 to 29 days.

Comparing the study periods, the median of the hospitalisation time decreased or stayed equal in all hospitals and weight groups. At KCH, significantly shorter hospitalisation times were achieved during the intervention in the weight group of **<1500g**, in Salima, the same was achieved in the weight group of **1501-2500g.**

These findings could corroborate the results of the aforementioned study, where enhanced KMC rates led to decreased hospitalisation times. As discussed 5.1.9 - *Reactions in case of Hypothermic Newborns*, KMC was documented in such a biased way that no further interpretation is possible. The partially decreased hospitalisation times are also not attributed to decreased hypothermia rates. They could, however, be attributed to an enhanced level of care. This would have to be proven by further studies.

The significantly longer hospitalisation times at LMU could be explained by higher survival chances of low birthweight and severely ill newborns in high-resource settings through better equipment and higher specialisation (59); this may have led to more surviving newborns with severe conditions and therefore prolonged hospital stays.

Limitations of Hospitalisation Time

In Dedza during pre-intervention another study was running simultaneously without our knowledge, and all newborns got antibiotic treatment for five days, which was completed in the hospital. This led to artificially longer stays.

5.1.8 Coinfections

Neonatal hypothermia is known to lead to higher infection rates (104). As the data from Dedza are biased (see below), they are not discussed.

Most antibiotics were prescribed in Salima. At KCH, between 77% and 85% of the newborns received antibiotics, while at LMU 48% received antibiotic treatment. KCH showed the expected effect of significantly less prescribed antibiotics during the

intervention. However, as this was not achieved through decreased hypothermia rates, an explanation might be an enhancement of care, which may have led to more hygienic conditions. Anyhow, this cannot be proven as hygiene conditions were not measured.

At LMU, better options to diagnose and exclude infections exist compared to Malawi, where most diagnoses are made considering singularly the clinical appearance and bacterial infections are, most of the time, not excluded by laboratory tests. Therefore, in Malawi, if a bacterial infection is suspected, antibiotics are given preventively. This automatically led to higher rates of prescribed antibiotics. Additionally, the actual infection rate might be higher in Malawi, as from personal experiences, hygiene instructions in the ward are not adhered to as meticulously as at LMU.

Concluding, to compare infection rates in Malawi and Germany, the prescription rate of antibiotics might not be the most accurate way. However, the experiences and data of this study give a hint to a possible need of enhanced hygienic measures in Malawian hospitals. Another point to mention is that it might be important to increase diagnostic possibilities in low-resource settings in order to decrease the prescription of antibiotics, as it is widely known that antimicrobial resistance is a threatening topic for global health and that an over prescription of antibiotics is one mechanism that leads to this threat (106, 107).

Limitations of Data about Coinfections

In Dedza, during the pre-intervention period, another study was running simultaneously and all newborns were prescribed antibiotics for five days. This biased the data significantly and Dedza was not interpreted.

5.1.9 Enhancement of Patient Care

Improvement of Temperature Surveillance through ThermoSpots

The increase in temperature surveillance through guardians using ThermoSpots was measured by the number of ticks on bedside sheets. However, as described below, the bedside sheets have mostly been completed incorrectly. Therefore, although the data show a significantly increased temperature surveillance during the intervention, this finding could not be verified and is not discussed.

The accuracy of ThermoSpot colours was proven in various studies. However, most of those studies only distinguished between a black (severe hypothermia) and a non-black spot (interpreted as no hypothermia) (80-83). A study in Malawi reported that mothers understood ThermoSpots' colours and were able to distinguish them (black and green) (80). Mole et al. found that additionally counting brown ThermoSpots (moderate hypothermia) as hypothermic increased the chance to detect hypothermia significantly (84). Our study went even further and also introduced a yellow/pale green colour to the guardians, including mild hypothermia into the detection range.

The pattern of all ticks that were made in the hypothermic range showed a reasonable distribution. Dedza showed the highest percentage of days with at least one hypothermic tick and, accordingly, measured most hypothermic body temperatures. Salima showed the lowest percentage of days with at least one hypothermic tick and, accordingly, measured the fewest hypothermic body temperatures. On closer inspection, however, the outcome was poor: a high incorrectness of up to 51% of the ticks on the individual bedside sheets was found when comparing them to the measured temperatures.

A reason for the high percentage of incorrect ticks could be a difficulty of the guardians to distinguish the colours. Since this study was the first one that included mild hypothermia, this difficulty was probably within the mildly hypothermic temperature range. Accordingly, our personal experience was that the distinction between mild hypothermia and normothermia was difficult even for the supervising personnel of the study, that was experienced in analysing ThermoSpots. This experience is supported by Mole et al., who reported that the interpretation of the colour change from green to not green was subjective (84). In our opinion, the colder a temperature of a newborn was, the more pronounced and easier detectable was the ThermoSpots' colour change. The significant decrease of moderate hypothermia in two weight groups in Dedza with high percentages of moderate hypothermia could be related to this: clearer colours in that temperature range may have led to higher certainty of the guardians about a hypothermic newborn and according reactions.

An observed bias regarding the colour interpretation is that the ThermoSpots turned blue through the external heat of radiant heaters. In addition, after reusing them various times, many ThermoSpots developed a thick, non-removable, adhesive layer on the side that was stuck to the newborns' skin. Following, they were yellow or red consistently, independently of the newborns' body temperature.

Next to the mentioned reasons for the high amount of wrong colour observations, the guardians were probably not used to paying attention to colours. We discovered, that in Chichewa, no specific word for “blue” exists and that it is described as “green of the sky”. This might be an indicator that culturally not much attention is payed to colours. An experience that underlines this theory was a situation directly after our vital signs assistant had explained the colours and meanings of ThermoSpots in detail to a group of guardians. To prove that the guardians had understood the program, they were asked about the colour of a ThermoSpot (clearly red). All of their answers were wrong. This specific experience shows that even though many guardians assured us that they had understood the intervention and were confident about the use of ThermoSpots, some of them had difficulties with the most crucial part of using the device. Therefore, as also this basic knowledge had to be taught, we underestimated the time, the explanations would take. Furthermore, we underestimated that one training per guardian was not sufficient. This leads to the conclusion that to correctly introduce ThermoSpots to guardians, more time spent on trainings would be needed. However, In the clinical routine, the lack of staff would be a problematic factor to realise this.

In addition, the inaccuracy of the temperature documentation by guardians may have resulted from a difficulty regarding the ticking itself. For further discussion of this argument see 5.2. *Bedside Sheets*.

However, with a correct understanding of the theoretical meaning of ThermoSpots, hypothermia and reactions to hypothermia, hypothermia rates theoretically should have decreased even if their documentation was erroneous. Therefore, difficulties with the documentation are most likely not the only factor that led to inaccuracies.

Because of the mentioned aspects, ThermoSpots were not feasible to reliably detect hypothermia in our study environment. The device functioned and was accurate and understandable for health workers at least for moderate and severe hypothermia. It has become clear, however, that simply explaining the device was not sufficient to enable guardians to detect hypothermia reliably and the task shift in temperature surveillance we tried to achieve was not obtained. In our study setting, a better basic education of the guardians would have been needed to enable them to use colours correctly. A change of the study-setting with more time to repeatedly teach guardians might be feasible in hospitals with sufficient nursing staff. Next to that, the objectives

of future studies might probably be more feasible if they aimed to reduce only moderate and severe hypothermia.

Reactions in case of Hypothermic Newborns

Studies on ThermoSpots in Malawi reported that mothers reacted correctly when ThermoSpots indicated hypothermia of a newborn (80, 84). In our study, as discussed, the interpretation of ThermoSpot colours was unreliable and we cannot be sure if, when a reaction to hypothermia was recorded, it was actually necessary. Furthermore, nurses who reacted to hypothermic newborns and documented this on a bedside sheet biased the findings as we cannot distinguish which actions were taken by guardians. However, nurses in focus group discussions and interviews stated that guardians often intervened against hypothermia.

Kangaroo Mother Care (KMC) was one of the reactions to neonatal hypothermia that we expected to lead to our objectives. As KMC is an easy method and practicable without further equipment, it has proven to be suitable in low-resource settings, including Malawi (108, 109). We hoped to enhance admissions to the KMC wards as KMC avoids hypothermia, reduces hospitalisation times, helps to achieve a better weight gain and improves the implementation of breast feeding (105, 110).

Newborns at KCH with admission weights of **≤2500g** were admitted significantly more often to the KMC ward during the intervention period. However, we could not attribute the increase to our intervention because the data are heavily biased as although few data were unknown in the final database, we noted many mistakes of the transmission from patient files to the database on this parameter at KCH. A better supervision of the transfer would have been needed to achieve unbiased data.

In our subjective observations, KMC was not frequently used when a hypothermic ThermoSpot was detected. At KCH and Dedza, this could be attributed to the fact that guardians were not allowed to stay in the nursery between feeding times. In Salima, where guardians were present all the time, we expected more use of KMC. For future studies it would be helpful to arrange exceptions and allow guardians to stay in the ward between feeding times for providing KMC on hypothermic newborns. This would also enable the guardians to recheck the hypothermic ThermoSpots after 30 minutes. On a long view it would be favourable to allow all guardians to stay with their newborns around the clock as “Rooming in” is part of the warm chain that should be provided for every newborn to prevent hypothermia (6). In addition, a study in Malawi reported that

the separation from their newborn led to maternal stress, which is unfavourable amongst others for lactation and malnourished children tend to be hypothermic (111). Next to “Rooming in” the option of KMC might have been needed to be emphasised stronger during the trainings to enhance the use of KMC in our intervention. Additionally, it might have been favourable if health workers had instructed guardians on KMC apart from the trainings, once it became necessary. However, the shortage of staff is a limitation factor for this.

Another reaction to discuss is “ask a nurse/clinician”. Although nurses in the focus group discussion mentioned that they had been asked for help, they also reported that guardians only asked if specific nurses were on duty, because other nurses would react rudely or refuse to help. Similarly to this statement, Gondwe et al. found that Malawian mothers thought nurses were rude (111).

There are studies that have shown that good communication skills of nurses are essential in general as parents want to work together towards a better health of their child (112). In our intervention, which included a task shift, the communication was even more essential. Therefore, a respectful attitude and a willingness of nurses to cooperate with guardians would have been crucial to make the intervention feasible. Better communication could lead to encouragement of guardians to report if they feel that something is wrong with their newborn. This would be an important step not only in terms of avoiding neonatal hypothermia. Therefore, nurse-guardian communication in Malawi is an issue that needs urgent interventions.

Some reactions to hypothermia were not feasible through a lack of resources. The hospitals did not provide linen and some guardians only owned one clean sheet, also socks and hats were rarely available. In Salima, many windows and the radiant heater were broken. Another factor was little knowledge of nurses. In one observed situation in Salima, a nurse told the guardian to turn the incubator off in order to react to hypothermia indicated by the ThermoSpot. Without question, this depends on the nurse on duty - we also witnessed nurses in Salima who reacted as desired to calls of guardians. It would have been necessary to study the resources more thoroughly perviously to the intervention in each hospital to achieve a significant impact and enable the guardians to react appropriately.

Inappropriate reactions according to the ticked colour were documented in Dedza and at KCH. This finding shows that some guardians did not detect the colours correctly, did not understand the use of ThermoSpots with correct reactions, or ticked incorrectly. A situation that underlines this, was a mother, who had been briefed a few days ago and was asked what she remembered of the training. She explained the meaning of the colours correctly but did not remember how to rewarm her newborn in case of hypothermia.

These findings strengthen the already discussed possibility that more time for repeated trainings and closer supervision would have been needed for better results, all of it resulting in a need of more staff. Furthermore, nurse-guardian communication would have been needed to be improved and the resources for reactions optimized. A successful task shift would only work in a more suitable environment. ThermoSpots could be implemented into the clinical routine and be helpful in the fight against neonatal hypothermia if (I) devices and colours are explained repeatedly and in a culturally sensitive way, (II) the guardians are encouraged to ask for help, (III) resources for reactions are available.

Guardians' Acceptance of ThermoSpots

Mole et al. used questionnaires to analyse the acceptability of ThermoSpots by Malawian guardians and interpreted the feasibility as good (84). Similarly, in our study, all interviewed guardians stated to be happy or very happy with the device. Additionally, they stated having understood how the device worked, to know what to do in case of hypothermia and that they felt safe about their newborns' temperature. They also stated that using ThermoSpots was fun and that they would recommend it to other guardians.

Next to the findings in the questionnaires, the consensus of the focus group discussion with guardians was positive: they stated that the procedures around ThermoSpots were clear, they had asked for help in case they were not sure about a colour and they always knew where to tick. Furthermore, the participants reported correct reactions to neonatal hypothermia. Some reported the problem of ThermoSpots turning blue when providing KMC, as the guardians' body temperature affected the device. All participants stated to be happy with ThermoSpots and that they

liked the way of provided explanations. Some even stated that they would rather trust the colour of a ThermoSpot than a nurse about their newborns' temperature.

Interpreting the guardians' statements on questionnaires and in the focus group discussion, the feasibility and acceptability of ThermoSpots was high. The findings encourage our hypothesis that guardians can be involved into thermo-surveillance and a shift of tasks is possible. However, the statement that ThermoSpots were used problem-free and correctly, is discrepant to the above observations and findings about the difficulties of guardians to follow the intervention. It would additionally disapprove that correctly used ThermoSpots have a positive impact on neonatal hypothermia, as no decrease was achieved in the hospital, the focus group discussion was held at.

As the answers of the focus group discussion and questionnaires might be biased (see below) and we found the discrepancies, unreliable answers of guardians are likely. Therefore, in theory, we expect the system of a task shift through ThermoSpots to work despite the discrepant findings. This was reinforced by statements of nurses: they thought, establishing ThermoSpots as clinical standard would minimise the nurses' work if implemented without an investigation (no bedside sheets, no consent forms, no questionnaire).

Limitations of the Focus Group Discussions

FGDs have proven as feasible in other studies with mothers and health workers in Malawi (108, 111), Ghana, Zambia and Tanzania (64, 71, 75). We hoped to collect valuable opinions about ThermoSpots with this method. This only succeeded in the discussion with health workers.

The data of the discussion with guardians are biased. As they were not used to discussions in such settings, it was difficult to receive answers and create interaction. Some guardians responded briefly to questions, but no discussion arose. The group seemed to agree with the opinion of single persons, however, we had the impression that some statements were dishonest, or the questions not correctly understood. For instance, when we asked about the colours the guardians had observed on ThermoSpots, first everyone answered, that they had always been green. After asking again, they stated that also hypothermic colours had occurred. Another example is that the guardians initially stated "the ThermoSpot is good and everyone loves it", but when asking again, problems with the device were mentioned. These experiences probably mean that the participating guardians tried to please the researchers and were afraid

to respond in a negative way, or that questions were misunderstood. Another difficulty was that the guardians had problems to understand fictive questions, for instance “What would you have done if...?” and responded that those situations had not occurred.

The focus group discussion was held only with guardians from the KMC ward. This biases the findings as they already had been involved into the intervention for a long period and had more practice than other guardians. Only one out of the twelve involved guardians did not tick correctly. This does not represent the average. The team, the KMC guardians built might have been helpful as experienced guardians were around to help unexperienced ones.

For further studies, a more diverse group, including guardians of all wards would be favourable for a focus group discussion. Furthermore, a more culturally sensitive environment with understandable questions for the participants and a more trustful setting would be needed to achieve valid qualitative data.

Limitations of the Guardians’ Questionnaire

The questionnaire with six questions to answer on a Likert scale was supposed to be completed by the guardian on discharge with help of the discharging nurse. As nurses did not collaborate without extra payment, incentives were introduced at KCH. Possible reasons for the refusal of collaboration have been discussed above. Additionally to the nurses’ refusal, some guardians of deceased newborns were not in the psychological condition to answer questions. This led to missing questionnaires.

We discussed the above-mentioned discrepancies between our observations and the guardians’ answers in the focus group discussion with health workers. They reassured that the guardians did answer positively and had two possible explanations for that; either guardians were afraid to be readmitted because nurses would want them to “understand first” if they stated that they had problems using ThermoSpots. Or the guardians were so happy about the discharge of their newborn and transferred the happiness to the answers on the questionnaire.

For future studies, a completion of questionnaires before discharge might be helpful to avoid the faced bias.

5.2 Limitations of the Intervention Design

Training for Guardians

Studies in Malawi showed that targeted training of mothers on health topics had a significant impact (113, 114), and Mole et al. and Kennedy et al. showed a high understanding of ThermoSpots (80, 84). Therefore, we considered trainings on ThermoSpots suitable. We followed suggestions on how to implement health education in low-resource settings by Hubley et al. and used verbal explanations, posters, and a practical demonstration of the colour change of ThermoSpots (115).

However, problems regarding the communication of the content occurred, as discussed in 5.1.9 - *Improvement of Temperature Surveillance through ThermoSpots*. Another problem was that guardians changed regularly. In Malawi, in many cases, relatives take turns in caring for a hospitalised newborn. As the training was held only once, many guardians were not briefed. In future studies, trainings should therefore be held repeatedly. The vital signs assistant stated that group teaching was more effective than individual teaching because by this guardians got in touch and afterwards helped each other with the interpretation of ThermoSpots. Daily group teachings might be an option to decrease the problems.

In addition to the difficulties with the communication of content and changing guardians, the support from nurses was lower than expected. This led to interruptions of inclusion of newborns and unsatisfactory briefing of guardians during nights and weekends, when the vital signs assistant was not present. Before starting the intervention, we assumed that the nurses' collaboration would be a given, as the implemented concept would (I) save newborn lives, (II) reduce their workload through a task shift towards guardians, and (III) require their help in trainings only on weekends and during night shifts. However, we had to start paying the nurses at KCH for their collaboration. A nurse stated in an interview: "I like participating in studies, if money is payed. Giving us a lot of money will help them (researchers) to have very, very good data. But why should I do more work if I don't profit in the end? It's only for the people of the study that profit […]". Some nurses also refused to help guardians in case of a hypothermia indicating ThermoSpot, because they felt that they would not profit from it.

These findings show that some nurses in Malawi work only for money and not for the health of newborns. Similarly, Leonard et al. reported that many Tanzanian nurses

did not perform health care as good as they could, nor always acted in the interest of patients even if they knew better, but worked harder if incentives were offered (116). One aspect, this could be attributed to, is a possible dullness towards neonatal deaths as they are common in Malawi (5). Also a lack of motivation of nurses is a possible issue, as reported by several studies in Malawi, Kenya and Tanzania, where this lack was related to the emotional burden of not being able to care adequately for patients through insufficient supplies, overwhelming work load through a shortage of staff and low salaries (94, 116, 117). In addition to those factors, we found that many nurses did not choose their work. A nurse explained in an interview that only few careers existed at the universities in Malawi and if too many students applied, and one did not have the highest grades, “they just put you into another career”. Another interviewed nurse stated: “I did not choose to become a nurse. I wanted to be a journalist. But they just put me into nursing school. […] I’m here now for four years. I’m not satisfied […]”. However, also within the nursing sector, not all of the nurses have freedom of choice, as one interviewee told us: “I chose to be a nurse […] and worked for some years as a nurse for adults […]. I afterwards applied to be part of the advanced training for the educational branch […] but was put into training for paediatrics and child health […]. I never wanted to work in the paediatric sector […] but I had no choice, so I agreed […]”. In addition to the focus on money and lack of motivation, also overworked nurses, a problem that has previously been shown in Malawi and led to refusals of participation in an investigation in Ethiopia (91, 94), could have contributed to refusals of participating due to a lack of time for training guardians.

Considering that overworked nurses might be a central point in the failure of involving them into the study, it is interesting that the chance to decrease workload in the long term was not motivative enough. This confirms the opinion of Hubley et al., who stated that benefits had to be achieved in short term to successfully integrate an intervention in low resource settings (115). Payment was a short-term benefit and did work in most cases. In Dedza and at KCH, nurses were noted to be collaborating more over time as they got used to ThermoSpots and saw the devices’ advantages. An implementation of ThermoSpots before starting the investigation might have helped to motivate nurses. Furthermore, it would have been helpful to investigate the resources and mindset of nurses in advance of the intervention.

Nurses in the focus group discussion stated that the training on ThermoSpots could easily be integrated into the briefing, each guardian gets on admission without much

time requirement. They stated that, as this was a study involving consent forms and bedside sheets, the required time increased. To verify this statement, experiences on the implementation of the device without a study surrounding would be needed. However, our discussed findings that in the Malawian setting several trainings would be needed for a correct implementation of ThermoSpots by guardians, speak against this theory.

Bedside Sheets

We expected that despite high illiteracy rates in Malawi (62% of adults in 2015), the guardians would know to make ticks in pictured boxes (118). However, the bedside sheets to document observed colours of ThermoSpots were used inconsistently and incorrectly. The statement of a nurse about this problem was: “Only the ticking was too difficult for many guardians as they are illiterate and even just holding a pen is too much for them. This still does not mean that they did not understand the ThermoSpots. It was about the ticking, they could just not do right […]. You should just maybe not rely on the ticks when you analyse your data.” Similar observations were made when observing the documentation process.

The dates on the sheets were additionally problematic as many guardians did not know the current date and ticked randomly on any day, which biased the data. We started to indicate dates only on the current day and to print sheets one-sided, which decreased the confusion.

At KCH, guardians who were asked why they did not use their bedside sheet stated: “the spot was green all the time anyway” and “my newborn was discharged two days ago and now had to stay because of dehydration. I thought I did not have to tick anymore”. Another guardian, who had lost her ThermoSpot on the previous day, continued to tick anyway and stated: “I am just ticking green because I know the Spot was green the days before”. These statements show that some guardians did not understand why documenting the colours was important and potentially explain missing and incorrect ticks.

Next to the probable misunderstanding of the purpose of documentation and how to document the temperature ranges, a subjectively observed shyness of the majority of guardians who were trying to please the hospital personnel might have led to inaccurate ticking. Some probably always ticked “green” because they were afraid of personnel thinking that they had failed in caring for their newborn, when she/he was

hypothermic. The statement of a guardian in the focus group discussion underlined this theory: “yes, I know where the green box is and always tick that box”.

In Salima, a problem regarding continuous ticking was that the guardians stayed in the nursery around the clock and the two-hourly interval for ticking was often missed. The bachelor students in charge of the study started calling the guardians one by one to tick every two hours, which enhanced the recording. This, however, biased the data as we wanted to measure how much temperature surveillance the guardians could provide themselves. In contrast to Salima, at KCH, a point in the focus group discussion with staff was that guardians were too busy with feeding during the short feeding times and therefore could not document the ThermoSpots’ colour. These arguments claim for a clear timeframe that provides enough time for the documentation in future studies.

In the districts, frequent power cuts were a disruptive factor that led to a lack of photocopies. The hospitals sometimes ran out of bedside sheets and the documentation was left out for some days. In all study sites, although the available pens were tied with rope, they disappeared regularly. Ticks might be missing because of the lack of pens.

The data collection of the ticks on bedside sheets is biased because one tick per day was counted in the same way as several ticks (expected use). Some wrongly fulfilled bedside sheets were identified, however, probably not all of them. Additionally, some newborns did not receive a ThermoSpot on their admission and the days that the newborn did not have a ThermoSpot yet incorrectly counted as if ticks were missing. Furthermore, a tick was considered as correct if a body temperature, measured on the same day was in the same temperature range. This implies bias of correctly documented colours without a temperature measurement on the same time point, and therefore correct ticks classified as wrong.

In Dedza, all days of all newborns in the final database indicated at least one tick. However, as we observed in our weekly visits that bedside sheets had unfilled days and were sometimes missing, and that not all newborns received their ThermoSpot on their admission day, the transmission was wrong. It seems that the data entering persons tried to cover up gaps, which nullifies the data.

5.3 Conclusion

The key message of this study is that even simple methods can be unsuitable in specific settings. We could not prove that the implementation of ThermoSpots in Malawi led to a decrease of neonatal hypothermia or a task shift, and most of our findings were not clearly interpretable. We underestimated the quantity of missing and incorrect data, overworked nurses, lack of supplies and the amount of instruction and guidance guardians in Malawi needed to successfully achieve a task shift. Our data evidence that neonatal hypothermia rates are high in Malawian hospitals and that thermal surveillance is insufficient. This underlines that interventions to fight neonatal hypothermia and increase its surveillance are essential. Our findings indicate a probable bias of ThermoSpots when they are used with radiant heaters and KMC, as they signalise fever because of the surrounding temperature. Furthermore, the device was not as well reusable as expected because it developed a thick glue layer after some time, falsifying its colours. In addition to this, the distinction of normothermic and mildly hypothermic colours was not intuitive. Consequently, ThermoSpots might be helpful to achieve a task shift and decrease moderate and severe neonatal hypothermia, but a more suitable study setting would be needed to examine this.

6 Summary / Zusammenfassung

6.1 German / Deutsch

Die neonatalen Mortalitätsraten in Subsahara-Afrika sind hoch und es besteht ein Mangel an medizinischen Fachkräften. Hypothermie von Neugeborenen in Ländern des globalen Südens ist häufig und führt zu erhöhter Morbidität und Mortalität.

Die Ziele unserer Studie waren, die Temperaturüberwachung von Neugeborenen in verschiedenen Umgebungen in Malawi zu beschreiben und die Hypothermie-Raten durch eine Intervention zu senken. Hierdurch wollten wir Morbidität, Mortalität und Hospitalisierungszeit verringern und die Gewichtszunahme steigern. Außerdem zielte unsere Studie darauf ab, zu untersuchen, ob eine Verschiebung von Aufgaben hin zu pflegenden Angehörigen durchführbar und kulturell akzeptiert ist.

Die interventionelle Studie mit prospektiver Kontrollgruppe weist eine Stichprobengröße von 1875 Neugeborenen auf. Die Daten wurden in zwei ländlichen und einem zentralen Krankenhaus in Malawi erhoben und mit einer deutschen neonatologischen Station verglichen, in welcher keine Intervention durchgeführt wurde. Wir intervenierten, indem wir das medizinische Personal und die pflegenden Angehörigen über Hypothermie von Neugeborenen unterrichteten und gleichzeitig versuchten, durch die Verwendung von intuitiven, kontinuierlichen Temperatur Anzeigern (ThermoSpots) eine Aufgabenverschiebung hin zu den pflegenden Angehörigen zu erlangen.

Durch fehlende Daten, ungenügende Kooperation vom Pflegepersonal und suboptimale Studienbedingungen zeigten sich viele unserer Methoden als unpassend und führten zu einer Verzerrung der Ergebnisse. Die Daten zeigten, dass Temperaturüberwachung in Malawi vernachlässigt wurde: zwischen 39%-77% der erwarteten Werte fehlten. Die Inzidenz von Hypothermie bei Aufnahme (Aufnahmegewicht-Gruppen: ≤1500gr: 50%-91%; 1501-2500gr: 26-84%, >2500gr: 19-51% der Neugeborenen) und während des Krankenhausaufenthaltes (≤1500gr: 30%-68%; 1501-2500gr: 17-56%, >2500gr: 11-50% aller Temperaturmessungen) in Malawi war in beiden Studienphasen hoch. Während der Intervention verzeichneten zwei Gewichtsgruppen in einem der ländlichen Krankenhäuser einen signifikanten Rückgang moderater Hypothermie (≤1500gr: p=0,004, >2500gr: p=0,01). Die Gewichtsabnahme zwischen Aufnahme und Tag sechs von Neugeborenen mit Aufnahmegewicht >2500gr sank während der Intervention im zentralen Krankenhaus

(p=0,02), ebenso die Häufigkeit von Infektionen (p=0,001). Mortalität und Krankenhausaufenthaltsdauer veränderten sich nicht signifikant.

Die Dokumentation der von ThermoSpots angezeigten Temperaturen durch pflegende Angehörige war in 38%-51% falsch. Wir beobachteten, dass es häufig Probleme mit der Befolgung des Studienprotokolls gab. Trotzdem war die Meinung von medizinischem Personal und pflegenden Angehörigen über das Hilfsmittel positiv. Die wenigen positiven Ergebnisse konnten nicht eindeutig auf unsere Studie zurückgeführt werden. Das System einer Aufgabenverschiebung und Reduktion von Hypothermie von Neugeborenen in Ländern des globalen Südens durch ThermoSpots könnte funktionieren, unsere Studienbedingungen waren jedoch unpassend. Bessere Bildung, engere Betreuung, zuverlässigere Daten und weniger überarbeitete Pflegekräfte wären erforderlich gewesen. Weitere Studien mit besser abgestimmten Studienbedingungen sind notwendig.

6.2 English

Neonatal mortality rates in sub-Saharan Africa are high and the shortage of medical staff is a known problem. Neonatal hypothermia is common in low-resource settings and associated with high morbidity and mortality.

The objectives of our study were to describe thermo-surveillance of newborns in different settings in Malawi and to reduce neonatal hypothermia rates through an intervention. We hereby wanted to decrease morbidity, mortality and hospitalisation times and to increase weight gain. Our study aimed to assess if a task shift to guardians was possible and culturally accepted. The interventional study with a prospective control group included a total sample size of 1875 newborns. Data were collected from two rural and one central hospital in Malawi and compared to the routine care of a German neonatal unit. We intervened by educating medical staff and guardians about neonatal hypothermia to achieve a task shift towards guardians using an intuitive, continuous temperature indicator (ThermoSpot).

Due to missing data, lack of nurses' cooperation and a suboptimal study setting many of our methods were not feasible and the results of our study are biased. We found that despite the intervention, temperature monitoring was neglected in Malawi: 39%-77% of the expected values were missing. The incidence of hypothermia on admission (admission weight groups: ≤1500g: 50%-91%; 1501-2500g: 26-84%, >2500g: 19-51% of newborns) and during hospitalisation (≤1500g: 30%-68%; 1501-

2500g: 17-56%, >2500g: 11-50% of all temperature measurements) in Malawi was high in both study periods. Two weight groups in a rural hospital had a significant decrease of moderate hypothermia (≤1500g: p=0.004, >2500g: p=0.01) during intervention. The weight loss from admission to day six of newborns weighing >2500g (p=0.02) and infection rates (p=0.001) decreased significantly in the central hospital during intervention. Mortality and hospitalisation time did not change significantly. The documentation by guardians of temperatures of ThermoSpots was wrong in 38%-51% and we observed many guardians with problems to follow the study protocol. Nevertheless, opinions of guardians and nurses about the device were positive.

The few positive outcomes could not clearly be attributed to our study. The system of a task shift and a reduction of neonatal hypothermia in low-resource settings through ThermoSpots might work but it was not feasible in our study environment. More education, closer supervision, more reliable data and less overworked nurses would have been necessary. Further studies in a more feasible setting are required.

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Appendix

Methodology

Study Files

Informed Consent Form English

Informed Consent Form

This Informed Consent Form is for the parents of all 0-28 days old babies in the nurseries and KMC (Kangaroo Mother Care) of Kamuzu Central, Dedza and Salima Hospitals. The title of our research project is “Assessing the use of simple device application to improve caregiver compliance and neonatal outcome”

University of Malawi
College of Medicine (CoM)
Paediatrics and Child Health
Campus Lilongwe

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

We are students of the College of Medicine, a constituent college of the University of Malawi and the LMU Munich in Germany. We are doing research on neonatal hypothermia, which is very common in Malawi. We will give you information and invite you and your baby to be part of this study.
You can talk to anyone about the research and take all the time you need to decide, if you want your child to take part in it. If there is something you don’t understand in this information sheet, feel free to ask us.

If a baby gets too cold (“Hypothermia”), the baby often gets sick or dies.
Many times a baby gets cold and the mother or nurse does not notice it, because the baby is not able to show it. This is why the mother or nurse does not think about warming up the baby to keep a good body temperature.
Sometimes the mother or nurse notices, that the baby is too cold but does not know, what to do to make the baby warmer.
In our study we want to test Smiling Faces (ThermoSpots), that show the mothers and nurses if the baby is too cold and to teach the mothers and nurses what to do if a baby is too cold. Like this we want to see, if the Smiling Faces can help the babies to stay healthy. We

are inviting all babies in our ward that are 0-28 days old to participate in the research on the Smiling Faces. The participation of your baby in this research is voluntary. It is your choice to participate or not.

Procedure
The Smiling Face will be placed on the baby's body. It changes its colour in response to the baby's body temperature. You will be taught on the change of colours and its interpretation to the baby's temperature. You will also be taught on how to act if the Smiling Face shows that the baby is too cold. Any time you see that your baby is too cold, you should warm it up by the actions we taught you or by asking us to help you.
We will give you a sheet where you can read and see pictures about what to do if your baby is too cold and a sheet where you should write down the colour of the Smiling Face four times a day. In the same time, we will collect information about the development of your baby's health.
After our study we want to compare the number of sick babies and the number of days spent in the hospital in the time we used the Smiling Faces to the number of sick babies and the number of days spent in the hospital in the time before we used the Smiling Faces. If proven helpful the ministry and other stake holders might recommend it in our protocols to reduce deaths and sickness due to hypothermia.

Duration
The research takes place over the whole time that your baby stays in the nursery.

Side Effects
The only side effect, the Smiling Faces might have, are slight skin rashes on your baby's skin.

Benefits
If you participate in this research, you will have the following benefits: it will be simpler for you to take good care of your baby as you will be able to see if it is too cold very easily. You will also learn a lot about how you can keep your baby warm and use these actions at home, too. This might help your baby to stay healthy. You will also help to find out if the Smiling Faces can help other babies and should be used more often.

Confidentiality
The information that we collect from this research project will be kept confidential. Information about your baby that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about your baby will have a number on it instead of your baby's name. Only the researchers will know what your baby's number is and we will lock that information up with a lock and key. It will not be shared or given to anyone.

Right to Refuse or Withdraw
Your baby does not have to take part in this research if you do not wish it to do so and refusing to participate will not affect your treatment at this clinic in any way. You may also stop participating in the research at any time you choose.

Who to Contact
If you have any questions you may ask the study staff, that will be here every day or the nurses, that will be here day and night.

This proposal has been reviewed and approved by COMREC, which is a committee whose task it is to make sure that research participants are protected from harm.

Part II: Certificate of Consent

I confirm that I have read the information of this study, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily that my baby participates as a participant in this research and understand that I am free to withdraw my baby's participation at any time without giving reason.

I am giving full consent to Doctors, clinicians and nurses to get necessary information through questions. I give permission to these individuals to have access to my child's record.

Date……..

Name……..……...

Signature…….…….

If illiterate

I have witnessed the accurate reading of the consent form to the guardians of the potential participant and they had the opportunity to ask questions. I confirm that they have given consent freely.

Date ……

Name of witness.……...

Signature of witness ……..

Thumb print of participant

Statement by the researcher/person taking consent

I have read out the information sheet to the parents of the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. The baby will get a ThermoSpot stuck to its skin
2. Mothers and nurses will be taught on how to read the ThermoSpot and how to react in case of a cold baby
3. Mothers will be asked to complete documentation sheets about their baby's temperature
4. Information about the health development of the baby will be collected

I confirm that the parents of the participant were given an opportunity to ask questions about the study, and all the questions asked by the parents of the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parents of the participant.

Date…… Name……

Signature……

Informed Consent Form Chichewa

Chikalata Chopempha Chilolezo

Chilolezo chimenechi ndi cha makolo kapena oyang'anira ana ongobadwa kumene kufikira ofka masiku makumi awiri ndi masiku asanu ndi atatu amene anagonekedwa muchipinda cha makanda odwala pazipatala za Kamuzu za Dedza ndi Salima. Kafukufuku umenewu ndi okhuzana ndi matenda akudzidzira kwa makanda.

Gawo lowamba-Uthenga wopita kwa mayi

Ndife ana a sukulu ochokera ku sukulu kauchenjede ya College of Medicine ya ku Malawi Kuno komanso sukulu ya LMU ya ku Munich ku Germany. Tikupanga kafukufuku wa matenda a kuzizira kwa ana a khanda, limene lili vuto mumalawi muno. Tikupatsani uthenga wa kafukufuku umenewu ndipo inuyo ndi mwana wamu mupemphedwa kuti mutenge nawo mbali mukafukufuku umenewu.

Mutha kuyankhula ndi wina aliyense pa zakafukufuku umenewu ndipo mutha kutenga nthawi ina iliyonse kupanga chiganizo chotengapo mbali kapena ayi. Ngati pali zina simuku mvetsetsa chonde funsani.

Mwana akazizidwa kwambiri, amadwarika kwambiri ndipo atha kumwalira. Ngati mwana wadzizidwa kwambiri kawiri kawiri mayi kapena anamwino sazindikira chifukwa mwana satha kuwonetsa. Ichi nchifukwa chake mayi sanga ganize zomutenthetsa mwanayu kuti akhale wotenthera. Nthawi zina amayi amatha kudziwa kuti mwana wawo wadzidzidwa koma satha kudziwa choti achite kuti thupi la mwana likhale lotenthera bwino.

Mukafukufuku wathuwu tikufuna kuyetsa njira yogwiritsa ntchito timapepala tankhope zotsekera (thermospot) zimene zingaonetse mayi kapena namwino kuti mwana wadzidzidwa kwambiri komanso tiphunzitsa a mayi ndi anamwino zoyenera kuchita kuti thupi la mwana litentherenso bwino. Tikufuna tione ngati tizipangizotu tingapangitse kuti matupi a ana a khanda akhale athanzi. Tikupemha ana onse kuchokera ongobadwa kumene mpaka masiku makumi awiri ndi masiku asanu ndi atatu kuti atenge nawo mbali mukafuku fuku umenewu. Kutengapo nawo mbali kwanu ndi kwa ufulu wanu, zili kwa inuyo kutero kapena ayi

Ndondomeko yake

Kapepala tankhope zotsekera tiziikidwa pa thupi la mwana wa khanda. Timasintha mutundu malingana ndi kadzidzilidwe kapena katenthedwe kathupi la mwanayu. Muphunzitsidwa pa ka sinthidwe kamitundu a kankhope kosekeraka. Komanso muphunzitsidwa zoti muchite mutundu wa kankhopeka ukasintha. Nthawi ina iliyonse thupi la mwana wanu likadzidzira

mukuyenera kupanga zinthu zimene tikuphunzitseni kapena mutha kufunsa mumodzi mwa ife kuti akuphunzitseni.

Tikupatsani pepala limene mungawerenge ndikuona zithunzi pa zimene mungapange mwana wanu aka dzidzidwa kwambiri, komanso pepala lina pamene mutachonge kankhope kamene kakuontsa pa thawi yoyikikayo patsiku. Panthawi yomweyo tizitoleranso uthenga wa mmene mwana wanu akukulira.

Tikamaleza kutolera uthenga umenewu tikufuna tifananize kachulukidwe ka ana odwala powona masiku amene ana amenewa akukhala ali muchipatala munthawi tisanayambe ndi thawi yimene tikhale tikugwiritsa ntchito timapepala tankhope zotsekeratu. Ngati zotsatira zake zingakhale zothandiza boma litha kuvomeleza kagwiritsidwe ka tizipangizotu ndikuchepetsa imfa za ana akhanda ku imfa za matenda akudzidzira kwa thupi la mwana.

Kafuku fuku umenewu utenga nthawi imene mwana wanu akhale alimuchipatala ndipo utha mukamatuluka muchipatala.

Kuipa kwa timapepala tankhope zotsekera kwa nwana wanu ndiloti nthawi zina atha kutuluka nsungu pa malo amene atamatidwe kapepalaka.

Kuthandiza Kwake
Kutengapo mbali kwanu kuthandiza kwambiri chifukwa mudziwa nthawi imene mwana wanu atakhale kuti wadzidzidwa kwamdiri komanso muphunzira mmene mungapangire mwana wanu akadzidzidwa kwambiri. Komanso mudziwa mmene timapepala tankhope zotsekeratimathandizra pakathandidzidwe ka mwana wanu.

Chinsinsi Mukafukufuku amenewu
Uthenga umene titatolere mukafuku fuku umenewu ukhala otetezedwa mokwanira. Uthengawu ukhala ufikiridwa ndi madotolo mene akupanga kafukufuku. Dzina la mwana wanu komanso dzina lanu siligwiritsidwa ntchito mmalo mwake tiyikapo nambala imene itayimire mayina amenewa. Zonse zimapepala zimene zitakhale ndi uthenga wa mwana wanu zisungidwa muma kabati osafikiridwa ndi anthu ena.

Ufulu wanu okana kutengapo mbali
Muli ndi ufulu ovomera kapena kukana kutengapo mbali mu kafukufuku umenenewu. Kuthandizika kwanu kwa muchipatala sikukhuzidwa ndikukana kapena kuvomera kwanu. Mutha kusankha kusiya kutengapo mbali mukafukufuku umenewu nthawi ina iliyonse mungafune.

Ngati muli ndi mafunso mutha kupeza ogwira ncthito mukafukufuku umenewu amene atakhalepo nthawi zonse.

Kafukufuku umenewu waunikidwa ndi kuvomelerezedwa ndi bungwe loona zakafukufuku pa sukulu ya kauchenjede ya College of Medicine yotchedwa COMREC. Imene imathandiza kuteteza anthu amene akutenga mbali mu makafukufuku mu Malawi.

Gawo Lachiwiri- Kupereka Chilolezo

Ine, ……, ndikupeleka chilorezo kwa madotolo, choti angathe kundifunsa mafunso ena aliwonse amene angafunikile mu kafukufuku ameneyu. Ndikutsimikiza kuti ndawerenga ndikumvetsetsa uthenga wakafukufuku ameneyu. Ndamvetsetsa kuti kutengapo mbali mukafukufuku ameneyu ndi kwakufuna kwanga ndipo ndikhoza kusiya mopanda kupereka chifukwa komanso osasokoneza chithandizo cha mwana wanga. Ndikupereka chilorezo kwa madotolo kuti atha kuona failo ya mwana wanga pamene ali mchipatala.

Tsiku :……

Dzina : …….

Sayini ……

Kwa Osatha Kuwerenga

Ine, ……, ndikupeleka chilorezo kwa madotolo, choti angathe kundifunsa mafunso ena aliwonse amene angafunikile mu kafukufuku ameneyu. Ndikutsimikiza kuti ndawerenga ndikumvetsetsa uthenga wakafukufuku ameneyu. Ndamvetsetsa kuti kutengapo mbali mukafukufuku ameneyu ndi kwakufuna kwanga ndipo ndikhoza kusiya mopanda kupereka chifukwa komanso osasokoneza chithandizo cha mwana wanga. Ndikupereka chilorezo kwa madotolo kuti atha kuona failo ya mwana wanga pamene ali mchipatala.

Tsiku ……

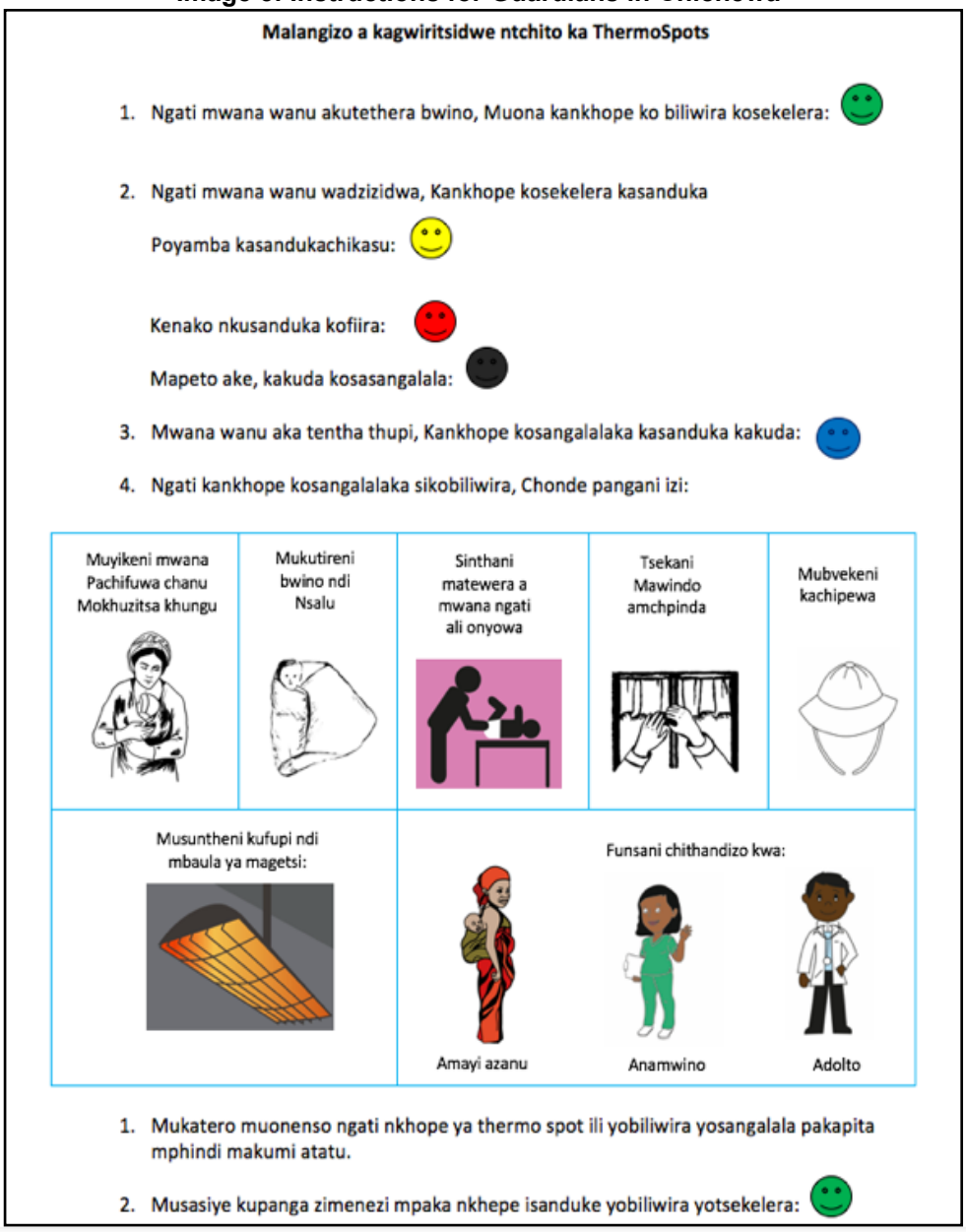
Dzina la mboni.……...

Sayini ya mboni ……..

Chidindo cha otengapo mbali

Instructions for Guardians Chichewa

Image 5: Instructions for Guardians in Chichewa



Illustrations: Luise Wuestling©. Modified after:
Open Learn Create. Kangaroo Mother Care (KMC) Milton Keynes; 2017 [retrieved 17th December 2017]. Available from: https://www.open.edu/openlearncreate/mod/oucontent/view.php?id=246&section=1.7.4.
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Clipart Guide. African Mother with her Child on her Back in a Kanga (Baby Sling) – Royalty Free Clipart Picture: Clipart Guide; [retrieved 5th January 2018]. Available from: https://www.clipartguide.com/_pages/0060-0808-2016-4420.html.
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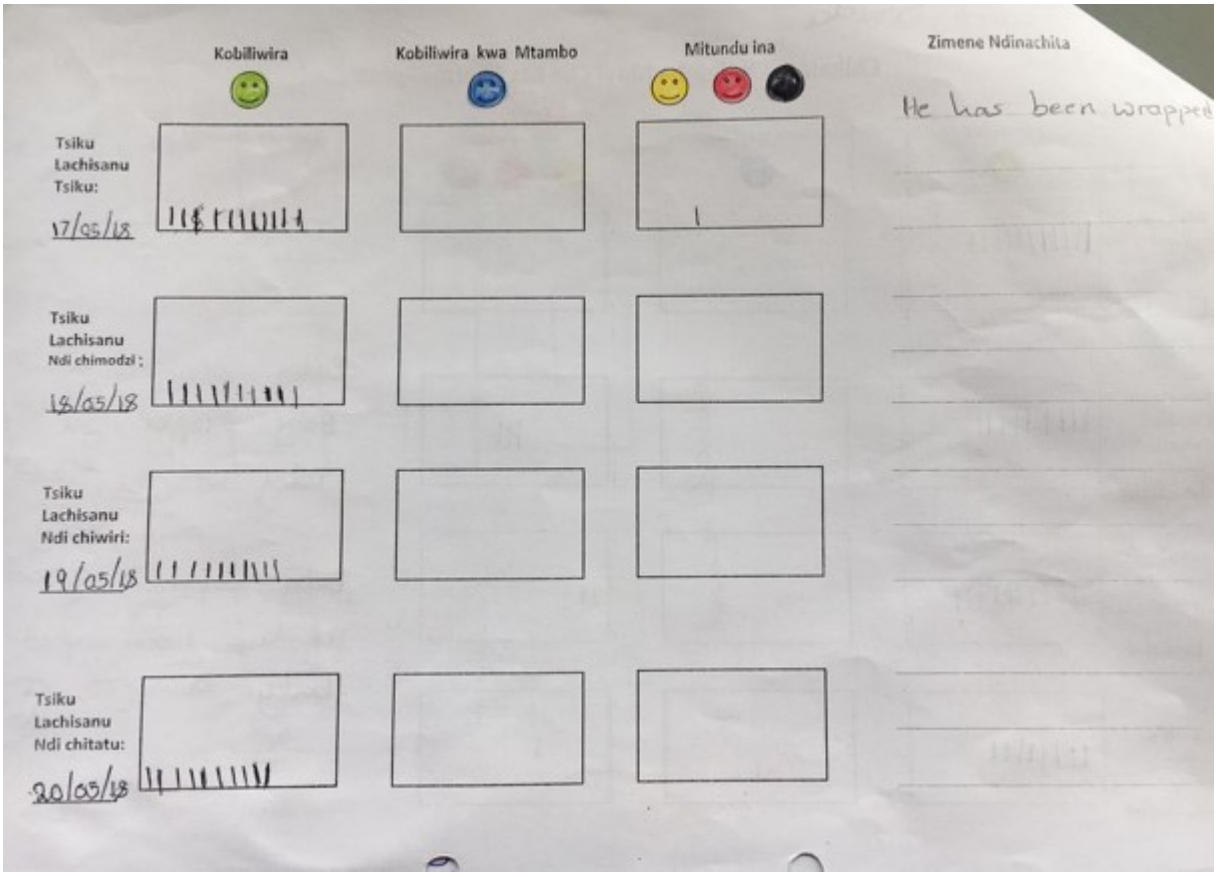
Feuerwehr Roesberg. [retrieved 5th January 2018]. Available from: http://www.feuerwehr-roesberg.de/Grafiken/.
Oneinhundered. White Baby Sun Hat [retrieved 18th December 2017]. Available from: http://www.oneinhundred.com/Upfiles/upimg1/White-baby-sun-hat--5188301.jpg.

Bedside Sheet for Guardians

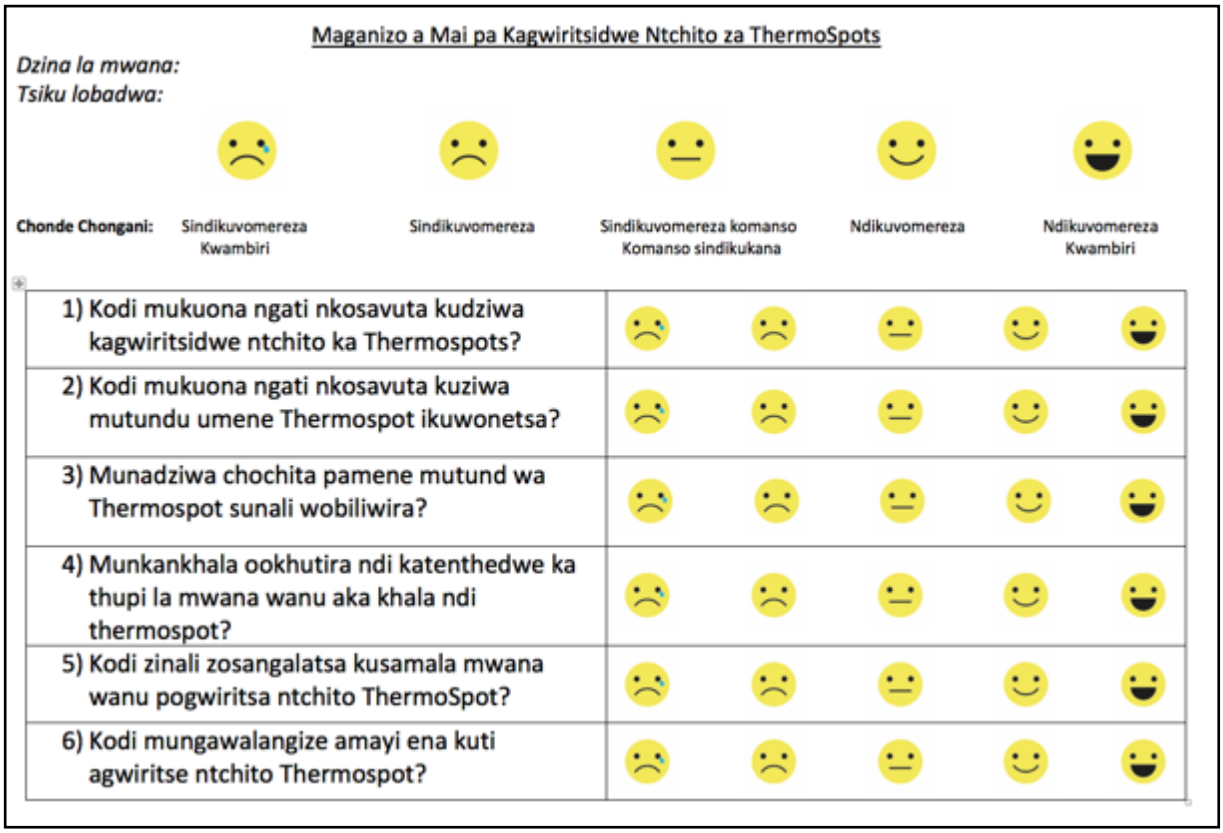
Image 6: Bedside Sheet in Chichewa



Translation: Tsiku Lachisanu Tsiku: Date; Kobiliwira: Green; Kobiliwira kwa Mtambo: Blue; Mitundu ina: Another colour; Zimene Ndinachita: Actions taken

Questionnaire for Guardians Chichewa

Image 7: Questionnaire for Guardians in Chichewa



Maganizo a Mai pa Kagwiritsidwe Ntchito za ThermoSpots

Dzina la mwana:
Tsiku lobadwa:

Chonde Chongani:	Sindikuvomereza Kwambiri	Sindikuvomereza	Sindikuvomereza komanso Komanso sindikukana	Ndikuvomereza	Ndikuvomereza Kwambiri
1) Kodi mukuona ngati nkosavuta kudziwa kagwiritsidwe ntchito ka Thermospots?					
2) Kodi mukuona ngati nkosavuta kuziwa mutundu umene Thermospot ikuwonetsa?					
3) Munadziwa chochita pamene mutund wa Thermospot sunali wobiliwira?					
4) Munkankhala ookhutira ndi katenthedwe ka thupi la mwana wanu aka khala ndi thermospot?					
5) Kodi zinali zosangalatsa kusamala mwana wanu pogwiritsa ntchito ThermoSpot?					
6) Kodi mungawalangize amayi ena kuti agwiritse ntchito Thermospot?					

Illustrations: Luise Wuestling©.
Modified after QuestionPro. Bipolare Likert-Skala Dallas; 2018 [retrieved 5th January 2018]. Available from: https://www.questionpro.com/blog/wp-content/uploads/2016/06/Bipolare-Likert-Skala.jpg.

Correction of Data and Criteria for Considering Values Implausible

Descriptive Data

Date of Birth and Date of Admission

If the date of admission was documented to have been earlier than the date of birth and no information to clarify the origin of the mistake was given, both dates were considered implausible (**KCH**: Pre: 5x, Int: 1x; **Dedza**: Pre: 1x). If the birth date was not fitting but could be derived by information about dates of admission/discharge, days of documented information, or the diagnosis/the place the newborn was admitted from, it was corrected retrospectively. Understandable typing errors were also corrected. (**KCH:** Pre: 1x, Int: 3x; **Dedza**: Pre: 4x, Int: 1x; **Salima**: Pre: 1x). In one case (**Salima** Int), the admission date had a detectable typing error and was corrected.

Age on Admission

If a documented age on admission did not match with the recorded birth- and admission date, the dates were considered correct, and the age on admission was adjusted accordingly (**KCH:** Pre: 9x, Int: 12x; **Dedza**: Pre: 3x, Int: 1x; **Salima**: Pre: 1x).

Age on Admission and admitted from the Labour Ward

In some cases, the newborn was supposed to have been admitted from the labour ward, although the age on admission was older than one day. Data about the admission from the labour ward only exist from KCH. These irregularities were ignored in the analyses (**KCH** Pre: 22x, Int: 25x).

Admitted from this Facility and Place of Birth

If a newborn was described to have been born at home but admitted from the same facility, both values were considered implausible (**Dedza**: Pre: 2x, Int: 1x). Also, if a newborn was described to have been born in the same facility and admitted on the first day of life but from home, both values were considered implausible (**Dedza**: Pre: 2x).

Gestational Age and Diagnosis Preterm

If the information about the gestational age and maturity of a newborn did not match, we tried to find out the correct value through other information (e.g. written comments in the data table). If no additional information was documented, both counted as implausible. If we found logically interpretable additional information, we

changed the diagnosis retrospectively, or considered only the gestational age implausible. Numbers of this procedure are shown in Table 15. In addition to Table 15, in **Dedza** Int, the diagnosis “Preterm” of three newborns counted as implausible because no gestational age was documented, and contrary information about the diagnosis was recorded.

If information about the maturity of a newborn was missing, but a birth weight of >3500g was documented, we assumed that the newborn was not preterm and added the diagnosis (missing → “no”) (**KCH**: Int: 4x). If the information was missing, but a birthweight of <2000g was documented, we assumed the newborn to have been preterm (missing → “yes”) (**KCH**: Pre: 2x).

Table 15: Modification of Gestational Age and Diagnosis "Preterm" – Numbers of Newborns

Modification	KCH		Dedza		Salima	
	Pre	Int	Pre	Int	Pre	Int
Both values implausible	0	1	2	1	5	5
Gestational age implausible	1	0	4	0	0	0
Prematurity yes → no	4	1	3	2	3	0
Prematurity no → yes	6	0	2	3	2	1

Int=Intervention; Pre=Pre-Intervention

Kangaroo Mother Care

In **Dedza** Int, seven newborns were reported to have been treated by KMC were retrospectively changed to “no KMC” because the guardians were advised to do KMC at home but were not admitted to the KMC ward.

Time until ThermoSpot was applied

Only **KCH** data exist. If the documented date of the application was before the admission date, the time until the application was considered implausible (3x). If the ticking started before the day of the signature on the consent form and briefing of the guardian, it was also counted as implausible (1x). If no admission date was known, the time until the ThermoSpot was applied remained missing (1x).

Room Temperatures

When documented room temperatures contained detectable typing errors, they were corrected retrospectively (**KCH** Pre: 4x, Int: 6x). Typing errors where the correct room temperature could not be derived were considered implausible (**KCH** Pre: 4x, KCH Int: 1x).

Primary Outcomes

Body Temperatures

At **KCH**, in-ear and axillar temperatures were measured. If they differed >1°C, both were considered implausible. If they differed <1°C but >0,5°C, they are named in Table 16 but were integrated into the analyses. If a temperature was shown on the thermometer as "not detectable" or documented after discharge, it was considered implausible and is shown in Table 16. Temperatures with detectable typing errors were corrected retrospectively (Pre: 13x axillar Temp, 14x in-ear Temp; Int: 6x axillar Temp, 11x in-ear Temp). In the intervention period, one temperature was >6°C different from the other measurements on the same day and counted as implausible and in one case, only the in-ear temperature was implausible. The latter case is not listed in Table 16. For analyses, only axillar temperatures were used for the Malawian hospitals.

Table 16: Plausibility of Body Temperatures KCH

Number of implausible temperatures	Reason for implausibility	Number of newborns	
		Pre	Int
1	Difference >0,5°C in ear - axillar	34	47
2	Difference >0,5°C in ear – axillar	3	10
3	Difference >0,5°C in ear – axillar	3	1
4	Difference >0,5°C in ear – axillar	1	1
5	Difference >0,5°C in ear – axillar	0	1
1	Difference >1°C in ear – axillar	14	21
2	Difference >1°C in ear - axillar	4	1
1	Difference to other temperatures on same day*	0	1
1	"not detectable" *	0	1
1	Temperature documented after discharge	7	8
2	Temperature documented after discharge	4	2
4	Temperature documented after discharge	1	0
9	Temperature documented after discharge	1	0
13	Temperature documented after discharge	1	0

**only axillar temperature*
Int=Intervention; Pre=Pre-Intervention

In the districts, only axillar temperatures were taken. Some were documented after discharge and counted as implausible (**Dedza**: Pre: 5x one Temp, 1x three Temps, 1x seven Temps; Int: 3x one Temp, 1x two Temps, 1x eight Temps; **Salima**: Pre: 6x one Temp, Int: 1x one Temp).

Case Fatality Rate

If the outcomes “death” and “discharge” were both answered with “yes” for the same newborn and references sufficiently suggested that one of them was correct (e.g., time of death, cause of death), the outcome without references was changed to “no” retrospectively (Discharge: **KCH:** Int: 3x; **Dedza**: Int: 1x. Death: **KCH**: Pre: 1x).

If insufficient references were detectable, the outcome and, if applicable, the cause of death were considered implausible (**KCH** Int: 1x). If a newborn was documented to have been discharged, but a comment stating “died” and a cause of death were reported, the outcome was changed to “death” retrospectively (**KCH**: Pre: 3x).

Secondary Outcomes

Weight

If two weights (including birth- and admission weight) differed by more than 10% on consecutive days and no additional weight was documented, both were considered implausible. If one of the differing weights matched with other reported weights, the not matching weight was deemed to be implausible. Also, weights that were reported after the date of discharge were considered implausible.

Table 17: Plausibility of Weights

Number of implausible weights	Reason for implausibility	Number of newborns					
		KCH		Dedza		Salima	
		Pre	Int	Pre	Int	Pre	Int
1	**Difference >10%**	28	39	5	1	5	4
2	**Difference >10%**	73	67	5	7	6	11
3	**Difference >10%**	2	7	0	0	4	0
4	**Difference >10%**	8	14	0	0	0	0
5	**Difference >10%**	1	2	0	0	1	0
6	**Difference >10%**	0	1	0	0	0	0
12	**Difference >10%**	0	1	0	0	0	0
1	**Date of discharge**	11	13	4	5	5	4
2	**Date of discharge**	1	0	0	1	0	0
3	**Date of discharge**	0	0	2	1	0	0
4	**Date of discharge**	1	0	0	0	0	0
5	**Date of discharge**	1	0	0	0	0	0

Int=Intervention; Pre=Pre-Intervention

In addition to Table 17, the following modifications were made:

- Weights with comprehensible typing errors were corrected retrospectively (**KCH** Pre: 8x, Int: 24x; **Dedza**: Pre: 1x).
- In **Dedza** Pre, 15 weights were marked as implausible because a retrospectively not traceable shifting mistake occurred during entering the data into the data base.
- At **KCH**, the last recorded weight was documented in addition to the regular weights from day one to twelve. If the last weight was measured within the period of the twelve days and the weights of the discharge day from both sources differed, but one of them fit in with the rest of the weights, the latter one was considered correct (**KCH**: Pre: 5x, Int: 7x). If no other weights were documented, the weight on that day was deemed to be implausible (**KCH**: Pre: 6x, Int: 8x).

Date of Discharge – Length of Stay

The length of stay was calculated by subtracting the admission date from the discharge date. In **Salima** Int, one discharge date was changed retrospectively due to a detectable typing error. In **Dedza** Pre, one discharge date was considered implausible because the length of stay would have been too many months to be true. In **Dedza** Int, one date of discharge was counted as implausible because it was indicated before the date of admission.

Guardians' Ticks and Reactions: Inconsistencies on Bedside Sheets

Table 18 shows the reported reasons for missing and implausible ticks on bedside sheets at KCH.

Table 18: Reported Reasons for missing/implausible Ticks and Reactions KCH

Reported Reason	N
Missing bedside sheet* (M)	6
Temporarily missing bedside sheet (M)	3
Bedside sheet not (always) used (M)	10
Wrong dates on bedside sheet* (M/I)	8
Ticks on more days than total length of stay* (I)	27
Unreadable ticking or ticking obviously wrong*[1] (M/I)	13
More ticks per day than possible*[2] (I)	40
Implausible ticking pattern*[3] (I)	13
Questionable ticks, no precise reason specified (I)	19
Guardian wrote "reaction due to hypothermia" in words but made no hypothermic tick (I)	1
Guardian wrote down reactions, most of them contrary to ticked colours. * Reactions (I)	1
No recorded ticks, no comment about the reason for missing data*	11
Missing documentation of ticks for a single colour on one day (transmission error) (M)*[4]	7
Multiple actions wrong → also correct ones were considered wrong (accidentally correct) (I)	1

M=led to missing ticks; I=led to implausible ticks
total Ns=reasons with: 478 newborns; other reasons: 2244 days of completed bedside sheets*
**: effecting all days – none counted*
**[1]: e.g. fully coloured boxes, same ticking every day*
**[2]: > 20 ticks per day were counted as more than possible*
**[3]: only hypo- and hyperthermic ticks on one day/ >2 days and at least 1/3 of all ticked days with all temperature ranges ticked on one day*
**[4]: only one colour missing; the rest of the day was counted*

In the districts, only days with more ticks than possible (**Dedza**: 24, **Salima**: 2), ticks on more days than the length of stay of the newborn (**Dedza**: 7, **Salima**: 1) and ticks with implausible ticking pattern (**Dedza**: 0, **Salima**: 0) were marked as implausible retrospectively (N of completed days on Bedside Sheets: Dedza=421, Salima=267). The data entering students did not use the option to comment on the data, so more precise information about the plausibility of ticks is missing.

Correctness of Colour Observations by Guardians

If at least one measured temperature was in the same range as a tick, the tick counted as right. If a temperature range was ticked, that was not measured on the same day, the tick counted as right, as ticking happened more frequently than measuring. If no tick was drawn in the range of a measured temperature or if a bedside sheet showed implausible ticks, the whole day counted as wrong. If no temperature was documented by health workers on a day, the correctness of ticks on that day counted as unknown.

Guardians' Acceptance of ThermoSpots - Questionnaire

If the bedside sheet was not used but the guardian answered all questions with "I agree/strongly agree", the answers were considered implausible (**KCH**: 7x). If the bedside sheet was not used but the guardian answered at least one question with "I cannot decide" or "I disagree/strongly disagree", the answers were included into the analyses (**KCH**: 1x). If the file of a newborn did not have a bedside sheet, the questionnaire was considered correct (**KCH**: 4x). In some cases, all days of the bedside sheet were considered implausible. The questionnaire of those guardians counted nevertheless (**KCH:** 35x answer "I strongly agree" to all questions, 7x answers "I agree/strongly agree", 5x answer "I agree" to all questions, 1x answers "I cannot decide/agree/strongly agree"; **Dedza:** 3x answer "I strongly agree" to all questions, 4x answer "I agree" to all questions, 1x answers "I cannot decide/agree", **Salima:** 1x answer "I strongly agree" to all questions).

Results in Appendix

Maternal Risk Factors

<u>Early Rupture of Membranes</u>

If the indicated date of the rupture of membranes was more than one day before delivery but "early rupture of membranes >18 hours" was denied, both values were considered implausible (**KCH**: Pre: 11x, Int: 5x). If only the date was implausible (e.g. also mismatch to date of birth), "early rupture of membranes" was counted in the analyses (**KCH** Int: 1x).

The database of LMU was structured differently. Changes were made to fit the LMU data into the same shape as the Malawian data for comparisons:

- If ROM ≤18 hours before delivery: counted as "no" (28x)
- If ROM reported as "yes" without detailed length: counted as "implausible" (27x)
- If ROM reported as "unknown": counted as "missing" (10x)

<u>Meconium in Amniotic Fluid and Meconium Aspiration</u>

Some newborns were diagnosed with meconium aspiration, but present meconium in the amniotic fluid was denied. The data were not marked as implausible and analysed anyway (**KCH**: Pre: 24x, Int: 3x).

Presumptive Diagnoses

For the diagnosis "Prematurity" see p. 86.

Diagnosis Low Birth Weight

The diagnosis low birth weight was corrected retrospectively using the documented birth weights. Newborns with a birthweight of < 2500g were considered as low birth weight (**KCH**: Pre: 250x, Int: 240x; **Dedza** Pre: 40x, Int: 12x; **Salima**: Pre: 31x, Int: 19x). Newborns with implausible birth weight and no information about low birth weight were documented as implausible (**KCH**: Pre: 1x, KCH Int: 2x).

Diagnosis Respiratory Difficulties

The symptoms severe chest-indrawing, tachypnoea, breathing difficulties, nasal flaring, grunting and gasping, as well as the diagnoses transient tachypnoea of the newborn and RDS (Respiratory Distress Syndrome) were summarised as "respiratory difficulties".

Diagnosis Aspiration

The diagnoses blood aspiration and meconium aspiration were summarised as "aspiration". If the cause of death was documented as meconium aspiration, but meconium aspiration was not documented in the diagnoses, it was retrospectively added as diagnosis (**KCH:** Pre: 1x, Int: 1x).

Diagnosis Convulsions

The symptom twitching was integrated into the diagnosis convulsions.

Diagnosis Hypoglycaemia

The diagnosis diabetes was included in the diagnosis hypoglycaemia.

Diagnoses Asphyxia and HIE (Hypoxic Ischaemic Encephalopathy)

If a newborn had a documented HIE but no documented asphyxia, asphyxia was retrospectively added (**KCH**: Pre: 6x, Int: 4x).

Diagnosis Surgical Intervention

The diagnosis post stoma (**KCH**: Pre: 1x) was added to "surgical intervention".

Symptoms “No spontaneous Movements, Floppy, Lethargic, Not Crying”

Rules for summarizing the symptoms:

- Symptoms no spontaneous movements, lethargic, floppy, not crying when documented on the first day of life → added to low APGAR score (**KCH:** Pre: 2x, Int: 2x; **Dedza:** Pre: 9x; **Salima:** Pre: 3x, Int: 5x)
- Symptoms no spontaneous movements, lethargic, floppy, not crying when documented after the first day of life → summarised as lethargic (**Dedza**: Pre: 2x; **Salima** Pre: 2x, Int: 2x)

Incomprehensible Diagnosis

At **KCH** Pre, the diagnosis “entropian condition” was made in one case. As this diagnosis was incomprehensible to us, it was ignored.

Method of Feeding

If all possible feeding methods were indicated as “no”, they were considered implausible (**KCH**: Int: 2x).

Presumptive Causes of Death

At **KCH** Int, one cause of death was documented as “RDS due to heart failure”. As this is no plausible chain of causality, the value was considered implausible. In another case at **KCH** Int, the cause of death of a newborn with diagnosed respiratory distress syndrome was documented as severe chest indrawing and was added to respiratory cause. If the cause of death was documented as prematurity, but neither the diagnosis prematurity was documented, nor the gestational age was in the preterm range, the cause of death was considered implausible (**KCH:** Pre: 2x). In **Dedza** Pre, four newborns with low birth weight as their indicated cause of death were added to the cause of death prematurity.

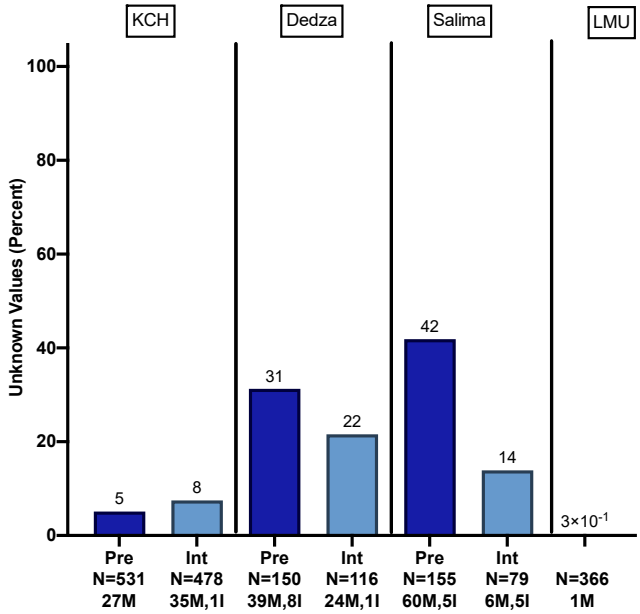
Results

Quality of Documentation

The database contains many missing and implausible values. This chapter describes the quality of documentation of the variables used in the calculations. The amount of insufficiently documented variables is shown: implausible and missing values are summarised as unknown values and shown as percentage of the total sample sizes. The proportion of implausible and missing values is indicated (M=Missing, I=Implausible).

Gestational Age

Figure 13: Quality of Documentation – Gestational Age



Pre=Pre-Intervention; Int=Intervention
M=Missing; I=Implausible

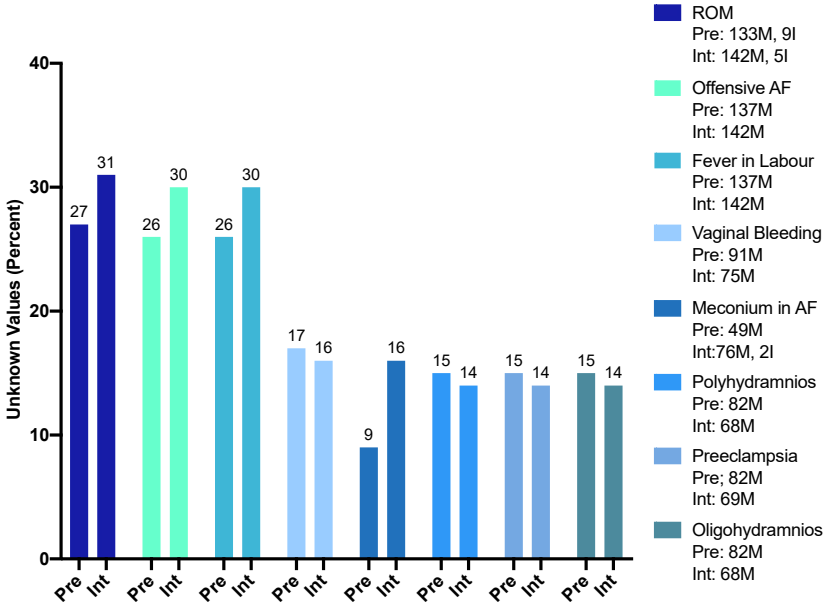
Maternal Risk Factors

The data are biased as in the districts the way of documentation changed between the study periods. In Dedza during pre-intervention, newborns with no information (=missing), were entered into the database as if their mother had no risk factors, while during intervention, missing information was correctly entered as unknown. The same happened in Salima, but the other way around: during pre-intervention, missing information was correctly entered as unknown, during intervention missing information was incorrectly entered as no maternal risk factors.

Figure 14 shows the quality of documentation of specific maternal risk factors at KCH. In the district hospitals and at LMU, data about maternal risk factors were documented in a reduced way. The percentages of unknown values are: Early Rupture of Membranes: Dedza (N=266): 1% (1M) Pre, 41% (48M) Int; Salima (N=234): 7% (11M) Pre, 0% Int. Maternal Fever in Labour: Dedza: 0% Pre, 49% (56M, 1I) Int; Salima: 7% (11M) Pre, 0% Int. Offensive Amniotic Fluid: Dedza: 1% (1M) Pre, 47%

(55M) Int; Salima: 6% (9M) Pre, 0% Int. At LMU (N=366), only data about Early Rupture of Membranes were documented, 60% (191M, 27I) are unknown.

Figure 14: Quality of Documentation - Maternal Risk Factors KCH



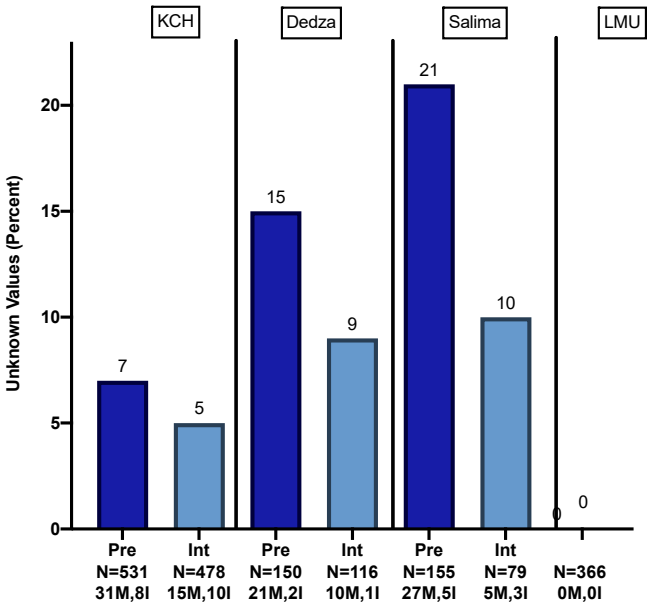
ROM=early rupture of membranes
AF=amniotic fluid; Pre=Pre-Intervention, Int=Intervention
N KCH Pre: 531; KCH Int: 478; N LMU:366

Mode of Delivery

The mode of delivery was documented at KCH and LMU. The percentages of unknown values are: KCH: 2% (9M) Pre, 2% (11M) Int. LMU: 36% (133M).

Birth Weight

Figure 15: Quality of Documentation – Birth Weight



Pre=Pre-Intervention; Int=Intervention
M=Missing; I=Implausible

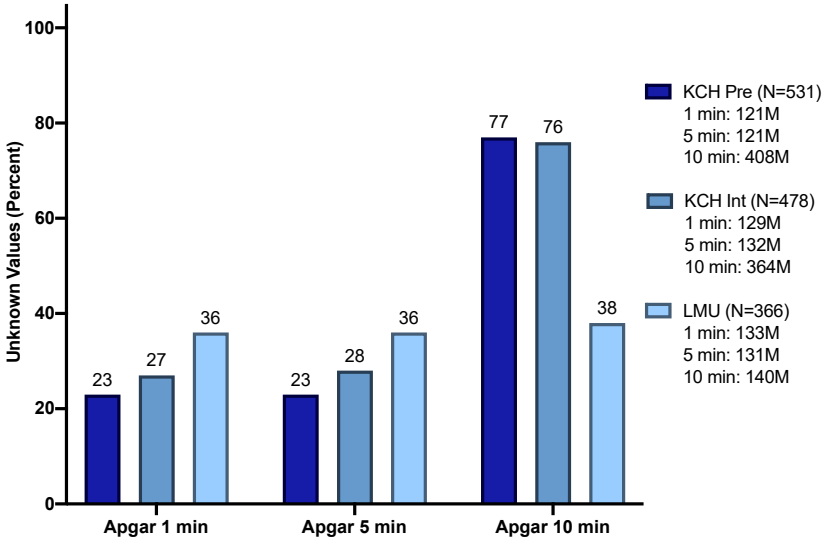
Multiple Births

The birth of a newborn as singleton or in a multiple birth was documented at KCH (N=1009) and LMU (N=366). The percentages of unknown values are: KCH: 0% Pre and Int, LMU: 0% (1M).

Apgar Scores

Apgar scores were documented at KCH and LMU.

Figure 16: Quality of Documentation: Apgar Scores



Pre=Pre-Intervention, Int=Intervention
M=Missing

Treatment immediately after Birth

These data are biased. In Dedza, documentation changed in between: during pre-intervention, newborns with no information (=missing), were entered into the database as if they had not received treatment. During intervention, missing information was correctly entered as unknown. The same happened in Salima the other way around: during pre-intervention, missing information was correctly entered as unknown, during intervention missing information was incorrectly entered as no treatment. At LMU, also, sometimes no value was entered instead of a "not done" (e.g. at CPR). Stimulation was not documented at LMU.

Table 19: Quality of Documentation - Treatment immediately after Birth

	KCH		Dedza		Salima		LMU
	Pre N=531	Int N=478	Pre N=150	Int N=116	Pre N=155	Int N=79	N=366
Stimulation	29 (155M)	33 (158M)	1 (2M)	45 (52M)	17 (26M)	0	-
Suctioning	29 (155M)	33 (158M)	1 (2M)	45 (52M)	19 (29M)	0	47 (171M)
Bag Valve	29 (155M)	33 (158M)	1 (1M)	45 (52M)	19 (29M)	0	7 (26M)
O_2	29 (155M)	33 (158M)	1 (1M)	17 (20M)	4 (6M)	0	8 (29M)
CPR	29 (155M)	33 (158M)	0	16 (19M)	3 (4M)	0	37 (136M)

Values in front of parenthesis: unknown data in percent
Bag Valve=bag valve ventilation, CPR=cardio pulmonary resuscitation, O_2=oxygen support
Pre=Pre-Intervention; Int=Intervention

Postnatal Application of Vitamin K

The postnatal application of vitamin K was recorded at KCH. The percentages of unknown values are: 2% (10M,N=531) Pre, 1% (5M,N=478) Int.

Sex

The percentages of unknown values are: KCH: 1% (4M,N=531) Pre, 7% (33M,N=478) Int; Dedza: 2% (3M,N=150) Pre, 9% (10M,N=116) Int; Salima: 3% (5M,N=155) Pre, 4% (3M,N=79) Int; LMU: 0% (N=366).

Age on Admission

The percentages of unknown values are: KCH (N=366): 1% (5I) Pre, 0% (1I) Int; Dedza (N=266): 1% (1I) Pre, 1% (1M) Int; Salima (N=234): 1% (2M) Pre, 0% Int; LMU: 1% (2M).

Place from which the Newborns were Admitted

The place, the newborns were admitted from, was documented in the Malawian hospitals. At KCH (N=1009) and Salima (N=266), all values are known. In Dedza (N=234), the percentages of unknown values are: 3% (5I) Pre, 1% (1I) Int.

Presumptive Diagnoses

These data are biased as in the districts, symptoms and diagnoses of the whole hospital stay were entered and at KCH, only symptoms and diagnoses on admission. In addition, in Salima, symptoms without any information were wrongly entered as "not present" instead of "unknown".

The percentages of unknown values, whether a specific diagnosis/symptom was given or not are: KCH: 1% (79M,3I) Pre, 1% (45M,3I) Int, Dedza: 0% (2M,3I) Pre, 0% (2M,4I) Int; Salima: 0% (10M,4I) Pre, 0% (1M,5I) Int. N=19 possible diagnoses/symptoms per newborn, N newborns: KCH Pre: 531, KCH Int: 478, Dedza Pre: 266, Dedza Int: 116, Salima Pre: 155, Salima Int: 79.

Table 20 shows the median of the number of documented symptoms and/or diagnoses per newborn. The documentation of diagnoses was different at LMU.

Table 20: Number of Documented Presumptive Diagnoses

	KCH Pre N=531	KCH Int N=478	Dedza Pre N=150	Dedza Int N=116	Salima Pre N=155	Salima Int N=79
Minimum	0.0	1.0	1.0	1.0	1.0	1.0
25% Percentile	2.0	2.0	2.0	2.0	1.0	1.0
Median	3.0	3.0	2.0	3.0	2.0	2.0
75% Percentile	4.0	4.0	4.0	4.0	3.0	4.0
Maximum	9.0	6.0	6.0	6.0	6.0	6.0

Pre=Pre-Intervention; Int=Intervention

Prematurity as a Diagnosis

The percentages of unknown values are: KCH: 1% (7M,N=531) Pre, 2% (9M,N=478) Int; Dedza: 2% (1M,2I,N=150) Pre, 3% (4I,N=116) Int; Salima: 4% (2M,4I,N=155) Pre, 6% (5I,N=79) Int. Diagnoses at LMU were reported differently.

Mode of Transport to the Hospital

In many cases, inborn patients had a documented mode of transport to the hospital. We assume that the health workers did not differentiate between the mothers' mode of transport to the hospital for delivery and the mode of transport of a newborn. This biased the data and the sample sizes were adjusted to only the newborns who were admitted from home or referred.

The percentages of unknown values are: KCH: 44% (76M,N=171) Pre, 86% (124M,N=144) Int; Dedza: 46% (17M,N=37) Pre, 20% (8M,N=41) Int; Salima: 75% (44M,N=59) Pre, 21% (5M,N=24) Int; LMU: 1% (2M). Due to the high percentages of unknown values, no further calculations were realised.

Origin of Family

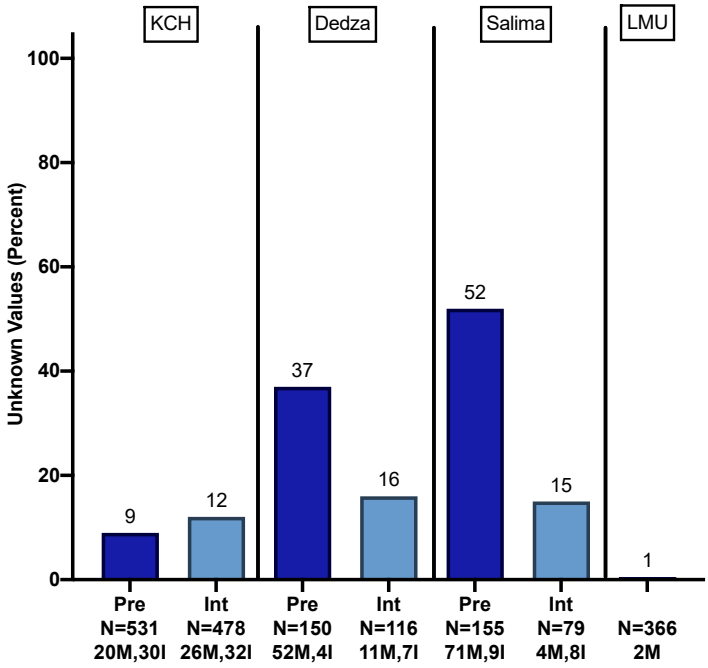
The origin of the families of the newborns (rural/urban), was documented at KCH. The percentages of unknown values are: 10% (51M,N=531) Pre, 16% (74M,N=478) Int.

Age of Mothers

The age of the mothers of the newborns was recorded at KCH. 17% of the data are missing in both periods (Pre: 88M,N=531; Int: 79M,N=478).

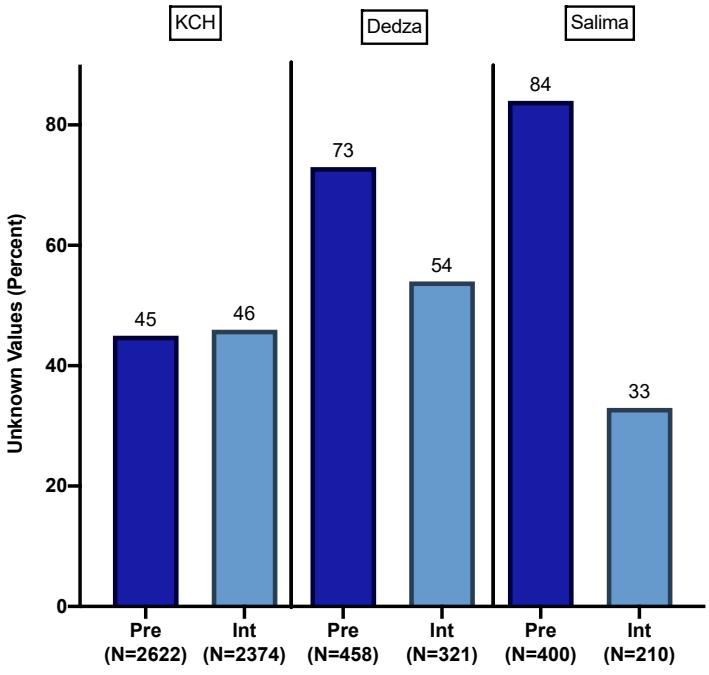
Body Weight on and after Admission

Figure 17: Quality of Documentation Admission Weights



Pre=Pre-Intervention; Int=Intervention
M=Missing; I=Implausible

Figure 18: Quality of Documentation – Weights Day 2-12



N = Number of expected weights
Pre=Pre-Intervention; Int=Intervention

At LMU, no weights from during the in-hospital time were documented. Table 21 shows the exact daily percentages and proportions of missing and implausible values of weights after admission.

Body Weight Day 1-12, exact daily percentages

Table 21: Quality of Documentation – Weights Day 1-12

	KCH Pre	KCH Int	Dedza Pre	Dedza Int	Salima Pre	Salima Int
Day 1	N,M not known*, 25I	N,M not known*, 44I	Admission Weight*[1]	Admission Weight*[1]	Admission Weight*[1]	Admission Weight*[1]
Day 2	49 (N=490,190M,50I, 2L)	50 (N=443,160M,59I, 2L)	56 (N=103,49M,9I,10 L)	49 (N=92,40M,5I,1L)	83 (N=109,84M,7I,1L)	33 (N=66,17M,5I)
Day 3	45 (N=413,162M,24I, 2L)	51 (N=361,157M,27I, 1L)	82 (N=89,72M,1I,1L)	52 (N=71,36M,1I,2L)	89 (N=91,75M,6I)	36 (N=59,14M,7I)
Day 4	46 (N=346,149M,9I,5 L)	44 (N=302,114M,20I, 2L)	84 (N=81,67M,1I)	49 (N=57M,28M,1L)	81 (N=67,48M,6I)	23 (N=35,6M,2I,1L)
Day 5	45 (N=302,122M,13I, 2L)	44 (N=279,108M,14I, 2L)	85 (N=67,57M,1L)	45 (N=42,19M,3L)	81 (N=57,46M)	21 (N=19,4M,1L)
Day 6	47 (N=248,101M,15I, 3L)	38 (N=235,80M,10I,1 L)	83 (N=42,35M,0I,1L)	59 (N=22,13M,1L)	75 (N=28,21M,2L)	43 (N=14,6M)
Day 7	49 (N=195,85M,11I,2 L)	39 (N=191,68M,7I,2L)	82 (N=22,18M)	73 (N=15,11M,1L)	95 (N=20,18M,1I)	50 (N=6,3M)
Day 8	46 (N=163,70M,5I,1L)	46 (N=151,62M,7I,1L)	71 (N=14,10M,0I2L)	80 (N=10,8M)	80 (N=10,7M,1I)	25 (N=4, 1M)
Day 9	50 (N=139,64M,5I,2L)	46 (N=125,52M,5I)	50 (N=10,5M,1L)	71 (N=7,5M)	75 (N=8,6M)	50 (N=4, 2M)
Day 10	41 (N=127,46M,6I,1L)	52 (N=110,50M,7I,2L)	66 (N=9,5M,1L)	100 (N=2,2M)	100 (N=4,4M)	67 (N=3, 2M)
Day 11	29 (N=110,29M,3I)	52 (N=93,43M,5I)	33 (N=9,3M)	100 (N=2,2M)	100 (N=4,4M)	–
Day 12	31 (N=98,30M)	44 (N=82,34M,2I,1L)	44 (N=9,4M)	100 (N=2,2M)	100 (N=2,2M,2L)	–

Value in front of parentheses: percentage of unknown values
N=number of weights that should have been taken
L=late: weights that were reported after discharge were marked as "L", they did not count into the percentages
Pre=Pre-Intervention; Int=Intervention
**KCH day 1: N and M not known because admission may have been after weighing round*
**[1]Dedza, Salima day 1: only admission weight documented, quality of documentation admission weight: p.100*

Body Temperatures Day 1-12

Table 22: Quality of Documentation – Body Temperatures Day 1-12

	KCH Pre	KCH Int	Dedza Pre	Dedza Int	Salima Pre	Salima Int
Day 1*	72*[1] (N=2080,1484M,6I)	54*[1] (N=1844,995M,1I)	76*[1] (N=248,180M)	54*[1] (N=214,117M)	85*[1] (N=240,204M,1I)	33*[1] (N=134,45M)
Day 2	48 (N=1960,936M,7I,6L)	47 (N=1772,826M,5I)	68 (N=318,215M,3L)	36 (N=276,99M)	72 (N=327,235M,2I)	26 (N=198,52M)
Day 3	57 (N=1652,941M,1I,1L)	58 (N=1444,834M,3I,2L)	70 (N=267,185M,2L)	39 (N=210,81M,3L)	71 (N=273,195M,1L)	37 (N=177,66M)
Day 4	60 (N=1384,825M,1I,15L)	61 (N=1208,728M,3I,2L)	72 (N=243,175M)	51 (N=171,87M,2L)	71 (N=201,143M)	50 (N=105,51M,2L)
Day 5	61 (N=1200,729M,2I,7L)	64 (N=1120,711M,3I,3L)	74 (N=201,148M,1I)	55 (N=126,69M,6L)	78 (N=171,134M,3L)	39 (N=57,21M,1I)
Day 6	67 (N=988,664M,1I,2L)	61 (N=940,578M)	82 (N=126,103M,3L)	50 (N=67,33M,1L)	79 (N=84,66M,1L)	64 (N=42,27M,1L)
Day 7	65 (N=776,505M,0I,2L)	62 (N=768,473M,3I,4L)	82 (N=66,54M)	51 (N=45,23M)	90 (N=60,54M)	61 (N=18,11M)
Day 8	68 (N=648,437M,1I,2L)	60 (N=604,362M,1I)	81 (N=42,34M,3L)	57 (N=30,17M,1L)	90 (N=30,27M)	67 (N=12,8M)
Day 9	70 (N=552,384M)	64 (N=500,318M,3I)	77 (N=30,23M,1L)	81 (N=21,17M)	88 (N=24,21M,1L)	83 (N=12,10M)
Day 10	71 (N=504,355M,1I)	71 (N=440,313M,1L)	74 (N=27,20M,1L)	100 (N=6,6M)	83 (N=12,10M,1L)	100 (N=9,9M)
Day 11	63 (N=436,275M)	70 (N=372,259M,2I)	74 (N=27,20M,1L)	100 (N=6,6M)	92 (N=12,11M)	-
Day 12	63 (N=388,245M)	71 (N=328,233M)	78 (N=27,21M,1L)	100 (N=6,6M)	100 (N=6,6M)	-

Value in front of parentheses: percentage of unknown values
N=number of temperatures that should have been taken
L=late: temperatures that were reported after discharge are marked as "L", they did not count into the percentages
** Day 1: These numbers are biased as they were calculated with the assumption that all measurements of the admission day were supposed to be taken, but, if a newborn could have been admitted later on that day*
**[1]Day 1: Ns were calculated based on three temperatures to be taken at KCH and two temperatures to be taken in the districts*

Respiratory Support

The respiratory support (O_2 and CPAP=Continuous positive airway pressure) was documented at KCH and LMU. The percentages of unknown values are: KCH: 0% (2M,N=531) Pre, 0% (1M,N=478) Int; LMU: 0% (1M,N=366).

Method of Feeding

The percentages of unknown values are: KCH: 3% (11M,3I,N=531) Pre, 1% (5M,2I,N=478) Int; Dedza: 3% (1M,4I,N=150) Pre, 2% (1M,1I,N=116) Int; Salima: 3% (4I,N=155) Pre, 1% (1I,N=79) Int. At LMU, data were documented differently.

Kangaroo Mother Care

The percentages of unknown values are: KCH (N=1009): 1% (3M) Pre, 0% (2M) Int; Dedza (N=266): 0% Pre and Int; Salima (N=234): 1% (2M) Pre, 0% Int. The KCH data are biased (see 5.1.9). At LMU, no data were documented.

Coinfections - Application of Antibiotics

The percentages of unknown values are: KCH 0% (2M,N=531) Pre, 0% (1M, N=478) Int; Dedza: 0% Pre (N=150) and Int (N=116); Salima: 1% (2M,N=155) Pre, 0% Int (N=79); LMU: 14% (50M).

Hospitalisation Time

The length of stay was only calculated for surviving newborns. The percentages of unknown values are: KCH: 1% (1M,5I,N=427) Pre, 1% (2I,N=374) Int; Dedza: 4% (1M,3I,N=93) Pre, 1% (1I,N=86) Int, Salima: 2% (2M,N=104) Pre, 0% (N=56) Int; LMU: 1% (4M,N=366).

Case Fatality Rate

Referred and absconded newborns were not tracked for their outcome. Table 23 shows the percentages of referred and absconded newborns in relation to discharged and deceased newborns. When excluding newborns with not tracked outcome due to absconding/ referrals, the percentages of unknown values are: KCH: 0% (1M,N=521) Pre, 0% (1I,N=464) Int; Dedza: 1% (1M,N=131) Pre, 2% (2M,N=116) Int; Salima: 0% (N: 122 Pre, 76 Int). LMU was excluded.

Table 23: Percentages of not tracked Newborns

	KCH (N=1007)	Dedza (N=263)	Salima (N=234)
Referred/Absconded	2.4	9.9	19.2
Discharged	79.5	68.0	68.4
Deceased	18.1	22.1	12.4

N= Number of documented outcomes
Pre=Pre-Intervention, Int=Intervention

Presumptive Causes of Death

The percentages of unknown values are: KCH: 5% (5M,N=93) Pre, 11% (9M,1I,N=89) Int; Dedza: 8% (3M,N=37) Pre, 5% (1M,N=21) Int; Salima: 0% (N=18) Pre, 9% (1M,N=11) Int. N= Number of newborns, who died

Implausible values occurred at KCH Pre (2I), but those cases had other plausible causes of death documented. The percentages of newborns with two documented causes of death are: KCH: 48% Pre, 46% Int; Dedza: 3% Pre, 5% Int; Salima: 22% Pre, 0% Int. 5% at Salima Pre and KCH Int had three documented causes of death.

Room Temperatures

The percentages of unknown values, based on the taken body temperatures (including implausible values), are: KCH: 40% (1991M,7I; N=4972) Pre, 35% (1740M,1I; N=4940) Int. In Dedza and Salima, more room temperatures than expected were taken (Dedza Int: +5%; N=226, Salima Int: +16%; N=184). N: Number of room temperatures supposed to be taken).

At LMU, room temperatures were not documented.

Time until ThermoSpot Application

Only KCH data exist. The percentage of unknown values is: 2% (7M,4I, N=1009).

Guardians' Questionnaire

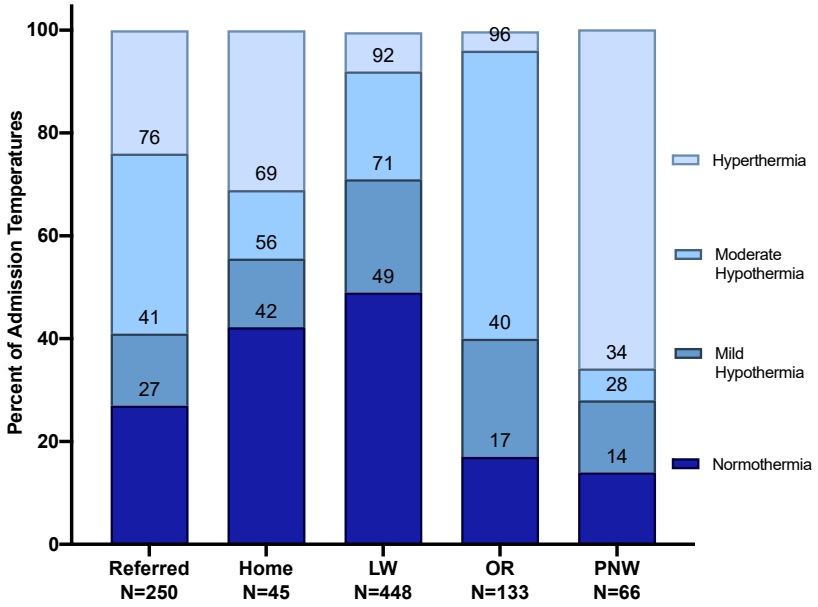
The percentages of not answered questions are: KCH: 22% (596M,42I,N=1009), Dedza: 1% (7M,N=266), Salima: 25% (120M,N=234).

Additional Results

Admission Temperature & Place admitted from KCH

Quality of Documentation: p. 98

Figure 19:
Admission Temperature & Place, admitted from KCH



N=number of newborns with specific place, admitted from and admission temperature
Pre=Pre-Intervention; Int=Intervention; OR=Operation Room; L W=Labour Ward
As only one newborn was admitted with severe hypothermia (L W), this group is not illustrated

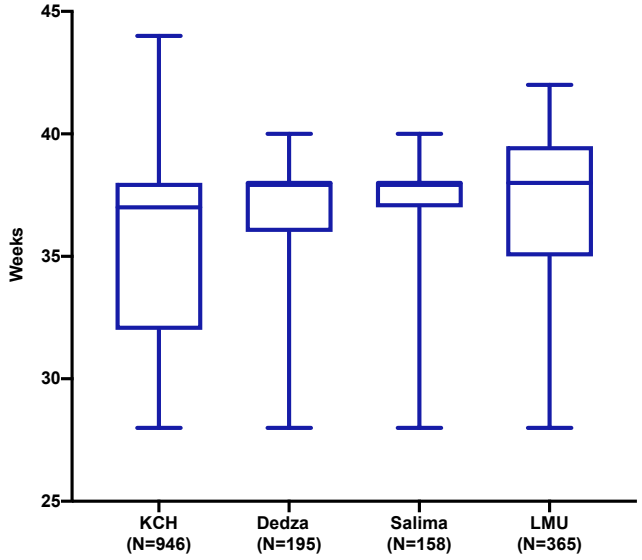
The temperature ranges were summarised into “hypothermia” and “no hypothermia” for significance testing. Comparing the three groups of this facility, newborns admitted from the labour ward and operation room were significantly more often hypothermic on admission than newborns admitted from the postnatal ward (LW-OR: p=0.09; LW-OR/ Theatre-OR: p<0.0001).

Gestational Age

Quality of Documentation: p. 95

Few diagnostic possibilities led to vague calculations as only fundus height and Ballard Score were used to calculate the gestational age (119). Figure 19 shows boxplots of the ranges of gestational ages in the different hospitals. There was no significant difference between the study periods in any hospital. At KCH, the gestational ages were significantly smaller than in the other hospitals. At LMU, the gestational ages were significantly smaller than in Dedza (KCH-Dedza: p=0.01; KCH-Salima /KCH-LMU: p<0.0001; Dedza-LMU: p=0.004). Table 24 shows the exact data, used for significance testing.

Figure 20: Gestational Age



N=Number of known Gestational Ages

Table 24: Gestational Age – Numbers of Newborns

Weeks	KCH Pre (N=503)	KCH Int (N=442)	Dedza Pre (N=104)	Dedza Int (N=91)	Salima Pre (N=90)	Salima Int (N=68)	LMU (N=365)
28	28	29	6	2	2	2	2
29	14	3	0	1	0	0	1
30	36	24	6	3	1	1	6
31	10	10	0	1	0	1	10
32	56	44	9	5	5	2	16
33	20	14	3	0	0	0	15
34	26	40	2	4	1	1	30
35	14	12	3	2	1	1	28
36	38	49	7	10	10	5	25
37	56	63	12	15	22	15	41
38	122	90	47	38	42	36	46
39	29	26	7	6	4	2	54
40	47	27	2	4	2	2	61
41	4	5	0	0	0	0	26
42	3	5	0	0	0	0	4
43	0	0	0	0	0	0	0
44	0	1	0	0	0	0	0

N=Number of known gestational ages
Pre=Pre-Intervention; Int=Intervention

Maternal Risk Factors

Quality of Documentation: p. 95
Percentages were calculated based on the total of known values for the single risk factor.

At KCH, present meconium in the amniotic fluid was reported most frequently (22%, N=884), followed by pre-eclampsia (9.1%, N=858) and vaginal bleeding (5.7%, N=843). Early rupture of membranes (N=720), poly- (N=859) and oligohydramnios (N=859), maternal fever in labour (N=730) and offensive amniotic fluid (N=730) were reported in <3.0%. In Dedza and Salima, only data about an early rupture of

membranes (N Dedza=217, N Salima=223), maternal fever in labour (N Dedza=210, Salima=223) and offensive amniotic fluid (N Dedza=210, N Salima=225) were collected, all of them were reported in <3.0%.

Mode of Delivery

Quality of Documentation: p. 96

At KCH (N=989) 64% of the newborns were born by spontaneous vaginal delivery, 32% by caesarean section and 3.6% by vacuum extraction. The study periods were not significantly different. At LMU, 39% were born by spontaneous vaginal delivery, 52% by caesarean section and 9.1% by vacuum extraction.

Multiple Births

Quality of Documentation: p. 97

The percentages of newborns per parity are (N KCH=1009, N LMU=365): singletons: KCH 90%, LMU 85%; twins: KCH 9.5%, LMU 12%; triplets: KCH 0.6%, LMU 2.5%. At KCH, the difference between the study periods was not significant.

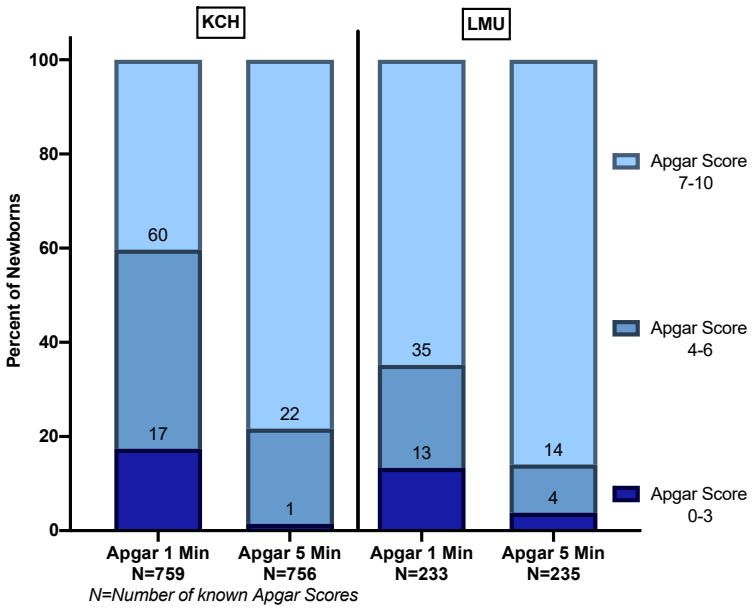
Apgar Scores

Quality of Documentation: p. 97

The 10 minutes Apgar score was documented in < 50% and was not analysed. These data are biased as Apgar Scores at KCH were often inaccurate.

Figure 21 shows the distribution of Apgar Scores at KCH and LMU. There was no significant difference between the study periods at KCH.

Figure 21: Apgar Scores



Treatment immediately after Birth

Quality of Documentation: p. 97
These data are biased. In Dedza, documentation changed in between: during pre-intervention, newborns with no information (=missing), were entered into the database as if they had not received treatment. During intervention, missing information was correctly entered as unknown. The same happened in Salima the other way around: during pre-intervention, missing information was correctly entered as unknown, during intervention missing information was incorrectly entered as no treatment. At LMU, also, sometimes no value was entered instead of a "not done" (e.g. at CPR). Stimulation was not documented at LMU.

Table 25: Percentages of Treatment immediately after Birth

	KCH	Dedza	Salima	LMU
Stimulation	79 (N=696)	26 (N=212)	39 (N=208)	--*
Suctioning	62 (N=696)	28 (N=212)	32 (N=205)	46 (N=195)
Bag Valve	44 (N=696)	27 (N=213)	29 (N=205)	46 (N=340)
O_2	35 (N=696)	39 (N=245)	29 (N=228)	42 (N=337)
CPR	5.2 (N=696)	3.6 (N=247)	3.5 (N=230)	7.0*[1] (N=230)

CPR=cardio pulmonary resuscitation; O_2=oxygen support
N=number of newborns with known values of the specific treatment
**Stimulation was not documented at LMU but always happens*
**[1]We know from other sources, that CPR was done in 0.06% of the newborns at LMU. The high percentage here occurred due to many cases, that did not receive CPR but were entered as "missing"*

Postnatal Application of Vitamin K

Quality of Documentation: p. 98

At KCH, 46% of the newborns received vitamin K after birth. No significant difference between the study periods was shown. No LMU data exist, but most likely all newborns did receive vitamin K. No data for the districts exists.

Sex

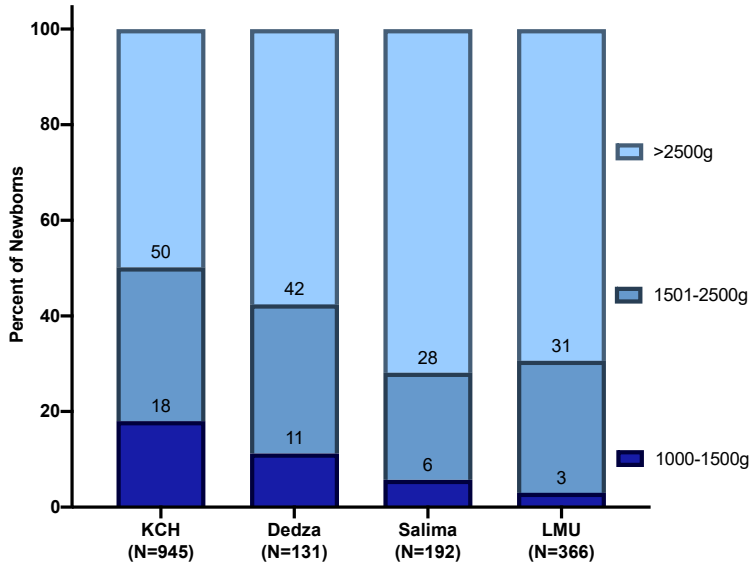
Quality of Documentation: p. 98

The percentages of female newborns are: KCH (N=1009): 45%, Dedza (N=266): 42%, Salima (N=234): 43%, LMU (N=366): 47%. No significant difference in the gender distribution between the study periods was found.

6.2.1.1 Birthweight

Quality of Documentation: p. 96

Figure 22: Birthweight



The study periods did not differ significantly in any hospital. Birthweights at KCH and Dedza were significantly more often in the low ranges than in Salima and at LMU. In Dedza, birthweights were significantly more often in the low ranges than in Salima and at LMU (KCH-Salima/ KCH-LMU: $p<0.0001$; Dedza-Salima: $p=0.04$; Dedza-LMU: $p=0.0004$).

Presumptive Diagnoses

Quality of Documentation: p. 98

The samples were divided into premature and term newborns (if unknown, the newborn was excluded). For some newborns, various presumptive diagnoses were documented, so they were counted in multiple diagnoses. Percentages were calculated based on the number of newborns with known data about the specific diagnosis (to calculate specific Ns see rows of implausible/missing values in Table 26).

For significance testing, the diagnoses were summarised into groups (bold titles in Table 26 + LBW; “Only Prem/Prem+LBW” were not included). In premature newborns, the differences between the study periods were not significant (Dedza was not tested as criteria were not met). In term newborns, a significant difference between the study periods was shown in Salima, where infections and symptoms were diagnosed significantly more often and adaptation issues significantly less often in the pre-intervention period ($p=0.002$).

Table 26: Percentages of presumptive Diagnoses

Diagnosis	Preterm				Term			
	KCH	Dedza		Salima	KCH	Dedza	Salima	
	N=502	Pre N=46	Int N=32	N=41	N=491	N=181	Pre N=122	Int N=60
Only Prem/ Prem+LBW	11	6.5	31	12	--	--	--	--
LBW	84	94	97	85	7.2	7.2	6.6	10
Asphyctic Incident								
Birth Asphyxia	26	22	13	39	43	41	34	49
HIE	1.0	11	6.3	0.0	4.7	5.0	0.8	0.0
Aspiration	3.0	0.0	3.1	0.0	17	11	6.6	3.3
Infection								
Pneumonia/ Bronchiolitis	0.6	2.2	3.1	7.3	2.7	8.8	6.6	8.3
Sepsis	14	13	6.3	32	32	45	66	53
Meningitis	0.8	0.0	0.0	2.4	3.3	0.6	3.3	0.0
Symptoms								
Jaundice	8.0	6.5	3.1	4.9	9.3	8.3	5.8	0.0
Hypothermia	4.4	0.0	0.0	24	3.7	3.9	6.6	10
Fever	0.8	6.5	3.1	2.4	7.3	18	22	6.7
Convulsions	1.0	0.0	3.1	4.9	3.1	10	1.7	1.7
Lethargic	0.0	2.2	3.1	0.0	0.0	3.3	1.7	0.0
Adaptation								
Respiratory Difficulties	69	44	53	46	41	35	15	35
Low Apgar Score/Floppy	0.8	6.5	13	2.4	3.1	11	1.6	6.7
Other*	7.8	2.2	13	12	20	21	15	20
Missing	1.6*8 0.2*2 0.4*5	0.0	0.0	0.0	6.1*1; 0.2*2; 1.4*3; 1.8*10	0.6*3	0.8*2; 2.5*6; 3.3*7	1.7*2
Implausible	0.2*4 0.4*9	0.0	0.0	0.0	0.2*4	0.0	0.0	0.0

N=Number of Newborns; for differing Ns see rows missing/implausible
BW=Birthweight, LBW=Low Birthweight, Prem=Prematurity
Newborns with more than one documented presumptive diagnosis counted various times
Some premature newborns were admitted without additional diagnoses to "LBW" (first row)
*Missing/Implausible: If the percentage is tagged with *X, it only counts for the diagnoses determined as X, the other diagnoses have 0.0% of missing/implausible values*
** Values summarised in "Other": Table 27*

*1: 30M	**Term:** ***KCH:*** *LBW*
*2: 1M	**Prem:** ***KCH:*** *Birth Asphyxia, Pneumonia/Bronchiolitis, Jaundice* **Term:** ***KCH:*** *Pneumonia/Bronchiolitis, Sepsis;* ***Dedza:*** *Convulsions, Lethargic;* ***Salima Pre:*** *Jaundice,* ***Salima Int:*** *Birth Asphyxia*
*3: 7M	**Term:** ***KCH:*** *Jaundice*
*4: 1I	**Prem:** ***KCH:*** *Low Apgar Score/Floppy* **Term:** ***KCH:*** *LBW*
*5: 2M	**Prem:** ***KCH:*** *Convulsions, Lethargic*
*6: 3M	**Term:** ***Salima Pre:*** *Convulsions*
*7: 4M	**Term:** ***Salima Pre:*** *Lethargic*
*8: 8M	**Prem:** ***KCH:*** *LBW*
*9: 2I	**Prem:** ***KCH:*** *LBW*
*10: 9M	**Term:** ***KCH:*** *Convulsions, Lethargic*

Table 27: Presumptive Diagnoses summarised in "Other"

Reason for Admission summarised in "Other"	Preterm						Term					
	KCH		Dedza		Salima		KCH		Dedza		Salima	
	Pre N= 259	Int N= 243	Pre N= 46	Int N= 32	Pre N=27	Int N= 14	Pre N= 265	Int N= 226	Pre N= 101	Int N= 80	Pre N= 122	Int N= 60
	Birth Circumstances											
Pre-partum Haemorrhage Mother	2	0	0	0	0	0	0	0	0	0	0	0
Foetal Distress	1	0	0	0	0	0	1	0	0	0	0	0
Nuchal Cord	0	0	0	0	0	0	1	0	0	0	0	0
Vacuum Extraction	1	2	0	0	0	0	3	7	0	0	0	0
Birth Injury	1	0	0	0	0	0	0	1	1	0	0	4
HIV Exposed	1	0	0	0	0	0	0	0	0	0	0	0
	Infectious Symptoms											
Cough	0	1	0	0	0	0	1	1	2	5	0	0
Sneezing	0	0	0	0	0	0	1	0	0	0	0	0
Secretions	1	0	0	0	0	0	0	0	0	0	0	0
Uncontrollable Crying	1	0	0	0	0	0	1	0	2	0	0	0
Irritability	0	0	0	0	1	0	0	0	0	0	4	0
Foul Smelling	0	0	0	0	0	0	3	0	0	0	0	0
Cord Infection	0	0	0	0	0	0	0	0	0	0	1	0
Ear Discharge	0	0	0	0	0	0	0	0	0	0	0	1
Eye Discharge	0	0	0	0	0	0	1	0	0	0	0	0
Painful Urinating	0	0	0	0	0	0	0	0	0	0	1	0
Risk for Infection	0	0	0	0	0	0	1	0	0	0	0	0
	Congenital											
Genetic Syndrome*	1	0	0	0	1	0	0	0	0	1	0	2
Spina Bifida	1	0	0	0	0	0	8	6	1	1	0	0
Hydrocephalus	2	0	0	0	0	0	1	1	0	0	0	0
Cleft Lip	0	0	0	0	0	0	2	0	0	0	0	0
Multiple Malformations	0	0	0	0	0	0	1	0	0	0	0	0
Conjoined Twin	0	0	0	0	0	0	0	2	0	0	0	0
Webbed Neck	0	0	0	0	0	0	1	0	0	0	0	0
Ear Polyp	0	0	0	0	0	0	0	0	0	0	1	0
Tumorous Mass	0	0	0	0	0	0	0	1	0	0	0	0
Macroglossia	0	0	0	0	0	0	0	0	0	1	0	0
Macrosomia	0	0	0	0	0	0	1	0	0	0	0	0
Hypospadias	0	1	0	0	0	0	0	0	0	0	0	0
Hydronephrosis	0	0	0	0	0	0	2	0	0	0	0	0
Bladder Ectopia	0	0	0	0	0	0	1	1	0	0	0	0
Inguinal Hernia	0	0	0	0	0	0	0	1	0	1	0	0
Umbilical Hernia	0	0	0	0	0	0	0	0	1	0	0	0

	Cardiovascular											
Cardiac Disease	1	1	0	0	0	0	2	3	0	3	0	0
Cyanosis	1	0	0	0	0	1	2	1	0	0	0	1
Oedema	0	0	0	1	0	0	2	0	1	0	0	0
Neonatal Ophthalmia	0	0	0	1	0	0	0	0	0	1	0	0
Haemangioma	0	0	0	0	0	0	1	0	0	0	0	0
	Hematologic											
Anaemia	0	2	0	0	0	0	0	1	0	0	0	0
Haemophilia	1	0	0	0	0	0	0	1	0	0	0	0
Bleeding*[2]	1	2	0	0	0	0	1	1	0	0	0	0
Haematoma	0	0	0	0	0	0	0	0	0	1	0	0
	Dermatologic											
Skin Rash	0	0	1	0	0	0	2	0	0	0	2	1
Granulomatous Tissue	0	0	0	0	0	0	0	1	0	0	0	0
Pustules	0	0	0	0	0	0	0	0	0	1	0	0
Staph. Skin Infection	0	0	0	0	0	0	0	0	0	0	1	0
Abscesses	0	0	0	0	0	0	0	0	0	0	2	0
Impetigo	0	0	0	0	0	0	2	0	0	0	0	0
	Traumatic											
Femur Fracture	0	0	0	1	0	0	0	0	0	0	0	0
Painful Leg	0	0	0	1	0	0	0	0	0	0	0	0
Burn Injuries	1	0	0	0	0	0	0	0	0	0	0	0
	Gastrointestinal											
Feeding Problems	0	1	0	0	0	0	3	1	3	2	2	2
Dehydration	1	0	0	0	0	0	0	1	0	0	1	0
Hypoglycaemia	2	3	0	0	2	0	2	2	0	0	1	0
Hiccup	0	0	0	0	0	0	1	0	0	0	0	0
Vomiting	0	1	0	0	0	0	0	1	2	2	1	0
Oesophageal Atresia	2	0	0	0	0	0	0	0	0	0	0	0
Pylorus Stenosis	0	0	0	0	0	0	0	0	0	1	0	0
Bowel Obstruction	0	0	0	0	0	0	2	1	0	1	0	0
Diarrhoea	0	0	0	0	0	0	0	0	0	0	1	0
Faecal Impaction	0	0	0	0	0	0	2	1	0	2	0	0
Foul smell Meconium	0	1	0	0	0	0	0	0	0	0	0	0
Distended Abdomen	0	1	0	0	0	0	0	0	0	1	0	1
Disturbed Abdomen	0	0	0	0	0	0	0	0	1	0	0	0
Hirschsprung Disease	0	0	0	0	0	0	0	1	0	0	0	0
Rectovaginal Fistula	0	0	0	0	0	0	0	1	0	0	0	0
Tracheoesophageal Fistula	0	1	0	0	0	0	0	1	0	0	0	0

	Observation											
For Observation	0	0	0	0	0	0	4	2	0	0	0	0
Surgical Intervention	0	0	0	0	0	0	3	0	0	0	0	0

Reasons, that did not suit into summarising topics are entitled in the same words as described by health workers; some terms are unusual
**: Trisomy 21, Turner syndrome, Edward syndrome*
**2: nose, gastro intestinal & vaginal, cord;*
**3: Staph.=staphylococcal, Pre=Pre-Intervention; Int=Intervention*

Origin of Family

Quality of Documentation: p.99

At KCH, 57% of the families came from villages, 43% from cities. The difference between the study periods was not significant. As Dedza and Salima are situated in rural areas, it may be assumed that all families lived in a rural surrounding, although no data were collected in the districts.

Age of Mothers

Quality of Documentation: p.99

The age of mothers was recorded only at KCH. The difference between the study periods was not significant. In Table 28, the age groups between 14 and 19 years are shown separately to give an overview of the number of teenage pregnancies. 19% of the mothers were younger than 20 years.

Table 28: Age of Mothers KCH

Age	Number of Mothers
14	1
15	2
16	10
17	28
18	59
19	63
20-48	679

Respiratory Support

Quality of Documentation: p.102

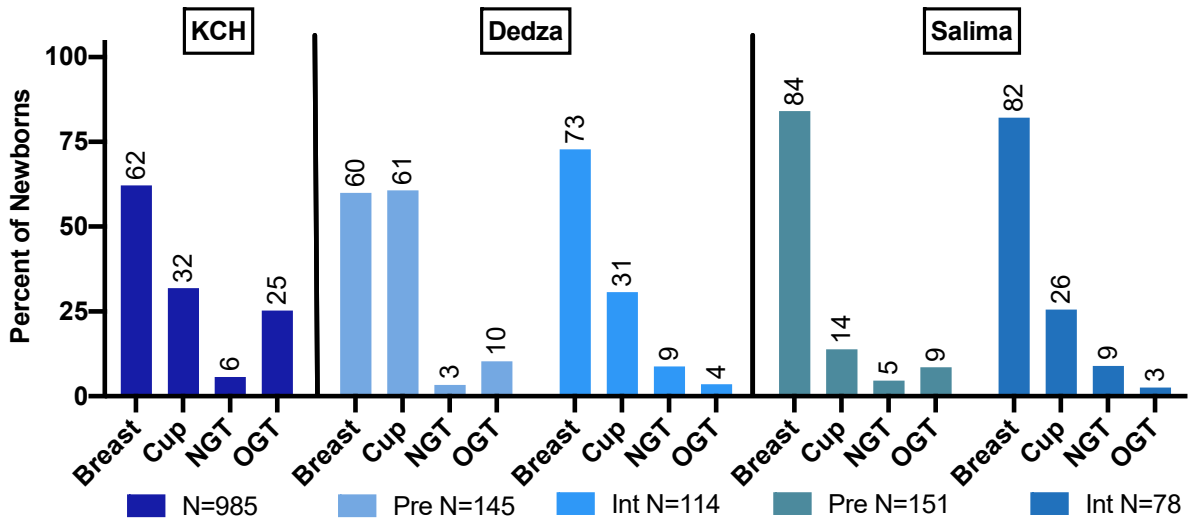
At KCH, the documented respiratory support the newborns received during their hospital stay was: Pre (N=531): 40% O_2, 26% CPAP; Int (N=478): 35% O_2, 24% CPAP. During intervention, significantly less O_2 was prescribed ($p<0.0001$). At LMU (N=365), O_2 support was reported in 16%. If also the hypothermic body temperatures had decreased significantly during the intervention, it could have been discussed if due to ThermoSpots, body temperatures rose and therefore, less newborns needed oxygen support.

Method of Feeding

Quality of Documentation: p.102

Figure 23 shows the percentages of the method of feeding, the newborns received. Some newborns counted several times as they were fed by various methods (Percentages of newborns fed by various methods: KCH: 22%; Dedza: 33% Pre, 16% Int; Salima: 11% Pre, 19% Int). Differences between the study periods were significant in the districts. In Dedza, significantly more newborns were alimented by breast and by nasogastric tube and significantly less by cup feeding during intervention. In Salima, more newborns were alimented by cup feeding during intervention (Dedza: p=0.0002, Salima: p=0.046).

Figure 23: Method of Feeding



N=number of newborns with at least one known method of feeding
OGT: orogastric tube, NGT: nasogastric tube, Pre:Pre-Intervention, Int:Intervention

Presumptive Causes of Death

Quality of Documentation: p.103
These data are biased as in some cases, only prematurity was reported, in some cases prematurity and the secondary issue that led to death, and in some cases only secondary issues that led to death.

Table 29 shows the reported causes of death of preterm and term newborns. The sample sizes of the districts are too small for significance testing. The difference between the study periods at KCH was not significant in the group of premature newborns. The group of term newborns was summarised into three groups ("Asphyctic Incident", "Infection" and "Others", including respiratory cause, jaundice and hypothermia) to achieve adequate sample sizes for analysis. The difference was not significant.

Table 29: Percentages of Causes of Death

Cause of Death	Preterm					Term				
	KCH	Dedza		Salima		KCH	Dedza		Salima	
	N= 125	Pre N=14	Int N=12	Pre N=7	Int N=4	N= 58	Pre N=23	Int N=9	Pre N=11	Int N=7
Prematurity	65	29	8.3	86	25	-	-	-	-	-
Asphyctic Incident										
Birth Asphyxia	11	7.1	0.0	29	0.0	24	78	11	91	57
HIE	4.0	0.0	8.3	0.0	0.0	28	0.0	56	0.0	43
Aspiration	1.6	0.0	0.0	0.0	0.0	8.6	4.4	0.0	0.0	0.0
Infection										
Sepsis	9.6	0.0	0.0	0.0	0.0	21	13	0.0	0.0	0.0
Meningitis	0.8	0.0	0.0	0.0	0.0	6.9	0.0	0.0	0.0	0.0
Respiratory Cause	53	36	42	57	50	12	0.0	0.0	0.0	0.0
Jaundice	0.8	0.0	0.0	0.0	0.0	3.4	0.0	0.0	0.0	0.0
Hypothermia	3.2	7.1	25	0.0	0.0	0.0	0.0	0.0	9.1	0.0
Other*	6.4	4.4	25	0.0	0.0	19	4.4	11	9.1	0.0
Missing	8.0	21	0.0	0.0	25	3.4	4.4*3	11.1	0.0	0.0
Implausible	0.0	0.0	0.0	0.0	0.0	3.4*1 1.7*2	0.0	0.0	0.0	0.0

Newborns with more than one documented cause of death counted various times
N=number of deceased newborns
Pre=Pre-Intervention; Int=Intervention
*Missing/Implausible: If the percentage is tagged with *X, it only counts for the diagnoses determined as X, the other diagnoses have 0.0% of missing/implausible values*
**Values summarised in "Other":*

Table 30
1: 2 I premature;
2: 1 I respiratory problems, 1 I other;
3: 1 M respiratory problems, 1 M hypothermia

Table 30: Causes of Death, summarised in "Other"

Cause of Death, summarised in "Other"	Preterm						Term					
	KCH		Dedza		Salima		KCH		Dedza		Salima	
	Pre N=65	Int N=60	Pre N=14	Int N=12	Pre N=7	Int N=4	Pre N=28	Int N=30	Pre N=23	Int N=9	Pre N=11	Int N=7
Aspiration	0	0	0	2	0	0	0	0	0	1	0	0
Pneumonia	1	1	0	1	0	0	2	0	0	0	1	0
Convulsions	0	0	0	0	0	0	0	1	0	0	0	0
Skin Rash	0	0	1	0	0	0	0	0	0	0	0	0
Dehydration Hypoglycaemia	0	2	0	0	0	0	0	0	1	0	0	0
Multiple	0	0	0	0	0	0	1	0	0	0	0	0
Genetic	1	0	0	0	0	0	0	0	0	0	0	0
Hydrocephalus	0	0	0	0	0	0	0	1	0	0	0	0
Spina Bifida	1	0	0	0	0	0	0	2	0	0	0	0
Cardiac	1	0	0	0	0	0	0	0	0	0	0	0
Cardio-Pulmon. Arrest	3	0	0	0	0	0	1	0	0	0	0	0
Intraoperative	0	0	0	0	0	0	0	2	0	0	0	0

For some newborns, more than one cause of death was documented, they counted various times
N=number of deceased newborns
Pulmon.=Pulmonary; Pre=Pre-Intervention; Int=Intervention

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Affidavit

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Ich erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Titel:

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