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Clinical information quality of digital health technologies: protocol for an international eDelphi study.

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Abstract

Introduction

Digital Health Technologies (DHTs) such as electronic health records, clinical decision support systems and electronic prescribing systems, are widely used in healthcare. While adoption of DHTs can improve healthcare delivery, Information Quality (IQ) problems associated with DHTs can compromise quality and safety of care. The Clinical Information Quality (CLIQ) Framework for Digital Health is a novel approach to assessing the quality of clinical information from DHTs. This study aims to appraise the CLIQ framework by exploring clinicians' perspectives on the relevance, definition and assessment of IQ dimensions as defined in the framework. This study will adapt the CLIQ framework to the needs of clinical information users – the clinicians. The contextualized CLIQ framework will offer a pragmatic approach to assessing clinical information from DHTs and may help to forestall IQ problems that can compromise quality and safety of care.

Methods and analysis

The electronic Delphi (eDelphi) approach will be used to engage a heterogenous group of clinicians with patient-facing and/or information governance roles, recruited through purposive and snowball sampling techniques. A semi-structured online questionnaire will be used to explore clinicians' perspectives on relevance, definition, and assessment of IQ dimensions in the CLIQ framework. Survey responses on the relevance of dimensions will be summarized using descriptive statistics to inform decisions on retention of dimensions and termination of the study, based on pre-specified rules. Analysis of the free-text responses will be used to revise definition and assessment of dimensions.

Ethics and dissemination

Ethics approval has been obtained from the Imperial College Research Governance and Integrity Team (Imperial College Research Ethics Committee [ICREC] Reference number: 20IC6396). The results of the study will be published in a peer-reviewed journal and presented at scientific conferences.

Keywords: Information Quality, Digital Health Technology, Patient Safety, Information Systems, Expert Opinion, Face Validity, Content Validity

Strength and Limitations

1. A systematic, practical, affordable, and transparent eDelphi approach will be used to engage clinicians on IQ of DHTs.
2. Heterogeneity of the expert panel, with panellists drawn from multiple clinical professions and countries, will enrich the findings and enhance the external validity of the CLIQ framework.
3. This study will simultaneously take advantage of the clinical experience and information governance expertise of clinicians.
4. Contextualizing the CLIQ framework to the needs of the clinicians will result in a pragmatic approach to assessing IQ of DHTs in clinical practice.
5. Validation based on expert panel approach is limited to face and content validity with further assessment required for appraising the construct validity and applicability of the CLIQ framework in clinical practice.

INTRODUCTION

Digital Health Technologies (DHTs) such as electronic health records, clinical decision support systems and electronic prescribing systems, are widely used in healthcare (1). While widespread adoption of DHTs can improve healthcare delivery, information quality (IQ) problems associated with DHTs can compromise quality and safety of care (2). Patient safety incidents, relating to delayed, missing, partial or wrong information and resulting in patient harm or deaths, have been reported in the literature (3–5). For example, a patient had seizures due to incorrect mapping of different formulations of an epilepsy medication in the electronic prescription system (3).

Although the negative impact of poor IQ of DHTs is well documented in the literature, not much is known about how to assess the quality of clinical information from DHTs. A systematic review published in 2021 identified ten IQ frameworks that are relevant to assessment of clinical information from DHTs (7). Although these frameworks define fundamental dimensions that describe specific aspects of information, none offered a pragmatic approach to assessing information in clinical practice. Drawing on the findings of this systematic review, the Clinical Information Quality (CLIQ) framework (Table 1) was developed to provide a pragmatic approach to assessing the quality of clinical information from DHTs. This study aims to appraise the CLIQ framework by exploring clinicians' perspectives on the relevance, definition and assessment of IQ dimensions as defined in the framework. This will help to contextualise the CLIQ framework to the needs of the information users as recommended in IQ literature (8,9). Clinicians are the end users of clinical information from DHTs.

Table 1: Clinical Information Quality Framework for Digital Health[1]

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

[1] Table 1 was originally published in an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. ©Kayode Philip Fadahunsi, Siobhan O'Connor, James Tosin Akinlua, Petra A Wark, Joseph Gallagher, Christopher Carroll, Josip Car, Azeem Majeed, John O'Donoghue. Originally published in the Journal of Medical Internet Research (https://www.jmir.org), 17.05.2021

METHODS AND ANALYSIS

Study Design

This study will use an electronic Delphi (eDelphi) approach, which is a systematic, practical, affordable and transparent method of engaging multiple stakeholders from different locations and integrating their opinions to achieve consensus (10,11). The eDelphi approach promotes equal participation and prevents dominance of the panel by outspoken participants, which often characterizes physical committee meetings (12). In addition, the iterative process of the eDelphi method enables participants to reconsider their opinions based on collective responses (11).

Steering Committee

This eDelphi study will be coordinated by a steering committee comprising of healthcare professionals and researchers with interest in digital health (KPF, NM, JG, PAW AM, JC). The steering committee developed the CLIQ framework (7), from which the initial items of the eDelphi study will be generated. The committee will be responsible for recruiting the panellists of the eDelphi study. In addition, the committee will make decisions regarding retention, removal or redefinition of IQ dimensions based on the inputs of the panellists according to prespecified decision and stoppage rules.

Generation of Initial Items

The initial survey for the eDelphi study (Appendix 1) has been generated from the infographic CLIQ framework (7) and the accompanying assessment questionnaire developed based on evidence from literatures. The survey documentation and content cover the following:

1. Brief information about the study with a link to the patient information leaflet
2. Request for Informed Consent
3. Collection of demographic data of participants to confirm eligibility for the study and for descriptive purposes. This includes occupation.
4. Likert scale questions on relevance of IQ dimensions and categories.
5. Multiple choice questions on definition, assessment, and categories of IQ dimensions.
6. Free text questions on modification of definition, assessment, and categories of IQ dimensions.
7. Collection of email addresses of participants for feedback purposes and as a contact method for the next round of survey.

Decision Rules

Although there is no standard criteria for consensus in an eDelphi study, there is a need to predefine what constitutes a consensus to enhance objectivity and reduce analysis bias (11). Most previous Delphi studies use 60% agreement or higher as threshold for consensus (13). In this study, a*n IQ* dimension will be considered relevant and retained in the final framework when at least 70% of the panellists, in any round of the survey, choose the options of strongly relevant or somewhat relevant when rating it. On the other hand, a dimension will be considered irrelevant and removed when at least 70% of the experts, in any round of the survey, choose the options of strongly irrelevant or somewhat irrelevant when rating it. The decision on whether to retain or remove any dimension for which no consensus is reached by the end of the study will be made by the steering committee based on the data from all the rounds (11).

Stoppage Rule

The eDelphi rounds will be stopped when consensus has been reached as described above on the relevance of at least 80% of all the IQ dimensions. The stoppage rule will be applied from the first round if no new dimensions are suggested by the respondents, or from the second round after the respondents may have scored any suggested new dimension. The eDelphi study will be terminated at the end of the third round irrespective of the level of consensus achieved (13). This alternative stoppage rule is necessary to prevent the need to continue the eDelphi rounds if consensus is not achieved within a reasonable time frame (11) which will be regarded as 6-8 months in this study.

Participant Recruitment

A heterogenous group of clinicians will be selected including doctors, nurses, pharmacists, and other healthcare professionals with patient-facing and/or information governance roles. Heterogeneity of panellists will allow a wide range of perspectives and enhance external validity of the framework (10). There are no clear guidelines about the sample size of an eDelphi study (13). However, the literature suggests 8-15 participants when the sample is homogenous with a caveat to avoid extremely large sample sizes because the amount of data could be unmanageable (10). We therefore estimated that 40 participants will be required to accommodate different categories of clinicians (doctors, nurses, pharmacists and others), but increased the sample to 50 to account for 20% drop-out during the eDeplhi rounds (13). Thus, we aim to recruit up to 50 participants to accommodate various clinician groups and compensate for drop-out during the eDelphi rounds as well as ensure geographical diversity.

The following eligibility criteria will be used to nominate clinicians that will be invited for the survey:

1. Prior or current experience with using DHTs in patients' care.
2. Information governance role or personal interest in information governance.
3. Proficiency in English Language to understand and complete the surveys.
4. Willingness to participate in a multiple-round eDelphi study (up to three rounds).

We are particularly interested in clinicians with information governance roles (chief clinical information officer, chief nursing information officer, Caldicott guardian etc.) as they typically have prior or current experience with using DHTs. Thus, the study will benefit simultaneously from their subject matter expertise and practical user experience. However, we did not limit participation to this group of clinicians with information expertise alone as we are aware that these roles do not exist in many countries especially in low- and middle-income countries. In addition, recruiting clinicians with varying level of expertise will encourage wide range of opinions.

Study Procedures

The study will start with purposive nomination of the panellists by the members of the steering committee. The snowball sampling technique will be used to recruit additional panellists. The survey will be set up using Qualtrics software (Qualtrics, Provo, UT). The functionality of the survey will be tested by the members of the steering committee prior to its administration. Each of the panellists will then be invited by an introductory email containing a brief overview of the study and the link to the survey. Up to two reminders will be sent at least two weeks apart to encourage participation by those who did not respond to the initial email.

Only items on which consensus has not been reached and any newly suggested item(s) in the previous round will be included in the next round. The survey will be terminated based on the

stoppage rule earlier listed. The first round of the survey started in June 2021. The study is expected to last between 6 and 8 months.

Data Analysis Plan

Survey responses on the relevance of dimensions will be summarized using descriptive statistics including frequencies, percentages, ranges, and medians. The descriptive statistics will be used to provide concise feedback to the participants and to inform decisions on retention of IQ dimensions and termination of the study as already described. The feedback on the statistical summary of group response will be sent in the email inviting participants for the next round of the survey.

The free-text suggestions on the modification of the definition, assessment and categories of IQ dimensions will be analysed based on the reflexive thematic analysis approach (14). This will provide an opportunity to go beyond the texts to decode the intended meaning of the suggested modifications. It is however important to highlight that the purpose of thematic analysis in this study is to provide an in-depth understanding of the contributions of the panellists with the aim of revising the definition of IQ dimensions and the approach of assessment, as appropriate. We have therefore adapted the thematic analysis process to include the following steps:

1. Familiarization with the data by reading the free texts contribution of the panellists repeatedly.
2. Coding of the data to highlight the issues raised with regards to the definition and assessment of CLIQ dimensions.

3. Development of themes by identifying patterns of the suggested modifications, reflecting on them in the context of the overall dataset and defining the essence of each theme.

The themes will then be considered by the steering committee and used to revise the definition and assessment of dimensions as appropriate. The feedback on the free text suggestions and the changes that have been made this will be incorporated into the subsequent round of the survey.

Data Management and Storage

A data impact assessment and dataset registration were completed through the Imperial College Faculty of Medicine Data Privacy Impact Assessment Tool. This was done to address potential gaps and comply with relevant legal obligations. Data will be stored securely in an access restricted Imperial College shared drive in accordance with General Data Protection Rules (15), the Data Protection Act (2018) and the Imperial College Data Protection Policy (16). Data will be stored for a minimum of 10 years after the study completion or longer if needed for further reference.

Ethics and Dissemination

Ethics approval has been obtained from the Imperial College Research Governance and Integrity Team (Imperial College Research Ethics Committee [ICREC] Reference number: 20IC6396). Detailed information about the study will be presented in a participant information sheet containing information on the study objectives, expectation of the participants, duties of the researchers and relevant contacts (Appendix 2). Informed consent will be obtained electronically from each participant at the beginning of the online survey and

before the eDelphi study questions. Participants may refuse to participate or withdraw from the study without giving any reasons at any point. However, any data collected and analysed prior to participant withdrawal will be retained.

Individual responses of the participants will be pseudonymised before being added to the secure drive. Feedback to each participant will only contain descriptive statistical summaries of the group responses. Each research participant will be assigned a research code, known only to the first author. Personal information, which could be used to directly identify participants such as their email addresses, will be kept confidential and known only to the first author. The results of the eDelphi study will be published in a peer-reviewed journal and presented at scientific conferences. Panellists will only be listed in the publication with their prior consent.

Patient and Public Involvement

Patients will not be involved directly in the design and conduct of the study as the study is aimed at DHTs used by healthcare professionals in a clinical setting. The members of the steering committee who designed and will oversee the study are mostly clinicians with research interest in digital health and the members of the expert panel *will be* clinicians with practical experience of using DHTs.

DISCUSSION

This study seeks to appraise the CLIQ Framework by exploring clinicians' perspectives on the definition, relevance, and assessment of IQ dimensions in the framework. The initial CLIQ framework defined IQ dimensions that are relevant to assessing DHTs, based on systematic review of literature, without obtaining inputs from information users or specifying

how IQ could be assessed (7). However, this study will obtain direct inputs from clinicians which will ensure that the dimensions in the contextualised CLIQ framework are those considered relevant by clinicians – the users of clinical information from DHTs. Inputs from the clinicians will also ensure that the questionnaire for assessing clinical information from DHTs is written in a clear and concise language that is well-understood by clinicians. The contextualised CLIQ framework from this study will comprise of two related instruments – an infographic framework and an assessment questionnaire. The infographic framework will define IQ dimensions that are relevant to assessing clinical information thus providing a useful guide to understanding IQ requirements for DHTs. The questionnaire will offer a pragmatic approach to assessing clinical information from DHTs. The questionnaire could be used, for example, to obtain feedback about IQ of named DHTs from clinicians using them in clinical practice.

This study has several strengths and limitations. Firstly, the eDelphi methods offers a systematic, practical, affordable, and transparent approach to integrating opinions of clinicians on IQ of DHTs. Heterogeneity of the expert panel, with panellists drawn from multiple clinical professions and countries, will ensure variety of inputs and enhance the external validity of the CLIQ Framework. In addition, this study will take advantage of the clinical experience and information governance expertise of participating clinicians thus combining practical user experience and subject matter expertise. However, we acknowledge that validation based on expert panel approach is limited to face and content validity (17). We are therefore planning a pilot assessment to evaluate the construct validity of the contextualized CLIQ framework and assess its applicability in clinical practice.

The contextualized CLIQ framework will offer a pragmatic approach to assessing clinical information from DHTs. The framework could be used in quality improvement initiatives relating to DHTs especially in health facilities. Such use may help to identify and forestall IQ problems that can compromise quality and safety of care.

Authors' Contributions: KPF conceived the study and drafted the manuscript. KPF, NM, PAW, JG, AM and JC are part of the steering committee. They oversaw the development of methods, including participant recruitment, data collection and data analysis. They also revised the manuscript for important intellectual content.

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Competing Interests statement: No conflict of interest.

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Word Count: 2619

Clinical Information Quality Framework for Digital Health Technologies

Introduction

Q1 Digital health technologies (DHTs), such as electronic health records, clinical decision support systems and electronic prescribing systems, are widely used in patient care. Researchers at Imperial Colllege London have developed an instrument for assessing the quality of clinical information from DHTs based on evidence from literature. This could help to prevent injuries and deaths associated with poor quality clinical information from DHTs. This study aims to obtain your inputs as a healthcare professional using information from DHTs. Kindly read further information about the study in the participant information sheet.

Consent

Q2 If you are happy to proceed the with this study, please complete the consent form below:

☐ I confirm that I have read and understood the participant information sheet, version 1.4 dated 3 November 2020, and have had the opportunity to ask questions which have been answered fully. (1)

☐ I give consent for information collected about me to be used to support other research in the future, including those outside of the European Economic Area (EEA). (8)

☐ I give consent to being contacted about the potential to take part in other research studies. (9)

☐ I understand that my participation is voluntary, and I am free to withdraw at any time, without giving any reason and without my legal rights being affected. (10)

☐ I give permission for Imperial College London to access my research records that are relevant to this research. (11)

☐ I consent to take part in the above study. (12)

Participant Information

Q3 Please select which best describes your clinical role.

- ○ Doctor (1)
- ○ Nurse/Nurse Practitioner/Advanced Care Practitioner (2)
- ○ Pharmacist/ Clinical Pharmacist (3)
- ○ Physiotherapist/Occupational Therapist (4)
- ○ Physician Associate (5)
- ○ Others (e.g. Community Health Worker, Healthcare Surveillance Officer) (6)

Display This Question:
If Please select which best describes your clinical role. = Others (e.g. Community Health Worker, Healthcare Surveillance Officer)

Q4 If others, please specify

_____

Q5 In which country do you currently reside?

▼ Afghanistan (1) ... Zimbabwe (1357)

Q6 Gender

- ○ Male (1)
- ○ Female (2)
- ○ Prefer not to say (3)

Q7 Please state how long you have used digital health technologies such as electronic health record, electronic prescribing system, telemedicine and clinical decision support system in clinical practice?

▼ 1 year (4) ... 10 years and above (13)

Q8. How relevant to quality and safety of care do you consider each of these attributes of clinical information from DHTs?

	Strongly relevant	Somewhat relevant	Neither relevant nor irrelevant	Somewhat irrelevant	Strongly irrelevant
Accuracy: the extent to which information is free from errors.	○	○	○	○	○
Completeness: the extent to which no needed information is missing.	○	○	○	○	○
Interpretability: the extent to which information can be understood.	○	○	○	○	○
Plausibility: the extent to which information makes sense in the light of existing knowledge.	○	○	○	○	○
Provenance: the extent to which the source of information is trustworthy.	○	○	○	○	○
Relevance: The extent to which information is useful for the intended task.	○	○	○	○	○
Accessibility: the extent to which information is easily obtainable.	○	○	○	○	○
Portability: the extent to which information is available in different systems.	○	○	○	○	○
Security: the extent to which information is protected from unauthorized access.	○	○	○	○	○
Timeliness: the extent to which up-to-date information is available when needed.	○	○	○	○	○
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 easily maintained (13)	○	○	○	○	○

Clinical Information Quality Assessment (Accuracy)

Q9. Would you include, exclude or modify the following question when assessing quality of clinical information from DHTs?
Accuracy: Is the information from the digital health technology free of errors?
☐**Very Accurate**. The information from the digital health is completely free of errors.
☐**Accurate**: The information from the digital health technology is free of errors that could lead to adverse events.
☐**Inaccurate**: The information from the digital health technology contains few errors that could lead to adverse events.
☐**Very inaccurate**: The information from the digital health technology contains 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.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude or modify the following question when assessing quality of clinical in... = Modify

Q10 Please state any modification you would like to suggest regarding definition and assessment of accuracy?

_____

_____

_____

_____

_____

Clinical Information Quality Assessment (Completeness)

Q11. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Completeness: Is no needed information missing from the digital health technology?
☐**Very complete**: No information is missing from the digital health technology.
☐**Complete**: No information required for clinical decision (diagnosis, treatment or prognosis) is missing from the digital health technology.
☐**Incomplete**: Few information required for clinical decision (diagnosis, treatment or prognosis) are missing from the digital health technology.
☐**Very incomplete**: Several information required for clinical decision (diagnosis, treatment or prognosis) are missing from the digital health technology.

- ○ Include as it is (1)
- ○ Exclude (4)
- ○ Modify (5)

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q12 Please state any modification you would like to suggest regarding definition and assessment of completeness.

_____

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Clinical Information Quality Assessment (Interpretability)

Q13. Would you include, exclude or modify the following question when assessing quality of clinical information from DHTs?
Interpretability: Could the information from the digital health technology be understood to make clinical decision?
☐**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)
☐**Interpretable**: Standard resources provided to aid interpretation of the information from the digital health technology (e.g. reference range)
☐**Uninterpretable**: Information from the digital health technology cannot be interpreted without seeking clarification from its author.
☐**Very uninterpretable**: Completely meaningless information not suitable for clinical decision.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude or modify the following question when assessing quality of clinical in... = Modify

Q14 Please state any modification you would like to suggest regarding definition and assessment of interpretability.

_____

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Clinical Information Quality Assessment (Plausibility)

Q15. Would you include, exclude or modify the following question when assessing quality of clinical information from DHTs?
Plausibility: Does the information from the digital health technology make sense based on common knowledge?
☐**Very plausible**. The information from the digital health technology agrees with common knowledge (e.g. raised inflammatory markers in a patient with sepsis).
☐**Plausible**. The information from the digital health technology agrees with common knowledge if exceptional circumstances are considered (e.g. normal inflammatory markers in a patient with sepsis due to delayed immune response)
☐**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%)
☐**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).

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude or modify the following question when assessing quality of clinical in... = Modify

Q16 Please state any modification you would like to suggest regarding definition and assessment of plausibility.

_____

_____

_____

_____

_____

Clinical Information Quality Assessment (Provenance)

Q17. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Provenance: Is the source of the information in the digital health technology trustworthy?
☐**Very trustworthy**: The information in the digital health technology is from highly trustworthy source (e.g. UN Agencies, Official Government Agencies, Academic institutions, Hospitals).
☐**Trustworthy**: The information in the digital health technology is from recognised private corporations (e.g. non-governmental organisations, registered charities).
☐**Untrustworthy**: The information in the digital health technology is from sources with obvious conflict of interest (e.g. pharmaceutical companies, tobacco companies).
☐**Very untrustworthy**: Unverifiable source of information and unsubstantiated claims (e.g. broadcast information on social media, no references), unsuitable for clinical decision

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q18 Please state any modification you would like to suggest regarding definition and assessment of provenance.

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Clinical Information Quality Assessment (Relevance)

Q19. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Relevance: Is the information from the digital health technology useful for the intended task?
☐**Very relevant**: All information from the digital health technology is useful for the intended task
☐**Relevant**: Most of the information from the digital health technology is useful for the intended task?
☐**Irrelevant**: Most of the information from the digital health technology not useful for the intended task
☐**Very irrelevant**: None of the information from the digital health technology is useful for the intended task

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q20. Please state any modification you would like to suggest regarding definition and assessment of relevance.

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Clinical Information Quality Assessment (Accessibility)

Q21. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Accessibility: Is the information easily obtainable from the digital health technology?
☐**Very accessible**: The information from the digital health technology is obtainable with no difficulties at the point of care.
☐**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)
☐**Inaccessible**: The information from the digital health technology is not obtainable at the point of care.
☐**Very inaccessible**: The information from the digital health technology is not obtainable at all.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q22. Please state any modification you would like to suggest regarding definition and assessment of accessibility.

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Clinical Information Quality Assessment (Portability)

Q23. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Portability: Is the information from the digital health technology accessible in different systems?
☐**Very portable**: The information from the digital health technology is accessible at all levels of healthcare system (primary, secondary & tertiary).
☐**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).
☐**Unportable**: The information from the digital health technology is only accessible at the level of care where it was created.
☐**Very unportable**: The information from the digital health technology is only accessible on the computer system where it was created.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q24 Please state any modification you would like to suggest regarding definition and assessment of portability.

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Clinical Information Quality Assessment (Security)

Q25 Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Security: Is the information in the digital health technology protected from unauthorised access?
☐ **Very secure**: The information in the digital health technology is securely protected against unauthorized access using multiple strategies (e.g. password and swipe card).
☐ **Secure**: The information in the digital health technology is securely protected against unauthorised access using a single strategy (e.g. requires only password).
☐ **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)
☐ **Very insecure**: The information is publicly accessible (e.g. information on hospital website)

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q26 Please state any modification you would like to suggest regarding definition and assessment of security.

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Clinical Information Quality Assessment (Timeliness)

Q27 Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Timeliness: Is up-to-date information from the digital health technology available when it is needed?
☐ **Very timely**: Up-to-date information is available from the digital health technology at the point of care with no delays.
☐ **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)
☐ **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)
☐ **Very untimely**: The information from the digital health technology is outdated and/or not available when needed for clinical decision

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q28 Please state any modification you would like to suggest regarding definition and assessment of timeliness.

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Clinical Information Quality Assessment (Conformance)

Q29. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Conformance: Is the information from the digital health technology presented in the desired format?
☐ **Very conformant**: All the information from the digital health technology conforms to international or local standards (e.g. SI units).
☐ **Conformant**: Most of the information from the digital health technology conforms to international or local standards.
☐ **Non-conformant**: Most of the information from the digital health technology do not conform to local or international standards.
☐ **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).

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q30. Please state any modification you would like to suggest regarding definition and assessment of conformance.

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Clinical Information Quality Assessment (Consistency)

Q31. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Consistency: Is the information presented in the same format within the digital health technology?
☐ **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.
☐ **Consistent**: Most of the information is presented consistently in the same format within the digital health technology.
☐ **Inconsistent**: Most of the information is not presented in the same format within the digital health technology.
☐ **Very inconsistent:** Multiple formats of information which is potentially confusing and unsafe for clinical decision.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q32 Please state any modification you would like to suggest regarding definition and assessment of consistency.

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Clinical Information Quality Assessment (Maintainability)

Q33. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Maintainability: Could the information within the digital health technology be easily maintained?
☐ **Very maintainable**: The information within the digital health technology could be maintained without difficulties.
☐ **Maintainable**: The information within the digital health technology could be maintained with minor difficulties resolvable at the point of care.
☐ **Unmaintainable:** The information within the digital health technology could not be easily maintained.
☐ **Very maintainable**: The information within the digital health technology could not be maintained at all.
NB: Maintainance includes activities such as storing, auditing, updating date.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q34 Please state any modification you would like to suggest regarding definition and assessment of maintainability.

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Q35. CLIQ Framework for Digital Health Technology

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

Q36. Would you like to retain or modify the above categories?

- ○ Retain the categories
- ○ Modify the categories

Display This Question:

If Would you like to retain or modify the above categories? = Modify the categories

Q37 Please state how you would want the categories to be modified.

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Q38 Thank you for taking part in this eDelphi survey. Please provide your email so we can share the summary of the findings with you and contact you for the subsequent round.

_____

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PARTICIPANT INFORMATION SHEET

Clinicians' Perspectives on Information Quality of Digital Health Technologies

Kayode Fadahunsi, Nikolas Mastellos, Petra Wark, Joseph Gallagher, Azeem Majeed, Josip Car

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

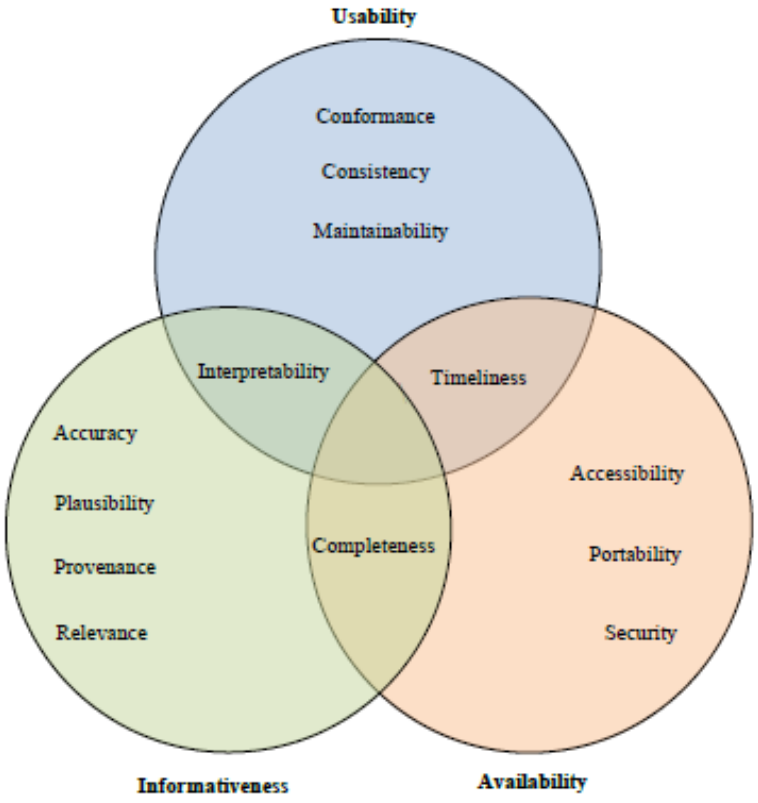
You can find out more about how we use your information

- 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.*

BMJ Open

Clinical information quality of digital health technologies: protocol for an international eDelphi study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-057430.R1
Article Type:	Protocol
Date Submitted by the Author:	02-Mar-2022
Complete List of Authors:	Fadahunsi, Kayode; Imperial College London, Primary Care and Public Health, School of Public Health Wark, Petra; Imperial College London, Primary Care and Public Health, School of Public Health; Coventry University, Centre for Intelligent Healthcare, Institute for Health and Wellbeing Mastellos , Nikolaos; Imperial College London, Primary Care and Public Health, School of Public Health Gallagher, Joseph; University College Dublin, gHealth Research Group, School of Medicine Majeed, Azeem; Imperial College London, Primary Care and Public Health, School of Public Health Car, Josip; Imperial College London, Primary Care and Public Health, School of Public Health; Nanyang Technological University, Centre for Population Health Sciences, LKC Medicine,
Primary Subject Heading:	Health informatics
Secondary Subject Heading:	Public health
Keywords:	Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, Information management < BIOTECHNOLOGY & BIOINFORMATICS, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Clinical information quality of digital health technologies: protocol for an international eDelphi study.

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Abstract

Introduction

Digital Health Technologies (DHTs) such as electronic health records, clinical decision support systems and electronic prescribing systems, are widely used in healthcare. While adoption of DHTs can improve healthcare delivery, Information Quality (IQ) problems associated with DHTs can compromise quality and safety of care. The Clinical Information Quality (CLIQ) Framework for Digital Health is a novel approach to assessing the quality of clinical information from DHTs. This study aims to appraise the CLIQ framework by exploring clinicians' perspectives on the relevance, definition and assessment of IQ dimensions as defined in the framework. This study will adapt the CLIQ framework to the needs of clinical information users – the clinicians. The contextualized CLIQ framework will offer a pragmatic approach to assessing clinical information from DHTs and may help to forestall IQ problems that can compromise quality and safety of care.

Methods and analysis

The electronic Delphi (eDelphi) approach will be used to engage a heterogenous group of clinicians with patient-facing and/or information governance roles, recruited through purposive and snowball sampling techniques. A semi-structured online questionnaire will be used to explore clinicians' perspectives on relevance, definition, and assessment of IQ dimensions in the CLIQ framework. Survey responses on the relevance of dimensions will be summarized using descriptive statistics to inform decisions on retention of dimensions and termination of the study, based on pre-specified rules. Analysis of the free-text responses will be used to revise definition and assessment of dimensions.

Ethics and dissemination

Ethics approval has been obtained from the Imperial College Research Governance and Integrity Team (Imperial College Research Ethics Committee [ICREC] Reference number: 20IC6396). The results of the study will be published in a peer-reviewed journal and presented at scientific conferences.

Keywords: Information Quality, Digital Health Technology, Patient Safety, Information Systems, Expert Opinion, Face Validity, Content Validity

Strength and Limitations

1. A systematic, practical, affordable, and transparent eDelphi approach will be used to engage clinicians on IQ of DHTs.
2. Heterogeneity of the expert panel, with panellists drawn from multiple clinical professions and countries, will enrich the findings and enhance the external validity of the CLIQ framework.
3. This study will simultaneously take advantage of the clinical experience and information governance expertise of clinicians.
4. Contextualizing the CLIQ framework to the needs of the clinicians will result in a pragmatic approach to assessing IQ of DHTs in clinical practice.
5. Validation based on expert panel approach is limited to face and content validity with further assessment required for appraising the construct validity and applicability of the CLIQ framework in clinical practice.

INTRODUCTION

Digital Health Technologies (DHTs) such as electronic health records, clinical decision support systems and electronic prescribing systems, are widely used in healthcare (1). While widespread adoption of DHTs can improve healthcare delivery, information quality (IQ) problems associated with DHTs can compromise quality and safety of care (2). Patient safety incidents, relating to delayed, missing, partial or wrong information and resulting in patient harm or deaths, have been reported in the literature (3–6). For example, a patient had seizures due to incorrect mapping of different formulations of an epilepsy medication in the electronic prescription system (3).

Although the negative impact of poor IQ of DHTs is well documented in the literature, not much is known about how to assess the quality of clinical information from DHTs. A systematic review published in 2021 identified ten IQ frameworks that are relevant to assessment of clinical information from DHTs (7). Although these frameworks define fundamental dimensions that describe specific aspects of information, none offered a pragmatic approach to assessing information in clinical practice. Drawing on the findings of this systematic review, the Clinical Information Quality (CLIQ) framework (Table 1) was developed to provide a pragmatic approach to assessing the quality of clinical information from DHTs. This study aims to appraise the CLIQ framework by exploring clinicians' perspectives on the relevance, definition and assessment of IQ dimensions as defined in the framework. This will help to contextualise the CLIQ framework to the needs of the information users as recommended in IQ literature (8,9). Clinicians are the end users of clinical information from DHTs.

Table 1: Clinical Information Quality Framework for Digital Health[1]

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

[1] Table 1 was originally published in an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. ©Kayode Philip Fadahunsi, Siobhan O'Connor, James Tosin Akinlua, Petra A Wark, Joseph Gallagher, Christopher Carroll, Josip Car, Azeem Majeed, John O'Donoghue. Originally published in the Journal of Medical Internet Research (https://www.jmir.org), 17.05.2021

METHODS AND ANALYSIS

Study Design

This study will use an electronic Delphi (eDelphi) approach, which is a systematic, practical, affordable and transparent method of engaging multiple stakeholders from different locations and integrating their opinions to achieve consensus (10,11). The eDelphi approach promotes equal participation and prevents dominance of the panel by outspoken participants, which often characterizes physical committee meetings (12). In addition, the iterative process of the eDelphi method enables participants to reconsider their opinions based on collective responses (11).

Steering Committee

This eDelphi study will be coordinated by a steering committee comprising of healthcare professionals and researchers with interest in digital health (KPF, NM, JG, PAW AM, JC). The steering committee developed the CLIQ framework (7), from which the initial items of the eDelphi study will be generated. The committee will be responsible for recruiting the panellists of the eDelphi study. In addition, the committee will make decisions regarding retention, removal or redefinition of IQ dimensions based on the inputs of the panellists according to prespecified decision and stoppage rules.

Generation of Initial Items

The initial survey for the eDelphi study (Appendix 1) has been generated from the infographic CLIQ framework (7) and the accompanying assessment questionnaire developed based on evidence from literatures. The survey documentation and content cover the following:

1. Brief information about the study with a link to the participant information leaflet
2. Request for Informed Consent
3. Collection of demographic data of participants to confirm eligibility for the study and for descriptive purposes. This includes occupation.
4. Likert scale questions on relevance of IQ dimensions and categories.
5. Multiple choice questions on definition, assessment, and categories of IQ dimensions.
6. Free text questions on modification of definition, assessment, and categories of IQ dimensions.
7. Collection of email addresses of participants for feedback purposes and as a contact method for the next round of survey.

Thus, the survey questions relating to the CLIQ Framework are divided into two parts. The first part will explore the relevance of the dimensions in the CLIQ Framework from the perspective of the panellists. The second part will obtain their suggestions on modification to the definitions, assessment and categories of the IQ dimensions in the CLIQ Framework. The relevance of the IQ dimensions will be assessed based on the panellists' perspective on the relevance of the dimensions to quality and safety of care using a 5-point Likert scale. This captures different range of options and allows to distinguish between categories that people make naturally, without a strong cognitive load (strongly relevant, somewhat relevant, neither relevant nor irrelevant, somewhat irrelevant and strongly irrelevant).

Decision Rules

Although there is no standard criteria for consensus in an eDelphi study, there is a need to predefine what constitutes a consensus to enhance objectivity and reduce analysis bias (11). Most previous Delphi studies use 60% agreement or higher as threshold for consensus (13).

In this study, a*n IQ* dimension will be considered relevant and retained in the final framework when at least 70% of the panellists, in any round of the survey, choose the options of strongly relevant or somewhat relevant when rating it. On the other hand, a dimension will be considered irrelevant and removed when at least 70% of the experts, in any round of the survey, choose the options of strongly irrelevant or somewhat irrelevant when rating it. The decision on whether to retain or remove any dimension for which no consensus is reached by the end of the study will be made by the steering committee based on the data from all the rounds (11).

Stoppage Rule

The eDelphi rounds will be stopped when consensus has been reached as described above on the relevance of at least 80% of all the IQ dimensions. The stoppage rule will be applied from the first round if no new dimensions are suggested by the respondents, or from the second round after the respondents may have scored any suggested new dimension. The eDelphi study will be terminated at the end of the third round irrespective of the level of consensus achieved (13). This alternative stoppage rule is necessary to prevent the need to continue the eDelphi rounds if consensus is not achieved within a reasonable time frame (11) which will be regarded as 6-8 months in this study.

Participant Recruitment

A heterogenous group of clinicians will be selected including doctors, nurses, pharmacists, and other healthcare professionals with patient-facing and/or information governance roles. Heterogeneity of panellists will allow a wide range of perspectives and enhance external validity of the framework (10). There are no clear guidelines about the sample size of an eDelphi study (13). However, the literature suggests 8-15 participants when the sample is

homogenous with a caveat to avoid extremely large sample sizes because the amount of data could be unmanageable (10). We therefore estimated that 40 participants will be required to accommodate different categories of clinicians (doctors, nurses, pharmacists and others), but increased the sample to 50 to account for 20% drop-out during the eDeplhi rounds (13). Thus, we aim to recruit up to 50 participants to accommodate various clinician groups and compensate for drop-out during the eDelphi rounds as well as ensure geographical diversity.

The following eligibility criteria will be used to nominate clinicians that will be invited for the survey:

1. Prior or current experience with using DHTs in patients' care.
2. Information governance role or personal interest in information governance.
3. Proficiency in English Language to understand and complete the surveys.
4. Willingness to participate in a multiple-round eDelphi study (up to three rounds).

We are particularly interested in clinicians with information governance roles (chief clinical information officer, chief nursing information officer, Caldicott guardian etc.) as they typically have prior or current experience with using DHTs. Thus, the study will benefit simultaneously from their subject matter expertise and practical user experience. However, we did not limit participation to this group of clinicians with information expertise alone as we are aware that these roles do not exist in many countries especially in low- and middle-income countries. In addition, recruiting clinicians with varying level of expertise will encourage wide range of opinions.

Study Procedures

The survey will be set up using Qualtrics software (Qualtrics, Provo, UT). The functionality of the survey will be tested by the members of the steering committee prior to its

administration. The study will start with purposive nomination of the panellists by the members of the steering committee. Steering committee members will be asked to nominate panellists both within and beyond their professional networks. Nomination of the panellists by the steering committee members will be based on the pre-determined eligibility criteria discussed above, subject to confirmation by another committee member who will check the profile of the nominees against the eligibility criteria. Each of the panellists will be invited by an introductory email containing a brief overview of the study and the link to the survey. The snowball sampling technique will then be used to recruit additional panellists by asking the nominated panellists to share the eDelphi invitation to other eligible participants. Questions about participants' occupation and prior digital health experience will be included in the survey to further confirm the eligibility of the panellists. Up to two reminders will be sent at least two weeks apart to encourage participation by those who did not respond to the initial email.

Only items on which consensus has not been reached and any newly suggested item(s) in the previous round will be included in the next round. The survey will be terminated based on the stoppage rule earlier listed. The first round of the survey started in June 2021. The study is expected to last between 6 and 8 months.

Data Analysis Plan

Survey responses on the relevance of dimensions will be summarized using descriptive statistics including frequencies, percentages, ranges, and medians. The descriptive statistics will be used to provide concise feedback to the participants and to inform decisions on retention of IQ dimensions and termination of the study as already described. The feedback

on the statistical summary of group response will be sent in the email inviting participants for the next round of the survey.

The free-text suggestions on the modification of the definition, assessment and categories of IQ dimensions will be analysed based on the reflexive thematic analysis approach (14). This will provide an opportunity to go beyond the texts to decode the intended meaning of the suggested modifications. It is however important to highlight that the purpose of thematic analysis in this study is to provide an in-depth understanding of the contributions of the panellists with the aim of revising the definition of IQ dimensions and the approach of assessment, as appropriate. We have therefore adapted the thematic analysis process to include the following steps:

1. Familiarization with the data by reading the free texts contribution of the panellists repeatedly.
2. Coding of the data to highlight the issues raised with regards to the definition and assessment of CLIQ dimensions.
3. Development of themes by identifying patterns of the suggested modifications, reflecting on them in the context of the overall dataset and defining the essence of each theme.

The themes will then be considered by the steering committee and used to revise the definition and assessment of dimensions as appropriate. The feedback on the free text suggestions and the changes that have been made will be incorporated into the subsequent round of the survey.

Data Management and Storage

A data impact assessment and dataset registration were completed through the Imperial College Faculty of Medicine Data Privacy Impact Assessment Tool. This was done to address potential gaps and comply with relevant legal obligations. Data will be stored securely in an access restricted Imperial College shared drive in accordance with General Data Protection Rules (15), the Data Protection Act (2018) and the Imperial College Data Protection Policy (16). Data will be stored for a minimum of 10 years after the study completion or longer if needed for further reference.

Ethics and Dissemination

Ethics approval has been obtained from the Imperial College Research Governance and Integrity Team (Imperial College Research Ethics Committee [ICREC] Reference number: 20IC6396). Detailed information about the study will be presented in a participant information sheet containing information on the study objectives, expectation of the participants, duties of the researchers and relevant contacts (Appendix 2). Informed consent will be obtained electronically from each participant at the beginning of the online survey and before the eDelphi study questions. Participants may refuse to participate or withdraw from the study without giving any reasons at any point. However, any data collected and analysed prior to participant withdrawal will be retained.

Individual responses of the participants will be pseudonymised before being added to the secure drive. Feedback to each participant will only contain descriptive statistical summaries of the group responses. Each research participant will be assigned a research code, known only to the first author. Personal information, which could be used to directly identify participants such as their email addresses, will be kept confidential and known only to the

first author. The results of the eDelphi study will be published in a peer-reviewed journal and presented at scientific conferences. Panellists will only be listed in the publication with their prior consent.

Patient and Public Involvement

Patients will not be involved directly in the design and conduct of the study as the study is aimed at DHTs used by healthcare professionals in a clinical setting. The members of the steering committee who designed and will oversee the study are mostly clinicians with research interest in digital health and the members of the expert panel *will be* clinicians with practical experience of using DHTs.

DISCUSSION

This study seeks to appraise the CLIQ Framework by exploring clinicians' perspectives on the definition, relevance, and assessment of IQ dimensions in the framework. The initial CLIQ framework defined IQ dimensions that are relevant to assessing DHTs, based on systematic review of literature, without obtaining inputs from information users or specifying how IQ could be assessed (7). However, this study will obtain direct inputs from clinicians which will ensure that the dimensions in the contextualised CLIQ framework are those considered relevant by clinicians – the users of clinical information from DHTs. Inputs from the clinicians will also ensure that the questionnaire for assessing clinical information from DHTs is written in a clear and concise language that is well-understood by clinicians. The contextualised CLIQ framework from this study will comprise of two related instruments – an infographic framework and an assessment questionnaire. The infographic framework will define IQ dimensions that are relevant to assessing clinical information thus providing a useful guide to understanding IQ requirements for DHTs. The questionnaire will offer a

pragmatic approach to assessing clinical information from DHTs. The questionnaire could be used, for example, to obtain feedback about IQ of named DHTs from clinicians using them in clinical practice.

This study has several strengths and limitations. Firstly, the eDelphi methods offers a systematic, practical, affordable, and transparent approach to integrating opinions of clinicians on IQ of DHTs. Heterogeneity of the expert panel, with panellists drawn from multiple clinical professions and countries, will ensure variety of inputs and enhance the external validity of the CLIQ Framework. In addition, this study will take advantage of the clinical experience and information governance expertise of participating clinicians thus combining practical user experience and subject matter expertise.

However, we acknowledge that validation based on expert panel approach is limited to face and content validity (17). We are therefore planning a pilot assessment to evaluate the construct validity of the contextualized CLIQ framework and assess its applicability in clinical practice. We acknowledge that the initial nomination of the panellists may lead to selection bias as steering committee members may tend to recruit colleagues they know personally, rather than via their wider professional networks. These colleagues may be more likely to participate than people invited through other sources. We have therefore put in place multiple measures to reduce the risk of selection bias. The snowball sampling technique will ensure that only a fraction of participants will likely be recruited directly by the steering committee members. The eDelphi approach will make it impossible for any of the panellists to dominate the decision-making process. Finally, we will compare the responses of the panellists who were recruited directly and those who were recruited by snowball techniques.

The contextualized CLIQ framework will offer a pragmatic approach to assessing clinical information from DHTs. The framework could be used in quality improvement initiatives relating to DHTs especially in health facilities. Such use may help to identify and forestall IQ problems that can compromise quality and safety of care.

Authors' Contributions: KPF conceived the study and drafted the manuscript. KPF, NM, PAW, JG, AM and JC are part of the steering committee. They contributed to the development of methods, including participant recruitment, data collection and data analysis. They also revised the manuscript for important intellectual content.

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Competing Interests statement: No conflict of interest.

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Clinical Information Quality Framework for Digital Health Technologies

Introduction

Q1 Digital health technologies (DHTs), such as electronic health records, clinical decision support systems and electronic prescribing systems, are widely used in patient care. Researchers at Imperial Colllege London have developed an instrument for assessing the quality of clinical information from DHTs based on evidence from literature. This could help to prevent injuries and deaths associated with poor quality clinical information from DHTs. This study aims to obtain your inputs as a healthcare professional using information from DHTs. Kindly read further information about the study in the participant information sheet.

Consent

Q2 If you are happy to proceed the with this study, please complete the consent form below:

☐ I confirm that I have read and understood the participant information sheet, version 1.4 dated 3 November 2020, and have had the opportunity to ask questions which have been answered fully. (1)

☐ I give consent for information collected about me to be used to support other research in the future, including those outside of the European Economic Area (EEA). (8)

☐ I give consent to being contacted about the potential to take part in other research studies. (9)

☐ I understand that my participation is voluntary, and I am free to withdraw at any time, without giving any reason and without my legal rights being affected. (10)

☐ I give permission for Imperial College London to access my research records that are relevant to this research. (11)

☐ I consent to take part in the above study. (12)

Participant Information

Q3 Please select which best describes your clinical role.

- ○ Doctor (1)
- ○ Nurse/Nurse Practitioner/Advanced Care Practitioner (2)
- ○ Pharmacist/ Clinical Pharmacist (3)
- ○ Physiotherapist/Occupational Therapist (4)
- ○ Physician Associate (5)
- ○ Others (e.g. Community Health Worker, Healthcare Surveillance Officer) (6)

Display This Question:
If Please select which best describes your clinical role. = Others (e.g. Community Health Worker, Healthcare Surveillance Officer)

Q4 If others, please specify

_____

Q5 In which country do you currently reside?

▼ Afghanistan (1) ... Zimbabwe (1357)

Q6 Gender

- ○ Male (1)
- ○ Female (2)
- ○ Prefer not to say (3)

Q7 Please state how long you have used digital health technologies such as electronic health record, electronic prescribing system, telemedicine and clinical decision support system in clinical practice?

▼ 1 year (4) ... 10 years and above (13)

Q8. How relevant to quality and safety of care do you consider each of these attributes of clinical information from DHTs?

	Strongly relevant	Somewhat relevant	Neither relevant nor irrelevant	Somewhat irrelevant	Strongly irrelevant
Accuracy: the extent to which information is free from errors.	○	○	○	○	○
Completeness: the extent to which no needed information is missing.	○	○	○	○	○
Interpretability: the extent to which information can be understood.	○	○	○	○	○
Plausibility: the extent to which information makes sense in the light of existing knowledge.	○	○	○	○	○
Provenance: the extent to which the source of information is trustworthy.	○	○	○	○	○
Relevance: The extent to which information is useful for the intended task.	○	○	○	○	○
Accessibility: the extent to which information is easily obtainable.	○	○	○	○	○
Portability: the extent to which information is available in different systems.	○	○	○	○	○
Security: the extent to which information is protected from unauthorized access.	○	○	○	○	○
Timeliness: the extent to which up-to-date information is available when needed.	○	○	○	○	○
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 easily maintained (13)	○	○	○	○	○

Clinical Information Quality Assessment (Accuracy)

Q9. Would you include, exclude or modify the following question when assessing quality of clinical information from DHTs?
Accuracy: Is the information from the digital health technology free of errors?
☐**Very Accurate**. The information from the digital health is completely free of errors.
☐**Accurate**: The information from the digital health technology is free of errors that could lead to adverse events.
☐**Inaccurate**: The information from the digital health technology contains few errors that could lead to adverse events.
☐**Very inaccurate**: The information from the digital health technology contains 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.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude or modify the following question when assessing quality of clinical in... = Modify

Q10 Please state any modification you would like to suggest regarding definition and assessment of accuracy?

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_____

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Clinical Information Quality Assessment (Completeness)

Q11. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Completeness: Is no needed information missing from the digital health technology?
☐**Very complete**: No information is missing from the digital health technology.
☐**Complete**: No information required for clinical decision (diagnosis, treatment or prognosis) is missing from the digital health technology.
☐**Incomplete**: Few information required for clinical decision (diagnosis, treatment or prognosis) are missing from the digital health technology.
☐**Very incomplete**: Several information required for clinical decision (diagnosis, treatment or prognosis) are missing from the digital health technology.

- ○ Include as it is (1)
- ○ Exclude (4)
- ○ Modify (5)

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q12 Please state any modification you would like to suggest regarding definition and assessment of completeness.

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Clinical Information Quality Assessment (Interpretability)

Q13. Would you include, exclude or modify the following question when assessing quality of clinical information from DHTs?
Interpretability: Could the information from the digital health technology be understood to make clinical decision?
☐**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)
☐**Interpretable**: Standard resources provided to aid interpretation of the information from the digital health technology (e.g. reference range)
☐**Uninterpretable**: Information from the digital health technology cannot be interpreted without seeking clarification from its author.
☐**Very uninterpretable**: Completely meaningless information not suitable for clinical decision.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude or modify the following question when assessing quality of clinical in... = Modify

Q14 Please state any modification you would like to suggest regarding definition and assessment of interpretability.

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Clinical Information Quality Assessment (Plausibility)

Q15. Would you include, exclude or modify the following question when assessing quality of clinical information from DHTs?
Plausibility: Does the information from the digital health technology make sense based on common knowledge?
☐**Very plausible**. The information from the digital health technology agrees with common knowledge (e.g. raised inflammatory markers in a patient with sepsis).
☐**Plausible**. The information from the digital health technology agrees with common knowledge if exceptional circumstances are considered (e.g. normal inflammatory markers in a patient with sepsis due to delayed immune response)
☐**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%)
☐**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).

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude or modify the following question when assessing quality of clinical in... = Modify

Q16 Please state any modification you would like to suggest regarding definition and assessment of plausibility.

_____

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Clinical Information Quality Assessment (Provenance)

Q17. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?

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

☐**Very trustworthy**: The information in the digital health technology is from highly trustworthy source (e.g. UN Agencies, Official Government Agencies, Academic institutions, Hospitals).

☐**Trustworthy**: The information in the digital health technology is from recognised private corporations (e.g. non-governmental organisations, registered charities).

☐**Untrustworthy**: The information in the digital health technology is from sources with obvious conflict of interest (e.g. pharmaceutical companies, tobacco companies).

☐**Very untrustworthy**: Unverifiable source of information and unsubstantiated claims (e.g. broadcast information on social media, no references), unsuitable for clinical decision

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q18 Please state any modification you would like to suggest regarding definition and assessment of provenance.

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Clinical Information Quality Assessment (Relevance)

Q19. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Relevance: Is the information from the digital health technology useful for the intended task?
☐**Very relevant**: All information from the digital health technology is useful for the intended task
☐**Relevant**: Most of the information from the digital health technology is useful for the intended task?
☐**Irrelevant**: Most of the information from the digital health technology not useful for the intended task
☐**Very irrelevant**: None of the information from the digital health technology is useful for the intended task

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q20. Please state any modification you would like to suggest regarding definition and assessment of relevance.

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Clinical Information Quality Assessment (Accessibility)

Q21. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Accessibility: Is the information easily obtainable from the digital health technology?
☐**Very accessible**: The information from the digital health technology is obtainable with no difficulties at the point of care.
☐**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)
☐**Inaccessible**: The information from the digital health technology is not obtainable at the point of care.
☐**Very inaccessible**: The information from the digital health technology is not obtainable at all.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q22. Please state any modification you would like to suggest regarding definition and assessment of accessibility.

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Clinical Information Quality Assessment (Portability)

Q23. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Portability: Is the information from the digital health technology accessible in different systems?
☐**Very portable**: The information from the digital health technology is accessible at all levels of healthcare system (primary, secondary & tertiary).
☐**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).
☐**Unportable**: The information from the digital health technology is only accessible at the level of care where it was created.
☐**Very unportable**: The information from the digital health technology is only accessible on the computer system where it was created.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q24 Please state any modification you would like to suggest regarding definition and assessment of portability.

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Clinical Information Quality Assessment (Security)

Q25 Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Security: Is the information in the digital health technology protected from unauthorised access?
☐ **Very secure**: The information in the digital health technology is securely protected against unauthorized access using multiple strategies (e.g. password and swipe card).
☐ **Secure**: The information in the digital health technology is securely protected against unauthorised access using a single strategy (e.g. requires only password).
☐ **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)
☐ **Very insecure**: The information is publicly accessible (e.g. information on hospital website)

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q26 Please state any modification you would like to suggest regarding definition and assessment of security.

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Clinical Information Quality Assessment (Timeliness)

Q27 Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Timeliness: Is up-to-date information from the digital health technology available when it is needed?
☐ **Very timely**: Up-to-date information is available from the digital health technology at the point of care with no delays.
☐ **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)
☐ **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)
☐ **Very untimely**: The information from the digital health technology is outdated and/or not available when needed for clinical decision

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q28 Please state any modification you would like to suggest regarding definition and assessment of timeliness.

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Clinical Information Quality Assessment (Conformance)

Q29. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Conformance: Is the information from the digital health technology presented in the desired format?
☐ **Very conformant**: All the information from the digital health technology conforms to international or local standards (e.g. SI units).
☐ **Conformant**: Most of the information from the digital health technology conforms to international or local standards.
☐ **Non-conformant**: Most of the information from the digital health technology do not conform to local or international standards.
☐ **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).

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q30. Please state any modification you would like to suggest regarding definition and assessment of conformance.

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Clinical Information Quality Assessment (Consistency)

Q31. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Consistency: Is the information presented in the same format within the digital health technology?
☐ **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.
☐ **Consistent**: Most of the information is presented consistently in the same format within the digital health technology.
☐ **Inconsistent**: Most of the information is not presented in the same format within the digital health technology.
☐ **Very inconsistent:** Multiple formats of information which is potentially confusing and unsafe for clinical decision.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q32 Please state any modification you would like to suggest regarding definition and assessment of consistency.

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Clinical Information Quality Assessment (Maintainability)

Q33. Would you include, exclude, or modify the following question when assessing quality of clinical information from DHTs?
Maintainability: Could the information within the digital health technology be easily maintained?
☐ **Very maintainable**: The information within the digital health technology could be maintained without difficulties.
☐ **Maintainable**: The information within the digital health technology could be maintained with minor difficulties resolvable at the point of care.
☐ **Unmaintainable:** The information within the digital health technology could not be easily maintained.
☐ **Very maintainable**: The information within the digital health technology could not be maintained at all.
NB: Maintainance includes activities such as storing, auditing, updating date.

- ○ Include as it is
- ○ Exclude
- ○ Modify

Display This Question:

If Would you include, exclude, or modify the following question when assessing quality of clinical i... = Modify

Q34 Please state any modification you would like to suggest regarding definition and assessment of maintainability.

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Q35. CLIQ Framework for Digital Health Technology

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

Q36. Would you like to retain or modify the above categories?

- ○ Retain the categories
- ○ Modify the categories

Display This Question:

If Would you like to retain or modify the above categories? = Modify the categories

Q37 Please state how you would want the categories to be modified.

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Q38 Thank you for taking part in this eDelphi survey. Please provide your email so we can share the summary of the findings with you and contact you for the subsequent round.

_____

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PARTICIPANT INFORMATION SHEET

Clinicians' Perspectives on Information Quality of Digital Health Technologies

Kayode Fadahunsi, Nikolas Mastellos, Petra Wark, Joseph Gallagher, Azeem Majeed, Josip Car

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

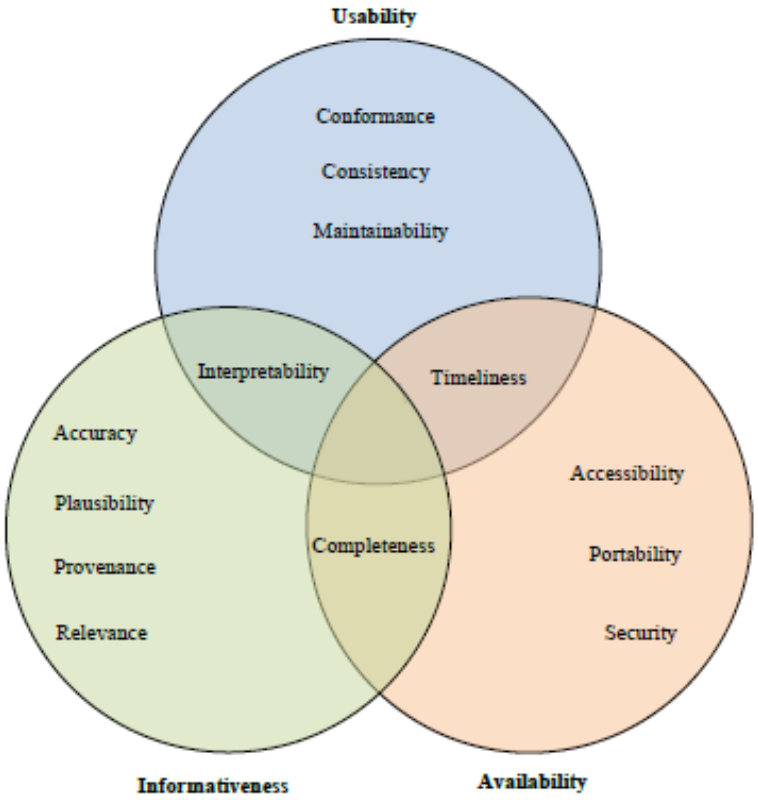
You can find out more about how we use your information

- 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.*