**Participant Information Sheet**

Study coordinator: Elizabeth Fagbodun (Imperial College London)

Chief Investigator Contact: Professor Anthony Gordon, Professor of Anaesthesia and Critical Care, NIHR Research Professor, Imperial College / St Marys Hospital, Praed Street, London, W2 1NY

T: 02033126328 Email: anthony.gordon@imperial.ac.uk

For study queries:

Contact: Elizabeth Fagbodun

Tel: (0)7548094320 Email: e.fagbodun@imperial.ac.uk

For Clinical queries:

Contact: Dr Matthieu Komorowski

Tel: 07578 975 175 Email: m.komorowski14@imperial.ac.uk

1. **Study Title:** Passive evaluation in operational environment of the AI Clinician decision support system for sepsis treatment
2. **Invitation Paragraph**

You are being invited to take part in a research study evaluating the use of an Artificial Intelligence (AI) tool to aid the decision of clinicians when determining the dose of drugs for septic patients. Before you decide it is important for you to understand why the research is being done and what it will involve.

We will assess the AI decisions by human evaluators: off-duty clinicians will evaluate the clinical correctness/appropriateness of AI suggested decisions. The evaluators will classify the AI suggested actions in different categories, such as “likely safe”, “likely inappropriate”, “possible too low”, or “possibly too high”.

Please read the following information regarding the research and what it involves. This will allow you to decide whether you wish to take part. Please ask if you require any further information about the study.

Thank you for reading this.

1. **What is the purpose of this study?**

Sepsis is life-threatening organ dysfunction due to severe infection and affects (pre-COVID) 250,000 patients annually in the UK, of whom 48,000 die. The cornerstone of sepsis resuscitation is the administration of intravenous fluids and/or vasopressors to maintain blood flow to prevent organ failure. However, uncertainty around correct dosing and timing of treatments, partially due to clinical syndrome heterogeneity, leads to poorer outcomes and increased ICU resource use. We tackle this problem using AI that learned from ICU electronic health records to provide personalised treatment recommendations to clinicians.

This study aims to assess the acceptability of this tool to clinicians. By understanding more about the views of clinicians on the tool we will be able to look at potential barriers in implementing this in standard care. We also hope to confirm the technical feasibility to inform future large scale clinical trials.

1. **Why have I been chosen?**

You have been invited to take part in this study due to your professional role as a clinician within the NHS. Up to 15 clinicians will participate in these qualitative assessments.

1. **Do I have to take part?**

No. Taking part in this study is optional. There will be no detriment to working relationships if you decide not to take part in this study. You will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you remain free to withdraw at any time and without giving a reason. In the event that you withdraw from the study, no further data will be collected from you.

1. **What will happen to me if I take part?**

Following the invitation to participate, a time will be arranged to assess the decisions of the AI tool. This will take place at a time that is convenient for you in person (within Imperial College NHS Healthcare Trust or University College London Hospitals NHS Trust (delete as appropriate)) on a dedicated laptop.

The assessment of the decisions of the tool will last approximately 1 hour and will involve exclusion/inclusion of patients into the study and the evaluation of recommendations made by the AI Clinician. Clinicians will examine the doses and classify the AI suggested actions in different categories, such as “likely safe”, “likely inappropriate”, “possible too low”, or “possibly too high”. There will be a free-text box to enable the user to provide feedback on their decisions. Once the assessment is complete your response will be saved within the system. There are no personal identifiers recorded on the system and it is anonymous. The laptop will be placed back in the dedicated storage area once the assessment is complete.

Including time for consent, any questions and the assessment completion, the total duration of a session will be up to 60 minutes. Each clinician will be asked take part in 4 - 10 sessions.

All data will be stored under an anonymised identifier within a secure NHS server within Imperial College NHS Trust or University College London Hospitals NHS Trust (delete as appropriate).

The study sample will include NHS clinicians working at Imperial College Healthcare NHS trust and University College London Healthcare NHS trust.

1. **What do I have to do?**

A suitably convenient time will be arranged for review of the AI clinician tools decisions and completion of the survey. You will be asked to read and sign a consent form prior to commencement of the research study.

1. **What are the possible disadvantages of taking part?**

We are asking that clinicians take part in 4 - 10 sessions each, therefore you will be remunerated for your time. Clinicians that take part in the study will also be acknowledged as a collaborator.

1. **What are the possible benefits of taking part?**

There are no benefits to the participants however, long-term this study aims to improve patient survival by optimising the dose of treatments for septic patients. This will lead to reduced use of precious intensive care resources and reduction in healthcare costs. We hope that this study will provide useful data to facilitate further clinical trials in the future. Clinicians who take part in the study will be remunerated up to £100 for time spent in the study. This will be a paid as a reimbursement into your bank account.

1. **What if something goes wrong?**

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Professor Anthony Gordon, anthony.gordon@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you.

1. **What happens when the research study stops?**

The data will be analysed, written up, and fed back to all participants through written reports and distribution of any published papers.

1. **How will we use information about you?**

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

* 10 years after the study has finished in relation to data subject consent forms.
* 10 years after the study has completed in relation to primary research data.

We will need to use information from you for this research project.

This information will include your name, job role and place of work. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**LEGAL BASIS**

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research.  This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

**INTERNATIONAL TRANSFERS**

There may be a requirement to transfer information to countries outside the UK(for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

**SHARING YOUR INFORMATION WITH OTHERS**

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

* Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

**WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED**

You can find out more about how we use your information

by asking one of the research team

* by sending an email to e.fagbodun@imperial.ac.uk , or farah.al-beidh04@imperial.ac.uk
* by ringing us on (0)7548094320 or (0)771 405 1401.

**COMPLAINT**

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London’s Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

**What will happen to the results of the research study?**

The results of this study will be analysed and distributed to participating clinical departments in the form of a written report. It is also anticipated that this data will be published in peer reviewed journals. A copy of any published material will also be made available to participants.

No participants will be identified in any of the published material.

**Who is organising and funding the research?**

This research is supported by a grant from NIHR-NHSX.

**Who has reviewed the study?**

This study was given a favourable ethical opinion for conduct in the NHS (or private sector) by South Central - Hampshire B REC.

**Contact for Further Information**

If any further information is required, please contact Dr Mattheiu Komorowski

(m.komorowski14@imperial.ac.uk)

Thank you for participating in this study.