Supplementary file 3
Information Sheet

Background of the study:

While the neonatal deaths accounted for a larger share [2.4 million (47%)] of under -5 deaths over time, ambitious goals defined by Every Newborn Action Plan targets to reduce global neonatal mortality rate to less than 10 per 1000 live births by 2035. In 2019, Nepal reported neonatal mortality rate of an estimated 20/1000 live births, stillbirth rate of 18 per 1000 total births. Initiation of breathing is critical in the physiologic transition from intrauterine to extra uterine life. Approximately 1 in 10 babies born require help to breathe immediately after birth and without help the baby may die or suffer severe brain damage. Prior studies in Nepal have demonstrated that implementation of a comprehensive quality improvement package with Helping Babies Breathe(HBB) improved care and neonatal outcome. However, these improvements do not always remain sustainable and long-term in clinical practice inside the delivery room. This can be due to several gaps health facilities have, and by recognizing the reoccurring errors, preparations can be done and preventive measures can be undertaken for better neonatal outcome. In this context, video and sound recording of actual neonatal resuscitation can facilitate optimal team performance and outcomes.

Purpose of the study

The MALA approach introduces video recording in Neonatal Resuscitation as a standard of care quality assurance activity to enhance health workers learning and create opportunities to improve newborn safety.

The purpose of this study is to develop a system that can automatically identify the treatment of the newborn during newborn resuscitation and create a timeline to initiate resuscitation steps. The result obtained from this study can be used by health facilities in improving quality care while performing newborn resuscitation. This study will also help in collecting information regarding resuscitation practices and it can be useful in improving the quality of newborn resuscitation performance.

Method:

A video and sound recording system will be established as a means of evaluating the treatment the newborn receives during resuscitation. Practice of resuscitation in actual clinical settings will be documented with the use of a tablet-based application and a video recorder which will be mounted on the radiant warmer. The video will only display the baby (crying, breathing and chest movements) and the hands of the resuscitation team with resuscitation activities (stimulation, suctioning, and bag-and-mask ventilation).

Possible Harms and Benefits:

Participation in this study will cause no harm to health workers and newborns. The result of this study will contribute to improve the quality of newborn care by allowing the perinatal centers to achieve the neonatal resuscitation program's goal. It will contribute to review policies that govern the neonatal resuscitation services provision, availability of equipment and staffs who are trained and if they are competent to deliver consistent and reliable high – quality resuscitation practices. Collecting non-interference resuscitation practice with unalterable objective data will facilitate individual learning, identify and address system issues leading to better team performance and patient safety.
This study is sensitive to Nepali culture and social values.

Voluntary participation:

Your participation in this study will be completely voluntary. If you agree to participate in this study, and if there is a need to resuscitate the baby, the process of resuscitation will be monitored through video recording. Involvement in this study will not influence or affect the health of newborn or health workers.

Confidentiality:

All information collected during the study will be kept strictly confidential and not shared with anyone outside the study team. The data will be coded so that the personal identity and individual data of mother and newborn from video recording will not be identified and are traceable only with the code key which will be held by the study researchers, no one else will have access to it. All the details obtained will be solely used for study purpose only.

What happens if you wish to terminate your participation?

Your participation will be completely voluntary. If you decide not to participate at any point before or during the study, the process of video recording will be stopped immediately, and already recorded videos will be discarded from further use.. However, since your participation in the study is crucial in achieving the purpose of the study, we look forward to your support.

If you have further inquiries or questions, you may contact the principal investigator of this study.

Principal Investigator:
Honey Malla (Golden Community, Lalitpur)
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Informed Consent Sheet

For Health Workers working at high risk delivery room in Bharatpur Hospital.

Name of the participant ..... Age.....
Address..... Contact .....

I am aware that ……. from Golden Community has invited me to participate in a study that aims to investigate whether or not the implementation of MALA is feasible and acceptable.

I have carefully read / listened to all the information written in the information sheet submitted.
In that sheet, I found the purpose and process of the study explained in a language that was easily understood. This study collects the unaltered information regarding neonatal resuscitation practice through video recording. It has been clearly explained to me that this information is used in improving the quality of neonatal resuscitation practice. The study's purpose, potential risks / benefits and other relevant information have been explained to me in details. My participation in the video and sound recording is voluntary, and I understand that I can withdraw my participation at any point before or during the recording and I do not need to provide any reason to discontinue my participation from the study.

I understand that my participation in this study will not influence my relationship with the newborn and his/her family or any other health care professionals and will not affect the service that I will provide to the newborn. Also, my participation in this study poses no risks to my duties.

I understand that in this study video and sound recording will be done which means that you will monitor the resuscitation of the baby and only my hands performing resuscitation activities (stimulation, suctioning and bag and mask ventilation) are displayed along with the newborn You will be mainly focused on the treatment and outcome of the resuscitated baby.

During this process, I will get a study ID and all information will be kept in confidential manner.

I understand that researchers and other responsible persons associated with this study will use the information collected solely for study purpose only. I have also been informed that my participation in this study will not provide me any kind of financial compensation. I agree to participate in this study and to provide the necessary support during the study.

Health Worker's signature: ..... Investigator's signature .....

Date: .....