UNIVERSITAS GADJAH MADA

Universitas Gadjah Mada, Yogyakarta, Indonesia

A cluster randomised control trial of continuous quality improvement to improve antenatal HIV, syphilis and Hepatitis B detection and treatment in Indonesia

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PARTICIPANT INFORMATION SHEET AND CONSENT FORM

OBSERVATIONS - FACILITY CASE STUDIES

Please read this information sheet before you decide to take part. Please ask if there is anything that is not clear.

Why are we doing this research?

We are conducting this research as part of the MENJAGA study. This is a collaboration between Universitas Gadjah Mada, the London School of Hygiene and Tropical Medicine, United Kingdom, and the Kirby Institute University of New South Wales, Australia, which aims to eliminate newborn infection with HIV/syphilis/hepatitis B in Indonesia through improved detection and treatment in pregnant women.

Why have I been selected to take part in this study?

Your facility has been randomly selected to participate in the continuous quality improvement intervention under the MENJAGA trial. We have chosen your facility purposively for this study to represent the experiences of participating in the intervention.

The primary purpose of this study is to understand the realities of frontline healthcare providers working at primary healthcare facilities in providing antenatal care and diagnostic testing. We aim to understand your day-to-day work, represent your perspectives, experiences and challenges faced during routine activities at this facility and in participating in the MENJAGA intervention. We are not here to assess your performance or quality of care, rather we're here to understand how the health facility runs. We hope to do this by visiting your health facility a number of times, spending time with you, and other members of staff, conducting informal interviews, discussions and semi-structured observations. We also want to do some more formal interviews about what you do throughout your workday.

We are asking your permission for this health facility to participate in this study because you are responsible for the management of this health facility.

What does this study involve?

If you agree, we would like to visit your health facility a number of times and observe the process of providing antenatal care and HIV/syphilis/hepatitis B testing services. We would

like to speak with you informally to understand your work and your perspective on changes or new practices that are implemented in this facility.

What will happen if I give my consent to this study?

Members of our team will talk to you about the study and explain what taking part would mean for you. After you have had all your questions answered, you will be asked to sign a Consent Form, to confirm that we can conduct observations in your health facility. These observations will be carried out informally by 1 or 2 members of the research team over the course of several visits. The team members will take written notes about their observations. Within the health facility, photos will only be taken if consent has been obtained from the person in charge and all individuals concerned. We will also conduct more formal interviews with members of staff who have consented to being interviewed. If the staff member agrees, we will audio record the interviews.

Do I have to give my consent?

No. It is completely up to you to decide if we can or cannot conduct this study. Even if you agree, you will be free to withdraw your consent at any time. Your decision will not affect your relationship with Universitas Gadjah Mada or with your employer or any other associated institution now or in the future.

What are the benefits of being involved in the study?

We know that understanding the day-to-day work of any facility can help improve implementation of a policy or system change. Unless we are aware of what really happens in clinics, we cannot gain a real understanding of how new policies or practices, such as the impact of quality improvement activities, are put into practice and what their effects will be on staff and patients. We hope the information obtained from this study will give voice to your perspective of working at a primary health facility.

You and your health facility may not benefit directly from being involved in the study. However, we hope our analysis will provide valuable information for researchers, health staff and policy makers seeking to improve the HIV/syphilis/hepatitis B treatment and prevention services for pregnant women in Indonesia. If you give your consent, during one of the visits to share and discuss the results of the study, we will provide some refreshments to staff at the health facility and provide a small compensation of IDR 100,000.

Are there any risks involved in joining the study?

We may take some of your time during our visits to your facility. We may ask some questions that you do not want to answer, but you can just tell us that and we will stop asking such questions. If you feel that we are getting in the way of care, you can always ask us to leave the area and we will not be offended. We do not think there are any other risks to you participating in the study because we will keep the answers that you give us confidential and only the researchers will know about them. We will not share any information you share with us or any notes of what we observe with your supervisor or colleagues. We will keep all the information in a special password-protected computer at

the universities and organisations where we work. When we write up the report, we will not use your name or the name of the health facility.

Will my details and the information I give you be securely stored?

Yes. All information will be anonymised and securely stored at Universitas Gadjah Mada in Yogyakarta, Indonesia. You will NOT be identified in any reports or publications.

What will you do with the study findings?

After the study has been completed the results will be analysed. This can take up to 3-6 months. A plain language summary report in Indonesian and English will be produced and provided to people who took part in the study, community groups and key stakeholders. The results of the study will also be written up and submitted for publication in medical journals and may also be presented at national and international meetings and scientific conferences. We may use the information you provide during our observations and discussions with you. However, these will not contain any personal information that will make it possible for you to be identified

Who has approved this study?

This study has been approved by Universitas Gadjah Mada Ethics Committee and the Research Ethics Committee of the London School of Hygiene and Tropical Medicine.

Who can I speak to if I have a problem?

If you would like any more information about this study please contact **Christa Dewi** (+62 813-2548-5582, email christa_dw@yahoo.com) or **Swasti Sempulur** (+62815-689-3803, email swasti274@gmail.com).

If you would like to speak to someone not directly involved with the study you may contact the Ethics Committee in Indonesia by phone or e-mail (+628112666869; email: mhrec_fmugm@ugm.ac.id)**.** Any complaint you make will be investigated promptly and you will be informed of the outcome. If you are unable to make a call or to access e-mail, you may contact **Christa Dewi** or **Swasti Sempulur** who will contact the Ethics Committee in UGM on your behalf.

+ + THANK YOU + +

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CONSENT FORM

1. I (name)..... agree to participate as a participant in the study described in the Participant Information Sheet set out above ***(or: attached to this form).***
2. I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the information sheet has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. I understand that I can withdraw from the study at any time without prejudice to my relationship to Universitas Gadjah Mada.
5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. I understand that if I have any questions or complaints relating to my participation in this research, I may contact **Christa Dewi** (+62 813-2548-5582, email christa_dw@yahoo.com) or **Swasti Sempulur** (+62815-689-3803, email swasti274@gmail.com), who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Signature of participant	**Please PRINT name**	**Date**
Signature of witness	**Please PRINT name**	**Date**

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REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Universitas Gadjah Mada or any healthcare provider or other organisation or my medical attendants.

Signature Date

Please PRINT Name:

The section for Revocation of Consent should be forwarded to **Christa Dewi** (+62 813-2548-5582, email christa_dw@yahoo.com) or **Swasti Sempulur** (+62815-689-3803, email swasti274@gmail.com).