Key indicators of ethical challenges in digital healthcare: A combined Delphi exploration and confirmative factor analysis approach with evidence from Khorasan province in Iran

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Abstract

Despite the undoubted benefits of digital healthcare, ethical challenges have become one of the biggest concerns amongst academic scholars and digital healthcare experts. Despite the extant literature on some of these challenges, knowledge gaps still exist in revealing which indicators are more important than others. This research, joining in the ongoing investigation, aims to explore and empirically validate the key indicators of ethical challenges in digital healthcare. We conduct two studies using a combined exploratory and confirmatory approach. We apply the Delphi method for exploring and forecasting the key indicators in the first study. The key indicators are validated in the second study employing confirmatory factor analysis of survey data. The Delphi experts are 26 medical professionals and academic professors in Iran. A sample of 210 survey observations was collected from general hospital staff in Iran. Our results suggest that there are six key indicators of ethical challenges in digital healthcare: *procedure values, responsibility, privacy, autonomy, security, justice*. This research contributes to the knowledge of ethical concerns in applying digital technologies in healthcare, particularly identifying and validating the key indicators of the ethical challenges. The results provide practical implications for decision-makers in the current and future digital healthcare sector.

Keywords: Ethical challenge; Digital healthcare; Delphi; Procedural value; Responsibility

1. Introduction

Digital healthcare refers to the use of digital technologies to collect, share, and analyse information on health and wellbeing, which ultimately contributes to improving individual health and enhancing the quality of healthcare (Sharma et al., 2018). Like many other industries and sectors, healthcare has been transforming by digitalisation and the advancement of modern technologies. Digital healthcare comprises various modern technology applications and systems such as hospital information systems, personal digital assistant, telemedicine, ePrescription (electronic prescription), eHealth (electronic health), mHealth (mobile health), wireless health or wireless sensors, wellbeing apps, health 2.0 or medicine 2.0, EHRs (Electronic Health Records), EMRs (Electronic Medical Records), healthcare gamification, health information technology, big data, digital personal assistants, and wearable technologies.

The benefits of digital healthcare cannot be overstated. Digital healthcare can decrease inefficiencies in service delivery, improve accessibility, reduce costs, and increase health services quality (Iyawa et al., 2016). In particular, digital healthcare can be an inevitable and practical solution to the current problems that the global healthcare section is facing. For instance, along with the rise of life expectancy, the number of patients with chronic diseases and the cost of modern treatments have been on the rise. In this regard, digital healthcare technologies, including the Internet, smartphones, mHealth and eHealth allow digital data to be shared among patients, physicians, family, and a broader healthcare community, leading collaboration between them to enhance healthcare (Morley, 2017). In this sense, digital healthcare has shifted the paradigm in the health sector from the “paternalistic model” to “democratisation of care”; which provides an opportunity to create a culture of self-care in society as it can empower individuals and their families to improve their health (Sonnier, 2016; Rezaei et al., 2020).

Besides the positive aspects, the literature has also discussed the dark sides or concerns of digital healthcare. Ethical challenges in digital healthcare, such as confidentiality, privacy and inequality concerns fall into this category of argument in the literature (Maksimović and Vujović, 2017). Borland and Martin (2019) argue that digital patient access applying to NHS in the UK might have an equality issue since on some occasions, illness can be diagnosed only through direct contact with patients' symptoms; and on other occasions, some older people may have difficulty with computer literacy (Glasper, 2019). However, among the others, such as legal (George et al., 2013), social (Carter et al., 2020), and regulatory concerns (Vayena et al., 2018), ethical challenges have become one of the most popular concerns and ongoing topics among academics as well as digital healthcare experts (e.g. Solomonides, 2015; Aicardi et al., 2016; Kleinpeter, 2017; Vayena et al., 2018; Carter et al., 2020). The ethical issues are crucial due to their significant role in introducing digital technologies into the healthcare systems and the effect on digital healthcare practices (George et al., 2013; Kleinpeter, 2017; Carter et al., 2020).

While we agree that the list of the fragmented indicators in the current literature helps raise the awareness to the public about the importance of the ethics challenges, it won't help healthcare professionals and executives at the implementation level as there lacks consensus about key ethical challenges. The research gap in this aspect is understandable as the implementation of digital technologies and systems in healthcare is currently at the early stage of development and still has high uncertainty and complexity in this field. While researchers are struggling to identify all ethical challenges, revealing which indicators are more important than others becomes critical for digital healthcare implementation. In view of the literature gap and the practical importance of digital healthcare, this research aims to explore and empirically validate the key indicators of ethical challenges in digital healthcare.

To meet this end, we conduct two studies. Delphi analysis is employed to predict and explore key indicators of ethical challenges in digital healthcare in the first study. Delphi is an appropriate method for this study since the domain experts work together and yet independently predict challenges regarding technology applications (e.g., Fritschy and Spinler, 2019; Rikkonen, Tapio and Rintamäki, 2019; Kattirtzi and Winskel, 2020). In the second study, we utilise survey data collected from professionals for the Confirmatory Factor Analysis (CFA) to validate the Delphi's findings. This study contributes to the knowledge of ethical challenges associated with digital healthcare. The result of this study captures insights into an increasing concern while it lacks research.

For the remainder of the paper, we first systematically review the literature and analyse the initial indicators of ethical challenges in the healthcare and wellbeing sector. Then, we conduct Study One, using the Delphi method for exploring the key indicators of ethical challenges in digital healthcare. In Study Two, we conduct a confirmatory factor analysis of survey data. A discussion of our findings follows, and we conclude the study at the end.

2. Literature review

Digital technology in healthcare, along with its benefits for general healthcare such as monitoring, preventing, screening, diagnosing and treating health-related issues, face a variety of ethical challenges including privacy, confidentiality, personal health data protection, equity in access to health services, accountability, the effectiveness of patient empowerment, and the quality of health information (Fricker et al., 2015b). The ethical challenges posed by digital healthcare expansion are complex and multidimensional (O'Connor et al., 2016). It could be relevant to the stages (e.g., before, during and after) of the digital technology usages (Taipale et al., 2017; Cao et al., 2019; Garousi Mokhtarzadeh et al., 2020), or to the stakeholder groups by responsibility such

as medical versus or non-medical treatments (Hosmer and Kiewitz, 2005), or different technologies and systems (Torous and Roberts, 2017). Kopala and Mitchell (2011), Ozair et al. (2015), and Lee (2017) discuss various ethical issues arising in the use of Electronic Health Records (EHR) such as privacy and confidentiality, security breaches, system implementation, informed consent, data validity, data inaccuracies, and patients' commitment to participate in the health education system EHR.

There are various forms of digital healthcare, which are relevant to various technology applications. mHealth refers to the proliferation of smartphone usage in healthcare, which posed some ethical challenges. In this regard, Ataç et al. (2013) highlight that the ethical problems arise due to sharing poor information, disruption of patient-physician communication, unclear and inaccurate reports, the security of electronic personal information, reliability, undistinguished responsibility, and unpredicted errors. Torous and Roberts (2017) investigate the ethical use of mobile health technology and its effect on the relationship between psychiatrists and patients. The results suggest that mHealth should enhance the psychiatrist-patient relationship, rather than replace it.

Telemedicine is relevant to remote clinical services, such as diagnosis and monitoring. Telemedicine technologies have advantages for the healthcare system, such as assessing patients with medical equipment, reducing hospital costs, saving time, and providing specialised support services in remote areas that are difficult to access. Botrugno (2018) examines the relevance of EU legislation to telemedicine and identified ethical concerns, including privacy problems, and determining the responsibility of specialists. Since telemedicine services require the involvement of specialists, including nurses, physicians, and ICT providers, patient information is easily accessible to different people. Therefore, using these technologies increases the risk of data abuse and privacy violations.

Electronic health (eHealth) refers to the use of the Internet and web technologies to provide healthcare services (Kleinpeter, 2017). eHealth is associated with health, equality of access to eHealth technologies, the concepts of body and illness, and communication between patient and physician. Kluge (2007) discusses eHealth's ethical challenges from the legal perspectives and highlights challenges including moral laws, lack of agreement on international ethical mechanisms, and lack of ethical educational standards in professional training of employees.

In the eHealth area, Townsend et al. (2015) focused on the use of health-related Internet information by patients and patients–health care professionals (HCP) to find out how the patient-HCP relationship can be influenced by it. Notably, they discussed challenges emerging in the patient-HCP relationship such as participation, roles, responsibilities, and relationships shift and examining the explicit participation ethical indicators that arise in patient-HCP interactions, thereby increasing Internet information in the health-related field. Similarly, Eysenbach (2000) indicated the main ethical issue of incorrect information and emphasised the necessity of assessing Internet data accuracy.

Wearable digital technology, such as wearable cameras in medical science, is used to investigate health behaviours that can produce a wide range of visual data. Kelly et al. (2013) investigate the ethical issues involved in the use of wearable technology in image-based research in the field of health behaviour; the results suggest that informed consent, privacy, and confidentiality, equality, and the safety of information are the main concerns. Similarly, big data can have a considerable impact on the health of society and humanity. Big data has raised ethical concerns and has doubled the need for moral education and equipping epidemiologists with ethical tools (Knoppers and Thorogood, 2017; Salerno et al., 2017).

After understanding different ethical issues relevant to various digital healthcare technology applications, we conducted a systematic literature review to identify the key factors of ethical

challenges in digital healthcare. Keywords used for searching the relevant literature include "ethical challenges", "ethical drawbacks", "ethical issues", "digital health", and "eHealth" in five databases including "science direct", "ProQuest", "springer", "emerald" and "google scholar". We limited the publishing years ranging from 2000 to 2020.

The results of 17 peer-reviewed journal articles are classified into four domains of the ethical challenges in digital healthcare: ethical (ET), social (SC), legal (LG), and governmental/ regulatory (GR) (Table 1). Further, the initially identified challenges from the literature are clustered in six key indicators of ethical challenges: justice (JUS) - fair and equal access to digital technology facilities and healthcare, autonomy (AUT) - to empower informed patients, privacy (PRI) - non-disclosure of private information to others, security (SEC) - safety of patients information, responsibility (RES) - to be accountable and trustworthy of using technology, and procedural values (VAL) - procedural transparency and inclusiveness, etc.

Table 1

A summary of key ethical challenges in digital healthcare literature.

Row	Year	Authors	Domains of challenges				Focus Area	Method		Key ethical challenges						
			ET	SC	LG	GR		Survey	SLR	VAL	JUS	PRI	SEC	RES	AUT	Other
1	2001	Dyer	✓				Medicine and Health on the Internet		✓							✓
2	2007	Brown & Adams	✓				Ubiquitous healthcare		✓		✓		✓	✓		✓
3	2007	Anderson	✓	✓	✓		eHealth	✓	✓	✓			✓		✓	
4	2008	Kluge	✓				Future eHealthcare		✓							✓

Row	Year	Authors	Domains of challenges				Focus Area	Method		Key ethical challenges						
			ET	SC	LG	GR		Survey	SLR	VAL	JUS	PRI	SEC	RES	AUT	Other
5	2011	Whitehouse et al	✓		✓	✓	eHealth		✓							✓
6	2013	George et al	✓		✓	✓	eHealth		✓							✓
7	2015	Solomonides et al	✓				Digital Health		✓							✓
8	2015	Jumelle & Ispas	✓				Digital Health		✓	✓	✓		✓		✓	
9	2016	Aicardi et al	✓				Digital health data	✓	✓	✓		✓	✓			
10	2016	European ~~Ethics Group~~Commision	✓				New health technologies		✓		✓			✓		
11	2018	Vayena et al	✓			✓	Digital health		✓			✓	✓	✓		
12	2018	Pesapane et al	✓		✓	✓	Digital medical devices			✓				✓		✓
13	2019	Maher et al	✓				Digital healthcare			✓						✓
14	2019	Guan	✓				Digital healthcare and medicine			✓						✓
15	2019	Brall et al	✓				Digital health	✓	✓		✓			✓	✓	
16	2020	Carter et al	✓	✓	✓		Breast cancer care									✓
17	2020	Martinez-Martin	✓				Digital mental health therapy		✓	✓	✓	✓	✓	✓		

As Table 1 denotes, only three among the seventeen articles are empirical (i.e. survey), and the other fourteen are based on the review of relevant literature. This result suggests that the key indicators of digital healthcare extracted from the literature have not or limitedly been empirically

examined. Moreover, the indicators identified in the literature review studies are based on current or past experiences. The future or potential ethical challenges of digital healthcare are yet to be investigated or forecasted. These identified limitations in the extant studies are considered in the design of this current study.

Multi-criteria decision-making approaches, including AHP and ANP, are popular in measuring the importance of criteria and ranking critical factors (Turskis et al., 2015; Yu et al., 2020). However, this study applied a two-stage approach combining Delphi and CFA as it is more appropriate for our research purpose. In the first stage, we employed the Delphi method. The experts' opinions were gathered to explore the key indicators of ethical challenges in digital healthcare and ranking the importance of current identified ones. Further, the results of the key indicators from the Delphi methods will be empirically validated using survey data collected from the professional in the healthcare industry in the second stage. Neither AHP nor ANP is more appropriate than CFA for the validation purpose in the second stage.

3. Study One: Delphi for an exploratory analysis

3.1. Delphi method

Delphi method is applied for this study exploring and predicting key indicators of the ethical challenges in digital healthcare. Delphi is a useful research method, particularly with advantages for forecasting and predicting the challenges and dynamics of technology applications (Gordon, 1994; Heiko, 2012; Fritschy and Spinler, 2019; Rikkonen, Tapio and Rintamäki, 2019; Kattirtzi and Winskel, 2020). Delphi method has several unique features (Dalkey and Helmer, 1963; Rowe and Wright, 1999), making it an appropriate design for this study. *First*, Delphi experts can predict and estimate what is more likely to happen based on their many years' expertise in their domain. *Second*, expert opinions will remain anonymous since the data is collected through a research

moderator. The anonymity minimises the likelihood of the dominant expert effect. It reduces the risk of conformity biases and socio-psychological pressures, which is more likely to happen in other group communication forms, such as focus group interviews (Dewar and Friel, 2013). *Third*, the Delphi method allows experts to change or modify their opinions in a series of consequent rounds of interviews, with no fear of losing their reputation and credibility, especially when the research moderator informed them of the other experts' different viewpoints, which sound reasonable (Hjarnø, Syed and Aro, 2007; Hsu and Sandford, 2007; Nielsen and Thangadurai, 2007; Steurer, 2011).

Moreover, the literature suggests that although data can be collected through multiple-choice questionnaires, it highly appreciated employing face-to-face interviews with open-ended questions for engaging more in-depth discussion (Rikkonen, 2005; ~~Rikkonen and Tapio, 2009~~Varonen and Tapio, 2009; Varho et al., 2016). In medicine and healthcare literature, the Delphi technique has been widely adopted for collection empirical evidence (e.g. Hasson et al., 2000; Boulkedid et al., 2011; Trevelyan and Robinson, 2015; Toma and Picioreanu, 2016; Ravensbergen, 2019). Therefore, the first part of this research builds on the wealth of the Delphi technique to explore the key indicators of the ethical challenges in digital healthcare.

3.2. The panel of experts

The Delphi method's key parameters are panellists' expertise of the subject matter, the panel size, and the selection method (Rikkonen, Tapio and Rintamäki, 2019), and continuous engagement throughout the participation process (Dalkey and Helmer, 1963). In recruiting such panel members, we applied the snowball sampling method to identify and select the panel members (Etikan and Bala, 2017; Jafari Sadeghi and Biancone, 2018) within Khorasan province in Iran. We searched and identified a shortlist of 20 publicly well-known professionals in hospitals and domain

professors in universities in the province in a preliminary step. We invited the experts to participate in our research project by individual visits, emails and phone calls. Then through their introduction and recommendation, six more were invited and agreed to join us as the Delphi experts. As a result, we have a sample of 26 participants. Such a sample size is typical in the scientific study using Delphi technique (De Loë et al., 2016).

Then, the panel of 26 experts was split into two groups, with 13 members in each group. The first group comprises academic experts, who have experience in teaching and researching in the field of medicine, healthcare, and wellbeing for at least ten years. The second group comprises industry experts such as executives and managers, who have been working in the healthcare sector (e.g., hospitals, health labs, etc.) for a minimum of ten-years. The demographic statistics of the Delphi panel members are displayed in Table 2.

Table 2

Descriptive of the panel members.

	Education Level		**Experience (over ten years)**		
	Master	PhD	Teaching	Research	Executive
Academic experts (professors)	0	13	3	9	1
Industrial experts (executives)	9	4	1	1	11
Total	9	17	4	10	12

3.3. The procedure

The process of reaching experts' agreement in the Delphi method relies on some assumptions. For instance, individuals are rational experts; they share and discuss their opinions in predicting future challenges and dynamics in the topic (Steinert, 2009; Rikkonen and Tapio, 2009; Van de Linde and Van der Duin, 2011; Tapio, 2013). After each round, feedback for the previous round results has been provided to the panel experts. The Panel experts then could modify their judgment based on the last series until they reach an agreement.

In the first round, the six key indicators of the ethical challenges are from the initial systematic literature review and the indicators informed the structured Delphi questions. Then open questions were followed for exploring detailed measurement items of ethical challenges in digital healthcare. For example, participants were asked: "*To what extent do you agree or disagree that equity in access is an ethical issue in digital healthcare*?" A 5-point Likert scale was used for the measure. Then an open-ended question was followed to invite the participant to explore more detailed information about the response. As such, participants were asked: "*How do you understand this as an ethical concern in the process of digital healthcare?*" and "*What would be other possible concerns which are not listed here but relevant to ethical challenges in digital healthcare?*".

After we collected the first-round questionnaires, the variables' scores were determined, and their mean, standard deviation, and Kendall's Coefficient of Concordance (i.e. Kendall's W) were analysed.

In the second round, the respondents were informed about the other panel members' responses in the first round. Participants were asked to rank again the importance of those agreed indicators of the answers from the first round and the ranking used a 5-point Likert scale. This process was repeated in the third round, and finally, by expert's consensus, 26 variables were obtained in the third round. The three-round process of reaching the consensus is in line with Hsu and Sandford's (2007) suggestion that three or four rounds can be conducted based on previous successful research using Delphi. Figure 1 summarises the process of the Delphi method employed in this research.

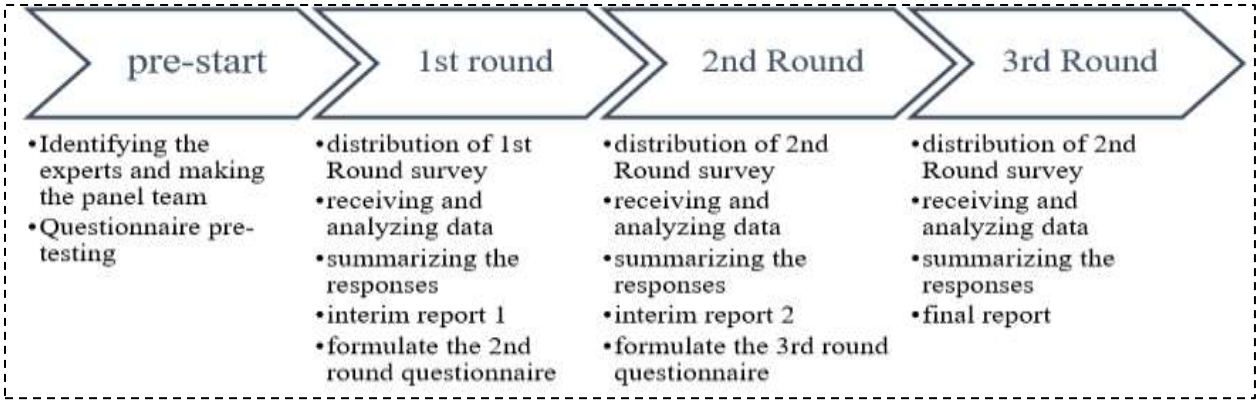

Fig. 1. The steps of the Delphi method.

3.4. Consensus

The consensus was reached in the third rounds of the Delphi analysis in this study. The procedure to the panellists and the structure of the survey remained the same for the three rounds. SPSS software was utilised for the analysis.

Table 3 shows the descriptive statistics for the three rounds of Delphi synthesis. The result of low variation of standard deviations across the consecutive rounds suggests that the panel members had a reasonable consensus for each of the three rounds of the research process (Rikkonen, Tapio and Rintamäki, 2019). Also, the standard deviations in the third round were lower than their counterparts in the first and second rounds, suggesting a reliable convergence of the result in the third round. Moreover, in our analysis, 51% of group members ranked the two highest importance scores (i.e. '4' and '5') on the 5-point Likert scale, with all Means over 2.5, suggesting a reliable consensus (Keeney, 2010; Giannarou and Zervas, 2014).

Table 3

Descriptive statistics of Delphi rounds.

Key indicators	**Measurement items**	**1st Round**		**2nd Round**		**3rd Round**	
		Mean	SD	Mean	SD	Mean	SD

Process values	Q1. Equity in Access	3.46	.582	3.46	.582	3.38	.496
	Q2. Exclusion	4.04	.774	4.04	.774	3.81	.491
	Q3. Equal Treatment	3.23	.652	3.23	.652	3.35	.485
Responsibility	Q4. Non-Discrimination	4.35	.485	4.35	.485	4.35	.485
	Q5. Non-Stigmatisation	3.81	.981	4.19	.849	4.73	.533
	Q6. Data Ownership	4.46	.859	4.69	.471	4.69	.471
	Q7. Empowerment	4.42	.643	4.42	.643	4.58	.504
Privacy	Q8. Freedom of Choice	3.12	.711	3.12	.711	3.42	.504
	Q9. Informed Consent	3.12	.909	3.12	.909	3.46	.582
	Q10. Awareness of Data Collection	3.35	.562	3.35	.562	3.42	.571
	Q11. Awareness of Data Use	3.46	.508	3.46	.508	3.46	.508
Autonomy	Q12. Right To (not) Know the Result	4.00	.980	4.38	.804	4.58	.452
	Q13. Data Protection	4.65	.485	4.65	.485	3.38	.402
	Q14. Confidentially	4.15	.834	4.31	.788	4.50	.510
	Q15. Data Sharing	4.38	.637	4.38	.637	4.54	.510
	Q16. Intended/Unintended Use of Data	3.88	.588	3.92	.560	4.38	.571
Security	Q17. Data Storage	3.46	.948	3.54	.989	3.38	.571
	Q18. Safety of Information	4.23	.815	4.23	.815	4.46	.508
	Q19. Protection Against Unauthorised Access/Use of Data	4.58	.643	4.58	.643	4.27	.452
Justice	Q20. Trust	4.58	.703	4.81	.402	4.81	.402
	Q21. Balance of Power	3.50	.510	3.50	.510	3.50	.510
	Q22. Relation Between Stakeholders	4.42	.578	4.50	.510	4.50	.510
	Q23. Benefit and Benefit Sharing	4.23	.863	4.54	.706	4.62	.571
	Q24. Transparency	4.62	.496	4.62	.496	4.88	.326
	Q25. Accountability	4.27	.724	4.31	.679	4.42	.504
	Q26. Inclusiveness	3.23	.765	3.23	.765	3.35	.485

Kendall's W is a non-parametric test for assessing agreement among the Delphi experts' ratings (Schmidt, 1997). Kendall's W ranges between '0' reflecting 'no agreement' and '1' indicating the 'complete agreement' (De Jesus et al., 2019). However, it can be claimed that consensus is achieved if Kendall's W Coefficient ≥0.5 (Schmidt, 1997; Okoli and Pawlowski, 2004; Paré et al., 2013). Table 4 represents Kendall's W test for three rounds of our Delphi analysis. Our findings reveal that the consensus was achieved in the third round of Delphi analysis, as highlighted by Kendall's W of 0.616. This confirms that a satisfactory level of agreement, i.e.

over 60 per cent consensus, between experts on the importance of ethical challenges indicators has been reached.

Table 4

Kendell's Coefficient of Concordance (W).

	1st Round	**2nd Round**	**3rd Round**
Q	26	26	26
Kendall W	.385	.461	.616
Chi-Square	250.086	299.539	400.202
DF	25	25	25
Sig.	.000	.000	.000

3.5. Conceptual model

As a summary, we conceptualise the key ethical challenges in digital healthcare. The six key indicators are referred to as the measures of ethical challenges in digital healthcare, including justice (JUS), autonomy (AUT), privacy (PRI), security (SEC), responsibility (RES), and procedural values (VAL). Figure 2 displays the conceptual model, which illustrates the relationship between the dependent variables, i.e. the six reflective measures of the key ethical challenges, and the independent variable, i.e. ethical challenges (E.CH) in digital healthcare. To assess the conceptual model, we proceed to Study Two, collecting survey data for a confirmatory factor analysis using Structural Equation Modelling technique (SEM).

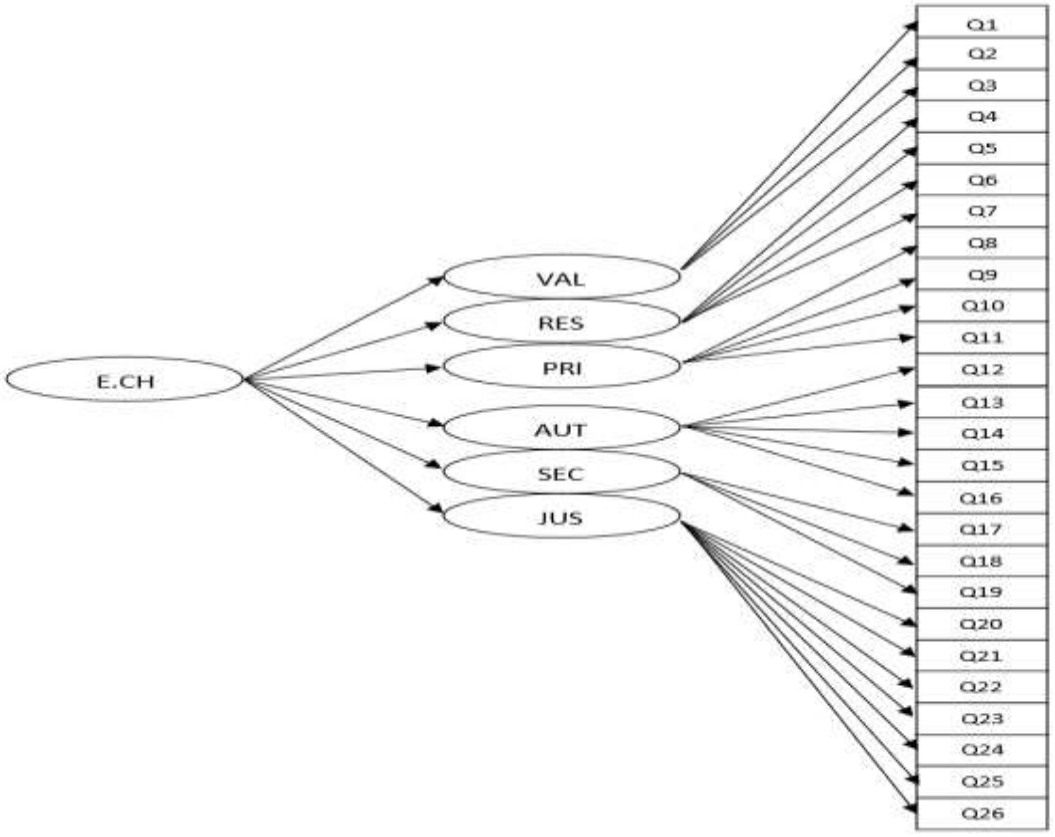

Fig. 2. Conceptual model.

4. Study Two: Survey data for confirmatory factor analysis

4.1. Questionnaire survey

In the second study, we collected the survey data for the empirical examination of the conceptual model. As for data collection, we used the adapted version of the questionnaire employed for Study One. Participants were asked, for instance, "Please indicate how you would agree that equity in access is an ethical issue in digital healthcare on the scale of 1 (extremely disagree) to 5 (extremely agree)". Since experts have reached the consensus for all indicators explored in Study One, the open-ended questions were excluded from the questionnaire (Appendix A).

The target population is around 420 people. They are composed of all employees (consisting of nurses, health and safety officers, midwives, paramedics, social workers and lab technicians etc.), managers and physicians working in hospitals, clinics and laboratories in Khorasan province, Iran. Based on the Cochran formula at the error level of 0.05 (d=0.05), the appropriate sample size was determined "n=200", 349 copies of printed questionnaires were distributed in the workplace and collected by the research group. As a result, a sample of 210 complete responses was received (see Table 5), reflecting an over 60 per cent response rate.

Table 5

Descriptive statistics of the second survey sample.

Job	Place of Work			Gender		Frequency
	Hospitals	Clinics	Laboratories	Male	Female	
Manager	11	6	9	12	14	26
Physicians/ Doctors	73	49	22	77	67	144
Health Workers/ Staff	19	8	13	11	29	40
Total	103	63	44	100	110	210

4.2. Measurement model analysis

To confirm the validity of the key indicators of the ethical challenges, we first examine the measurement models for the six indicators. The results are displayed in Figure 3. The six measurement models have loadings ranging from 0.44 to 0.88; Cronbach's Alpha values ranging from 0.72 to 0.93 (Table 6); suggest internal consistency of the six measurement models.

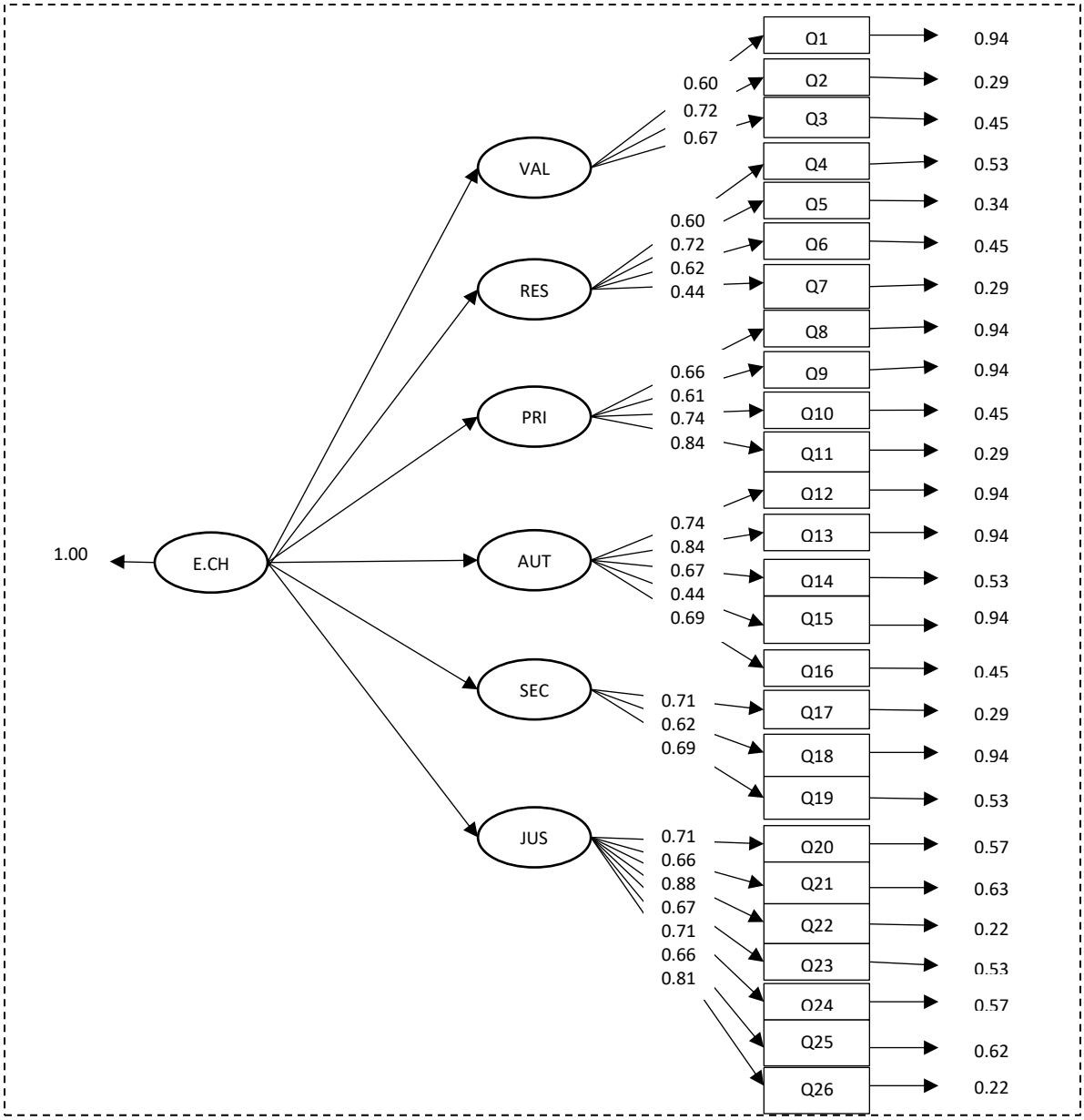

Fig. 3. Measurement model analysis

4.3. Confirmatory factor analysis

We perform a second-order confirmatory factor analysis model to validate the key indicators to the ethical challenges. The second-order factor (i.e. Ethical challenges) is reflectively measured by six first-order factors measured by 26 items (Table 6). The results show that the six coefficients range from 0.74 (*Autonomy*) to 0.98 (*Security*), suggesting that all fall in high effect sizes and the

factor loadings are acceptable. Also, t values range from 5.56 to 7.84, indicating that the concept of ethics challenges is significantly related to its six indicators, namely, *Procedure Values, Responsibility, Privacy, Autonomy, Security* and *Justice*. R square values, ranging from 0.55 (*Autonomy*) to 0.96 (*Security*) indicate that *Security* can be explained mostly by *Ethics Challenges* while *Autonomy* the least.

Table 6

Second-order confirmatory factor analysis (standardised solution).

Second-order variable	First-order factors	Item	λ coefficients	δ (measurement errors)	t-value	R^2	Cronbach's alpha
Ethical Challenges	Process values	Q1-Q3	0.75	0.44	5.56	0.56	0.73
	Responsibility	Q4-Q7	0.80	0.37	6.05	0.64	0.85
	Privacy	Q8-Q11	0.75	0.44	5.68	0.56	0.74
	Autonomy	Q12-Q16	0.74	0.45	5.60	0.55	0.72
	Security	Q17-Q19	0.98	0.029	7.84	0.96	0.93
	Justice	Q20-Q26	0.78	0.37	5.71	0.61	0.80

$\rho < 0.05$ (two-tailed)

4.4. Model fit

The goodness of fit of a statistical model indicates how well a model fits a set of observations (Marsh, Hau, and Grayson, 2005). Primary model fit indexes are the Chi-square test (x^2/df), the Goodness of Fit Index (GFI), Adjusted Goodness of Fit Index (AGFI), and Root Mean Square Error of Approximation (RMSEA) (Mulaik *et al.*, 1989). The two most prominent indices from the LISREL output are the Chi-square test (x^2/df) and the RMSEA. Table 7 shows the test results of the main model fitness indices, e.g. Chi-square (1.4376, p = 0.0417), RMSEA (0.047), GFI (0.92), AGFI (0.91), suggesting good model fit (Marsh et al., 2005).

Table 7

Fitness indices.

Fit indices	Reference value (good fit)	Model value
$\chi 2$/df	$\chi 2$ /df<3	1.4376
P-Value	P-Value <0.05	0.0417
RMSEA	RMSEA<0.05	0.047
GFI	More than 0.9	0.92
AGFI	More than 0.9	0.91

5. Discussion

Our results suggest that *procedural values* are identified as a key indicator of ethical challenges in digital healthcare. The concept is defined by three components, namely, transparency, accountability, and inclusiveness, which are consistent with the results of Fricker et al. (2015a), Kopala and Mitchell (2011), and Ozair et al., (2015) in healthcare technology; Parimbelli *et al*. (2018) on the ethical challenges in telemedicine; Salerno *et al*., (2017) in big data.

Responsibility is identified as another key indicator of ethical challenges. This challenge consists of trust, the balance of power, the relationship between stakeholders (e.g. technology user, government, and provider) and benefit-sharing. The essential elements in the development and implementation of the digital healthcare system are to take responsibility, which builds up the level of acceptance, satisfaction and trust of patients and users. Also, responsibility is seen as the balance of power, authority and benefit-sharing. The level of responsibility of individuals can determine the extent of this balance of power in digital healthcare. Our findings are in line with some previous studies in the digital health record, eHealth, and telemedicine (Kopala and Mitchell, 2011; Ataç, Kurt and Yurdakul, 2013; Townsend et al., 2015; Botrugno, 2018).

Our research suggests that a*utonomy* is another key indicator of ethical challenge in digital healthcare. This is a relatively new concept and has not been given enough attention in the previous research though literature has suggested that patient awareness and informed consent are of the

most important ethical challenges in eHealth (Lee, 2017), mHealth (Galderisi and Caputo, 2017), and big data (Salerno *et al.*, 2017). Our results suggest that digital healthcare tools should protect autonomy and independence to patients and their families during the treatment cycle. Autonomy has a direct relationship with human dignity. The relevant challenges include freedom of choice in treatment, informed consent, complete awareness of how patient data are collected and used, and the right to know (or not to know) the patient's medical results.

Privacy refers to the right to privacy and non-personal disclosure of one's information to others so that any supervision or interference by individuals, organisations and the government is subject to obtaining permission from her/his legal representative and caregiver. Privacy is perhaps one of the most critical indicators of ethical challenges in digital healthcare, including collecting, recovering, and sharing patient medical data. Our results define four groups of privacy measures; data protection, confidentiality, data sharing, intended/unintended uses of data. This is consistent with the results of Sharma et al., (2018) and Resnik (2011) in healthcare ethics record, Kleinpeter (2017) in eHealth technology, Salerno et al. (2017) in big data, and Kelly et al. (2013) in wearable cameras digital technology.

Justice is defined by equal access to digital technology facilities and health, equity in access to treatment, non-discrimination and non-stigmatisation in treatment, equity in data ownership, and empowerment. The definitions and measurement of justice are also consistent with some previous study in digital health technology (e.g. Dickens and Cook, 2006; Kluge, 2007; Ataç, Kurt and Yurdakul, 2013; Fricker et al., 2015b; Galderisi and Caputo, 2017; Lisa M Lee, 2017; Cvrkel, 2018).

Security is another indicator of ethical challenges in digital healthcare. *Security* is a significant factor in general digital technology applications. It is more prominent in digital healthcare, where individual patients' private and sensitive information is vulnerable and might be accessed by others

without notification to the patients. Security needs more attention in digital healthcare due to its portability. With the transfer of large volumes of patient treatment data between different treatment departments and individuals, the risk of personal information disclosure of patients in healthcare increases. Security in data storage, the safety of information, protection against unauthorised access, and data use are the components of security. Our findings confirm with the results of Fricker et al. (2015b), Kopala and Mitchell (2011), Lee (2017) and Ozair et al., (2015) in HER technology, Galderisi and Caputo (2017), and Cvrkel (2018) in mHealth and Salerno et al. (2017) in big data and Dickens and Cook (2006) in telemedicine and Kelly et al. (2013) in wearable health technologies.

6. Conclusion

6.1. Theoretical contributions

This study applied the Delphi method and established 26 items measuring six key indicators of ethical challenges in digital healthcare. The six key ethical challenges indicators are process values, responsibility, autonomy, privacy, justice, and security. We conceptualised the indictors in a model and empirically verified the conceptual model using SEM confirmatory factor analysis.

Our result addressed a literature gap where scholars have started to pay attention. That is, along with positive impacts, digital healthcare's negative perspectives, such as ethical concerns, should not be overlooked. However, it still lacks research in the extant literature. Perhaps, this is because employing new forms of digital systems and technologies in healthcare is still at an early stage of development. Therefore, there lacks sufficient evidence for such research. Or perhaps, it is due to the sensitivity of the research context, and hence it is difficult to get access to valuable data for the research purpose.

By addressing the literature gap in this field, this study made a significant theoretical contribution, specifically, to the literature concerned with the dark side of applying digital technologies for healthcare (George et al., 2013; Fricker et al., 2015b; Kane, 2016; Guan, 2019; Brall et al., 2019). We used field evidence and empirically established a conceptual model of ethical challenges in digital healthcare. Thus, we contributed to the operationalisation of the ethical challenges with six key indicators and 26 measurement items. This is our original contribution to the literature, particularly associated with digital healthcare.

Moreover, this paper applied a two-step approach combining exploratory and confirmatory methods in two studies while most previous literature established outcomes only based on either survey or literature review. From the methodological perspective, the results from the combined research methods such as the one used in this study are more reliable than those using single source or single study in most of the existing literature in the field.

6.2. Practical implications

Our results offer some practical implications for managers in healthcare or tech firms' managers in managing the digital transformation process in the healthcare sector. We used a combined Delphi - CFA method in this research, and the results can predict the ethical challenges in future digital healthcare. This paper draws attention to the six key indicators of ethical challenges of using digital technologies and systems in healthcare: justice (JUS), autonomy (AUT), privacy (PRI), security (SEC), responsibility (RES), and procedural values (VAL). For instance, the system developers and the governance of such systems need to think about the information's privacy when deciding on who to grant access. The importance of these challenges is highlighted in the Commission Staff Working Document (CFWD), issued by the European Commission. CFWD provides a comprehensive view of applicable state-of-the-art legislation for

using digital technologies such as mobile applications in the digital healthcare and wellbeing system (EC, 2014).

6.3. Limitations and future research

This study contains limitations which suggest future research directions. Our current research focuses on the ethical aspect of the challenges associated with digital healthcare. However, the reality is far more complicated than the technologies related to ethical challenges. For example, Dickens and Cook (2006) consider the migration of medical specialists and professional physicians. They have moved from low-source areas to rich countries, where the widening inequality in medical services, legal-cultural conflict in different countries, and communication problems caused by semantic differences in language are the main challenges in telecommunications services. For future studies, we call for scholars to extend our research to social and cultural, regulatory and legal aspects of the challenges.

Also, this study was limited to Iran's context, where social values are different from western countries, and where healthcare infrastructure and digital transformation might be less developed compared to other countries. Therefore, care should be taken to generalise the result from this study to other contexts, particularly of more advanced economies. This also suggests another area for future research, where scholars can set a different research context.

Furthermore, this research's scope was limited to a two-step method to explore and validate the key ethical challenges in digital healthcare. However, for such a complex social question, we call for more empirical research to understand the perspectives of the key ethical indicators in various practical cases.

Appendix A. Questionnaire for Study Two

Section 1

Please select all from the follows that describe you.

I am a …

man	woman

I work as a …

Manager	Physician/ Doctor	Health Worker/ Staff

I work in …

Hospital	Clinic	Laboratory

Section 2

To what extent you agree or disagree that each of the following items is an ethical issue in digital healthcare? (extremely agree=5, extremely disagree=1).

	Items of Ethical Challenges	5	4	3	2	1
Q1	Equity in Access					
Q2	Exclusion					
Q3	Equal Treatment					
Q4	Non-Discrimination					
Q5	Non-Stigmatisation					
Q6	Data Ownership					
Q7	Empowerment					
Q8	Freedom of Choice					
Q9	Informed Consent					
Q10	Awareness of Data Collection					
Q11	Awareness of Data Use					
Q12	Right To (not) Know the Result					
Q13	Data Protection					
Q14	Confidentially					
Q15	Data Sharing					
Q16	Intended/Unintended Use of Data					
Q17	Data Storage					
Q18	Safety of Information					
Q19	Protection Against Unauthorised Access/Use of Data					
Q20	Trust					
Q21	Balance of Power					
Q22	Relation Between Stakeholders					
Q23	Benefit and Benefit Sharing					
Q24	Transparency					
Q25	Accountability					
Q26	Inclusiveness					

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