

# Validation of a novel framework to assess clinical information in digital health technologies: structural equation modelling

Kayode Philip Fadahunsi, Petra A. Wark, Nikolaos Mastellos, Ana Luisa Neves, Joseph Gallagher, Azeem Majeed, Josip Car

Submitted to: Journal of Medical Internet Research on: March 06, 2024

**Disclaimer:** © **The authors. All rights reserved.** This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on it's website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressively prohibit redistribution of this draft paper other than for review purposes.

### Table of Contents

Original Manuscript	. 5
Supplementary Files	35
Figures	36
Figure 1	37
Figure 2	38

## Validation of a novel framework to assess clinical information in digital health technologies: structural equation modelling

Kayode Philip Fadahunsi<sup>1</sup>; Petra A. Wark<sup>1, 2</sup>; Nikolaos Mastellos<sup>1</sup>; Ana Luisa Neves<sup>1</sup>; Joseph Gallagher<sup>1, 3</sup>; Azeem Majeed<sup>1</sup>; Josip Car<sup>1, 4</sup>

#### **Corresponding Author:**

Kayode Philip Fadahunsi Department of Primary Care and Public Health Imperial College London The Reynolds Building St Dunstan's Road London GB

#### Abstract

**Background:** Digital health is a critical driver of quality, safety, and efficiency in healthcare. However, poor quality of clinical information in Digital Health Technologies (DHTs) can compromise the quality and safety of care. The Clinical Information Quality (CLIQ) framework was developed as a pragmatic tool to assess the quality of clinical information in DHTs.

**Objective:** The aim of this study is to assesses the applicability, internal consistency, and construct validity of the CLIQ framework.

**Methods:** This study was conducted as a cross-sectional survey of healthcare professionals across the UK who regularly use SystmOne Electronic Health Records (EHRs). Participants were invited through emails and social media platforms. The CLIQ questionnaire, developed based on systemic review and international eDelphi study, was administered as an online survey. Spearman's correlation coefficients were computed to investigate the linear relationship between the dimensions in the CLIQ framework. The Cronbach's alpha coefficients were computed to assess the internal consistency of the global scale (i.e., CLIQ framework) and the sub-scales (i.e., the informativeness, availability and usability categories). Confirmatory factor analysis was used to assess the extent to which the survey data supported the construct validity of the CLIQ framework.

**Results:** A total of 109 healthcare professionals completed the survey, of which two-third (n = 67; 61.5%) were doctors and a quarter (n = 26; 23.9%) were nurses or advance nurse practitioner. Overall, the CLIQ dimensions had good quality scores except for portability which had a modest score. The inter-item correlations were all positive and not likely due to chance. The Cronbach's alpha coefficient for the overall CLIQ framework was 0.89 (95 CI%: 0.85 - 0.92). The confirmatory factor analysis provided a modest support for the construct validity of the CLIQ framework with the Comparative Fit Index (CFI) of 0.86 and Standardised Root Mean Square Residual (SRMR) of 0.08.

**Conclusions:** The CLIQ framework demonstrated a high reliability and a modest construct validity. The CLIQ framework offers a pragmatic approach to assessing the quality of clinical information in DHTs and could be applied as part of information quality assurance systems in healthcare settings to improve quality of health information.

(JMIR Preprints 06/03/2024:58125)

DOI: https://doi.org/10.2196/preprints.58125

#### **Preprint Settings**

1) Would you like to publish your submitted manuscript as preprint?

**✓** Please make my preprint PDF available to anyone at any time (recommended).

<sup>&</sup>lt;sup>1</sup>Department of Primary Care and Public Health Imperial College London London GB

<sup>&</sup>lt;sup>2</sup>Centre for Intelligent Healthcare, Institute for Health and Wellbeing Coventry University Coventry GB

<sup>&</sup>lt;sup>3</sup>gHealth Research Group School of Medicine University College Dublin Dublin IE

<sup>&</sup>lt;sup>4</sup>School of Life Course and Population Sciences King's College London London GB

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users. Only make the preprint title and abstract visible.

- No, I do not wish to publish my submitted manuscript as a preprint.
- 2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?
- ✓ Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain ves, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="https://example.com/above/linear-note, above]. I understand that if I later pay to participate in <a href="https://example.com/above/linear-note, above].">https://example.com/above/linear-note, above]. I understand that if I later pay to participate in <a href="https://example.com/above].">https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that if I later pay to participate in <a href="https://example.com/above]. I understand that it is the later pay to pay the later pay the later pay to pay the later pay th

## **Original Manuscript**

## Validation of a novel framework to assess clinical information in digital health technologies: structural equation modelling

Kayode Philip Fadahunsi,¹ Petra A Wark,¹,² Nikolaos Mastellos,¹ Ana Luisa Neves,¹ Joseph Gallagher,¹,³ Azeem Majeed,¹ Josip Car.¹,⁵

#### **Corresponding Author**

Kayode Philip Fadahunsi Department of Primary Care and Public Health, Imperial College London, London, United Kingdom K.Fadahunsi14@imperial.ac.uk

<sup>&</sup>lt;sup>1</sup>Department of Primary Care and Public Health, Imperial College London, London, United Kingdom

<sup>&</sup>lt;sup>2</sup>Centre for Intelligent Healthcare, Institute for Health and Wellbeing, Coventry University, Coventry, United Kingdom

<sup>&</sup>lt;sup>3</sup> gHealth Research Group, School of Medicine, University College Dublin, Dublin, Ireland

<sup>&</sup>lt;sup>4</sup>Leeds Teaching Hospital National Health Service Trust, Leeds, United Kingdom

<sup>&</sup>lt;sup>5</sup> School of Life Course and Population Sciences, King's College London

#### Abstract

#### Introduction

Digital health is a critical driver of quality, safety, and efficiency in healthcare. However, poor quality of clinical information in Digital Health Technologies (DHTs) can compromise the quality and safety of care. The Clinical Information Quality (CLIQ) framework was developed as a pragmatic tool to assess the quality of clinical information in DHTs. The aim of this study is to assesses the applicability, internal consistency, and construct validity of the CLIQ framework.

#### **Methods**

This study was conducted as a cross-sectional survey of healthcare professionals across the UK who regularly use SystmOne Electronic Health Records (EHRs). Participants were invited through emails and social media platforms. The CLIQ questionnaire, developed based on systemic review and international eDelphi study, was administered as an online survey. Spearman's correlation coefficients were computed to investigate the linear relationship between the dimensions in the CLIQ framework. The Cronbach's alpha coefficients were computed to assess the internal consistency of the global scale (i.e., CLIQ framework) and the sub-scales (i.e., the informativeness, availability and usability categories). Confirmatory factor analysis was used to assess the extent to which the survey data supported the construct validity of the CLIQ framework.

#### **Results**

A total of 109 healthcare professionals completed the survey, of which two-third (n = 67; 61.5%) were doctors and a quarter (n = 26; 23.9%) were nurses or advance nurse practitioner. Overall, the CLIQ dimensions had good quality scores except for portability which had a modest score. The interitem correlations were all positive and not likely due to chance. The Cronbach's alpha coefficient for the overall CLIQ framework was 0.89 (95 CI%: 0.85 - 0.92). The confirmatory factor analysis provided a modest support for the construct validity of the CLIQ framework with the Comparative

Fit Index (CFI) of 0.86 and Standardised Root Mean Square Residual (SRMR) of 0.08.

#### Conclusion

The CLIQ framework demonstrated a high reliability and a modest construct validity. The CLIQ framework offers a pragmatic approach to assessing the quality of clinical information in DHTs and could be applied as part of information quality assurance systems in healthcare settings to improve quality of health information

#### Introduction

Digital health, defined as "the field of knowledge and practice associated with the development and use of digital technologies to improve health" is critical to quality, safety, and efficiency of healthcare services (WHO, 2021, p.39). Digital health technologies (DHTs) can enhance the delivery of healthcare services in several ways (Gomes, Murray and Raftery, 2022). Electronic Health Records (EHRs) can make medical records readily available at the point of care (Institute of Medicine, 2003). Electronic Prescribing Systems (EPSs) can reduce the incidents of medication errors (Graf *et al.*, 2023). Clinical Decision Support Systems (CDSSs) can provide essential support to clinicians in patient care (Sutton *et al.*, 2020; Teufel and Binder, 2021). Mobile Health (mHealth) applications can support self-management of chronic diseases (World Health Organization, 2011). However, poor quality of clinical information in DHTs can compromise the quality and safety of care (Magrabi et al., 2011; Meeks et al., 2014). A systematic review of literature reported widespread incidents of delayed, missing, partial and wrong information in DHTs resulting in adverse outcomes and deaths (Kim, Coiera and Magrabi, 2017). Most of the information quality problems reported in the included studies were based on incidents reporting systems (Kim, Coiera and Magrabi, 2017). While retrospective lessons based on adverse events in the incidents reporting systems could be useful, it is more important to identify and address information quality problems as a proactive measure to prevent adverse events.

To assess information quality in DHTs, we developed the Clinical Information Quality (CLIQ) Framework (Fadahunsi et al., 2021, Fadahunsi et al., 2022). The CLIQ framework identifies, defines, and integrates 14 dimensions that are relevant to assessing the clinical information in DHTs (Fadahunsi et al., 2022). The dimensions in the CLIQ framework are grouped into three categories – informativeness, availability and usability. The informativeness category relates to the usefulness of clinical information in patient care. Dimensions in the informativeness category include accuracy, completeness, interpretability, plausibility, relevance, and trustworthiness. The availability category

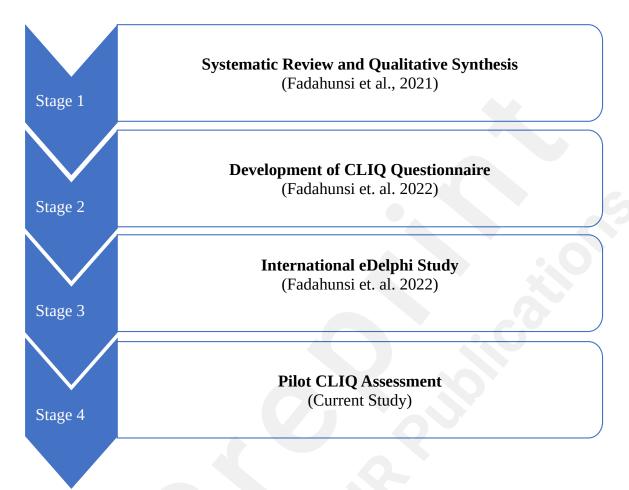
relates to the functionality of the DHTs holding clinical information. Dimensions in this category include accessibility, portability, searchability, security, and timeliness. The usability category – comprising conformance, consistency of presentation, and maintainability – concerns the ease of use of clinical information. The definitions of the dimensions in the CLIQ Framework are presented on Table 1.

Table 1: Clinical Information Quality Framework for Digital Health Technologies

Informativeness: the use	fulness of digital information for clinical purposes					
Accuracy	The extent to which information is accurate.					
Completeness	The extent to which no required information is missing.					
Interpretability	The extent to which information can be interpreted.					
Plausibility	The extent to which information makes sense based on clinical knowledge.					
Trustworthiness	The extent to which the source of information is trustworthy and verifiable.					
Relevance	The extent to which information is useful for patient care.					
Availability: the function	nality of the system holding clinical information					
Accessibility	The extent to which information is accessible.					
Portability	The extent to which information can be moved or transferred between					
	different systems.					
Searchability	The extent to which needed information can be found.					
Security	The extent to which information is protected from unauthorized access,					
	corruption, and damage.					
Timeliness	The extent to which information is up to date.					
Usability: the ease of use	of clinical information					
Conformance	The extent to which information is presented in a format that complies with					
	institutional, national, or international standards.					
Consistency of	The extent to which presentation of information adheres to the same set of					
presentation	institutional, national, or international standards.					
Maintainability	The extent to which information can be maintained (e.g., modified,					
	corrected, updated, adapted, and upgraded) to achieve intended					
	improvement.					

The CLIQ Framework was developed in four successive stages as shown in Figure 1. An initial CLIQ framework was developed through a systematic review and qualitative synthesis of existing information quality frameworks for DHTs (Fadahunsi et al., 2021). A CLIQ assessment questionnaire was then developed based on the CLIQ framework and further evidence from literature (Fadahunsi et al., 2022). The questionnaire offers a pragmatic approach to assessing clinical information in DHTs based on relatable clinical scenarios. The framework and the accompanying questionnaire were revised via an international eDelphi study among clinicians from 10 different countries (Fadahunsi et

al., 2022). Finally, the framework was validated based on a pilot CLIQ assessment of EHRs among healthcare professionals in the UK. This paper describes the pilot CLIQ assessment which is aimed to assesses the applicability, internal consistency, and construct validity of the CLIQ framework.



**Figure 1: Stages of CLIQ Framework Development** 

#### Methods

#### **Study Design**

This study was conducted as an online cross-sectional survey of healthcare professionals across the UK who use SystmOne EHRs (The Phoenix Partnership Ltd (TPP) Horsforth, Leeds, UK). The cross-sectional survey approach allowed the assessment of the applicability, internal consistency, and construct validity of the CLIQ framework. The online approach offered a convenient, affordable, and pragmatic way of conducting a study and collecting data. The choice of SystmOne was informed by its wide use across different healthcare settings in the UK, including general practices, urgent care centres, social care services, hospitals, and prison medical services to manage about sixty-one million EHRs (TPP, 2024). Ethical approval was obtained from the Imperial College Research Ethics Committee (21IC7415).

#### **Study Participants**

Eligibility criteria for the study included being a healthcare professional with a clinical role and a regular user of SystmOne (defined as using SystmOne as part of routine professional activities to document clinical information). Administrative staff using SystmOne and healthcare professionals using SystmOne occasionally (e.g., to check clinical records) were not eligible to participate in the study. Participants were invited through emails and social media platforms, including Facebook, LinkedIn, WhatsApp, Yammer, Digital Health Networks, and the Future NHS Collaboration platform. Although there is no consensus about the adequate sample size needed to validate a questionnaire, the literature recommends recruiting at least ten participants for each item of the scale being validated as a rule of thumb (Boateng *et al.*, 2018). As there are 14 dimensions of the CLIQ framework, this was equivalent to 140 participants in our study.

#### **Data Collection**

Healthcare professionals were invited to use the CLIQ framework to evaluate the information quality of SystmOne. The survey questionnaire comprised the 14 items of the CLIQ framework and two

questions about the occupation of the respondents to assess their eligibility (Appendix 1). The responses were made mandatory to avoid missing data, which could limit the assessment of the construct validity (Woulfe *et al.*, 2022). An invitation containing a link to the participant information sheet, the consent form, and the questionnaire was shared with the healthcare professionals electronically through the channels described earlier. Two reminders, at least two weeks apart, were sent to encourage participation. Healthcare professionals were also encouraged to share the invitation with colleagues. Participation was voluntary. Participants could withdraw from the study at any time without giving any reasons. However, once the survey was submitted, the data could not be withdrawn as the responses were anonymous. The questionnaire was administered through an online survey platform, Qualtrics (Qualtrics, Provo, Utah, USA).

#### **Data Analysis**

The survey result was downloaded from Qualtrics in an excel format and imported into SPSS version 20 (IBM Statistics, Armonk, New York, USA). SPSS was used to conduct descriptive statistical analyses and compute correlation coefficients and Cronbach's alpha scores.

The three options for each dimension (e.g., accurate, partly accurate and not accurate) were recoded into the integers 1, 2 and 3, representing low, modest, and good quality, respectively. A descriptive statistical analysis was conducted and interpreted to demonstrate the applicability of the CLIQ framework. The distribution of the responses was expressed as frequencies, percentages, means and standard deviations.

Spearman's correlation coefficients were computed to investigate the linear relationship between the dimensions in the CLIQ framework. The ordinal nature of the data informed the choice of Spearman's coefficients. Correlation coefficients of 0.1 - 0.2 were regarded as poor, 0.3 - 0.5 as fair, 0.6 - 0.7 as moderate, and 0.8 - 0.9 as very strong (Chan, 2003).

The Cronbach's alpha coefficient was computed to assess the internal consistency of the global scale

(i.e., CLIQ framework) and the sub-scales (i.e., the informativeness, availability and usability categories). A Cronbach's alpha coefficient of 0.7 or above was regarded as an indication of the reliability of the scale, and an alpha coefficient between 0.6 and 0.7 was considered acceptable (Taherdoost, 2018).

The SPSS data file was subsequently exported to SPSS Amos version 28 (IBM Statistics, Armonk, New York, USA) to assess the construct validity of the CLIQ framework. Confirmatory factor analysis, a structural equation modelling technique, was used to assess the extent to which the survey data supported the construct validity of the CLIQ framework (Ullman and Bentler, 2013). Confirmatory factor analysis was adopted because the CLIQ framework has multiple sub-scales (i.e., informativeness, availability and usability categories) that were pre-determined (Fadahunsi *et al.*, 2021).

The maximum likelihood estimation method was used for the confirmatory factor analysis. The model fit was assessed based on the Standardised Root Mean Square Residual (SRMR) and Comparative Fit Index (CFI) as recommended in the literature for studies with a sample size less than 250 (Hu and Bentler, 1999). A CFI greater than 0.9 and an SRMR less than 0.08 indicate model fit (Hu and Bentler, 1999).

#### Results

#### **Participants Characteristics**

A total of 109 healthcare professionals completed the survey, with two-thirds (n = 67; 61.5%) being doctors and almost a quarter (n = 26; 23.9%) being nurses or advanced nurse practitioners. The rest of the participants had other clinical occupations. Table 2 presents the distribution of the participants by occupation.

*Table 2: Distribution of the Occupation of the Survey Participants (n = 109)* 

Occupation	n (%)

Doctors	67 (61.5)
Nurses and Advanced Nurse Practitioners	26 (23.9)
Health Care Assistant	5 (4.6)
Physiotherapists and Occupational Therapists	4 (3.7)
Pharmacists	2 (1.8)
Podiatrists	2 (1.8)
Physician Associates	1 (0.9)
Therapy Support Workers	1 (0.9)
Community Health Workers	1 (0.9)

#### Participants' Assessment of Quality of the Dimensions

The mean quality score assigned to each dimension ranged from 2.2 for portability to 2.9 for security of clinical information in SystmOne (1, 2, and 3 indicate low, modest, and good quality respectively). Most participants (n = 97; 89%) ranked security of clinical information in SystmOne as good while only more than a third of the participants (n = 42; 38.5%) ranked portability of clinical information in SystmOne as good. The summary of the assessment result is presented in Table 3.

Table 3: Clinical Information Quality of SystmOne as Assessed by the Participants

Dimension	Assessme D	Mean score (SD)		
	Good	Modest	Low	
Accuracy	73 (67.0)	32 (29.4)	4 (3.7)	2.6 (0.6)
Completeness	63 (57.8)	43 (39.4)	3 (2.8)	2.6 (0.6)
Interpretability	82 (75.2)	26 (23.9)	1 (0.9)	2.7 (0.5)
Plausibility	92 (84.4)	17 (15.6)	0	2.8 (0.4)
Relevance	89 (81.7)	20 (18.3)	0	2.8 (0.4)
Trustworthiness	94 (86.2)	15 (13.8)	0	2.9 (0.3)
Accessibility	77 (70.6)	31 (28.4)	1 (0.9)	2.7 (0.5)
Portability	42 (38.5)	49 (45.0)	18 (16.5)	2.2 (0.7)
Searchability	56 (51.4)	49 (45.0)	4 (3.7)	2.4 (0.6)
Security	97 (89.0)	12 (11.0)	0	2.9 (0.3)
Timeliness	71 (65.1)	35 (32.1)	3 (2.8)	2.6 (0.5)
Conformance	77 (70.6)	27 (24.8)	5 (4.6)	2.7 (0.6)
Consistency of presentation	77 (70.6)	22 (20.2)	10 (9.2)	2.6 (0.7)
Maintainability	70 (64.2)	33 (30.3)	6 (5.5)	2.6 (0.6)

#### **Inter-Item Correlation**

There were positive correlations between all possible pairs of dimensions in the CLIQ framework as shown on Table 4. All the correlation coefficients were statistically significant (represented as asterisks) except for the correlations of portability with each of plausibility, relevance, trustworthiness, and security. There is a strong statistically significant correlation between conformance and consistency (Spearman's rho = 0.751, p<0.01).

*Table 4: Inter-items Correlation Matrix* 

	Accuracy	Completeness	Interpretability	Plausibility	Relevance	Trustworthiness	Accessibility	Portability	Searchability	Security	Timeliness	Conformance	Consistency	Maintainability
Accuracy	1.00	0.56**	0.36**	0.20*	0.38**	0.34**	0.38**	0.24*	0.44**	0.23*	0.38**	0.47**	0.49**	0.38**
Completeness		1.00	0.46**	0.35**	0.41**	0.43**	0.39**	0.25**	0.50**	0.41**	0.51**	0.49**	0.52**	0.53**
Interpretability			1.00	0.33**	0.27**	0.32**	0.28**	0.22*	0.36**	0.40**	0.34**	0.65**	0.51**	0.39**
Plausibility				1.00	0.45**	0.56**	0.21*	0.08	0.31**	0.33**	0.27**	0.28**	0.34**	0.38**
Relevance					1.00	0.43**	0.42**	0.13	0.36**	0.29**	0.30**	0.27**	0.29**	0.44**
Trustworthiness						1.00	0.32**	0.15	0.30**	0.46**	0.34**	0.26**	0.39**	0.35**
Accessibility							1.00	0.41**	0.42**	0.22*	0.26**	0.39**	0.41**	0.35**
Portability								1.00	0.44**	0.04	0.36**	0.30**	0.36**	0.39**
Searchability									1.00	0.28**	0.35**	0.47**	0.46**	0.60**
Security										1.00	0.30**	0.32**	0.39**	0.38**
Timeliness											1.00	0.35**	0.38**	0.46**
Conformance					6.(0)							1.00	0.75**	0.52**
Consistency													1.00	0.56**
Maintainability				66										1.00
P < 0.05* P < 0.01** P < 0.001**														

https://preprints.jmir.org/preprint/58125 [unpublished, non-peer-reviewed preprint]

#### **Internal Consistency of the CLIQ Framework**

The Cronbach's alpha coefficients and corresponding 95% confidence intervals (CI) for the informativeness, availability, and usability sub-scales were 0.78 (95% CI: 0.70 - 0.84), 0.69 (95% CI: 0.58 - 0.77) and 0.83 (95 CI%: 0.77 - 0.88), respectively. Once security was removed from the availability subscale, the Cronbach's alpha coefficient for the availability sub-scale increased marginally to 0.70 (95% CI: 0.60 - 0.78). The Cronbach's alpha coefficient for the overall CLIQ framework is 0.89 (95 CI%: 0.85 - 0.92).

#### **Construct Validity of the CLIQ Framework**

Although the Chi-square Goodness of Fit test ( $\chi$ 2=155.69; P<0.001;  $\chi$ 2 / df = 2.10) did not demonstrate fitness of the model, CFI (0.86) and SRMR (0.08) suggest that the model fits modestly with the data. All the factor loadings (i.e., covariance estimates) were positive and statistically significant, as shown in Table 5. Significant tests (Standard Error, Critical Ratio, and p value) were not reported for the first item in each category (i.e., accuracy, accessibility, and conformance) because their unstandardised covariance values were fixed as 1 which is a standard procedure in Confirmatory Factor Analysis.

Table 5: Standardised and Unstandardised Estimates of the Covariance

	Standardised covariance	Unstandardised covariance	Standar d Error	Critica l Ratio	P-value
	estimates	estimates			
Accuracy	0.64	1.00	N/A	N/A	N/A
Completeness	0.76	1.18	0.18	6.41	P<0.001
Interpretability	0.59	0.77	0.15	5.27	P<0.001
Plausibility	0.52	0.53	0.11	4.72	P<0.001
Relevance	0.56	0.61	0.12	5.00	P<0.001
Trustworthiness	0.59	0.57	0.11	5.24	P<0.001
Accessibility	0.60	1.00	N/A	N/A	N/A
Portability	0.45	1.13	0.28	3.99	P<0.001
Searchability	0.72	1.43	0.25	5.66	P<0.001
Security	0.46	0.50	0.13	4.03	P<0.001
Timeliness	0.56	1.05	0.22	4.73	P<0.001
Conformance	0.82	1.00	N/A	N/A	N/A
Consistency	0.85	1.20	0.12	9.64	P<0.001
Maintainability	0.73	0.94	0.12	8.05	P<0.001

The statistical significance of positive standardised covariance estimates for all information quality dimensions supports the placement of the dimensions in their respective category. This is further illustrated in the path diagram presented in Figure 2. The high values of estimated covariances between the latent variables and the observed variables support the construct validity of the model. Still, the high covariance estimates between the latent variables (informativeness, availability and usability) indicate overlap of the categories.

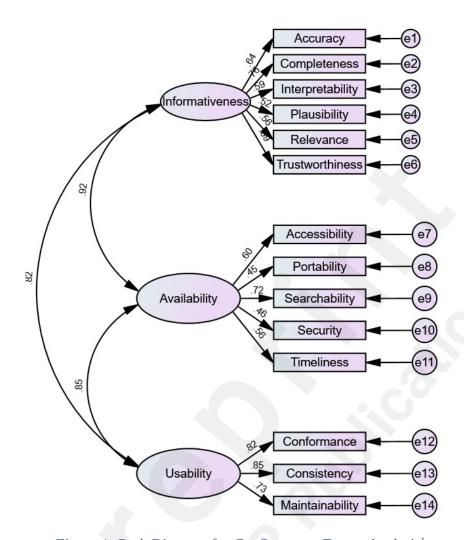


Figure 1: Path Diagram for Confirmatory Factor Analysis<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> The rectangular shapes represent the observed variables (i.e., information quality dimensions) that were directly measured in the survey. The circular shapes represent the latent variables (i.e., information quality categories) that could be inferred from the measured variables. The abbreviation e represents error. The connecting arrows represent covariances, with the accompanying numbers representing their estimates.

#### **Discussion**

#### **Principal Findings**

The study assessed the applicability, internal consistency, and construct validity of the CLIQ framework based on the pilot CLIQ assessment of SystmOne EHRs. Overall, the CLIQ dimensions had good quality scores except for portability which had a modest score. The inter-item correlations were all positive and not likely due to chance. The Cronbach's alpha score demonstrated a good internal consistency of the CLIQ framework and its informativeness, availability and usability subscales. The results of the Confirmatory Factor Analysis provided a modest support for the construct validity of the CLIQ Framework.

#### **Comparison with Previous Literature**

The combination of good security and modest portability of clinical information in SystmOne indicates the possibility of a trade-off between security and portability. Portability might have been limited inadvertently to improve the security of clinical information. Similar trade-offs, such as between accessibility and security, have been documented in the literature (Eppler and Wittig, 2000). Software developers need to be vigilant to identify potential trade-offs that may compromise the quality and safety of care.

The positive and mostly significant correlations between the items in the scale indicated a close relationship between the dimensions (Akoglu, 2018). This was not unexpected because all dimensions are components of the same CLIQ framework. The generally low values of the correlations demonstrated that the dimensions, although related, are distinct (Akoglu, 2018). The high correlation between conformance and consistency of presentation is understandable, as both concern presentation of information.

The overall good internal consistency of the CLIQ framework and its sub-scales (i.e., informativeness, availability and usability) indicates the reliability of the CLIQ framework (Taherdoost, 2018). As such, the study could not rely on fit indices primarily influenced by

sample size, such as the Chi-square goodness of fit index (Boateng *et al.*, 2018). However, the index least affected by sample size, the SRMR (Hu and Bentler, 1999), supports the model fit.

This study used similar methods as a study on the validation of the Modified Enlight Suite (MES), a generic mHealth assessment questionnaire (Woulfe *et al.*, 2022). Woulfe *et al.*, (2022) demonstrated an overall good internal consistency and modest construct validity of the MES based on a survey of over a thousand medical students and healthcare professionals who assessed a freely downloadable COVID-19 app in Ireland (Wolfe et al., 2022). The differences in the uptakes of the two studies are probably related to the choice of DHTs and study population. The current study population was limited to healthcare professionals using SystmOne. In contrast, the MES study was open to all healthcare professionals and medical students who could download the Irish COVID-19 app.

#### **Strengths and Weaknesses**

To the best of our knowledge The CLIQ framework is the first information quality framework for DHTs, of which the internal reliability and construct validity have been assessed. Only the face and content validity of most existing information quality frameworks were assessed (Fadahunsi *et al.*, 2021). The current study went a step further and explored the internal consistency and construct validity of the CLIQ framework. In addition, the choice of SystmOne EHRs for testing the CLIQ framework ensured participation of a multidisciplinary population of healthcare professionals across different settings thus enhancing a wider applicability of the framework. The use of mandatory responses in the survey to avoid missing values is also a strength. Rather than relying on statistical methods to address missingness, this study used actual data from participants, thus producing a more reliable result.

However, the low response rate limited the demonstration of the construct validity of the

CLIQ framework (Boateng *et al.*, 2018). The low uptake of the current survey was probably due to the busy schedules of the healthcare professionals at a time when the National Health System (NHS) was under immense pressure due to COVID-19 pandemic. Therefore, the modest construct validity of the CLIQ framework as demonstrated in this study should be interpreted with caution. Nevertheless, the sample size was sufficient to demonstrate the applicability and reliability of the CLIQ framework. The CLIQ framework will likely be used within individual healthcare institutions with a limited population of healthcare professionals. Thus, a large sample size was less relevant to assessing its applicability. In addition, the narrow confidence intervals for the Cronbach's alpha coefficients showed that the sample size was sufficient for the reliability study.

#### **Implications for Practice**

#### Information Quality Assurance System

The CLIQ research highlights the importance of information quality and its relevance to the quality and safety of care. Therefore, establishing a robust system for information quality assurance in healthcare institutions is essential. Such an information quality assurance system entails regular checks and monitoring, data validation, and information quality audits (World Health Organization, 2022). The CLIQ framework could be a useful tool for information quality audits. The information quality assurance system should be integrated into the information governance system, where one already exists, to prevent duplication and fragmentation. Designating clinicians with additional informatics training to oversee such information quality assurance system is necessary to ensure its successful implementation because they understand the clinical and technological aspects of patient care (Lee, 2022). Although healthcare institutions within high-income countries have designated clinical informatics roles, such as the chief clinical information officer, the job description is still evolving (Sridharan, Priestman and Sebire, 2018). It is both vital to introduce these roles in

health facilities and expand the responsibilities to include information quality assurance.

#### Informatics Training and Education for Healthcare Professionals

The CLIQ framework demonstrates that information quality is multidimensional, and understanding its meaning, relevance, and assessment requires some training. The clinicians who participated in the international eDelphi study expressed concerns that healthcare professionals without informatics training might be unfamiliar with information qualityrelated terms (Fadahunsi et al., 2022b). In addition, information quality problems, such as missing and inaccurate information, could result from human errors (Magrabi et al., 2016). Informatics training could provide healthcare professionals with knowledge about the meaning, relevance, and assessment of information quality. Strategies that can be used to prevent information quality problems such as proper documentation, adequate record keeping, and data validation techniques can also be taught. Therefore, informatics training should be included in healthcare professionals' pre- and post-qualification education competencies to keep them up to date of the ever-changing information landscape in digital health (Davies et al., 2022). However, care should be taken not to complicate an alreadycomplex medical curriculum with extensive informatics training (Davies et al., 2022). Rather, efforts should be made to provide appropriate level of informatics training that is commensurate with needs

Although informatics training could build health professional's competencies around information quality, mistakes will continue to occur irrespective of healthcare professional's competencies because 'to err is human' (Institute of Medicine, 2000). Therefore, it is vital to institute a system that reduces incidence and impact of errors.

#### **Automated Error Detection and Data Validation Systems**

The quality of clinical information could be improved by setting up automated error detection and data validation systems in DHTs. Machine learning (ML) and Artificial Intelligence (AI)

algorithms could be applied for automated data validation and real-time error detection with errors flagged during data entry (Khan and Yairi, 2018). Automated error detection and data validation systems could reduce the likelihood of wrong data entry as well as prompt early correction of errors before patient safety is compromised. However, lack of trust in ML and AI could make healthcare professionals ignore or override automated warnings and alerts (Nicora *et al.*, 2022).

#### Interoperability and Integration of Digital Health Systems

Interoperability enhances seamless flow of information across different DHTs such as EHRs, laboratory information system and electronic triage system (Iroju *et al.*, 2013). Seamless health information exchange between multiple platforms improves quality of clinical information (Lehne *et al.*, 2019). Accuracy is enhanced because information is obtained directly from source with elimination of possible changes during transcription (Iroju *et al.*, 2013). Since the same information is shared across different platforms, the format of presentation will be consistent. Communication between systems enhances timely access to up-to-date information in or near real-time (Lehne *et al.*, 2019). Although interoperability of digital health systems is desirable, a huge cost is often required for its implementation. Concerns about security of information may also be an obstacle due to increased access to information (Iroju *et al.*, 2013). Security concerns could be addressed by obtaining prior informed consent for information sharing from patients when they register with the health service.

#### **User-friendly Design Interface**

The quality of data entry could be improved with a user-friendly design interface (Wilbanks and Moss, 2021). Accuracy and completeness of the information in the DHTs could be enhanced with features such as drop-down menus, pre-population fields and validation prompts. Faulty design interface can affect consistency of presentation and conformance. A

drop down with different units of the same medication can lead to medication errors (Kim, Coiera and Magrabi, 2017). Searchability of information improves when the design interface allows smooth navigation through the digital system.

#### **Implications for Policy**

#### **Information Quality Requirements**

Policies and guidelines are needed to define and communicate information quality requirements for DHTs. Policies should communicate the official position of an institution on information quality requirements while guidelines should provide clear guidance on how to meet the requirements. The CLIQ framework could be used as a conceptual guide for information quality requirements. Policies and guidelines are needed to address issues relating to information quality, including interoperability, privacy and confidentiality, information format, design interface, training etc. These issues should be addressed collectively in a single information quality policy and/or individually with different guidelines based on the needs of the institution. It is essential to consider whether the information is used locally, nationally, or internationally. The process of formulating, implementing, and disseminating the policies needs to involve all stakeholders, as described subsequently.

#### Collaboration and Partnerships among Information Stakeholders

The development of the CLIQ framework demonstrates the importance of multidisciplinary and international collaboration in the development of information quality standards. The CLIQ framework was developed with inputs of scores of professionals from over ten countries. Establishing and implementing information quality standards require collaboration among healthcare organisations, software developers and vendors, regulatory bodies, patient support group, professional organisations etc. Collaboration will ensure buy-in of all information stakeholders and facilitate the implementation process.

#### Certification and Regulation

Enforcement of information quality standards for DHTs requires regulatory oversights. Regulatory bodies for DHTs in different countries and regions, such as the United States Food and Drug Administration (FDA) and Medicines and Healthcare Regulatory Agency (MHRA), need to include information quality requirements as part of prequalification criteria for DHTs. Information quality of DHTs should be assessed using evidence-based approach such as the CLIQ framework before they are certified for use in healthcare facilities. Only DHTs that meet specified prequalification criteria, including information quality requirements, should be certified by the regulatory bodies.

#### **Implication for Future Research**

#### **Evidence-based Approach**

The CLIQ framework was developed and validated using an approach which combined evidence from literature and empirical studies. We conducted a systematic review of frameworks, rather than interventions, based on the BeHeMoTh procedure (Fadahunsi *et al.*, 2019). The international eDelphi study obtained quantitative and qualitative evidence from clinicians across ten countries (Fadahunsi *et al.*, 2022). The Pilot CLIQ assessment used a systematic approach to investigate the reliability and validity of this novel tool. Overall, the evidence-based approach used while developing the CLIQ framework provides a methodological model which could be adopted in future research while developing pragmatic frameworks.

#### **Information Quality Research**

The systematic review of literature showed a dearth of information quality research relating to DHTs (Fadahunsi *et al.*, 2021). As DHTs are used more commonly worldwide, there is an increased need for information quality research to match the growth in technological innovations. The CLIQ framework demonstrates the importance of information quality research in addressing contemporary issues relating to DHTs. Some information quality

dimensions, which were hitherto not included in most existing information quality frameworks for DHTs, are included in the CLIQ framework. Searchability and maintainability are more relevant due to technological advancement which has made it possible to capture, process and store an increasing volume of digital information. Searchability, that is, locating needed information from the wide range of available information, is thus essential. Maintainability of information is also important to ensure that information quality is not sacrificed with increasing quantity of information. Similarly, portability has become more relevant than ever with the current tendency towards integration and interoperability of DHTs.

#### **Patient Perspective on Information Quality**

The current study focussed on healthcare professionals as end-users of clinical information in DHTs. However, patients have also become end-users of clinical information in DHTs. Patients are increasingly viewing and contributing more information into DHTs, especially since the COVID-19 pandemic (Clarke, Pariza and Wolters, 2020). Multiple DHTs, such as AskmyGp (Evergreen Health Solution Ltd, Salford, Manchester United Kingdom), eConsult (eConsult Health Ltd, Marsh Wall, London, UK) and Accurx (Accurx Ltd, Shoreditch, London, United Kingdom) allow patients to enter text using their own words and upload photos, that could be saved in the EHRs. In addition, many wearable devices and mobile applications generate consumer health data, nowadays, that could be imported into the EHRs. It would therefore be useful to explore the patients' perspective on information quality in future studies and incorporate their views and suggestions into the CLIQ Framework.

#### Conclusion

The CLIQ research highlights the importance of information quality and its relevance to the quality and safety of care. The CLIQ framework demonstrated a high reliability and a modest construct validity. The CLIQ framework offers a pragmatic approach to assessing the quality

of clinical information in DHTs and could be applied as part of information quality assurance systems in healthcare settings to improve quality of health information.

#### References

Akoglu, H. (2018) 'User's guide to correlation coefficients', *Turkish Journal of Emergency Medicine*, 18(3), pp. 91–93. doi: 10.1016/j.tjem.2018.08.001.

Boateng, G. O. *et al.* (2018) 'Best Practices for Developing and Validating Scales for Health, Social, and Behavioral Research: A Primer', *Frontiers in Public Health*, 6(June), pp. 1–18. doi: 10.3389/fpubh.2018.00149.

Chan, Y. H. (2003) 'Biostatistics 104: Correlational Analysis', *Singapore Medical Journal*, 44(12), pp. 614–619. doi: 10.1201/9781003073116-14.

Clarke, G., Pariza, P. and Wolters, A. (2020) *How has COVID-19 affected service delivery in GP practices that offered remote consultations before the pandemic?*, *The Health Foundation*. Available at: https://www.health.org.uk/news-and-comment/charts-and-infographics/how-has-covid-19-affected-service-delivery-in-gp-practices.

Davies, A. *et al.* (2022) 'Creation of a core competency framework for clinical informatics: From genesis to maintaining relevance', *International Journal of Medical Informatics*. Elsevier B.V., 168(February), p. 104905. doi: 10.1016/j.ijmedinf.2022.104905.

Eppler, M. J. and Wittig, D. (2000) 'Conceptualizing Information Quality: A Review of Information Quality Frameworks from the Last Ten Years Goals', in *Conference on Information Quality*, pp. 1–14.

Fadahunsi, K. P. *et al.* (2019) 'Protocol for a systematic review and qualitative synthesis of information quality frameworks in eHealth', *BMJ Open*. BMJ Publishing Group, 9(3), p. e024722. doi: 10.1136/bmjopen-2018-024722.

Fadahunsi, K. P. et al. (2021) 'Information quality frameworks for digital health technologies:

Systematic review', *Journal of Medical Internet Research*, 23(5), pp. 1–12. doi: 10.2196/23479.

Fadahunsi, K. P. *et al.* (2022) 'Assessment of Clinical Information Quality in Digital Health Technologies: International eDelphi Study', *Journal of Medical Internet Research*, 24(12). doi: 10.2196/41889.

Gomes, M., Murray, E. and Raftery, J. (2022) 'Economic Evaluation of Digital Health Interventions: Methodological Issues and Recommendations for Practice', *PharmacoEconomics*. Springer International Publishing, 40(4), pp. 367–378. doi: 10.1007/s40273-022-01130-0.

Graf, A. *et al.* (2023) 'Going digital in Germany: An exploration of physicians' attitudes towards the introduction of electronic prescriptions – A mixed methods approach', *International Journal of Medical Informatics*. Elsevier B.V., 174(March), p. 105063. doi: 10.1016/j.ijmedinf.2023.105063.

Hu, L. T. and Bentler, P. M. (1999) 'Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives', *Structural Equation Modeling*, 6(1), pp. 1–55. doi: 10.1080/10705519909540118.

Institute of Medicine (2000) *To err IS human, Nursing Critical Care.* Edited by Committee on Quality in America. Washington DC: Institute of Medicine. doi: DOI 10.17226/9728.

Institute of Medicine (2003) *Key Capabilities of an Electronic Health Record System: Letter Report, Health San Francisco*. Washungton DC: the National Academies Press. Available at: http://iom.nationalacademies.org/hmd/Reports/2003/Key-Capabilities-of-an-Electronic-Health-Record-System.aspx%0Ahttp://iom.nationalacademies.org/hmd/reports/2003/key-capabilities-of-an-electronic-health-record-system.aspx%0Ahttp://scholar.google.com/schol.

Iroju, O. *et al.* (2013) 'Interoperability in Healthcare: Benefits, Challenges and Resolutions', *International Journal of Innovation and Applied Studies*, 3(1), pp. 262–270. Available at: http://www.ijias.issr-journals.org/abstract.php?article=IJIAS-13-090-01.

Khan, S. and Yairi, T. (2018) 'A review on the application of deep learning in system health management', *Mechanical Systems and Signal Processing*, 107, pp. 241–265. doi: 10.1016/j.ymssp.2017.11.024.

Kim, M. O., Coiera, E. and Magrabi, F. (2017) 'Problems with health information technology and their effects on care delivery and patient outcomes: a systematic review', *Journal of the American Medical Informatics Association : JAMIA*, 24(2), pp. 246–250. doi: 10.1093/jamia/ocw154.

Lee, J. (2022) 'The Chief Medical Informatics Officer's (CMIO) View: Clinical, Technical and Leadership Acumen', pp. 99–110. doi: 10.1007/978-3-030-91237-6\_9.

Lehne, M. *et al.* (2019) 'Why digital medicine depends on interoperability', *npj Digital Medicine*. Springer US, 2(1), pp. 1–5. doi: 10.1038/s41746-019-0158-1.

Magrabi, F. *et al.* (2011) 'Patient safety problems associated with heathcare information technology: an analysis of adverse events reported to the US Food and Drug Administration.', *AMIA Annu Symp Proc*, 2011(1), pp. 853–7. doi: 10.1001/archinternmed.2011.327.

Magrabi, F. *et al.* (2016) 'Identifying patient safety problems associated with information technology in general practice: an analysis of incident reports', *BMJ Quality and Safety*, 25, pp. 870–880. doi: 10.1136/bmjqs.

Meeks, D. W. et al. (2014) 'An analysis of electronic health record-related patient safety concerns', *Journal of the American Medical Informatics Association*. Oxford University

Press, 21(6), pp. 1053–1059. doi: 10.1136/amiajnl-2013-002578.

Nicora, G. *et al.* (2022) 'Evaluating pointwise reliability of machine learning prediction', *Journal of Biomedical Informatics*. Elsevier Inc., 127, p. 103996. doi: 10.1016/j.jbi.2022.103996.

Sridharan, S., Priestman, W. and Sebire, N. J. (2018) 'Chief Information Officer team evolution in university hospitals: interaction of the three 'C's (CIO, CCIO, CRIO)', *Journal of Innovation in Health Informatics*, 25(2), pp. 88–91.

Sutton, R. T. *et al.* (2020) 'An overview of clinical decision support systems: benefits, risks, and strategies for success', *npj Digital Medicine*. Springer US, 3(1), pp. 1–10. doi: 10.1038/s41746-020-0221-y.

Taherdoost, H. (2018) 'Validity and Reliability of the Research Instrument; How to Test the Validation of a Questionnaire/Survey in a Research', *International Journal of Academic Research in Management*, 5(3), pp. 28–36. doi: 10.2139/ssrn.3205040.

Teufel, A. and Binder, H. (2021) 'Clinical Decision Support Systems', *Visceral Medicine*, 37(6), pp. 491–498. doi: 10.1159/000519420.

The Phoenix Parnership Ltd (2024) *Clinical software to revolutionise healthcare*. Available at: https://tpp-uk.com/.

Ullman, J. B. and Bentler, P. M. (2013) 'Structural Equation Modeling', in Weiner, I., Schinka, J. A., and Velicer, W. F. (eds) *Handbook of Psychology*. John Wiley & Sons, Inc., pp. 661–619. doi: 10.1002/9781119111931.ch172.

Wilbanks, B. A. and Moss, J. A. (2021) 'Impact of Data Entry Interface Design on Cognitive Workload, Documentation Correctness, and Documentation Efficiency', *AMIA* ... *Annual* 

Symposium proceedings. AMIA Symposium, 2021, pp. 634–643.

Wold Health Organization (2021) *Global strategy on digital health 2020-2025*. Available at: http://apps.who.int/bookorders.

World Health Organization (2011) 'mHealth New horizons for health through mobile technologies'. Geneva: WHO. Available at: http://www.who.int/goe/publications/goe\_mhealth\_web.pdf.

World Health Organization (2022) *DATA QUALITY ASSURANCE Module 1 Framework and metrics*. Available at: http://apps.who.int/bookorders.

Woulfe, F. *et al.* (2022) 'Modification and Validation of an mHealth App Quality Assessment Methodology for International Use: Cross-sectional and eDelphi Studies', *JMIR Formative Research*, 6(8), pp. 1–10. doi: 10.2196/36912.

## **Supplementary Files**

### **Figures**

Stages of CLIQ framework development.



Path Diagram for Confirmatory Factor Analysis.

