EFFECTIVENESS AND ACCEPTABILITY OF AUDIOVISUAL AIDS FOR INCREASING KNOWLEDGE OF NEONATAL DANGER SIGNS AMONG PRIMIPAROUS WOMEN: A RANDOMIZED CONTROLLED TRIAL

A DISSERTATION IN PART FULFILLMENT OF THE REQUIREMENTS

FOR AWARD OF THE DEGREE OF

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DEDICATION

I dedicate this work to:

- To my husband **Allan Muchiri** for his outstanding support throughout my postgraduate studies.
- To my mother **Hon. Faith Gitau** for always believing in me and pushing me to excel in everything I do.
- To my brother **Gitu Njuguna** for modeling excellence in life.
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ABBREVIATIONS

- ANC Antenatal Care
- AVAS Audio Visual Aids
- FGDS Focus Group Discussions
- IMNCI- Integrated Management of Neonatal and Childhood Illnesses
- **KDHS** Kenya Demographic Health Survey
- **KNH** Kenyatta National Hospital
- KNH UON ERC Kenyatta Hospital- University of Nairobi Ethics And Research Committee
- MDG Millennium Development Goals
- **MOH** Ministry of Health
- NMR Neonatal Mortality Rate
- **PI** Principal Investigator
- PNC Postnatal Care
- **SDG** Sustainable Development Goals
- **U5MR** Under Five Mortality Rate
- **UNICEF** United Nations Children's Fund
- WHO World Health Organization

CASE DEFINITIONS AND OPERATIONAL TERMS

Audiovisual Aid: Training or educational materials directed at both the sense of hearing and the sense of sight

Neonate: A baby ≤ 28 days of age.

Neonatal Sepsis: A clinical syndrome associated with infection in a baby ≤ 28 days.

Signs: An objective indicator of disease.

ABSTRACT

Background

Worldwide, neonatal mortality accounts for 46% of under-five deaths. Kenya's neonatal mortality has remained relatively constant at 23 deaths per 1,000 live births. Lack of knowledge about neonatal danger signs delays care seeking increasing the risk of morbidity and mortality. Audiovisual aids have improved knowledge and care seeking in different settings.

Objective

To determine whether health education using audiovisual aids(educational video) and the mother and child health booklet among primiparous women increases knowledge of neonatal danger signs compared to use of the standard mother and child health booklet alone. To evaluate acceptability of audiovisual aids for health messaging on neonatal danger signs.

Study Design

A mixed methods cluster randomized controlled trial.

Methodology

The postnatal wards of Kenyatta National Hospital were randomized using the fair coin method. In both arms, baseline questionnaires assessed knowledge of neonatal danger signs. Mothers in the intervention arm received information using an 8-minute video together with information from the mother and child health booklet. Only the mother and child health booklet was used in the control arm. Post-intervention knowledge assessment interviews via phone calls were done on day 7 and day 28. Focus group discussions assessed acceptability of the video.

Results

At baseline, 153 mothers were enrolled (Intervention: 77, Control: 76). The two arms of the study were comparable for socio-demographics and care seeking. At week 1, the intervention arm had greater knowledge of *trouble breathing* (OR 2.5 95% CI 1.25-5) and *red swollen eyes with drainage* (OR 2.5 95% CI 1.4-5). At week 4, the intervention arm had greater knowledge of 5 of the 10 signs i.e. *less energy* (OR 2.5 95% CI 1.25-5), *fits* (OR 2.5 95% CI 1.1-5), *trouble breathing* (OR 3.3 95% CI 1.6-5), *skin pustules* (OR 2.5 95% CI 1.1-5) and *red swollen eyes with drainage* (OR 5 95% CI 2-10) About 85% of mothers thought the audiovisual aids were easy to follow and understand.

Conclusions

Audiovisual aids were associated with sustained knowledge of neonatal danger signs and were acceptable to most women as a health education tool.

Recommendations

Audiovisual aids should be availed at antenatal/ outpatient clinics and postnatal wards.

1. INTRODUCTION AND LITERATURE REVIEW

1.1 The Global picture

Globally, under-five deaths declined from 12.7 million in 1990 to 5.6 million deaths in 2016 (1,2). Despite achieving this reduction, the world, Kenya included, missed the Millennium Development Goal (MDG 4) target of 2015 which was aimed at reducing the under five mortality by two thirds of the 1990 rates (2). This is largely due to minimal reduction in neonatal mortality which now accounts for a large fraction of the under five mortality rate (U5MR) worldwide (1,2,3).

In 1990, neonatal mortality accounted for 40% of the under-five mortality but has risen in recent times to account for 46% of the under five mortality rate in 2016. This is despite an overall reduction in the neonatal mortality rate from 37 deaths per 1,000 live births in 1990 to 19 deaths per 1,000 live births in 2016. Worldwide, neonatal mortality continues to decline more slowly than the post-neonatal under-five mortality (1-59 months). Whereas the post neonatal under-five mortality declined by 58%, the neonatal mortality declined by 49% during the period 1990-2015 (1,5). These statistics underscore an urgent need to scale up interventions to increase neonatal survival.

The Sustainable Development Goals (SDGs number 3) incorporate the 'A Promise Renewed' and 'Every Newborn Action Plan' targets. These targets are aimed at reducing the under-five and neonatal deaths to as low as 25 deaths per 1,000 live births and the neonatal mortality rate to as low as 12 deaths per 1,000 live births respectively (1,2,4). In order to achieve these targets, a concerted effort by various stakeholders needs to be employed to harmonize achievements across the world. This is especially so in developing countries and more so in Sub-Saharan Africa (1).

Huge disparities have been documented in the distribution of the burden of under-five deaths across the world with 9 out of 10 under-five deaths occurring in low and lower middle income countries (2). Despite significant improvements in child survival, Sub-Saharan Africa continues to account for a large fraction of the under-five deaths and neonatal mortality.

1.2 The Kenyan Situation

At the end of the MDG era in 2015, Kenya was unable to reduce its under-five mortality by twothirds as outlined by MDG 4 (2). Furthermore, countries such as Eritrea, Gabon and Rwanda showed better rates (1,2).

The KDHS 2014 reports that Kenya has shown trends similar to global trends with a significant reduction in the under-five mortality since 1990 from 90 to 52 deaths per 1,000 in 2014. However, a much slower reduction in neonatal mortality was observed during the same period from 26 deaths per 1,000 in 1990 to 22 deaths per 1,000 in 2014 (6).

In 2016, UNICEF estimated Kenya's U5MR at 49 deaths per 1,000 live births. This was a significant improvement from previous estimates. Despite this commendable change, the neonatal mortality was noted to have remained relatively constant at 23 deaths per 1,000 accounting for 46% of the U5MR, an increase from 41% in the year 2000 (UN IGCME 2017)(1). This is well above the world estimate of 19 deaths per 1,000 live births and the SDG target of 12 deaths per 1,000 live births (1).

1.3 Neonatal Morbidity and Mortality

The neonatal period represents one of the most dangerous times in a child's life. A vast majority of neonatal deaths occur on the first day of life and overall in the first week of life (1,2,7,8,9) (Fig. 1). With the current trends, 7,000 neonates will continue to die every day mainly from preventable causes (1,6) (Fig.2).



Number of deaths by day in the first 28 days of life, 2013 (thousands)

Fig. 1: Neonatal Deaths by Age

(Source: Millennium Development Goals Report 2015, United Nations.)

The main conditions causing newborn deaths include prematurity, birth complications (including birth asphyxia) and infections. These account for about 82% of newborn deaths. Infections include sepsis, pneumonia, tetanus and diarrhea which are largely preventable (1) (Fig.2).



Fig. 2: Global Distribution of Deaths among Newborns by Cause, 2016.

(Source: UNICEF, Levels & Trends in Child Mortality Report, 2017.)

More than half of newborn deaths can be prevented by scaling up low cost evidence based interventions in the form of antenatal, intra-partum and postnatal care packages. Early recognition of danger signs has been touted as an important factor associated with improved neonatal outcomes and survival (1,10).

The Integrated Management of Neonatal and Childhood Illnesses (IMNCI) strategy developed by the World Health Organisation provides standard case definition for serious neonatal illness. Five danger signs have been adopted by the Ministry of Health in Kenya and included in the Mother and Child Health Booklet (11) (Fig.3).



Stops breastfeeding well



Has difficult or fast breathing



Feels hot or unusually cold





Becomes less active Whole body becomes yellow

Fig.3: Danger Signs in The Neonate

(Source: Mother and Child Health Booklet, Ministry of Health, Kenya.)

1.4 LITERATURE REVIEW

1.4.1 Clinical Predictors of Serious Illness in Neonates

The young infants study, a multicentre trial in various countries, tested clinical signs and symptoms that predicted severe illness requiring hospitalization for sick infants. They recruited infants under 2 months of age brought with illness to the health facilities. A total of 8889 infants were enrolled in the study and of these, 3177 infants were aged 0-6 days while 5712 infants were aged 7-59 days. Seven symptoms or signs predicted severe illness: *History of difficulty feeding* (OR 10.0, 95% CI, 6.9-14.5), *History of convulsions* (OR 15.4, 95% CI, 6.4-37.2), *Movement only when stimulated* (OR 6.9, 95% CI, 3.0-15.5), *Respiratory rate of 60 breaths per minute or more* (OR 2.7, 95% CI, 1.9-3.8), *Severe chest indrawing* (OR 8.9, 95% CI, 4.0-20.1), *Temperature of 37.5 degrees c or more* (OR 3.4, 95% CI, 2.4-4.9) and *Temperature below 35.5 degrees* c (OR 9.2, 95% CI, 4.6-18.6). The presence of one sign in these infants had a high sensitivity and specificity (12).

Bang et al in a community field study in India investigated clinical criteria to identify sepsis or pneumonia in neonates requiring treatment or referral. They enrolled 3567 neonates aged less than 28 days in 39 villages and found that the simultaneous presence of any two of seven clinical signs: *Reduced or stopped sucking, Weak or no cry, Limbs becoming limp, Vomiting or abdominal distension, Baby cold to touch, Severe chest indrawing* or *Umbilical infection* predicted death from sepsis with high sensitivity and specificity (13).

Opiyo et al in a study of 1236 ill infants less than 60 days presenting to a rural district hospital in Kenya found that the presence of at least one of the following signs: *A history of feeding difficulty, Breathing difficulty, Cough or Abnormal behavior, Fever or Indrawing* had a high sensitivity (94%) and was 40% specific for severe illness in infants aged 0–6days. In infants aged 7–59 days, the presence of one of the following: *history of feeding difficulty, abnormal behavior, breathing difficulty, fast breathing or indrawing, cyanosis and a bulging fontanel*, had a high sensitivity (97%) and moderate specificity (56%) for very severe illness (14).

These studies validate the use of simple clinical signs both in hospital and community settings for the detection of a critically ill neonate. Six of these danger signs have been incorporated into the WHO IMNCI guidelines and the Mother and Child Health booklet by the Ministry of Health (Fig. 3)

1.4.2 Knowledge of Neonatal Danger Signs

Many women remain ignorant of the signs that portend serious illness in their neonates. In Eastern Uganda, Waiswa et al used the three delays model to describe deaths in newborn babies. Sixty-four newborn deaths were investigated over a one year period. They also undertook health facility surveys in all major public and private health facilities. Self-administered questionnaires among 52 health providers were used to assess knowledge on maternal and newborn care. They found that the major contributing delays leading to death were caretaker delays in problem recognition or in deciding to seek care. This study underscored the need to improve health seeking among mothers of neonates (15).

Ogunlesi et al in Southwest Nigeria conducted a cross-sectional survey assessing maternal knowledge and care-seeking behaviors for newborn jaundice. They surveyed 100 mother-infant dyads and found that more than half of the women enrolled in the study had good knowledge of neonatal jaundice and in this group, they had good care seeking behavior at the onset of illness and were least likely to develop kernicterus as a complication. The mothers with good knowledge were relatively older, had tertiary education and had previous experience with newborn jaundice. These findings highlight the need to support first time mothers and those with lower level of education (16).

In South-Western Uganda, Sandberg et al conducted a pre intervention community survey assessing maternal knowledge of neonatal danger signs. They sampled 765 pregnant and recently delivered women from 120 villages using a two-stage cluster sampling method. More than half of the mothers knew at least one danger sign but less than 15 % knew two danger signs. They found no significant association between women attending the recommended number of antenatal care visits and their knowledge of danger signs (adjusted OR 1.0, 95% CI 0.8–1.4). This study underscores the need to scale up health education of mothers in antenatal care as well as those discharged (17).

A study done by Gathoni et al in KNH found that nearly all mothers knew at least one newborn danger sign. However, a large percentage were unable to recognize convulsions and difficulty in breathing as danger signs. This study outlined the need for health education to mothers (18).

Michieka et al conducted an ethnographic multidesign study and assessed the care seeking and knowledge for neonatal illness in the Kisii community of Kenya. About 12% of the respondents thought "red eyes" were a neonatal danger sign. Just under 15% thought "becoming yellow" was a danger sign and 14% perceived a foul smelling cord as a danger sign. Close to half of the respondents were unaware of the signs that indicate serious neonatal illness and require urgent management. Inadequate knowledge of neonatal danger signs at the community level is of concern and should be addressed adequately (19).

Opondo et al investigating the utilization of the Mother and Child Health Booklet by health care workers and caregivers in Mbagathi District Hospital, found that the majority (89.4%) of women received these booklets before delivery. However, only 71.1% had the importance of the booklet explained to them. Further, less than half of women interviewed found information in the 'When to Return Immediately' section of the mother and child health booklet useful. This section highlights neonatal danger signs. This study underscored the need to scale up utilization of the Mother and Child Health booklet that contains vital information on several neonatal danger signs and also highlights when one is to seek care during neonatal illness (20).

In the 2014 KDHS, more than 95% of mothers reported seeing a skilled provider at least once during the course of their antenatal care for their most recent birth. Two in every three births in Kenya were delivered by a skilled provider and more than half of the women reported having postnatal care in the first two days post delivery. Inadequate knowledge of neonatal danger signs in Kenya is of major concern as many of these women are coming into contact with skilled providers during antenatal visits and delivery. There is urgent need to scale up delivery of health information to mothers and increase their knowledge of neonatal danger signs. This may lead to a reduction in primary delays including time to seeking care and thus effectively lead to a reduction in neonatal morbidity and mortality (6,7).

1.4.3 Unwell Newborns in the Postnatal Wards of Kenyatta National Hospital

A study by Ng'ang'a et al in KNH looking at the prevalence of early neonatal sepsis among term newborns in the postnatal wards found that of the 449 neonates recruited, about a third were at risk for early onset sepsis. Of the newborns at risk, 12% had early onset neonatal sepsis and more than half had probable sepsis. Follow up via telephone was done on the third day of life and 2% of all neonates with probable sepsis had died. They concluded that there was a large number of "apparently well" neonates in the postnatal wards who had sepsis and this was not picked up by caretakers or health care workers. Kihara et al in KNH found that close to one in five children born at KNH died by the 10th week of life after discharge. These findings further underscore the need for maternal health education on danger signs to improve recognition of serious neonatal illness and the need for regular screening in the postnatal wards prior to discharge (21,22).

1.4.4 Utility of Audio Visual Aids for Health Education

Increasingly more studies are validating the use of audiovisual aids for health education.

Rasul et al conducted a study analyzing the effectiveness of audio visual aids in the teaching learning process at The Islamia University of Bahawalpur. It was found that among both students and lecturers, audiovisual aids make the teaching learning process effective and provide in depth detail to topics of discussion further improving understanding (23).

Bruton et al conducted a randomized control trial assessing physiotherapy breathing retraining for asthma. Patients from general practices in the UK who had a physician diagnosis of asthma were randomized to receive either the video self guided intervention, three face-to-face breathing retraining sessions, or standard care. Quality of life scores were significantly higher in the video group (mean 5.40, SD 1.14) and in the face-to-face group (5.33, SD 1.06) than in the usual care group (5.12, SD 1.17) (24).

Desta et al evaluated the effect of a mobile video show for community behavior change on maternal and newborn health in Ethiopia. The mobile video show was offered to young adult females in 51 villages. Qualitative data was collected through participant discussions in selected villages and focus groups while quantitative data was obtained from an endline survey. Data from this survey found significant differences (p < 0.001) in knowledge and beliefs about antenatal care, labor, and birth notification to health extension workers between those who were exposed to the mobile video show and those who were not (25).

Gross et al, using an experimental intervention study, evaluated the relative effects of introducing motivational videotapes and/or peer counseling in special supplemental nutrition program for women, infants, and children (WIC) clinics serving African-American women on breast-feeding duration. They enrolled 115 women who were randomly assigned to receive either no intervention, a motivational video package intervention, a peer-counseling intervention, or both interventions. Intervention groups reported higher proportions of women breast-feeding at 8 and 16 weeks postpartum than controls emphasizing the need for healthcare workers to employ innovative ways to encourage an increase the duration of breastfeeding among mothers (26).

1.4.5 Standard of Antenatal and Post-Natal Care at Kenyatta National Hospital

Women delivering in the labor wards of KNH are admitted into the admitting postnatal ward of the day. Here they are observed for a few hours and discharged within 24 hours. Women in the postnatal wards receive information on neonatal danger signs from nurses and other health care workers as outlined in the Mother and Child Health Booklet. Some women do not receive this information while in the wards because of the high turnover of patients. This forms a gap in the information made available to these mothers and innovative ways should be employed to increase health education on neonatal danger signs. This should be done especially taking into consideration the sheer number of women delivering there and the health worker capacity.

2. STUDY JUSTIFICATION AND UTILITY

Worldwide, Kenya included, there has been minimal decline in neonatal mortality compared to the post neonatal under five mortality. Neonatal mortality contributes to about half of all under five deaths and this trend is alarming.

According to the Kenya Demographic Health Survey (KDHS) of 2014, a large number of women come into contact with health workers during their pregnancy and after delivery. Despite this fact, several studies done in KNH have found that acceptable knowledge of neonatal danger signs among these women has not been achieved. This represents a huge missed opportunity for health education. Lack of knowledge regarding neonatal danger signs among mothers contributes to delayed health seeking behaviour putting newborns at risk of long term disability and death. This must be addressed urgently. The utilisation of health care facilities for antenatal care, delivery services and postnatal care has not translated to a significant reduction in neonatal morbidity and mortality. This coupled with poor utilisation of the Mother and Child Health Booklet has led to little improvement of the same.

Improving neonatal care should increasingly employ strategies aimed at prevention and early treatment of neonatal illnesses. Preventive measures must be critically looked into and implemented. This can be done using low cost interventions targeted at antenatal, intrapartum and postpartum care.

Audiovisual aids for learning have proved useful in different health settings for improving health seeking behaviour. Notably, Desta et al in Ethiopia showed that audiovisual aids improve knowledge and beliefs about antenatal care, labour and birth notifications to health extension workers. The use of audiovisual aids for health messaging on neonatal danger signs may prove useful for increasing knowledge of neonatal danger signs among mothers/ caregivers and subsequently improving their care seeking behaviour, instilling confidence and empowering these mothers to better care for their newborns.

This study set out to evaluate the use of audiovisual aids and the standard of care compared to standard of care alone in the postnatal wards of KNH. No studies have been done to show the effectiveness of audiovisual aids for health messaging on knowledge retention of neonatal danger signs.

3. RESEARCH QUESTION

Is the use of audiovisual aids and the mother and child health booklet for health education associated with increased knowledge retention of neonatal danger signs among mothers of neonates born at Kenyatta National Hospital compared to use of the standard mother and child health booklet?

3.1 Null Hypothesis

There is no difference in knowledge retention between study participants randomized to receive information on neonatal danger signs using audiovisual aids and the mother and child health booklet compared to those who receive information through use of the standard mother and child health booklet alone.

3.2 Main Objective

To determine whether the use of audiovisual aids and the mother and child health booklet for health education among primiparous women increases their knowledge retention of neonatal danger signs compared to use of the standard mother and child health booklet alone during the first 4 weeks of life.

3.3 Secondary Objectives

To evaluate the acceptability of audiovisual aids for health messaging to primiparous women in the postnatal wards.

4. RESEARCH METHODOLOGY

4.1 Study Design

This was a cluster randomized controlled trial utilizing both qualitative and quantitative methods of data collection.

4.2 Study Population

The study population was primiparous women admitted in the KNH postnatal wards.

4.2.1 Inclusion Criteria

Each of the mother-baby dyads recruited met the following criteria in order to be included into the study:

- Mothers of neonates in KNH postnatal wards born via spontaneous vertex delivery
- Term neonates weighing \geq 2,500 grams
- Informed consent given by the mother

4.2.2 Exclusion Criteria

Study participants meeting any of the following exclusion criteria were excluded:

- Mothers of neonates in KNH postnatal wards born via caesarian section (to reduce contamination from longer durations of stay in hospital)
- Neonates with an illness requiring admission at the time of the study
- Neonates admitted in the newborn unit

4.3 Study Site

Kenyatta National Hospital is the largest national referral and teaching hospital in Kenya. It has 50 wards with a bed capacity of 1,800. An average of 1,000 deliveries are conducted in a month among mothers from varying socioeconomic spheres. KNH has 3 postnatal wards each of which admits mothers in an alternating manner every 3 days. Out of these, two wards were chosen randomly to participate in the study and using the fair coin method, each was assigned either the intervention or control ward.

4.4 Study Period

The study was carried out during the 2nd quarter of the year 2017.

4.5 Sample Size Determination

The desired sample size was calculated using the formula (27):

$$n \ge \frac{\{u\sqrt{[\pi_1(1-\pi_1)+\pi_0(1-\pi_0)]}+v\sqrt{[2\pi(1-\pi)]}\}^2}{(\pi_0-\pi_1)^2}$$

Where:

N = *Sample size for each group*

U=One-sided percentage point of the normal distribution corresponding to (100% - the power). The power =80%, u=0.84

V=Percentage point of the normal distribution corresponding to the (two-sided) significance level. The significance level= 5%, v=1.96

 π_1 = The expected proportion of knowledge awareness after the intervention, assumed to be 80%

 π_0 = The baseline expected proportion of knowledge awareness at baseline. From a study in Uganda [17], this was estimated to be 58%

$$\bar{\pi} = \frac{\pi_1 + \pi_0}{2}$$

The size of difference in proportions between the intervention and control arm that we set out to detect was therefore 22%.

Thus applying the formula we obtained 68 study participants for each arm. An increment of 10% was also included in the sample size so as to account for loss to follow up. Thus the total sample size was 75 people within each group making for a cumulative total of 150 study participants.

4.6 Recruitment Procedure

Two post natal wards in KNH were randomly chosen and using the fair coin method, each was assigned to either intervention or control wards. Selection of two wards was done so as to minimize contamination/ spillover between the intervention and control arms, this ensured that the women in the different groups did not come in to contact with each other. Using a fair coin to assign the intervention or control wards was to reduce bias.

The intervention arm received education using audiovisual aids complemented by information in the Mother and Child Health Booklet. Those in the control arm received the standard of care which included information contained in the Mother and Child Health Booklet.

Potential participants were identified by screening admission registers and participant files from each ward. Mother-baby dyads who met the eligibility criteria within 24 hours of delivery were identified and recruited until the desired sample size was attained in both arms. The identified dyads were requested to participate in the study after which a written informed consent was obtained. Recruitment of eligible women in both the intervention and control arms was done simultaneously. A pre-designed written consent form outlined the objectives of the study, the study methods and procedures to be followed as well as the potential benefits and risks of participating in the study. A consent discussion was conducted by the investigator to ascertain understanding of the information provided on the form. Any queries raised by the mother were elaborately clarified prior to signing the consent form. This process was free from coercion and was explicitly voluntary.

All eligible mothers who met the inclusion criteria and gave informed consent in both the intervention and control wards received a structured and pre-tested questionnaire prior to intervention assessing their baseline knowledge of neonatal danger signs.

Clustering of groups controlled for spillover effect among the mothers in different groups.

4.6.1 Intervention Group

After administration of the pre-intervention questionnaire, those in the intervention wards received information on neonatal danger signs through a pre- reviewed 8 minute video obtained from 'The Global Health Media Project: Warning Signs in Newborns for Mothers and Caregivers' (globalhealthmedia.org). These videos are available for free under a Creative Commons Attribution-Non Commercial-No Derivs 3.0 Un-ported license (CC BY-NC-ND 3.0).

These videos were viewed by a maximum of 4 mothers at any one time using a large tablet device. Visibility and audibility of the videos was confirmed first prior to starting the video. This group also received information contained in the Mother and Child Health Booklet from the "When to Return Immediately" section. Questions and clarifications were tackled at the end of each session to ensure understanding. Those who did not have a Mother and Child health booklet received a hand out of the "When to Return Immediately" section of the Mother and Child Health booklet.

The video was offered in either English or Kiswahili depending on the mothers' preference and outlined the following 10 danger signs:

1)	Trouble feeding	6)	Trouble breathing
2)	Less energy	7)	Yellowness of the body
3)	Fits	8)	Umbilical redness
4)	Cold body temperature	9)	Skin pustules
5)	Hot body temperature	10)	Red swollen eyes with drainage

4.6.2 Control Group

Those in the control ward received information on neonatal danger signs as elaborated in the Mother and Child Health Booklet, as part of the standard of care. Pictures in the "When to Return Immediately" section of the book that outlines danger signs in a neonate were emphasized. Additional signs not in the book but contained in the video such as *fits, umbilical redness, red swollen eyes with drainage* and *skin pustules* were mentioned and small handouts of these signs given to every mother. Questions and clarifications were answered at the end of each session to ensure understanding. Those who did not have a Mother and Child booklet received a hand out of the "When to Return Immediately" section of the Mother and Child Health booklet.

4.6.3 Follow-Up

All enrolled mothers in both groups received two follow-up phone call interviews to assess their knowledge of neonatal danger signs following the health education offered to them prior to discharge. These follow-up interviews were done at the end of the first week on day 7 and the end of the fourth week on day 28 of life.

4.6.4 Focus Group Discussions

Three focus group discussions were conducted in the intervention ward. Two groups had 6 mothers and one group had 8 mothers. They were randomly selected from those who met eligibility criteria and had already received the intervention. The FGDs were conducted by the PI and a research assistant (a medical anthropologist) prior to discharge. Each session took approximately 45 minutes. An interview guide was used and the interviews recorded were later transcribed for further coding and analysis. A framework approach was used in this analysis.

5. DATA COLLECTION, MANAGEMENT AND ANALYSIS

Data collection was carried out by the principal investigator and one research assistant (a clinical officer) for the quantitative arm and one research assistant (a medical anthropologist) for the qualitative arm.

5.1 Quantitative Data

Data on knowledge of neonatal danger signs was collected from the identified participants using a pre-tested questionnaire administered using direct interviews by the principal investigator and the research assistant. Prior to entry into Epi Info version 7.1.2.0, data forms were reviewed for validity and completeness by a different person from the one who completed the forms (double entry and verification). Data was exported to IBM SPSS Statistics Version 24 for cleaning and analysis. Baseline data for the women in the two arms of the study were compared to assess the success of randomization. Intention to treat analysis was used to analyze and compare the intervention and control arms for the primary endpoint. The aim of the analysis was to compare knowledge retention between those who received information on neonatal danger signs using audiovisuals and those who received information through the standard of care.

Chi-square statistics and t-tests of median were used to test for significance for categorical (knowledge of neonatal danger signs) and continuous data (e.g. Age of the baby) respectively.

We compared the delta change in knowledge scores from baseline between the two groups and for each of the 10 neonatal danger signs. This was done at week 1 and week 4.

Multivariable analysis was used to develop a multivariable logistic regression model describing the independent differences in knowledge recall between intervention and control groups.

5.2 Qualitative data

A framework approach was used to analyze the focus group discussions. The tape-recorded interviews were transcribed verbatim. Data obtained in Kiswahili was first translated to English. The phrases or words that defied translation were reported as excerpts along with their literal translation (28).

Data cleaning and labeling was done following which the principal investigator and an experienced data analyst read through the transcripts for familiarization prior to thematic analysis.

Thereafter, the predominant themes obtained from the coding process were highlighted and documented using selected quotes to represent each theme. Data was then entered into a Microsoft Excel sheet and inductive thematic analysis was done to classify responses with themes that outlined acceptability of the audiovisual aid. Uniformity of the codes was established to produce concepts which were grouped together based on similarity to form categories. Linkages were made among the various categories by identifying the core themes.

5.3 Dissemination of Results

The findings of the study will be distributed to The Department of Paediatrics and Child Health at The University of Nairobi. Copies will also be availed to the University of Nairobi library. The results will be also be made available to health care workers within KNH and other policy makers will be appraised through conference presentations and publications. This study will provide information that can be used by health care planners and policy makers to possibly implement health education using audiovisual aids. This is a low cost intervention that may see an improvement in knowledge of neonatal danger signs.

6. CONTROL OF ERRORS AND BIASES

6.1 Completeness:

1. Avoiding missing data:

- Missed phone call interviews were rescheduled to the nearest date possible and frequent reminders of the planned interview date and time were done using text messaging.

-All questionnaires were checked manually for completeness of the data prior to data entry.

2. The research assistants were trained and provided with standard definitions of terminologies used in the questionnaire to ensure uniform interpretation of the terms.

6.2 Accuracy/Correctness

- Technical errors were minimized by ensuring audibility and visibility of the audiovisual aids. All women were asked to confirm audibility and visibility prior to viewing the videos. This was aimed at avoiding misinterpretation of the signs documented in the videos.
- 2. Double entry of data was done to increase accuracy of data sets.

6.3 Data Verification and Audit Procedures

Scheduled weekly audits were done to monitor missing, inaccurate data, and also lack of follow-up interviews.

6.4 Focus Group Discussions

- 1. The principal investigator was present for every focus group discussion to ensure consistency.
- 2. The principal investigator and an experienced data analyst (a medical anthropologist) read through the transcripts for familiarization and full emersion prior to thematic analysis.

7. STUDY ASSUMPTIONS

- 1. The enrolled mothers provided correct information for the questions asked during the interview session.
- 2. There was no misinterpretation of questions.

8. STUDY LIMITATIONS

- 1. The study was dependent on the willingness of the participants to provide accurate and truthful information. Accurate and concise information was given to the study participants and they were offered an opportunity to raise any queries or concerns about the study.
- 2. The study required recall on the part of the respondents and answers for the questions contained in the questionnaires may have been influenced by recall bias. The questions prone to recall bias included those assessing knowledge retention and those assessing health seeking behaviour.
- 3. The study was limited to primi-parous women and thus the study was prone to loss of external validity.
- 4. The study was open label with no blinding.

9. ETHICAL CONSIDERATIONS

Authorization To Conduct The Study

Permission was obtained from the Kenyatta Hospital- University of Nairobi Ethics and Research Committee (KNH-UON ERC) to collect and analyze the data for the study as part of the thesis dissertation. Copies of this protocol, the informed consent form as well as any subsequent modifications to either document were presented to the above named committee for written approval prior to commencing the study.

The videos used in this study were obtained from 'The Global Health Media Project' (globalhealthmedia.org). These videos are made available for free under a Creative Commons Attribution-Non Commercial-No Derivs 3.0 Un-ported license (CC BY-NC-ND 3.0).

Autonomy

The study was carried out after informed consent was obtained from mothers/caregivers of the neonates. The participants were allowed to withdraw from the study at any time.

Confidentiality

Strict confidentiality was observed throughout the entire study period and was held in trust by the principal investigator and the research staff. The study participants were given study identification numbers and no personal identification data was recorded.

Risks

No experimental drugs were employed in this study. The videos provided for health education on neonatal danger signs were non-invasive and posed no acute or long-term risks to the participants.

Safety

The study did not interfere with the overall care of the neonates while in the wards. Children with illness requiring admission or presenting with any of the danger signs were referred for urgent medical attention.

Benefits

The study provided education to the mothers on neonatal danger signs and knowledge on when to seek urgent medical attention during illness in the neonate. This increased the knowledge of danger signs and improved the mothers' confidence in her ability to care for her baby.

10. RESULTS

10.1 Descriptive Analysis of Baseline Characteristics

A total of 153 mother- baby dyads were enrolled into the study at baseline with 77women in the intervention and 76 women in the control wards respectively. The median age of the mothers was 22 years (IQR 21 - 25 years). The figure below shows the age distribution of the mothers.



Figure 4: Distribution Of Mothers' Age (Years) By Treatment Arm



Figure 5: Maternal Level of Education

Overall 75% of the women had completed at least secondary level education and above (Fig.5).

			RANDOMIZATION ARM						
Table 1: BASELINE CHARACT	ERISTICS	Α	Α			Total		P-	
		Vide	60	Con	trol			value	
		n	%	n	%	Ν	%	_	
	Median	22		23		22			
Median Maternal age	Percentile 25	20	20		21		21		
	Percentile 75	25		25		25		_	
Level of education	≥Secondary complete	57	74	59	77.6	116	75.8	0.8	
	Salaried employee	27	35.0	25	32.9	52	33.9		
Employment status	Casual /Self employed	10	12.9	10	13.2	19	12.4	0.4	
	Unemployed	40	51.9	41	53.9	81	52.9	_	
Marital status	Married	57	74	61	80.3	118	77.1	0.3	
Warnar status	Single/Divorced/	20	26	15	19.7	35	22.9	0.3	
Place of ANC	Public health facility	54	70.1	56	73.6	110	71.9	0.3	
Thee of Aire	Mission/Private Hosp.	23	29.9	20	26.3	43	28.1	1	
Number of ANC Visite	≤3	24	31.2	13	17.1	37	24.2	0.2	
Number of AINC VISIts	≥4	53	68.8	63	82.9	116	75.8	0.2	
Have Mother- Child booklet	Yes	36	46.7	35	46.1	71	46.4	0.2	
Have Moner- Child bookiet	No/Other	41	53.2	41	54	82	53.6	_ 0.2	
Given info on danger signs	Yes	18	23.4	12	15.8	30	19.6	0.3	
	Health Care Workers	51	66.2	61	80.3	112	73.2	0.05	
Source of health info	Husband/spouse	2	2.6	2	2.6	4	2.6	0.9	
	Family/member	35	45.5	30	39.5	65	42.5	0.5	
	Media	21	27.3	10	13.2	31	20.3	0.03	
Informed about PNC visit	Yes	55	71.4	63	82.9	118	77.1	0.1	
	48-72 hrs	8	10.3	9	11.8	17	11.1		
Return for review post-discharge	1-2 weeks	3	3.8	5	6.5	8	5.2	0.9	
rectain for review post discharge	6 weeks	44	57.1	49	64.5	93	60.7		
	Don't know		28.5	13	17.1	35	22.9		

Table 1: Baseline Characteristics of Enrolled Participants

Overall 77% of the women enrolled in this study were married. A third (33.9%) of the women were in salaried employment, half (52.9%) were unemployed and a small proportion (12.9%) were self employed.

Three quarters (75%) of the women had attended at least 4 antenatal care clinics, most of them (71%) at a public health facility. Asked about when they started attending ANC, about two-thirds of the mothers in both arms reported starting their first ANC visit between the 4th and 6th month of gestation. Only 46% of the mothers had the mother and child booklet and only one in five women (19%) had received information on neonatal danger signs. There was reasonable communication regarding postnatal clinic, with 77% reporting that they had been informed when to come back. Nevertheless, the quality of knowledge was wanting with 11% of the women being aware of the need to have a visit in the first 48 hours and less than 5% being aware of the 2 week visit.

As shown in Table 1, randomization was successful with the two arms of the study being comparable on social, demographic, health seeking behavior and access to health information. Minor difference were noted in their sources of health information with groups differing on the use of media for health information.

10.2 Completeness of Follow up

A total of 153 women met the eligibility criteria and were recruited into the study. Early in the study there was a slight difference in the proportion of women followed up with 85% of women in the intervention arm and 92% in the control arm being surveyed at week one. However by the end of the 4th week, 72% of the participants in both arms of the study being surveyed as shown in Fig. 6 and Table 2. The dropout rate at the end of the study was 28% with 21 women in both arms being lost to follow.



Fig.6: Completeness of Follow Up

The women who were lost to follow up in both groups were similar based on level of education, employment status, marital status, having the Mother and Child Health booklet and prior information given on danger signs as shown in Table 2. Women who were lost to follow up had significantly fewer ANC visits compared to those retained in the study (p=0.004). This was a consistent finding in both treatment arms.

Baseline C	Characteristics	Lost to follow up	Not lost to follow up	P- value
	Tertiary	14 (23.3)	46 (76.7)	
	Tertiary incomplete	3 (23.1)	10 (76.9)	-
Maternal level of	Secondary	14 (32.6)	29 (67.4)	0.6
education	Secondary incomplete	5 (25.0)	15 (75.0)	0.6
	Primary	5 (45.5)	6 (54.5)	-
	Primary incomplete	1 (16.7)	5 (83.3)	-
	Salaried employee	11 (20.8)	42 (79.2)	
Employment status	Casual laborer	0 (0.0)	2 (100.0)	
Employment status	Self-employed	3 (17.6)	14 (82.4)	0.2
	Unemployed	28 (34.6)	53 (65.4)	-
	Married	30 (25.6)	87 (74.4)	
Marital status	Single	11 (32.4)	23 (67.6)	0.2
	Divorced/Separated	1 (100.0)	0 (0.0)	-
Number of ANC Visits	>4	20 (30.3)	46 (69.7)	0.004
Hove Mether Child	Yes	16 (23.2)	53 (76.8)	
have Mouler-Clillu	No	25 (33.3)	50(66.7)	0.3
DOOKIEL	Other	1 (16.7)	5 (83.3)	-
Given information	Yes	9 (31.0)	20 (69.0)	0.6
on danger signs	No	32 (26.0)	91 (74.0)	0.6

Table 2: Baseline Characteristics Of Those Lost To Follow Up Vs.

Those Not Lost To Follow Up

10.3 Neonatal Mortality During the Course of Follow up

Four neonates developed danger signs within the course of follow up. Three (3.8%) neonates in the intervention arm developed danger signs all within the first week, and of these, 2 were admitted to hospital and one died while at home. The neonate who died developed danger signs at night and they were unable to seek timely care leading to unfortunate demise while at home. In the control arm only one (1.3%) neonate developed danger signs on day 10 of life and was treated without requiring admission to a health care facility. There was a higher rate of adverse outcomes in the intervention arm compared to the control arm but this difference was not significant (p=0.4).

10.4 Baseline Knowledge of Neonatal Danger Signs

The most frequently mentioned signs in both arms included *trouble feeding* (39%) and *hot body temperature* (67%). Among the least known danger signs in both groups were *fits* (3.3%), *cold body temperature* (6.5%), *umbilical redness* (0.7%), *skin pustules* (3.3%), and *red swollen eyes with drainage* (2%).

	RANDOMISATION ARM						
KNOWN DANGER SIGNS	Totals	A: Intervention	B: Control	P- value			
	N(%)	N(%)	N(%)				
Trouble feeding	61 (39.9)	30 (39.0)	31 (40.8)	0.8			
Less energy	36 (23.5)	17 (22.1)	19 (25.0)	0.7			
Fits	5 (3.3)	3 (3.9)	2 (2.6)	0.7			
Cold body temperature	10 (6.5)	3 (3.9)	7 (9.2)	0.2			
Hot body temperature	103 (67.3)	53 (68.8)	50 (65.8)	0.7			
Trouble breathing	15 (9.8)	7 (9.1)	8 (10.5)	0.8			
Yellowness of the body	26 (17.0)	15 (19.5)	11 (14.5)	0.4			
Umbilical redness	1 (0.7)	1 (1.3)	0 (0.0)	0.3			
Skin pustules	5 (3.3)	5 (6.5)	0 (0.0)	0.02			
Red swollen eyes with drainage	3 (2.0)	1 (1.3)	2 (2.6)	0.6			
None	15 (9.8)	7 (9.1)	8 (10.5)	0.8			

Table 3: Baseline Knowledge of Neonatal Danger Signs

Women in the intervention and control arms of the study were compared for their baseline knowledge of danger signs. At baseline, mothers in the intervention group had significantly better knowledge than the control group for only one symptom, *skin pustules* (6.5% versus 0%) (p=0.02) as shown in Table 3. In addition, mothers in the control group had better knowledge than the intervention group for *cold body temperature* (9.2% versus 3.9%) but this difference did not achieve statistical significance (p=0.2). About 10% of mothers in both groups were unable to identify any neonatal danger sign.

10.5 Knowledge of Neonatal Danger Signs at Week 1



Fig. 7: Percentage Increase in Knowledge of Neonatal Danger signs from Baseline (Week 1)

At week 1, women in both groups exhibited an increase of knowledge in all the 10 areas of assessment. Overall, in both arms of the study at week 1, there was a modest increase in the proportion of women demonstrating knowledge regarding danger signs post intervention. This increase ranged from as low as 18.2% for *cold body temperature* and *umbilical redness* to a high of 58.4% for *trouble in breathing* for women in the intervention arm of the study. The increase in knowledge for women in the control arm was from a low 11.8% in identification of *fits* as a danger sign and the highest improvement in knowledge was in three areas, *trouble feeding* (35.5%), *trouble feeding* (36.8%) and *yellowness of the body* (34.2%).

The proportionate increase in knowledge was large.

In the Control arm: At week 1, there was an increase in the number of women identifying *umbilical redness* (0 % to 17.1%), *skin pustules* (1% to 13%), *trouble breathing* (10.5% to 40.8%) and *red swollen eyes with drainage* (2.6% to 17.1%) (Fig.7).

<u>In the intervention arm</u>: At week 1, there was a greater increase in knowledge of 6 of the 10 areas of assessment compared to the control group (Fig.6). There was an increase in the women identifying *red swollen eyes with drainage* (1.3% to 29.9%), *umbilical redness* (1.3% to 18.2%), *trouble breathing* (9.1% to 64.9%), *fits* (3.9% to 20.8%), and *cold body temperature* (3.9% to 18.2%).

Table 4 shows the proportionate increase in knowledge and compares the intervention and control arm of the study at 1 and 4 weeks of follow-up. Women in the intervention arm were twice as likely to identify *trouble breathing* (OR 2.5 95% CI 1.25-5) and *red swollen eyes with drainage* (OR 2.5 95% CI 1.4-5) compared to controls. (Table 4).

Proportion of Improvement	Week	1		Odds	We	ek 4		Odds
in Knowledge of Neonatal Danger Signs	A %	B %	p- value	ratio (95% CI)	A %	B %	p- value	ratio (95% CI)
Trouble feeding	36.4	35.5	0.9	1.0 (0.5-2)	67.5	69.7	0.8	1.0 (0.5-2)
Less energy	33.8	23.7	0.2	1.6 (0.9-3.3)	66.2	81.6	0.01	2.5 (1.25-5)
Fits	20.8	11.8	0.1	2 (0.9-5)	75.3	86.8	0.04	2.5 (1.1-5)
Cold body temperature	18.2	21.1	0.6	0.8 (0.4-2)	85.7	88.2	0.6	1.25 (0.5-3.3)
Hot body temperature	22.1	25.0	0.6	0.9 (0.4-1.6)	83.1	78.9	0.5	0.7 (0.3-1.6)
Trouble breathing	58.4	36.8	0.003	2.5 (1.4-5)	55.8	78.9	0.001	3.3 (1.6-5)
Jaundice	32.5	34.2	0.9	0.9 (0.5-1.6)	71.4	75.0	0.6	1.25 (0.6-2.5)
Umbilical redness	18.2	17.1	0.8	1.1 (0.5-2.5)	87.0	90.8	0.4	1.6 (0.6-5)
Skin pustules	22.1	13.2	0.1	2 (0.9-5)	77.9	89.5	0.04	2.5 (1.1-5)
Red swollen eyes with drainage	29.9	15.8	0.03	2.5 (1.25-5)	74.0	92.1	0.001	5 (2-10)

 Table 4: Comparison of Improvement in Recognition Of Neonatal Danger Signs

10.6 Knowledge of Neonatal Danger Signs at Week 4



Fig. 8: Percentage Increase in Knowledge of Neonatal Danger signs from Baseline (Week 4)

At week 4, women in both groups exhibited a decay in knowledge in all the 10 areas of assessment from week 1. Nevertheless, in both arms of the study at week 4, a proportion of women continued to demonstrate knowledge regarding danger signs post intervention. The increase in knowledge from baseline to week 4 ranged from as low as 10.4% for *cold body temperature* to a high of 42.8% for *trouble in breathing* for women in the intervention arm of the study. The increase in knowledge for women in the control arm was from a low 4% in identification of *less energy* and *cold body temperature* to a high of 14.5% for *trouble breathing* (Fig 8). Women in both groups recorded a decay in knowledge to below baseline for *hot body temperature*, this was from a high of 68.8% to 64.9% for women in the intervention arm and from 65.8% to 57.9% for those in the control group.

<u>In the Control</u>: Women in this group continued to correctly identify signs such as *trouble feeding* (50%) and *red swollen eyes with drainage*. These women were less likely to identify *less energy*, *fits, trouble breathing, skin pustules* and *red swollen eyes with drainage* (Table 4).

<u>In the Intervention</u>: As shown in Table 4, women in the intervention group had a fivefold increase in their knowledge of *red swollen eyes with drainage* (OR 5 95% CI 2-10), a threefold increase in knowledge of *trouble breathing* (OR 3.3 95% CI 1.6-5), and a twofold increase in their knowledge of *less energy* (OR 2.5 95% CI 1.25-5), *fits* (OR 2.5 95% CI 1.1-5) and *skin pustules* (OR 2.5 95% CI 1.1-5). There was decay in knowledge to below baseline for hot body temperature (p=0.31).

Known danger signs	Arm	Baseline (%)	1 week (%)	Δ change X	4 week (%)	Δ change Y
Trouble feeding	А	39.0	63.6	24.6	55.8	16.8
Trouble reeding	В	40.8	67.1	26.3	50.0	9.2
Lagg aparat	А	22.1	44.2	22.1	42.9	20.8
Less ellergy	В	25.0	35.5	10.5	28.9	3.9
Fito	А	3.9	20.8	16.9	26.0	22.1
Fits	В	2.6	11.8	9.2	13.2	10.6
Cold body temperature	А	3.9	18.2	14.3	14.3	10.4
	В	9.2	23.7	14.5	13.2	4
Hathada tana antuna *	А	68.8	79.2	10.4	64.9	-3.9
Hot body temperature *	В	65.8	77.6	11.8	57.9	-7.9
Trouble breathing	А	9.1	64.9	55.8	51.9	42.8
Trouble breathing	В	10.5	40.8	30.3	25.0	14.5
Jour dias	А	19.5	44.2	24.7	35.1	15.6
Jaundice	В	14.5	38.2	23.7	26.3	11.8
Line il col no de ess	А	1.3	18.2	16.9	13.0	11.7
Uniblical rediless	В	0.0	17.1	17.1	9.2	9.2
Skin nustulas	А	6.5	24.7	18.2	24.7	18.2
Skin pustules	В	0.0	13.2	13.2	10.5	10.5
Red swollen eyes with	A	1.3	29.9	28.6	26.0	24.7
drainage	В	2.6	17.1	14.5	7.9	5.3

10.7 Comparison of Knowledge of Neonatal Danger Signs between Groups Table 5: Comparison of knowledge of danger signs between groups

At week 1, women in the intervention arm had greater knowledge scores in 6 of the ten areas of assessment but the differences were only significant for *trouble breathing* and *red swollen eyes with drainage* (Table 3).

At week 4, women in the intervention had significantly greater knowledge scores in all of 10 areas compared to controls but this was only statistically significant for *less energy*, *fits*, *trouble breathing*, *skin pustules* and *red swollen eyes with drainage* (Table 5).

It was noted that at week 4, both groups demonstrated decay in knowledge for all the 10 danger signs with both groups demonstrating a decay to below baseline on the topic of *hot body temperature* but there was no difference between the two groups (p=0.31).

Women in the control group were able to correctly identify signs such as *less energy*, *fits*, *trouble breathing*, *umbilical redness*, *skin pustules* and *red swollen eyes with drainage*.

10.8 Multivariate Analysis of Independent Differences In Knowledge Recall Between Intervention And Control

When placed in a logistic regression model for multivariate analysis, women in the intervention arm were noted to have a threefold increase in their knowledge of *trouble breathing* (OR 3.3, 95% CI 2-5) and a twofold increase in their knowledge of *skin pustules* (OR 2, 95% CI 1.1-3.3) and *red swollen eyes with drainage* (OR 2, 95% CI 1.1-5).

Neonotel Dongon Sign	Multivariate	95% C.I	p-value	
Neonatai Danger Sign	Odds Ratio	Lower	Upper	F
Trouble breathing	3.3	2	5	0.000
Skin pustules	2	1.1	3.3	0.05
Red swollen eyes with drainage	2	1.1	5	0.02

Table 6: Multivariate Analysis of Independent Differences in Knowledge Recall between Intervention and Control

10.9 Assessment of Acceptability of the Audiovisual Aids for Health Education

A total of 3 focus group discussions were conducted in the intervention arm. The groups were homogenous in regard to composition as they were all drawn from the same ward. Two groups had 6 mothers each while one group had 8 mothers in it. Each discussion lasted 45minutes.

Of the 20 mothers in the groups, 85% (17/20) reported that the videos were beneficial, easy to follow and allowed for improved understanding of these signs. Three of the mothers (15%) thought the videos were not beneficial as they were not available in their native language, they were too short and they would not have access to them while at home.

The results of the discussions are summarized into 3 main themes:

- 1) Informative nature of the videos
- 2) Elimination of myths
- 3) Accessibility

10.9.1 Informative Nature of the Videos

The video was informative in that the videos enabled them to recognize signs of serious illness not only in their own babies but also other babies within the community. They would then be able to rush these sick babies to the hospital early enough before the onset of untoward complications.

"I didn't know that I could carry my child without clothes so that he/she becomes warm so I learnt that if the child is cold I can help him/her with first aid of putting him/her on my body so that they can get warmth." (Group 1)

"It has helped me because it has showed me the importance of bringing a child to the hospital early if he/she has yellow fever or has eye problems." (Group 3)

10.9.2 Elimination of myths

There was consensus that the videos had eliminated some myths about danger signs that included the belief that a protein reaction is the cause of skin disease, treating discharging eyes with breast milk is a cure, reduced energy in the baby is due to satiety and shaking of the body (fits) is because of growing nerves.

"...and again there is that skin disease so sometimes one thinks it is protein or a bad reaction towards something but it is different." (Group 1)

"...the one who had taught me showed me that when the eyes start removing that dirt you put the milk from the breasts but I have come to know that it can be a disease." (Group 2)

"I heard if you see a child shake all of a sudden the eyeballs are in the middle and fixed looking at you, I heard that it is nerves developing, the baby is okay, it is just that the nerves are growing." (Group 1)

10.9.3 Accessibility

Most mothers agreed that the videos used in this study need to be more accessible even in the local setting at the community level. Some of the suggestions given as to how this can be achieved are: making the videos available in CD- ROMs, use of community educators, use of social media, use of local television channels, having the videos in the clinics and the training women champions to be ambassadors.

"If you would be having CDs it would be good so that you give us." (Group 1)

"The easiest way is to put it in clinics those in rural areas so that it reaches them because even if we tell them, if they have not seen it they cannot understand till you put it in the clinics in rural areas." (Group 2)

"...also along with that TV, it is also good you use people to educate them, when they watch you also educate them so that they know." (Group 2)

11. DISCUSSION

The primary objective of this study was to determine whether the use of audiovisual aids for health messaging to primi-parous women in the post natal wards of Kenyatta National Hospital would improve their knowledge of neonatal danger signs. The key findings of this study include the fact that there was poor knowledge of danger signs at baseline for all women. We also found that use of audio-visual aids and face to face teaching are effective for short term knowledge retention and audio-visual materials are effective for long-term knowledge retention of neonatal danger signs.

A large majority of women in our study relied on health care workers for information on newborn care yet few of those who had the mother and child health booklet had the "When to Return Immediately" section of the booklet explained to them. This is similar to findings by Amolo et al who found that more than half of the mothers in our setting relied principally on health care providers rather than family, media and peers for information on newborn care (29).

Amolo et al investigating the knowledge and attitude of postnatal mothers on essential newborn care practices at KNH found that lack of antenatal education was an independent predictor of poor maternal knowledge of newborn care. It is then not surprising that women in our study, both in the intervention and control groups had poor knowledge of signs such as *fits, trouble breathing, cold body temperature, umbilical redness, skin pustules,* and *red swollen eyes with drainage.*

These findings are congruent with those of Gathoni et al who found that a large percentage of women in the postnatal wards were unable to recognize convulsions and difficulty in breathing as danger signs. This study outlined the need for health education to mothers. Kibaru et al at Nakuru Central District, also found that few women were able to correctly identify signs of serious illness in their newborns. This needs to be addressed urgently if we are to reduce neonatal morbidity and mortality by increasing the ability of women to correctly identify signs of critical illness in their newborns (18, 29,30).

Both videos and face to face teaching were equally effective for short term knowledge of neonatal danger signs. This was seen in both treatment arms with a significant increase in knowledge from baseline for all danger signs at the end of week 1. These findings are similar to those of Bruton et al, who in evaluating physiotherapy breathing retraining for asthma found that videos and face to face teaching were equally effective at improving the quality of life among asthmatics. These methods should increasingly be employed for delivery of health messages (24).

In this study, the use of audiovisual aids was associated with increased and sustained long term knowledge of neonatal danger signs for both the intervention and control arms. These findings are similar to those of Desta et al in Ethiopia who found that a mobile video show was associated with improved knowledge and beliefs about antenatal care, labor and birth notification to a health extension worker. The proposed mechanisms by which the audiovisual aids in this study were effective include the ability of the mothers to visualize the signs, the use of real life situations and the availability of the video in both English and Kiswahili (25).

There was decay to below baseline for *hotness of body* for both groups post intervention. We postulate that the new acquired knowledge (about other danger signs) may have overshadowed their previous knowledge of this particular sign. In the intervention arm, we also postulate that the manner in which this sign is portrayed may require revision.

In both the intervention and control groups, there was a proportion of mothers who did not have improvement in their knowledge of danger signs post intervention in many areas, and we postulate that this may come from the style of presentation of the material that may need review by the authors. This would lead to improved understanding and knowledge retention of danger signs.

The second objective was to assess the acceptability of the audiovisual aids for health education. A vast majority of mothers reported that the videos were beneficial, easy to follow and allowed them to visualize the danger signs improving understanding. Many of the mothers thought it would be useful to have these videos in various areas within the hospital like the clinics but also in the community. About 15% were wary of the use of these videos because they were not available in their native language, they were too short and they would not have access to them while in the community. This limitation may be greatly outweighed by the potential advantage of using these videos.

It is important to note that no similar studies have been conducted assessing the effectiveness of audiovisual aids on improving knowledge of neonatal danger signs. However, being a resource limited setting with low numbers of staff, the use of this videos may improve the delivery of health messages.

Randomization was a key strength in this study and enabled minimization of selection bias. This was however not fully achieved as there were minor differences between groups at baseline for source of health information. There were also statistically significant differences between those who were lost to follow up in both treatment arms.

Loss to follow up (28% in each arm) was a weakness for this study. Many women were lost to follow up especially those with fewer ANC visit which may have been a reflection of their desire to utilize health care services.

This may have led to attenuation of the findings on effectiveness of the intervention. Dropout rates were similar to those of Kihara et al who investigated the efficacy of phone based counseling for promoting and supporting primi-parous women to exclusively breast feed. This study conducted in Kenyatta National Hospital had an overall dropout rate of 30%, similar to rates seen in our study (31).

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12. CONCLUSIONS

1. The use of audiovisual aids for health education was associated with sustained knowledge of neonatal danger signs at week 4. It was also associated with an increase in long term memory of neonatal danger signs such as *less energy*, *fits*, *trouble breathing*, *skin pustules* and *red swollen eyes with drainage*.

2. Audiovisual aids were beneficial, and allowed mothers to visualize the danger signs thus improving understanding.

13. RECOMMENDATIONS

1. Audiovisual aids including videos outlining neonatal danger signs should be availed at points of contact with mothers within health care facilities i.e. the antenatal clinics, postnatal wards and outpatient clinics.

2. Available videos for health messaging to mothers about neonatal danger signs should be translated into various vernacular languages and distributed to various healthcare facilities around the country in order to increase reach.

3. The sign hotness of body which may require re-evaluation as content in the video.

4. Similar studies in different settings should be carried out to further validate the above findings.

14. CONFLICT OF INTEREST

There was no conflict of interest in this study.

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16. APPENDICES

16.1 CONSENT FORM FOR PARTICIPATION IN THE STUDY

Code Number of Mother-Baby Pair: _____ Date (Dd/Mm/Yy): _____

<u>Study Title:</u> The Effectiveness and Acceptability of Audiovisual Aids for Increasing Knowledge of Neonatal Danger Signs among Primi-parous Women In The Postnatal Wards Of Kenyatta National Hospital.

Investigator:

Dr. Emily M. Njuguna (MBChB), Tel Number: 0720- 612996

Department Of Paediatrics and Child Health, University Of Nairobi.

Supervisors:

a) Prof. Ruth W. Nduati (MBChB, M. MED, MPH)

Professor, Department Of Paediatrics And Child Health, University Of Nairobi.

b) Prof. Rachel N. Musoke (MBChB, M.MED, F. Neonatology)

Professor And Neonatologist, Department Of Paediatrics And Child Health, University Of Nairobi.

c) Dr. Boniface O. Osano (MBChB, MMED, MPhil-MCH)

Lecturer, Department Of Paediatrics And Child Health, University Of Nairobi.

d) Dr. Juliana Muiva (MBCHB, MPhil-Paediatric Gastroenterology)

Paediatric Gastroenterologist, Kenyatta National Hospital.

Investigator's Statement:

We are requesting you and your child to kindly participate this research study. The purpose of this consent form is to provide you with the information you will need to help you decide whether to participate in the study. This process is called 'informed consent'. Please read this consent information carefully and ask any questions or seek clarification on any matter concerning the study with which you are uncertain. The investigator will be available to answer any questions that arise during the study and afterwards.

Introduction:

Newborns are susceptible to serious illness especially in the first few days of life. Failure to recognize signs of serious illness in the newborn has been shown to lead to serious consequences. This study seeks to find ways of increasing knowledge and ability of mothers to identify signs of serious illness early and to seek care in the appropriate time to avoid complications.

Benefits:

You will also receive education on the danger signs to look out for and what steps you can take if you notice any of these signs. The results of the research will also be used to improve health education on danger signs given in this hospital and to other caregivers.

<u>Risks:</u>

There will be no risks to you or your child and no invasive procedures will be carried out in the study that may harm your child.

Voluntariness:

The study will be fully voluntary. There will be no financial rewards to you for participating in the study. One is free to participate or withdraw from the study at any point. The study will call for some of your time. You will receive health education and may also be called upon to take part in a group discussion. Refusal to participate will not compromise you or your child's care in any way.

Confidentiality:

All the information obtained from you will be held in strict confidentiality. Any information that may identify you or your child will not be published or discussed with any unauthorised persons. No specific information regarding you, your child or your family will be released to any person without your written permission. Your research number will be used in place of your names. We will however discuss overall findings regarding all children who participated in the study without revealing you or your child's identity.

Problems Or Questions:

If you ever have any questions about the study or about the use of the results you can contact the principal investigator, Dr Emily M. Njuguna by calling 0720-612996.

If you have any questions on your rights as a research participant you can contact the Kenyatta National Hospital Ethics And Research Committee (KNH- ERC) By Calling 2726300 Ext. 44355.

I ______having received adequate information regarding the study research, risks, benefits hereby agree / disagree (cross out as appropriate) to participate in the study with my child. I understand that our participation is fully voluntary and that I am free to withdraw at any time. I have been given adequate opportunity to ask questions and seek clarification on the study and these have been addressed satisfactorily.

Parents Signature: _____ Date _____ I _____ declare that I have adequately explained to the above participant, the study procedure, risks, benefits and given him /her time to ask questions and seek clarification regarding the study. I have answered all the questions raised to the best of my ability.

Interviewer's Signature Date

FOMU YA IDHINI

Nambari Ya Utafiti Ya Mama Na Mtoto: _____

Tarehe: _

<u>Kichwa Cha Utafiti</u>: Matumizi Ya Vifaa Vya Kusikia Na Kuona Ili Kunongeza Ujuzi Wa Akina Mama Waliozaa Mara Ya Kwanza Kuhusu Ishara Za Hatari Zinazo Weza Kutokea Kwa Watoto, Katika Hospitali Kuu Ya Kenyatta

<u>Mtafiti:</u>

Dkt. Emily M. Njuguna (MBChB), Nambari Ya Simu: 0720- 612996

Idara Ya Afya Ya Watoto, Chuo Kikuu Cha Nairobi

Wasimamizi:

- a) Prof. Ruth W. Nduati (MBChB, MMED, MPH)Profesa, Idara Ya Afya Ya Watoto, Chuo Kikuu Cha Nairobi.
- b) Prof. Rachel N. Musoke (MBChB, MMED, F. Neonatology)Profesa, Idara Ya Afya Ya Watoto, Chuo Kikuu Cha Nairobi.
- c) Dr. Boniface Osano (MBCHB, MMED, MPhil-MCH)Mkufunzi, Idara Ya Afya Ya Watoto, Chuo Kikuu Cha Nairobi.
- d) Dr. Juliana Muiva (MBCHB, MPhil-Paediatric Gastroenterology)
 Daktari Wa Watoto, Hospitali Kuu Ya Kenyatta.

<u>Taarifa Ya Mtafiti:</u>

Tunawaomba wewe na mtoto wako kushiriki katika utafiti huu. Lengo la fomu hii ni kuwapa maarifa mnaohitaji ili muweze kuamua kama mtashiriki katika utafiti huu. Tafadhali soma fomu hii kwa makini na uulize swali kuhusu jambo lolote ambalo hulielewi. Mtafiti ataweza kuyajibu maswali yote yatakayo ulizwa kwa muda wa utafiti na hata baadaye.

<u>Utangulizi:</u>

Watoto wachanga wanaweza kuugua kwa hali ya mahututi, sanasana kwa siku tano za kwanza za maisha yao. Kutoweza kutambua magonjwa yanayowakumba kwa wakati huo unamadhara mengi. Utafiti huu unalenga kukuwezesha kupata maarifa ya kuweza kuyatambua mapema ishara za ugonjwa, na kutafuta usaidizi kwa wakati ufaao ili kuepuka shida zaidi.

Manufaa:

Utapokea mafunzo kuhusu ishara za hatari ambazo wafaa kuyatambua kwa haraka, na pia hatua utakazochukua unapotambua ishara hizi. Matokeo ya utafiti huu pia yatatumiwa kuimarisha elimu ya kiafya ya ishara za hatari katika hospitali hii na kwa wauguzi wengine.

Madhara:

Hakuna madhara yatakayokuadhiri wewe na motto wako katika utafiti huu. Hakuna jambo lolote litakalohatarisha afya ya motto wako katika utafiti huu.

Hiari:

Kushiriki kwako katika utafiti huu ni kwa hiari yako tu. Hakuna gharama yoyote kwako, na pia hakuna malipo yoyote kwa kushiriki katika utafiti huu. Waweza kutamatisha uhusika wako katika utafiti huu wakati wowote utakao. Kukataa kuhusika hakutahatarisha matibabu ya mtoto wako.

Usiri:

Habari zote utakazotupa zitawekwa siri. Habari yoyote itakayowezesha wengine kutmbua mtoto wako hazitachapwa au kuzungumzwa na watu wasiohusika na utafiti huu. Nambari zenu za utafiti ndizo zitakazotumika badala ya majina yenu. Taarifa yoyote kukuhusu wewe, mtoto wako na familia yenu itapatikana tu kwa ruhusa yako, kwa njia ya kuandika. Fahamu ya kwamba watafiti watazungumzia matokeo ya utafiti ya watoto wote watakohusika kwa kijumla. Mtoto wako hatatambulishwa katika mazungumzo hayo.

Kwa Matatizo Au Ufafanuzi:

Ikiwa ungependa maelezo zaidi kuhusu utafiti huu na matumizi ya matokeo yake, tafadhali wasiliana na mtafiti mkuu, Dr Emily M. Njuguna, Kupitia Nambari Ya Simu 0720-612996.

Ikiwa unngependa kuzijua haki zako kama mhusika katika utafiti huu, tafadahli wasiliana na kamati ya maadili na utafiti ya hospitali kuu ya kitaifa ya Kenyatta, kupitia nambari ya simu 2726300, Ugani Wa Simu 44355.

Idhini Ya Mhusika:

Mimi,

nikiwa nimepokea ujumbe na maelezo kamili kuhusu utafiti huu, madhara na faida yake, nakubali /

sikubali (chagua ifaayo) kuhusishwa pamoja na mtoto wangu. Ninaelewa vyema ya kwamba uhusika wetu ni wa kujitolea na niko huru kujitenga wakati wowote. Nimepewa fursa wazi kuuliza maswali na kupata ufafanuzi kamili kuhusu utafiti huu na nimeelezwa yale yote.

Sahihi Ya Mhusika:	Tarehe
Sahihi Ya Mtafiti:	Tarehe

16.2 INCLUSION AND EXCLUSION SCREENING ENROLLMENT FORM

Date: (Dd/Mm/Yy):

Code Number Of The Mother-Baby Pair:

Subject Initials: _____

Inclusion Criteria: Answers Must Be Yes For Both Questions

1. Mother of a neonate born via spontaneous vertex delivery. _____ Yes _____ No

2. Informed consent will be sought from the mothers. _____ Yes _____ No

Exclusion Criteria: If Any Answer Is Yes, Exclude Participant From Enrollment

1. Mother of neonate born via caesarian section.	Yes	No

2.Neonate with illness requiring admission.	Yes		No)
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3.Neonate admitted in the newborn unit. _____ Yes _____ No

4.Has mother been enrolled in this study previously. _____ Yes _____ No

16.3 BASELINE QUESTIONNAIRE:	(Dd/Mm/Yy)	
Code Number Of Mother-baby Pair:	Randomization Arm:	
Subject Initials:		
Date Signed Informed Consent: Dd/Mm/Yy)	_//	
Mobile Phone Number:		
1.Demographics		
i) age of the mother (yrs	8)	
ii) age of the baby (days))	
2. Maternal level of education:		
i)Tertiary	ii)Tertiary Incomplete	
iv)Secondary Complete	vi)Secondary Incomplete	
vii)Primary Complete viii)Primary Incomplete		
3. Employment status:		
i)Salaried Employee	ii)Casual Laborer	
iii)Self Employed	iv)Unemployed	
v)Other (Specify	y)	
4. Marital status:		
i)Married ii)Single iii)	_Divorced/Separated iv)Widowed	
5. Antenatal Care:		
i) Place where ANC was attended:		
A)Public Health Facility B)	Mission Facility	
C)Private Hospital D)	Private Clinic	
ii) Number of visits:		
A)>4 B)4 C)	_3 D)2 E)1 F)None	
iii) Gestation age at first ANC visit		
A)>7months B)	4-6 Months C)< 3months	
iv) Do you have a mother and child health	a booklet?	
A)Yes B)N	o C)Other	

6. Knowledge of neonatal danger signs:

i)Have you been given any information regarding danger signs in your newborn and when to return immediately?

A) Yes B) No ii)From who do you receive health information about your baby? A)_____Health Care Workers B)_____Husband/Spouse C)____Family Member D)____Media F)_____Traditional Healers E) _____Friends G) Other (Specify) iii) What danger signs when seen in your neonate should take you back to a health facility as soon as possible? A) Trouble Feeding F) Trouble Breathing B)____Less Energy G) Jaundice H)____Umbilical Redness C)____Fits D) Cold Body Temperature I) Skin Pustules J) Red Swollen Eyes With Drainage E) Hot Body Temperature iv) Have you been informed about the regular PNC visits after discharge from hospital? A) Yes B)_____No v) If yes above, how long post discharge should you have your child reviewed by a health care worker?

A) _____48-72 Hours B) _____1 Week C) _____2 Weeks D) _____6 Weeks

FOLLOW-UP QUESTIONNAIRE:

Code Number Of Mother-baby Pair:_____

Subject Initials: _____

Interview (2,3) Date (DD/MM/YY): __/_/___ Randomization Arm:_____

Mobile Phone Number:

1. _____Age Of The Baby (Days)

2. In our previous session, information on danger signs to watch out for in your baby was given to you. Which signs can you recall?

A)	Trouble Feeding	F)	Trouble Breathing
B)	Less Energy	G)	Jaundice
C)	Fits	H)	_Umbilical Redness
D)	_Cold Body Temperature	I)	Skin Pustules

E)_____Hot Body Temperature J)_____Red Swollen Eyes With Drainage

3. Has your child developed any health problems?

A)<u>Yes</u> B)<u>No</u>

4. If yes, which one? (mother to use recall only, do not preempt the answer)

A)	Trouble Feeding	F)	Trouble Breathing
----	-----------------	----	-------------------

B) Less Energy G) Jaundice

C)_____Fits H)____Umbilical Redness

D)____Cold Body Temperature I)____Skin Pustules

E)_____Hot Body Temperature J)_____Red Swollen Eyes With Drainage

5_____On what day of life did your baby develop this sign?

6. Did you seek care for this problem?

A)____Yes B)____No

7. How long after the onset of the danger sign did you seek care?

A)____<24 Hours B)____24-72 Hours C)≥72 Hours

8. Where did you seek care:

A)_____Home Based Care Ii)_____Traditional Healer Iii)_____Hospital

9. If care was sought in a hospital, was your baby admitted?

*Adapted From World Health Organization (WHO). International Standard Verbal Autopsy Questionnaires, 2007;5–52.

Serial Number	Code Number Of Mother- Baby Pair:	Randomization Arm: (<u>Mark Below):</u> I=Intervention C= Control	Mobile Number	Call 1 (Day 7) Date: <u>(Mark Below):</u> C=Completed NC=Not Completed	Call 2 (Day 28) Date: (<u>Mark</u> <u>Below):</u> C=Completed NC=Not Completed
1				Date: C/NC:	Date: C/NC:
2					
3					
4					
5					

16.4 CALL LOGS FOR FOLLOW UP INTERVIEWS:

16.5 FOCUS GROUP DISCUSSION INTERVIEW GUIDE:

Title: The Effectiveness and Acceptability of Audiovisual Aids for Increasing Knowledge of Neonatal Danger Signs among Primi-parous Women in The Postnatal Wards of Kenyatta National Hospital.

Number of participants present:

The purpose of the study is to conduct evaluative research to determine:

• Evaluate the acceptability of audiovisual aids for health education on neonatal danger signs.

Preamble:

- Welcome participants and introduce myself.
- Explain the general purpose of the discussion and why the participants were chosen.
- Discuss the purpose and process of the focus group discussion.
- Explain the purpose and presence of recording equipment.
- Outline general ground rules and discussion guidelines.
- Address the issue of confidentiality.
- Inform the group that information discussed is going to be analyzed as a whole and that participants names will not be used in any analysis of the discussion.

Focus group discussion norms

The group will be asked to suggest ground rules. After brainstorming, the following will be Included in the list.

- 1. Information provided in the focus group should be kept confidential.
- 2. We will be tape recording the group. We want to capture everything you have to say
- 3. There are no right or wrong answers. Every person's experience and opinion are important.
- 4. Try to be as audible as possible so that everyone can benefit from the discussion
- 5. Turn off cell phones (if possible). If you must answer leave quietly and take the shortest time possible.

Helping is my assistant. Her name ishe'll be taking notes and be here to assist me if i need any help.

Audiovisual aids:

- a. What was your experience with the audiovisual aid?
- b. What did you like about it?
- c. What are some of the challenges you experienced with the audiovisual aids?
- d. Is it useful to you?
- e. How best can we use this aid for health education in our local setting?

16.6 Confidentiality and Security Policy Form for Research Assistants

I understand and agree to maintain and safeguard the confidentiality of privileged information contained in this study. Further, I understand that any unauthorized use or disclosure of information residing on the practice information resource system may result in disciplinary action consistent with the policies and procedures of state and local agencies.

Date

Research Assistant's Signature

Date

Principal Investigator's Signature