

INTERCEPT Participant Information Sheet – Healthcare Workers

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 Universitas Diponegoro 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. You are free to decide whether to take part. This will not affect your employment, work duties, or relationship with the hospital. 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. Some of these bacteria are becoming resistant to the antibiotics used to treat them, which means the antibiotics stop working. This can make treatment difficult or sometimes impossible, especially when the bacteria become resistant to strong antibiotics called carbapenems. carbapenem resistance is a major problem in Indonesia. We want to find out where people might catch carbapenem-resistant bacteria so we can help prevent this from happening. To better understand on how these bacteria spread in hospitals, we also want to find out whether healthcare workers may carry these germs on their bodies or clothing during everyday patient care.

What's involved? We will collect swab samples from healthcare workers to look for carbapenem-resistant bacteria. These swabs help us understand whether bacteria are present in places that may accidentally spread germs during patient care. The types of swabs we will collect are:

- Nasopharyngeal swab: a soft swab will be gently inserted into the back of the nose for a few seconds. This may feel slightly uncomfortable but should not be painful.
- Hand swab: A swab will be taken from the surface of the hands to check for bacteria on the skin.
- Clothing swab: A swab will be collected from the front of the uniform or gown to see whether bacteria may be carried on fabrics.

All swabs will be collected by trained study staff. Each procedure will take only a few seconds.

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

- We will ask you a few questions about your role and work activities in the hospital
- We will collect nasopharyngeal, hand, and clothing swabs twice during the study over the next 6 weeks.
- We will record basic information such as your work area or shift patterns, but no personal identifiers will be shared outside the study team
- You can stop taking part at any time without any consequences for your work or employment.

What will happen to the samples that are collected from me? The samples will be sent to laboratory at Universitas Diponegoro and tested for drug-resistant bacteria. If we find any bacteria, they may be sent to researchers in the UK at LSTM for further analysis. 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. This information will be stored securely on computers at LSTM in the UK. Your name and contact details will not be included in this dataset, meaning no one will be able to identify you from the research result. We still 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 direct benefits to you from taking part. If we identify resistant bacteria on your hands, nose, or clothing, this does not mean you are ill or require treatment, as these organisms commonly colonise healthy individuals without causing disease. For this reason, individual test results will not be routinely provided. However, if you would like to know your own swab result, you may request this from the study team. Any result that is shared will be given privately together with an explanation to avoid misunderstanding. The information collected in this study will help us understand how drug-resistant bacteria spread in hospitals, which may support improved infection-prevention practices benefiting both patients and healthcare workers in the future.

What are the possible disadvantages and risks of taking part? The swab procedures may cause brief discomfort, especially the nasopharyngeal swab. There are no expected medical risks, and no procedures will affect your ability to work. You will need to give up a small amount of time for sampling.

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 participating in the study with Rp 100.000.

What if I change my mind? You can decide to stop participating in this study at any time, without giving a reason. Your decision will not affect your employment, duties, or relationship with the hospital. 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

Sponsorship and Funding. The project is funded by the UK government via UK Research and Innovation (UKRI) and the Indonesian government via DRTPM DIKTI. It is sponsored by LSTM and has been reviewed and approved by the research ethics committees at LSTM and Universitas Diponegoro.



Who to contact if you have questions or complaints. If you have any questions or complaints about any aspect of this study, please contact the 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. You can also contact the Principal Investigator, Joe Lewis by email at 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)