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PARTICIPANT INFORMATION SHEET

Clinicians' Perspectives on Information Quality of Digital Health Technologies

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We would like to invite you to take part in a research study. Before you decide, 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Digital health technologies, such as electronic health records and clinical decision support systems, are widely used in patient care. However, poor quality information from digital health technologies can lead to injuries and deaths. Currently, there is no consensus on how to assess the quality of clinical information from digital health technologies. We have recently developed an instrument for assessing the quality of clinical information produced by digital health technologies based on evidence from literature. The current study aims to obtain inputs of healthcare professionals who have used information from digital health technologies in patient care. It is expected that this study will lead to consensus on how to assess quality of clinical information from digital health technologies to determine if they are suitable for use in patient care. Assessment of information quality of digital health technologies will help in preventing injuries and deaths associated with the use of poor quality information in patient care.

Why have I been invited?

You have been invited because you are a healthcare professional with information governance or patient-facing role who have used information from digital health technologies in making decisions regarding patient care.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

You will be asked to complete 2-3 rounds of online surveys which would be about 2-4 weeks apart. Each round of online survey will take about 20 minutes.

What do I have to do?

You will be asked for your opinions about the criteria we have developed for evaluating information generated by digital health technologies.

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What are the possible risks of taking part?
We do not anticipate any physical risks from participating in the study. However, we acknowledge the data security risk that accompanies all forms of research and have put standard measures in place to protect your privacy. All data will be confidential and your personal information will not be identifiable in any report, publication or thesis that arise from this study. We will only acknowledge you as part of the expert panel that developed the framework if you give us your permission to do so.

What are the possible benefits of taking part?
Your participation will contribute to the development of an instrument for assessing the quality of clinical information produced by digital health technologies. The use of this instrument may help in preventing significant harms and deaths associated with poor quality information. In addition, your contribution will be acknowledged if you complete all the rounds of the survey and give consent to do so.

What if something goes wrong?
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 Principal Investigator (Prof Josip Car, Josip.Car@imperial.ac.uk) If you are still not satisfied with the response, you may contact the Research Governance and Integrity Team.

What will happen to the results of the research study?
This research will be published in scientific journals and presented in conferences. The findings will also be promoted through social and conventional media. The results will also be written up as part of PhD thesis.

Who is organising and funding the research?
There is no specific funding for this study. This study is part of the PhD of KPF at Imperial College London sponsored by the Federal Government of Nigeria. AM is supported by the National Institute for Health Research (NIHR), North West London Applied Research Collaboration.

Who has reviewed the study?
This study was given ethical approval by Imperial College Research Ethics Committee (ICREC) and the Joint Research Compliance Office (JRCO).

How can I contact you?
If you have questions, please feel free to contact: Becky Ward, Research Governance Manager, Imperial College London, +44 020 7594 9459. If you would like to speak to the researchers conducting this study, please contact Prof. Azeem Majeed

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(A.Majeed@imperial.ac.uk) or Prof Josip Car (J.Car@imperial.ac.uk), Department of Primary Care and Public Health, Imperial College London, United Kingdom.

Transparency notice

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write.
The information pack tells you more about this.

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

- Occupation
- Gender
- Email

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

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International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (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

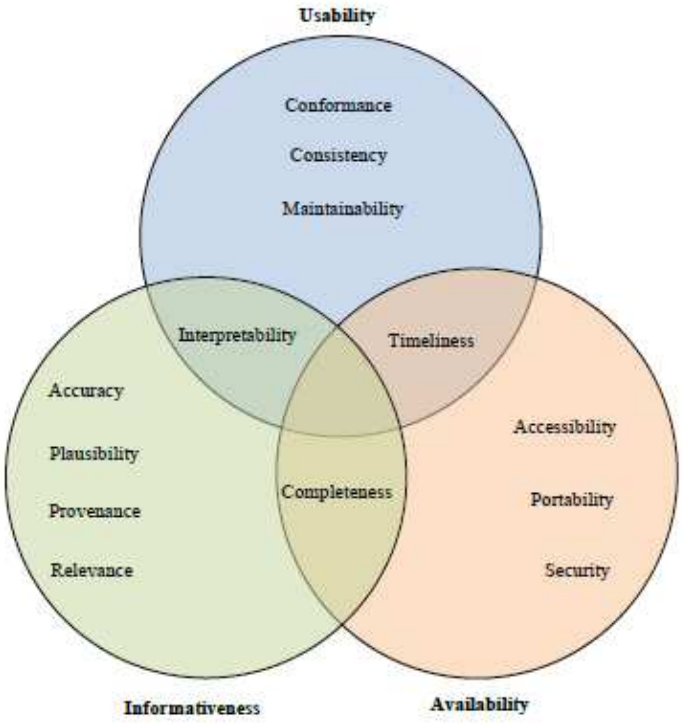
You can find out more about how we use your information

- By asking one of the research team
- By sending an email to Josip.Car@imperial.ac.uk, or
- by ringing us on +447477854209

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.

CLIQ FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES



Informativeness directly concerns the usefulness of digital information for clinical purposes	Accuracy	the extent to which information is correct
	Completeness	the extent to which no required information is missing
	Interpretability	the extent to which information can be understood
	Plausibility	the extent to which information makes sense based on common knowledge
	Provenance	the extent to which the source of information is trustworthy
	Relevance	the extent to which information is useful for the intended task
Availability concerns the functionality of the system holding clinical information	Accessibility	the extent to which existing information is easily obtainable
	Portability	the extent to which information is accessible in different systems
	Security	the extent to which information is protected from unauthorized access and corruption
	Timeliness	the extent to which current information is available on time
Usability concerns the ease of use of clinical information	Conformance	the extent to which information is presented in the desired format
	Consistency	the extent to which information is presented in the same format
	Maintainability	the extent to which information can be maintained

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CLIQ QUESTIONNAIRE FOR DIGITAL HEALTH TECHNOLOGIES

Section A: Assessment Profile

Date of Assessment Click or tap to enter a date.

Name of Digital Health Technology.....

Category of Digital Health Technology (Check the box that applies please)

☐ Electronic Health record
☐ Clinical Decision Support System
☐ Computerised Physician Order Entry
☐ Telemedicine Applications
☐ Mobile medical application
☐ Electronic Laboratory Information System
☐ Electronic Radiology Information System
☐ Others, specify please:

Your job specification
☐ Doctor
☐ Nurse Practitioner/ Advanced Clinical Practitioner
☐ Pharmacist
☐ Physiotherapist
☐ Others, specify please:

Section B: Informativeness

A. Accuracy: Is the information from the digital health technology free of errors?
1. ☐ **Very Accurate**. The information from the digital health is completely free of errors.
2. ☐ **Accurate**: The information from the digital health technology is free of errors that could lead to adverse event.
3. ☐ **Inaccurate**: The information from the digital health technology has few errors that could lead to adverse events.
4. ☐ **Very inaccurate**: The information from the digital health technology has several errors that could lead to adverse events.

NB: *Adverse event is an unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalisation or that results in death.*

B. Completeness: Is no required information missing from the digital health technology?
1. ☐ **Very complete**: No information is missing from the digital health technology.
2. ☐ **Complete**: No information required for clinical decision (diagnosis, treatment or prognosis) is missing from the digital health technology.
3. ☐ **Incomplete**: Few information required for clinical decision (diagnosis, treatment or prognosis) are missing from the digital health technology.
4. ☐ **Very incomplete**: Several information required for clinical decision (diagnosis, treatment or prognosis) are missing from the digital health technology.

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C. Interpretability: Could the information from the digital health technology be interpreted to make clinical decision?

1. ☐ **Very interpretable**: Additional resources provided to aid interpretation of the information from the digital health technology (e.g. arrows or colour coding to indicate abnormal results, indications of medication)
2. ☐ **Interpretable:** Standard resources provided to aid interpretation of the information from the digital health technology (e.g. reference range)
3. ☐ **Uninterpretable**: Information from the digital health technology cannot be interpreted without seeking clarification from its author.
4. ☐ **Very uninterpretable**: Completely meaningless information not suitable for clinical decision.

D. Plausibility. Does the information from the digital health technology make sense based on common knowledge?

1. ☐ **Very plausible**. The information from the digital health technology agrees with common knowledge (e.g. raised inflammatory markers in a patient with sepsis).
2. ☐ **Plausible**. The information from the digital health technology agrees with common knowledge if exceptional circumstances are also considered (e.g. normal inflammatory markers in a patient with sepsis due to delayed immune response)
3. ☐ **Implausible**: The information from the digital health technology disagrees with common knowledge (e.g. Arterial blood gasses with oxygen saturation of 60% when pulse oximeter records 94%)
4. ☐ **Very implausible**: The information from the digital health technology makes no sense at all based on common knowledge (e.g. physiological parameters incompatible with life).

E. Provenance: Is the source of the information in the digital health technology trustworthy?

1. ☐ **Very trustworthy**: The information in the digital health technology is from highly trustworthy source (e.g. UN Agencies, Official Government Agencies, Academic institutions, Hospitals).
2. ☐ **Trustworthy**: The information in the digital health technology is from recognised private corporations (e.g. non-governmental organisations, registered charities)
3. ☐ **Untrustworthy**: The information in the digital health technology is from sources with obvious conflict of interest (e.g. pharmaceutical companies, tobacco companies)
4. ☐ **Very untrustworthy**: Unverifiable source of information and unsubstantiated claims (e.g. broadcast information on social media, no references), unsuitable for clinical decision

F. Relevance: Is the information from the digital health technology useful for the clinical task (i.e. diagnosis, treatment or prognosis)?

1. ☐ **Very relevant**: All information from the digital health technology is useful for the clinical task
2. ☐ **Relevant**: Most of the information from the digital health technology is useful for the clinical task?
3. ☐ **Irrelevant**: Most of the information from the digital health technology not useful for the clinical task
4. ☐ **Very irrelevant**: None of the information from the digital health technology is useful for the clinical task

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Section C: Availability

G. Accessibility: Is the information easily obtainable from the digital health technology?

1. ☐ **Very accessible**: The information from the digital health technology is obtainable with no difficulties at the point of care.
2. ☐ **Accessible**: The information from the digital health technology is obtainable with minor difficulties that could be resolved at the point of care (e.g through a phone call to IT Department)
3. ☐ **Inaccessible**: The information from the digital health technology is not obtainable at the point of care.
4. ☐ **Very inaccessible**: The information from the digital health technology is not obtainable at all.

H. Portability: Is the information accessible in different systems?

1. ☐ **Very portable**: The information from the digital health technology is accessible at all levels of healthcare system (primary, secondary & tertiary).
2. ☐ **Portable**: The information from the digital health technology is accessible at all levels of healthcare with minor difficulties that could be resolved at the point of care (e.g. transferable on request).
3. ☐ **Unportable**: The information from the digital health technology is only accessible at the level of care where it was created.
4. ☐ **Very unportable**: The information from the digital health technology is only accessible on the computer system where it was created.

I. Security: Is the information in the digital health technology protected from unauthorised access?

1. ☐ **Very secure**: The information in the digital health technology is securely protected against unauthorized access using multiple strategies (e.g. password and swipe card).
2. ☐ **Secure**: The information in the digital health technology is securely protected against unauthorised access using a single strategy (e.g. requires only password).
3. ☐ **Insecure**: The information in the digital health technology is accessible to multiple healthcare professionals without a need for authorisation (e.g. information obtainable from the hospital without a need for personal log-in)
4. ☐ **Very insecure**: The information is publicly accessible (e.g. information on hospital website)

J. Timeliness: Is up-to-date information from the digital health technology available immediately it is needed at the point of care?

1. ☐ **Very timely**: Up-to-date information is available from the digital health technology at the point of care with no delays.
2. ☐ **Timely**: Up-to-date information is available from the digital health technology at the point of care with minor delays which do not affect the use of the information for clinical decision (e.g. slow log-in)
3. ☐ **Untimely**: Up-to-date information is unavailable from the digital health technology at the point of care due to major delays which affect the use of the information for clinical decision (e.g. system is down for a couple of hours)
4. **Very untimely**: The information from the digital health technology is outdated and not available when needed for clinical decision

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Section D: Usability

K. Conformance: Is the information from the digital health technology presented in the desired format?

1. ☐ **Very conformant**: All the information from the digital health technology conforms to international or local standards (e.g. SI units)
2. ☐ **Conformant**: Most of the information from the digital health technology conforms to international or local standards.
3. ☐ **Non-conformant**: Most of the information from the digital health technology do not conform to local or international standards
4. ☐ **Very conformant**: All the information from the digital health technology do not conform to local or international standards making it unsafe for clinical decision (e.g. medication doses presented without units).

L. Consistency: Is the information presented in the same format within the digital health technology?

1. ☐ **Very consistent**: All the information is presented consistently in the same format (e.g. consistently expressing Hb as g/dL) within the digital health technology.
2. ☐ **Consistent**: Most of the information is presented consistently in the same format within the digital health technology.
3. ☐ **Inconsistent**: Most of the information is not presented in the same format within the digital health technology.
4. ☐ **Very inconsistent:** Multiple formats of information which is potentially confusing and unsafe for clinical decision.

M. Manageability: Could the information within the digital health technology be easily maintained?

1. ☐ **Very manageable**: The information within the digital health technology could be maintained without difficulties.
2. ☐ **Manageable**: The information within the digital health technology could be maintained with minor difficulties resolvable at the point of care.
3. ☐ **Unmanageable:** The information within the digital health technology could not be easily maintained.
4. ☐ **Very manageable**: The information within the digital health technology could not be maintained at all.

NB: *Kindly answer this question based on any of the activities (i.e. store, save, update, acknowledge) that is/are relevant to your work.*