**Participant Information Sheet (Clinicians)**

**Study Title:** AI Clinician XP2 - A pilot study of the AI Clinician running in real time in the ICU

1. **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 evaluate your level of agreement with the AI Clinicians suggestions.

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.

In the AI Clinician XP1, we tested the safety of the AI Clinician when running in “shadow mode”, i.e., in pseudonymised batches of patient data presented to off-duty ICU clinicians.

In XP2, the AI Clinician will be running in real-time on dedicated computers at the bedside of actual patients in 4 ICUs across 2 NHS Trusts.

This present experiment will test the feasibility of running the AI Clinician in real-time in operational ICU’s, in preparation for a future large scale multicentric randomised trial that will test for an improvement in clinically relevant outcomes.

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 16 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?**

The system use is optional and can be **triggered manually** by 3 events: during the routine ward round (morning/afternoon, the doctor at the bedside notifies the local clinical research nurse), in the case of haemodynamic instability (for example in case of hypotension: MAP < 65 mmHg, the bedside nurse would in this case notify the research nurse) or on demand by clinician participants (e.g. in case of uncertainty with regards to optimal course of action, they would notify the research nurse).

When triggered, the research laptop is brought at the bedside by the research nurse, and the system is launched. You will then be able to see the patients’ anonymised data. We will first collect your initial recommendation for the patient without revealing the AI’s suggestion. You will then be shown recommendations by the AI Clinician tool and your feedback on this suggested dose will collected using a Likert scale.

This assessment should take approximately 2 minutes in total. 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. The system must be run at least once per week at each site.

After completion of the experiment you may also be contacted for a qualitative interview.

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.

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

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

We do not anticipate any disadvantages for taking part in this study. We are asking that clinicians use the system at least 4 times and you will be remunerated for your time.

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. You will be paid £50 for using the system at least 4 times and an additional £50 if you are selected for interview. 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 (Dr Matthieu Komorowski, m.komorowski14@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.

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

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[IRAS ID: 321582]

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.

The study is expected to finish in August 2024

For more information / confirmation regarding the end date please contact the study team, see ‘**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED’** for contact information.

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 within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records

to make sure that research is being done properly and the information held (such as contact) details is accurate

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. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - “performance of a task carried out in the public interest”); 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/)

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), (both organisations / Imperial College London) rely/relies on “scientific or historical research purposes or statistical purposes

**INTERNATIONAL TRANSFERS**

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. 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 UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

**SHARING YOUR INFORMATION WITH OTHERS**

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

* Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London 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.

**POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH**

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and 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/).

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

**COMMERCIALISATION**

Data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate ‘personal data’.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

**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 because some research using your data may have already taken place and this cannot be undone.

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 if this could affect the wider study or the accuracy of data collected.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**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
* by ringing us on (0)7548094320

**COMPLAINT**

* If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to **e.fagbodun@imperial.ac.uk**, or by ringing us on (0)7548094320

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Following our response, if you are not satisfied 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 remain unsatisfied 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)- via [www.ico.org.uk](http://www.ico.org.uk). Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

**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?**

Imperial College London is the study sponsor. 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 by XXX REC.

**Contact for Further Information**

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

(m.komorowski14@imperial.ac.uk)

Thank you for participating in this study.

A copy of the written information and signed Informed Consent form will be given to the participant to keep.