Consent form for Health Workers/ Providers (FGD)

Part I: Participant Information Sheet

This informed consent form is for focus group discussions with Health Workers/ Providers.

Study Title: Implementation research to develop and evaluate a mother-infant centred, pandemic-resilient, scalable model for improving the identification and management of possible serious bacterial infections in young infants in Uttar Pradesh, India
Principal Investigator: Ms. Aarti Kumar Dr. Vishwajeet Kumar
Organization: Community Empowerment Lab
Name of Sponsor: World Health Organization (WHO)
Version Date: October 01, 2022

Introduction

Namaskar ! My name is_____, and I am from the Community Empowerment Lab (CEL). For the last 20 years, our team has been working with communities and the health system to improve the health of mothers and babies. In our state of Uttar Pradesh, children under 2 months of age often get very sick because of infections. The government has already put some programs, systems and processes in place to facilitate early identification, care-seeking and management of infections in these young infants. However, it does not always work as intended, and many infants are deprived of timely care. Together with mothers, health workers, nurses, doctors and government functionaries, we are trying to improve the current system to better support mothers and families in identifying illnesses in their young infants, and helping them get access to early and effective treatment to cure infections. We are doing this study to develop innovations to refine this system, assess how it is working, and continue to improve and refine it so that a high proportion of sick infants are able to receive timely, appropriate and complete care. We would like to invite you to participate in this study as you provide care and/or health services to infants and may be in a position to contribute to this study with your experience and involvement.

This consent form may contain unfamiliar words or language. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or my team. You may also wish to talk to anyone who you feel comfortable with to share about this study and take your time to decide whether you want to participate in it or not.

Purpose of the study

The objective of the study is to identify the gaps, barriers in early identification of illnesses, care seeking practices and its management services at community and health facilities level and furthermore, to identify challenges posed due to the pandemic. We will develop and evaluate a model to improve early identification and management of illnesses and in particular, infections, in infants under 2 months of age. This model will be developed, implemented, and refined in one block of Kanpur Nagar district, with participation from mothers/ caregivers, health workers, health providers and other stakeholders.

Voluntary Participation

Your participation in this research is completely voluntary. It is your choice whether to participate or not. You have the right to withdraw your participation from this study at any time. Even if you do not agree to participate or if you withdraw from the study, it shall not adversely affect you in any way.

What if I agree to participate?

If you agree to participate, we will request you to sign this consent form to acknowledge that you have understood the purpose of this study and what it will involve, and agree to voluntarily participate in this study. I will share a copy of this consent form with you. You can withdraw at any time without giving a reason and that will not adversely affect you in any way. You will be requested to be seated along with other health workers/ providers, and I or one of my team members will conduct a group discussion with all of you.
With your permission, we would like to audio record the discussion. The audio recordings will be used in writing up the interview, to help make sure the write-up is accurate and complete. Only members of the research team shall have access to the recordings. The recording will be erased from the recorder as soon as it is transferred onto the computer. The computer files of the audio-recordings will be password protected during the study and destroyed at the end of the study. Refusing the recording does not mean you cannot participate in the study.

During the discussion, we will encourage all participants to share their experiences in providing care to young infants – the illnesses that they present with, the care-seeking patterns of their families, how do you or your team assess these babies, what treatments are given, and how the recommended treatment/ hospitalization is complied with by mothers/ families. We want to understand the end-to-end process from illness to outcome, and identify various barriers, bottlenecks and challenges, and also opportunities. We may also share some of our data and insights gained through our research so far, and share aspects of the model that we are trying to design with help from various stakeholders in order to improve the end-to-end process and outcomes. We would like to invite you to contribute to the development and improvement of this model with your ideas, insights and suggestions. We would also like to gain from your understanding of how this process can get impacted during challenging situations like the COVID-19 pandemic, and your thoughts and suggestions on how it can be made more resilient.

This discussion will take around 120 minutes. If you do not wish to answer any of the questions during the discussion, you may say so and the moderator/ facilitator will move on to another participant or the next question.

Confidentiality

We will ask you and others in the group not to talk to people outside the group about what was said in the group to keep the confidentiality. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential. All the information shared by you during the study will be kept strictly confidential and information will only be used for the purpose of the study and improving care of young infants. Your personal information will never be made public. All the information gathered will be stored securely and anonymously on a digital platform. The pooled responses to various questions from all respondents including you, but without any direct reference to you, will be analyzed and shared openly. The results of the study will be shared with your community, and a wider audience through various means, including scientific articles, meetings and other forms of public communication.

Risks & discomforts

There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. We will try our best to make you comfortable and will never share your confidential information with anyone. Please share with us if you have any problems, and we will try our best to overcome your problem. You do not have to answer any question if you feel the question(s) are too personal or if talking about them makes you uncomfortable. I also wish to inform that my team and I will follow all essential COVID-19 related protocols during our interactions. You have every opportunity to withdraw from the study if you feel uncomfortable at any point**.**

Benefits/Incentives for my participation

There will be no incentives or any direct benefit to you from participation in this research. Your participation will help us assess and improve the system that has been put in place to prevent and treat infections in young infants, and will be used to help society in general.

Who to Contact: This study has been reviewed by members of an ethical committee and approved by it. The task of this committee is to make sure that research participants are protected from harm. If you wish to find out more about any aspects of this or the study ethics, you can contact the following persons:

Ms. Aarti Kumar
CEO & Co-Founder
Community Empowerment Lab
F-09, 9th floor, F-Block, Tower-B,
Shalimar Grand, 10, Jopling Road,
Lucknow 226 001, Uttar Pradesh
Phone: +91-8810723107
Email: aarti.kumar@celworld.org

Mr. Vinay Pratap Singh
Director, Research Management
Community Empowerment Lab
Flat No. 202, Sai Samriddhi Apartment
Sector-M, Kakadev
Kanpur City 208025, Uttar Pradesh
Phone: +91-88107-25123
Email: vinaypratap.singh@celworld.org

This study has been reviewed and approved by the WHO Ethics Review Committee and Institutional Ethics Committees of the Community Empowerment Lab and GSVM Medical College, Kanpur Nagar. Being a participant in this study if you have any queries or concerns about your rights, you may contact CEL's ethics committee at the following address:

Institutional Ethics Committee

Community Empowerment Lab
F-09, 9th floor, F-Block, Tower-B, Shalimar Grand, 10, Jopling Road,
Lucknow-226001 Uttar Pradesh
Phone: 0522-4070395

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Part II: Certificate of Consent

A: Participant

I confirm that I have read/heard this consent form and understood the purpose, procedures, possible benefits and risks of this study. I was given an opportunity to ask questions and have received a satisfactory response to my questions, if any.

I understand that:

- My participation in this study is completely voluntary.
- I am free to withdraw my participation from this study at any time without giving any reason and without my rights being affected.
- I will be given a copy of this consent form for my own records.
- My participation in this study will be kept strictly confidential and anonymized data will be stored in a secure database.
- There is no financial incentive for participating in this study.

I voluntarily agree to participate in this study.

Yes ☐ **No** ☐

I agree for the recording of the discussion which will be used in writing up the interview by study team.

Yes ☐ **No** ☐

1) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

2) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

3) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

4) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

5) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

6) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

7) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

8) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

9) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

10) _____ _____
Name and Signature of participant Date (dd/mmm/yyyy)

B: Research team member obtaining consent:

I have explained the purpose, procedures, possible benefits and risks of this study to the potential participant and given them the opportunity to ask questions. I confirm that the consent was given freely.

_____ _____ _____
Name of Research Team Member Signature Date (dd/mmm/yyyy)