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 contextualised 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 heterogeneous 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 summarised 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 (ICREC) Reference number: 20IC6396. The results of the study will be published in a peer-reviewed journal and presented at scientific conferences.

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 10 IQ frameworks that are relevant to assessing IQ of DHTs in clinical practice.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.

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 characterises 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 (online supplemental appendix 1) has been generated from the infographic CLIQ framework7 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

Table 1 Clinical information quality framework for digital health

| 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 unauthorised 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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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 five-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. Most previous Delphi studies use 60% agreement or higher as threshold for consensus. In this study, an 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 contrary, 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.

**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. 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, which will be regarded as 6–8 months in this study.

**Participant recruitment**

A heterogeneous 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. There are no clear guidelines about the sample size of an eDelphi study. However, the literature suggests 8–15 participants when the sample is homogeneous with a caveat to avoid extremely large sample sizes because the amount of data could be unmanageable. 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 eDelphi rounds. 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-income and middle-income countries. In addition, recruiting clinicians with varying levels of expertise will encourage wide range of opinions.

**Study procedures**

The survey will be set up using Qualtrics software (Qualtrics, Provo, Utah, USA). 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 2 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 summarised 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 statisti-
cal summary of group response will be sent in the
e-mail 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 anal-
ysis 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. Familiarisation with the data by reading the free-text
contribution of the panellists repeatedly.
2. Coding of the data to highlight the issues raised with
regard to the definition and assessment of CLIQ di-

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 assess-
ment 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 Medi-
cine 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 Protec-
tion 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 (Impe-
rial College Research Ethics Committee (ICREC) Refer-
ence number: 20IC6396). Detailed information about
the study will be presented in a participant information
sheet containing information on the study objectives,
extpectation of the participants, duties of the researchers
and relevant contacts (online supplemental 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 pseud-
onymised before being added to the secure drive.
Feedback to each participant will only contain descrip-
tive 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, rele-
ance 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.3 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 info-
graphic 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. First, 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. We are therefore planning a pilot assessment to evaluate the construct validity of the contextualised 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 contextualised 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.

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Contributors 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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