



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

INTERVIEWS - PREGNANT WOMEN

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?

You have been invited to participate in this study because you have recently accessed antenatal care at one of the facilities involved in our research project.

What does this study involve?

If you choose to participate you will be asked questions on issues related to antenatal care during your pregnancy, your experiences of care, particularly in accessing HIV, syphilis and hepatitis B testing, and your perspectives on the quality of care provided to you.

What will happen if I agree to take part?

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 you agree to take part.

We will sit down in a private place and ask you some questions in an **interview** which may last 45-60 minutes. We will ask you for permission to record the interview using an electronic recorder. A member from the research team will listen to this recording and write down what was said using a computer. We do this to make sure we have understood what people are telling us and to help us compare information from a variety of different people and locations. If you prefer not to be recorded, however, you can still participate in the

study and we will take extensive notes during the interview. The information you give us will only be seen by the researchers who are working on this project - and maybe some other researchers who are interested in what is happening in Indonesia. We will not show your answers to any healthcare providers or other people working in this area. We will not use your name so in future, no one will be able to know that it is you who told us this information.

Do I have to join the study?

No. It is completely up to you to decide if you want to take part in the study or if you would rather not. You can also choose to answer some questions but not others if they make you feel uncomfortable. Even if you do decide to join the study, you are free to stop the interview and withdraw at any time. Whether you answer our questions or not won't affect the care that you receive from the healthcare providers at this facility. We do not work for any health facility and will not be involved in your care in any way. Your decision to participate or not participate in the interview or to withdraw at any time will not affect your relationship with Universitas Gadjah Mada now or in the future.

What are the benefits of being involved in the study?

You may not benefit directly from being involved in the study, but your participation will provide valuable information for researchers, health staff and policy makers in Indonesia seeking to improve the care pregnant women, like yourself, receive.

Are there any risks involved in joining the study?

The interview will take up some of your time. We may ask some questions that you do not want to answer, but you can just tell us that and we will stop the interview or ask the next question. We do not think there are any other risks to you participating in this study because we will keep the answers you give us secret and only the researchers will know about it. When we write up the study, we will not use your name or the name of the health facility where we did the research.

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 the interviews in the form of individual quotes in research reports or presentations. However, these will not contain any personal information that would 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 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 participate in 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).