INTERCEPT Participant Information Sheet - hospital inpatient

Project title: INTERCEPT: ***Interrupting proliferation of carbapenem resistance in Indonesia; clinical and genomic evaluation of pathways of transmission***

We invite you to take part in a research study run by Diponegoro University in Indonesia and the Liverpool School of Tropical Medicine (LSTM) in the United Kingdom (UK). Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. You are free to decide whether to take part. This will not affect the care you get from your own doctors. Ask us if anything is not clear or you would like more information.

Background to the study. Many common infections are caused by germs called bacteria. Many of these bacteria are becoming resistant to the antibiotics used to treat them, which means antibiotics stop working. This can make treatment difficult or impossible, especially when the germs become resistant to antibiotics called carbapenems. Carbapenem resistance is a big problem in Indonesia. We want to find out where people might catch carbapenem resistant bacteria so we can stop it happening.

What's involved? Drug-resistant bacteria can live in people's gut without causing any problems. To look for them we will either collect a stool (poo) sample from you or use a swab to collect a sample from inside the rectum. This is called a rectal swab. This involves a study team member inserting a thin cotton swab up your bottom 2-3 centimetres (1-2 inches) for 10 seconds, and then removing it and sending it to the lab. It is not usually painful.

If you decide to take part in this study, the following things will happen:

- We will ask you some questions about you and your health
- We collect stool or rectal swab samples from you while you are in hospital; three this week, then once a week while you are in hospital
- We will look at your medical records to see what antibiotics you are/have been prescribed, where in the hospital you have been, and details of your medical history.
- There will be no extra clinic or hospital visits as part of this study

What will happen to the samples that are collected from me? The samples will be sent to a lab at Diponegoro University and tested for drug-resistant bacteria. If we find any bacteria they may be sent to researchers in the UK at LSTM for further tests. Bacteria will be sent for a test to read their genetic code ("sequencing") to understand how resistance has come about. This test will happen in laboratories outside Indonesia. The samples will be stored securely in Indonesia and we won't do anything with these samples without asking you. Any bacteria we grow from these samples may be shared with other researchers and used in other experiments that are not related to this study.

How will we use information about you ("Data Protection")? We will need to use information from you for this research project. We will store this securely on computers at the Liverpool School of Tropical Medicine, in the UK. This information will not include your name and contact details – no one will be able to find out who you are from this information. We will need to record your name and contact details to make sure that we can collect all the samples and data we need for the study, but these details will stay in Indonesia. People who

do not need to know who you are will not be able to see your name or contact details. We will keep all information about you safe and secure. These details will be kept for five years, then destroyed. The data that does not include your name and address is called anonymised data, and this data will not be destroyed, but will be used to write our reports and will be made freely available to other researchers if they want to look at it. Data will be stored securely for at least five years following completion of the study.

What are the possible benefits of taking part? There will be no specific benefits to you of taking part. You will not get any extra treatments by taking part in this study. If we identify resistant bacteria in your gut, they will not be causing any problems and you would not need any treatment. Because of this, we will not tell you the results of the tests. The research will benefit people in the future by developing ways to stop the spread of drug-resistant bacteria.

What are the possible disadvantages and risks of taking part? The main disadvantage is that the rectal swab sampling may be uncomfortable, can rarely cause some bleeding and you will need to give up your time for this to happen.

Are there any costs to you if you participate in the study? It will not cost you anything to participate. You will be compensated for your time for participating in the study with Rp 100.000

What if I change my mind? You can decide to stop your involvement with the study at any time, without giving a reason. We will keep the data and samples collected up to the point at which you withdraw from the study.

Safeguarding. Everyone involved with this study is expected to behave ethically and follow the LSTM safeguarding guidelines. This means that they must not ask you for any financial, physical or sexual favours in return for taking part. If you experience any abuse or harassment or neglect by a study team member you can contact the local safeguarding lead Helmia Farida at helmia.f@fk.undip.ac.id. You can also raise a safeguarding concern directly with LSTM Safeguarding Officer Phillipa Tubb at safeguarding@lstmed.ac.uk or by telephone on +44 151 705 3744

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Who to contact if you have questions or complaints. In the event of a question complaint about any aspect of this study please contact Indonesian Investigator, dr. Helmia Farida, Sp.A(K), M.Kes, Ph.D by email at helmia.f@fk.undip.ac.id or by phone at 081225217878 or the UK Principal Investigator, Joe Lewis: joseph.lewis@lstmed.ac.uk or by phone at +44 151 702 3154. Complaints can also be made directly to the chair of the research ethics committee at LSTM (Dr Shevin Jacob, shevin.jacob@lstmed.ac.uk)