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Design and Validity of a Questionnaire to Assess National eHealth Architecture (NEHA): A Study Protocol

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Title Page

Design and Validity of a Questionnaire to Assess National eHealth Architecture (NEHA): A Study Protocol

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ABSTRACT

Introduction: eHealth is critically important to build strong health systems, and accelerate the achievement of sustainable development goals (SDGs), particularly universal health coverage (UHC). The eHealth architecture that can strengthen and support the health system needs to be formulated and established prior to the implementation and development of any national eHealth applications and services. The aim of this study is to design and validate a standard questionnaire to assess the current status of national eHealth architecture (NEHA) components.

Methods and analysis: This study will use a mixed methods design consisting of three phases: 1) item generation through review of evidences and experts opinions, 2) face and content validity of the questionnaire, and 3) determination of a range of possible scenarios for each item included in the questionnaire. This questionnaire is expected to generate critical and important information about status of NEHA components that will be useful for monitoring, formulating, developing, implementing and evaluating NEHA. Our paper will contribute, we envisage, to establishment of a socio-technical basis upon which governments and other relevant sectors can compare the policy interventions that boost the availability and utilization of eHealth services within their settings.

Ethics and dissemination: The Ethics Committee for Research at the Tehran University of Medical Sciences approved the study protocol. We will obtain informed consent from each participant and collect data anonymously to maintain confidentiality. The translation of the findings into future policy planning will include the production of a series of peer-reviewed articles, presentation of the findings at relevant eHealth conferences, and preparation of policy reports to the international organizations aiming to strengthen national capacity for better-informed eHealth architecture.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will propose a validated instrument with focus on the national eHealth architecture (NEHA) for the first time, which can create a comprehensive platform to compare the status of NEHA across various settings;

- The findings will advance the existing knowledge about the status of NEHA components in different countries.
- The latter will help develop eHealth architecture prior to implementation, scaling-up and developing any national eHealth solutions, which improve efficiency of health systems.
- The number of items are relatively high in the questionnaire, which may compromise participants' compliance;
- Although the questionnaire is comprehensive and applicable to any settings, detailed contextual factors affecting the process may not be captured given variations across different settings.

INTRODUCTION

Health systems have great opportunities to alleviate the healthcare resource constraints and reduce costs. This can be realised through investing in technology to help better co-ordinate the healthcare and move all the functions of the public health management into the service economy (1). The eHealth is an umbrella concept that can be described as the combined use of information and communication technologies (ICT) in the health sector as well as the use of digital data for clinical, educational, and administrative purposes. The eHealth solutions, i.e. telehealth, mobile health, electronic health records (EHR), electronic prescription (EP), etc., are considered cost-effective that can contribute to improving equity in access and patient safety, enhancing quality of healthcare delivery, implementing change management in healthcare organizations and promoting the exchange of information and quality of health data (2-13). eHealth may play a critical role in building the foundation for a robust health system toward the achievement of universal health coverage (UHC) as well as sustainable development goals (SDGs) for health (14), for instance by providing a platform for organizational learning (15). The importance of developing eHealth technologies and their successful implementation in the health systems have been well known for long (16).

The increased understanding on the importance of the eHealth has led many countries towards greater investment on related solutions (17). In the context of low and middle-income countries (LMICs), eHealth has become fundamental in managing the limited available resources to achieve better quality of care (18). Nevertheless, due to poor infrastructure, shortage of resources, as well as lack of political commitment and support, the implementation of ICT in the LMICs has been challenging.(19). High-income countries

experience various concerns and expectations of eHealth expectations and requirements than the LMICs (20). Hence, transferrable lessons need to be drawn for less advance settings in investing and adopting the eHealth solutions, which is a crucial step for successful transformation of their healthcare systems (21).

Prior to implement, scale-up and develop any eHealth solutions, healthcare systems require a clear understanding of their needs and expectations to develop a national eHealth architecture (NEHA). This may pave the way to accommodate the appropriate IT solutions that are tailored to countries' needs (22, 23). An evidence-informed NEHA is the backbone of eHealth system to design and implement eHealth solutions.

Our experience suggests that many countries have been implementing eHealth solutions into their healthcare settings, without developing a tailored (22, 24) eHealth architecture at the national level in priori. To promote successful e adoption of national eHealth policies, it is crucial to assess the current status of NEHA. This study is motivated since hitherto there is no validated instrument with focus on the NEHA components. This study aims to bridge this gap through designing and validating a questionnaire to understand NEHA. Our findings can contribute to a clearer picture of the existing situation, as well as creating a platform to compare the status of eHealth architecture across various settings, hence improving current practices.

METHIDS

This study will employ a mixed-methods design to construct and validate a questionnaire on the status of NEHA. The questionnaire will be developed during three phases: 1) item generation through review of the evidences and experts' opinions, 2) evaluate the face and content validity of the questionnaire to gain consensus regarding the relevancy and clarity of items, and 3) determination of a range of possible scenarios for each item included in the questionnaire. The flow of the study is described in figure 1. As explored through discussion with global experts in the field, currently there is no comprehensive validated questionnaire for evaluating the eHealth architecture components and this will be the first attempt to do so. Our study will provide necessary formation about the construction of the eHealth architecture at different settings, which will be useful to guide the formulation of tailored NEHA in different settings.

Conceptual model

The framework for the construction of the questionnaire will be adapted from eHealth architecture model in of the eHealth informatics- capacity-based eHealth architecture roadmap developed by the International Organization for Standardization in figure 2 (25).

This eHealth architecture model comprises different components that are aggregated under the following four general categories: 1) Governance and national ownership, 2) eHealth infostructure, 3) ICT infrastructure, and 4) Health process domain. Please see Appendix for full details of categories and their components.

The planning committee

We have established a planning committee of health service researchers, comprised of three experts in health policy and management, plus three experts in eHealth and health informatics. The committee have regular meetings, physical and mostly virtual, to design the research protocol, formulate various phases of study and approve required material for data collection.

Phase 1: item generation

The first phase of the instrument development process will be generating a comprehensive list of items that can represent the various aspects of each component. The most important sources to generate items will be a review of evidences as well as experts' opinions.

Source one: Review of the evidences

Reviewing the available evidences will enable us to identify the core items to inform the consensus-seeking process. Through discussions, the planning committee recommended three international documents to identify potentially relevant items. These include: 1) The eHealth Informatics-Capacity-Based eHealth Architecture Roadmap developed by the ISO (25); 2) The National eHealth Strategy Toolkit developed by the World Health Organization (WHO) - International Telecommunications Union (26), 3) Assessing the National Health Information System: An Assessment Tool developed by the WHO (27). These documents will be carefully examined and reviewed using the evaluation criteria of applicability and relevancy of items to each component. The items identified from the evidences will be examined and translated into survey-format statements. Statements will be effectively written based on the

most important statement of each component that clearly represents the status of NEHA components.

Source two: experts' opinions

The panel of experts will be used as a second source of item generation and selection. The expert panel is a practical method for obtaining opinions on a given question. This procedure will help the experts develop a broad range of items for each component. During this stage, to design the preliminary version of the questionnaire, the overlaps will be identified and merged, the wording of items will be checked for clarity, while relevance of included items will be re-examined. The items gathered through experts' opinions will be evaluated and new items will be generated, refined and synthesized using the evaluation criteria of applicability, comprehensiveness, and measurability in assessing the current status of the NEHA components, aiming to shape the preliminary version of the questionnaire.

One member of the research team (SMM) will be responsible for the data collection and respond to, through getting clearance from the entire research team, the possible inquiries from the experts. The experts will be emailed a link to the survey and invited to complete the first round within one week; a reminder will be sent if the response is not obtained after three week. The questionnaire will be developed in English, together with the cover letter, the invitation and reminders.

Phase 2: validation of the questionnaire

Face validity

We will use qualitative methods (i.e. sequential face-to-face review meetings and email correspondence) to determine face validity of the questionnaire. We will ask two experts from the planning committee to assess each item to decide about their "ambiguity", "relevancy", and "difficulty" (28).

Content validity

Using Waltz & Bausell's recommendation (29), we will use the Content Validity Index (CVI). The experts will evaluate the items based on a 4-point Likert scale on, *a) relevancy and b) clarity*. The CVI value of 0.79 or above will be considered satisfactory for each item. To avoid overlooking important items in our study, we may also ask the experts to add limited extra items for each component (table 1).

Table 1. Response scales used by the experts for rating the relevancy, clarity, and missing items

Relevancy		Clarity		Any missing item for each component?	
Description	***Scale***	***Description***	***Scale***	***Description***	***Scale***
How important is the item	1 = "Not Relevant"	How clear is the wording	1 = "Not Clear"	Is there any item for each component that we have not included?	1 = "No"
	2 = "Somewhat Relevant"		2 = "Somewhat Clear"		
	3 = "Quite Relevant"		3 = "Quite Clear"		2 = "Yes"
	4 = "Highly Relevant"		4 = "Highly Clear"		

Recruiting study participants

Following the principles of purposive sampling and through snowball technique, we will invite (through email contact) selected international experts and scholars with academic, policy and clinical backgrounds, whom have expertise in various disciplines of eHealth to fill in the questionnaire.

Procedure

The planning committee will finalize a package to be sent to participating scholars, i.e. a brief background and description of study, what is expected from them and the timeframe within which to complete the questionnaire. At this stage, participants will be invited to anonymously fill in the questionnaire, while they can modify and add new items to the list or provide further commentary using the free text space at the end of questionnaire.

Analysis

Data will be independently scrutinised and transcribed by a planning committee member (SMM) into IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp and the median score for all items will be calculated.

Phase 3: Determination of a range of possible scenarios for each item

When analysis will be completed, we will convene a panel of experts to determine a range of possible scenarios for each item included in the questionnaire. Selection process of the experts will be purposively congruent with this phase's aims. First, the planning committee will design preliminary possible scenarios for each item for each of the four situation (high, medium, low, and not at all). This will create inputs for panel of experts to give their views about various scenarios for the situation relevant to each item. We will set an 80% agreement as an indication of acceptable consensus for each item.

DISCUSSION

This will be the first and most comprehensive study to design and validate the questionnaire on NEHA using the mixed-methods design. The findings are anticipated to be useful for all countries and international organizations to assess, formulate, develop, implement, and evaluate eHealth architecture. The findings will help establish a socio-technical basis upon which governmental and others concerned bodies can compare the policy interventions that boost the availability and utilization of eHealth services. It is also valuable for governments to design and develop strategies and policies that could facilitate the adoption of eHealth and guide the use of ICTs toward the achievement of the desired goals.

Besides, our study will contribute to the growing body of research through designing a questionnaire that create insights into current status of eHealth architecture and identify areas for improvement. This questionnaire will also could examine the extent to which governments develop all components of eHealth architecture. Consequently, we hope that this study opens up further avenues of research to assess the status of eHealth architecture in different settings.

FOOTNOTES

Division of contributions: AT was responsible for conception, design, implementation, analysis, drafting the manuscript and supervision of the whole process of this study. He is principal investigator and guarantor. SMM is the principal researcher, who was involved in conception, development, implementation, data collection, analysis, and writing of this manuscript. SMT is member of research team and responsible for intellectual development of manuscript as well as technical consultation for validating the questionnaire. All authors read and approved the final manuscript.

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Competing interests: None declared.

Patient consent: Not required.

Ethics approval: The Ethics Committee for Research at the Tehran University of Medical Sciences approved the study protocol (Ref: IR.TUMS.SPH.REC.1396.3998).

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FIGURE LEGENDS

Figure 1. Breakdown of research phases.

Figure 2. eHealth Architecture Model (eHAM) according to ISO TR 14639 - Capacity Based eHealth Architecture Roadmap

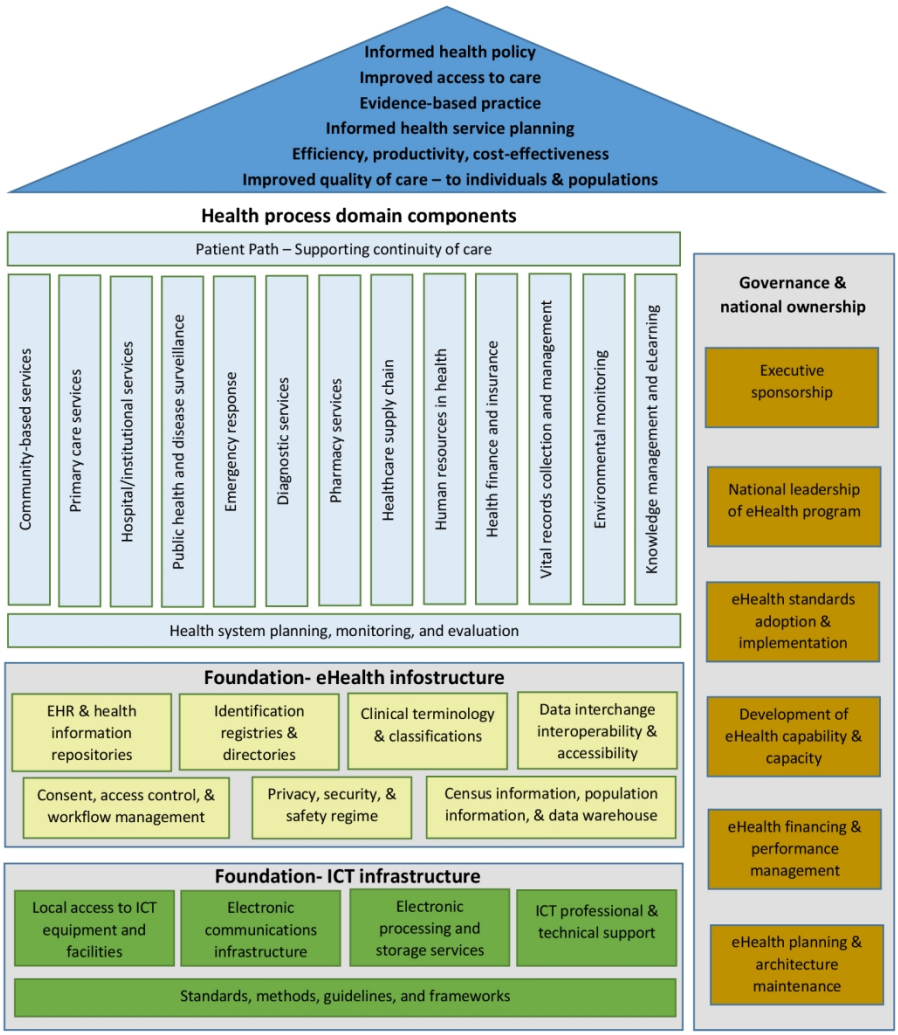

Figure 1. Breakdown of research phases

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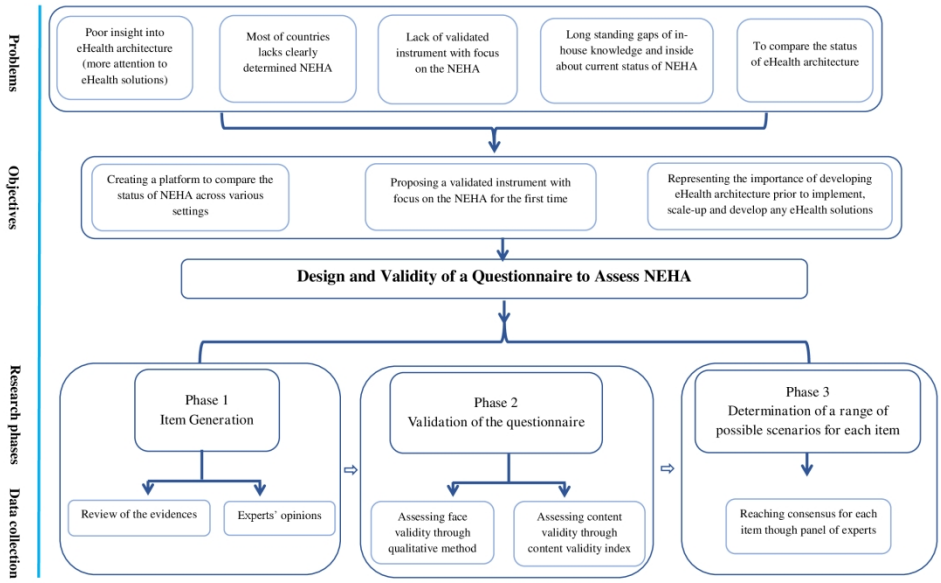

Figure 2. eHealth Architecture Model (eHAM) according to ISO TR 14639 - Capacity Based eHealth Architecture Roadmap

297x210mm (200 x 200 DPI)

Supplementary file

Table 1. Description of four categories of eHealth architecture model

Categories	Description	Components
Governance and national ownership	This is an important category of the eHealth architecture model since it represents the organizational and governance aspects of eHealth, including the financing, performance management and the development of local capability and capacity in Health Informatics.	1) Executive sponsorship; 2) National leadership; 3) eHealth standards adoption and implementation; 4) Development of eHealth capability and capacity; 5) eHealth financing and performance management; 6) eHealth planning and architecture maintenance.
eHealth infostructure	It includes those foundation components that exist at the national level or in some instances, the state/province level or both, acting as "cornerstone" resources that provide interoperability, both functional and semantic, plus related consent, privacy, and security controls for the transmission and broad sharing of data from various point-of-service systems, including repositories of domain data. These components also provide data processing and analytic capability supporting the secondary use of aggregate data.	1) EHR and health information repositories; 2) Identification registries and directories; 3) Clinical terminology and classifications; 4) Data interchange interoperability and accessibility; 5) Consent, access control, and workflow management; 6) Privacy, security, and safety regime; 7) Census information, population information, and data warehouse.
ICT infrastructure	It encompasses the core IT technologies including networking, servers, software, and IT human resources. In general, this is the most commonly found category in any country, all underpinned by relevant standards, methods, guidelines, and frameworks.	1) Local access to ICT equipment and facilities; 2) Electronic communications infrastructure; 3) Electronic processing and storage services; 4) ICT professional and technical support; 5) Standards, methods, guidelines, and frameworks.
Health process domain components	It addresses the various health process domains that comprise the set of services and processes delivered across the healthcare continuum. These processes generally involve both patients seeking and accessing healthcare services and providers offering these services. The health domains encompass a broad range of services intended to address clinical (provider) assessment of health problems coupled with diagnostic (test) assessments, therapeutics and related components such as payment for services and evaluation of services, provider and patient education and knowledge management, essentially the spectrum of patient-provider experiences that span the continuum of care.	1) Community-based services; 2) Primary care services; 3) Hospital/institutional services; 4) Public health and disease surveillance; 5) Emergency response; 6) Diagnostic services; 7) Pharmacy services; 8) Healthcare supply chain; 9) Human resources in health; 10) Health finance and insurance; 11) Vital records collection and management; 12) Environmental monitoring; 13) Knowledge management and eLearning; 14) Health system planning, monitoring, and evaluation

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ABSTRACT

Introduction: eHealth is critically important to build strong health systems, and accelerate the achievement of sustainable development goals (SDGs), particularly universal health coverage (UHC). To support and strengthen the health system, the eHealth architecture needs to be formulated and established prior to the implementation and development of any national eHealth applications and services. The aim of this study is to design and validate a standard questionnaire to assess the current status of national eHealth architecture (NEHA) components.

Methods and analysis: This study will use a mixed-methods design consisting of four phases: 1) item generation through review of evidences and experts' opinions, 2) face and content validity of the questionnaire, 3) determination of a range of possible scenarios for each item included in the questionnaire, and 4) evaluation of reliability. This questionnaire is expected to generate critical and important information about status of NEHA components that will be useful for monitoring, formulating, developing, implementing and evaluating NEHA. Our paper will contribute, we envisage, to establishment of a socio-technical basis upon which governments and other relevant sectors can compare the policy interventions that boost the availability and utilization of eHealth services within their settings.

Ethics and dissemination: The Ethics Committee for Research at the Tehran University of Medical Sciences approved the study protocol. We will obtain informed consent from each participant and collect data anonymously to maintain confidentiality. The translation of the findings into future policy planning will include the production of a series of peer-reviewed articles, presentation of the findings at relevant eHealth conferences, and preparation of policy reports to the international organizations aiming to strengthen national capacity for better-informed eHealth architecture.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will propose, following a robust and mixed-method design, a validated instrument with focus on the national eHealth architecture (NEHA);

- The findings will advance the existing knowledge about the status of NEHA components in different countries, which can create an evidence-based platform to learn from both achievements and mistakes for improving practices;
- The latter will help develop eHealth architecture prior to the implementation, scale up and development of any national eHealth solution, which can help improve the efficiency of health systems.
- The number of items are relatively high in the questionnaire, which may compromise participants' compliance;
- Although the questionnaire is comprehensive and applicable to all settings, it might overlook some contextual factors that might affect the process across different settings.

INTRODUCTION

Health systems have great opportunities to alleviate the healthcare resource constraints and reduce costs. This can be realized through investment in technology to help better healthcare coordination and move all functions of public health management into the service economy (1). As an umbrella concept, eHealth is defined as the combined use of information and communication technologies (ICT) in the health sector for clinical, educational, and administrative purposes. The eHealth solutions, i.e. telehealth, mobile health, electronic health records (EHR), electronic prescription (EP), etc., are considered as cost-effective applications for improving equity in access and patient safety, enhancing quality of healthcare delivery, implementing change management in healthcare organizations, and promoting the exchange of information and quality of health data (2-13). eHealth also plays a critical role in building the foundation for a robust health system towards universal health coverage (UHC), which builds the fundamental component of sustainable health development (14). eHealth technologies and their successful implementation in the health systems have been well-known for long (15).

The enhanced insight about eHealth has led the policy makers in many countries to expand their investment on various eHealth products (16). Like other settings, eHealth has become fundamental in managing the limited available resources to achieve more health for money and better quality of care in low and middle-income countries (LMICs) (17). Nevertheless, due to poor infrastructure, limited resources, and lack of political commitment and support, the implementation of ICT has been challenging in the LMICs (18). Concerns and

expectations from eHealth in high-income countries differ from the LMICs (19). Hence, less advance settings need to learn from transferrable lessons for investing and adopting the eHealth solutions. This is a crucial step for successful transformation of healthcare systems in the LMICs (20).

Being aware of various descriptions of the concept, we define eHealth architecture as structure of eHealth components, their functions and inter-relationships, as well as the principles and guidelines that govern their design and evolution over time (21). Before any attempt for production, implementation, and scaling-up eHealth solutions, healthcare systems require to develop a national eHealth architecture (NEHA) based on a clear understanding of their needs and expectations. This may pave the way to accommodate the appropriate IT solutions that are tailored to countries' needs (22, 23). An evidence-informed NEHA is the backbone of eHealth system to design and implement eHealth solutions.

Our experience suggests that many countries have been implementing eHealth solutions into their healthcare settings, without developing a tailored (22, 24) eHealth architecture at the national level in priori. To promote successful adoption of national eHealth policies, it is crucial to assess the current status of NEHA. This study is motivated since hitherto there is no validated instrument with focus on the NEHA components. Our research aims to bridge this gap through designing and validating a questionnaire to understand NEHA. Through: 1- painting a clearer picture of the existing situation, and 2- creating a platform to compare the status of eHealth architecture across various settings, our findings can contribute to, we hope, improve the increasing initiatives in adopting meaningful eHealth solutions anywhere.

METHODS

This study will employ a mixed-methods design to construct and validate a questionnaire on the status of NEHA. Our work will have four sequential phases: 1) item generation through review of the evidences and experts' opinions, 2) evaluating the face and content validity of the questionnaire to gain consensus regarding the relevancy and clarity of items, 3) determination of a range of possible scenarios for each item of the questionnaire, and 4) evaluation of reliability. The flow of the study is described in Figure 1. To the best of our knowledge, e.g. through discussions with global experts in the field, currently there is no comprehensive validated questionnaire for evaluating the eHealth architecture components. Our study will provide fundamental information about the construction of the eHealth

architecture, which may be used to guide the formulation of tailored NEHA in different settings.

The conceptual model

We will use the eHealth informatics- capacity-based eHealth architecture roadmap, developed by the International Organization for Standardization (ISO) [Figure 2] (25), as the main framework to construct the NEHA questionnaire. The framework comprises of the following four general categories: 1) Governance and national ownership, 2) eHealth infostructure, 3) ICT infrastructure, and 4) Health process domain (Appendix 1).

The planning committee

We have established a planning committee of six members: three experts in health policy and management, plus three experts in eHealth and health informatics. The committee have regular meetings, physical and mostly virtual, to design the research protocol, formulate various phases of study, and approve the required material for data collection. The research phases have been prepared and approved, through consensus, by the planning committee. We anticipate that data collection will be completed by December 2018.

Patients and public involvement

We will not involve patients and any member of public during the development of this study protocol.

Phase 1: item generation

The first phase of the instrument development process will be generating a comprehensive list of items that can represent the various aspects of each component. The most important sources for item generation will be evidence review and experts' opinions.

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Reviewing the available evidence will enable us to identify the core items to inform the consensus-seeking process. Through discussions, the planning committee recommended three international documents for identification of the potential relevant items: 1) The eHealth Informatics-Capacity-Based eHealth Architecture Roadmap developed by the ISO (25); 2) The National eHealth Strategy Toolkit developed by the World Health Organization (WHO) - International Telecommunications Union (26), and 3) The National Health Information System: An Assessment Tool, developed by the WHO (27). These documents were carefully examined and reviewed using the evaluation criteria for applicability and relevancy. Applicability refers to the extent to which the chosen items apply to eHealth architecture at

the country-level setting. Relevancy refers to the extent to which the chosen items provide information that can be linked to each component. The identified items will be examined and translated into survey-format statements. Statements will be effectively written to ensure the clarity and conciseness based on the most important statement of each component that clearly represents the status of NEHA components.

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The panel of experts will be used as a second source of item generation and selection. The expert panel is a practical method for obtaining opinions on a given question. This procedure will help experts develop a broad range of items for each component. Using purposive sampling technique, we will recruit four eHealth international experts from academic, policy, and clinical background, from both high and low-middle income countries, who have in-depth knowledge and experiences in health informatics and eHealth policy.

During this stage, to design the preliminary version of the questionnaire, the overlaps will be identified and merged, while the wording of included items will be examined for clarity and relevancy. The items gathered through experts' opinions will be evaluated and new items will be generated, refined and synthesized using the evaluation criteria of applicability, comprehensiveness, and measurability in assessing the current status of the NEHA components.

One member of the research team (SMM) will be responsible for data collection and responding to, subject to the entire research team's approval, the possible inquiries from the experts. We will email the experts with a link to the survey and invite them to complete the first round within one week. A reminder will be sent if the response is not obtained after three weeks. The questionnaire will be developed in English, together with the cover letter, the invitation and reminders.

Phase 2: validation of the questionnaire

Face validity

We will use qualitative methods (i.e. sequential face-to-face review meetings and email correspondence) to determine face validity of the questionnaire. We will ask two experts from the planning committee to assess each item to decide about their "ambiguity", "relevancy", and "difficulty" (28). We will ask experts to perform the tasks listed in Table 1.

Table 1. Tasks involved in the face validity step

Tasks	Description
Ambiguity	The extent to which an item is not open to more than one possible interpretation.
Relevancy	The extent to which an item would be relevance to its component.
Difficulty	The extent to which an item would be easily understood by readers.

Content validity

Using Waltz and Bausell's recommendation (29), we will use the Content Validity Index (CVI) to assess the content validity. The experts will evaluate the items based on a 4-point Likert scale on, *a) relevancy and b) clarity*. The CVI value of 0.78 or above will be considered satisfactory for each item. To avoid overlooking the important items, we will also ask the experts to add limited extra items for each component (Table 2).

Table 2. Response scales used by the experts for rating the relevancy, clarity, and missing items

Relevancy		Clarity		Any missing item for each component?	
Description	***Scale***	***Description***	***Scale***	***Description***	***Scale***
How important is the item	1 = "Not Relevant"	How clear is the wording	1 = "Not Clear"	Is there any item for each component that we have not included?	1 = "No"
	2 = "Somewhat Relevant"		2 = "Somewhat Clear"		2 = "Yes"
	3 = "Quite Relevant"		3 = "Quite Clear"		
	4 = "Highly Relevant"		4 = "Highly Clear"		

Recruiting study participants

Using purposive sampling and snowball technique, we will invite (through email contact) selected international experts and scholars with academic, policy and clinical backgrounds, whom have expertise in various disciplines of eHealth to fill in the questionnaire. To enhance its applicability and social validity, we will ask purposefully selected consumer representatives at the international level to validate the questionnaire.

The Procedure

The planning committee will finalize a package to be sent to participating scholars, i.e. a brief background and description of study, what they are expected to do and the timeframe for completing the questionnaire. We will use Limesurvey® (http://www.limesurvey.org), which

is an online open source survey application, to create the questionnaire, conduct the survey, and perform the analysis. We will ask the participants to fill in the questionnaire anonymously, while they can modify and add new items to the list or provide further commentary, using the free text space at the end of questionnaire.

Analysis

A member of planning committee (SMM), will independently scrutinize and transcribe data from Limesurvey into IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. The median score for all items will be calculated. For each item rated as "quite relevant/quite clear" or "highly relevant/highly clear", a value of 0.79 or above will be given. We will collate free text comments and conduct directed content analysis (30) to capture the opinions expressed at the end of each questionnaire.

Phase 3: Determination of a range of possible scenarios for each item

After the completion of analysis, we will convene a panel of experts to determine a range of possible scenarios for each item that is included in the questionnaire. The scenarios will be descriptive example for each item under each of the four situations (high, medium, low, and not at all), which will meet the gold standard of the conceptual model and will allow us to gather more complete and reliable information on the current status of NEHA within selected countries.

Selection process of the experts will be purposively congruent with this phase's aims. First, the planning committee will design preliminary possible scenarios for each item. This will create inputs for the panel of experts to give their views about various scenarios for the situation relevant to each item. We will set an 80% agreement as an indication of acceptable consensus for each item.

Phase 4: evaluation of reliability

The final phase in designing and validating the questionnaire is evaluating the reliability, and doing so will allow us to start the development and implementation phase. In doing so, we will estimate the internal consistency by calculating Cronbach's alpha coefficient, ranges from 0.0 to 1.0, with the cutoff point at 0.70, more than which is generally considered as an acceptable level for internal consistency (31).

DISCUSSION

This will be the first and most comprehensive study to design and validate the questionnaire on NEHA using the mixed-methods design. The findings are anticipated to be useful for all countries and international organizations who intend to assess, formulate, develop, implement, and evaluate eHealth architecture. The findings will help establish a socio-technical basis, upon which governmental and others concerned bodies can compare the policy interventions that boost the availability and utilization of eHealth services. It is also valuable for governments to design and develop strategies and policies that could facilitate the adoption of eHealth and guide the use of ICTs toward the achievement of the desired goals.

Finally, this questionnaire will enable national evaluators to examine the extent to which the governments develop various components of eHealth architecture anywhere. Therefore, our study will contribute to the growing body of research that aim to create insights into the current status of eHealth architecture and identify the areas in need for improvement. As such, we hope that this study will open up further avenues to assess the status of eHealth architecture in different settings.

FOOTNOTES

Division of contributions: AT was responsible for conception, design, implementation, analysis, drafting the manuscript and supervision of the whole process of this study. He is principal investigator and guarantor. SMM is the principal researcher, who was involved in conception, development, implementation, data collection, analysis, and writing of this manuscript. SMT is member of research team and responsible for intellectual development of manuscript as well as technical consultation for validating the questionnaire. All authors read and approved the final manuscript.

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Competing interests: None declared.

Patient consent: Not required.

Ethics approval: The Ethics Committee for Research at the Tehran University of Medical Sciences approved the study protocol (Ref: IR.TUMS.SPH.REC.1396.3998).

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FIGURES' LEGEND

Figure 1. Breakdown of research phases

Figure 2. eHealth Architecture Model (eHAM) according to ISO TR 14639 - Capacity Based eHealth Architecture Roadmap

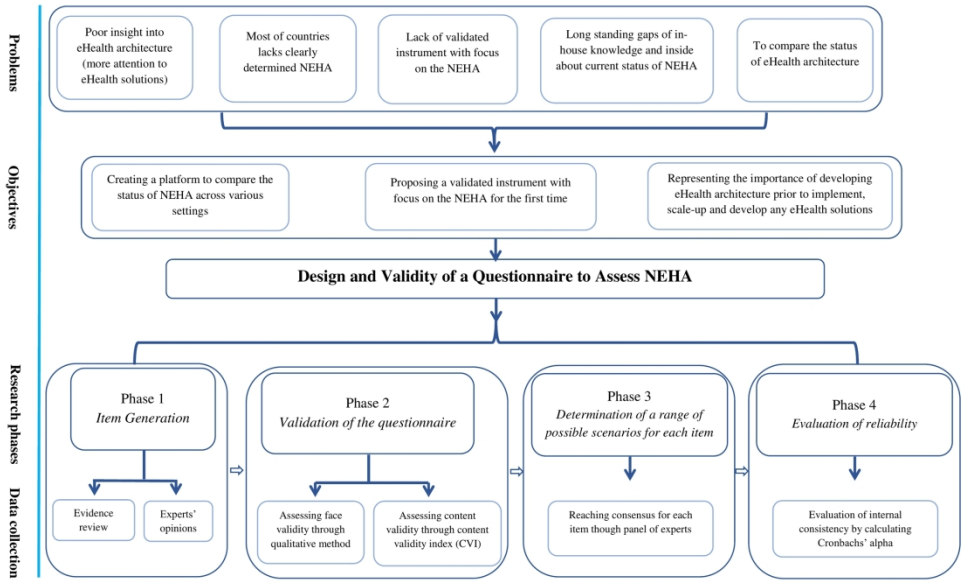
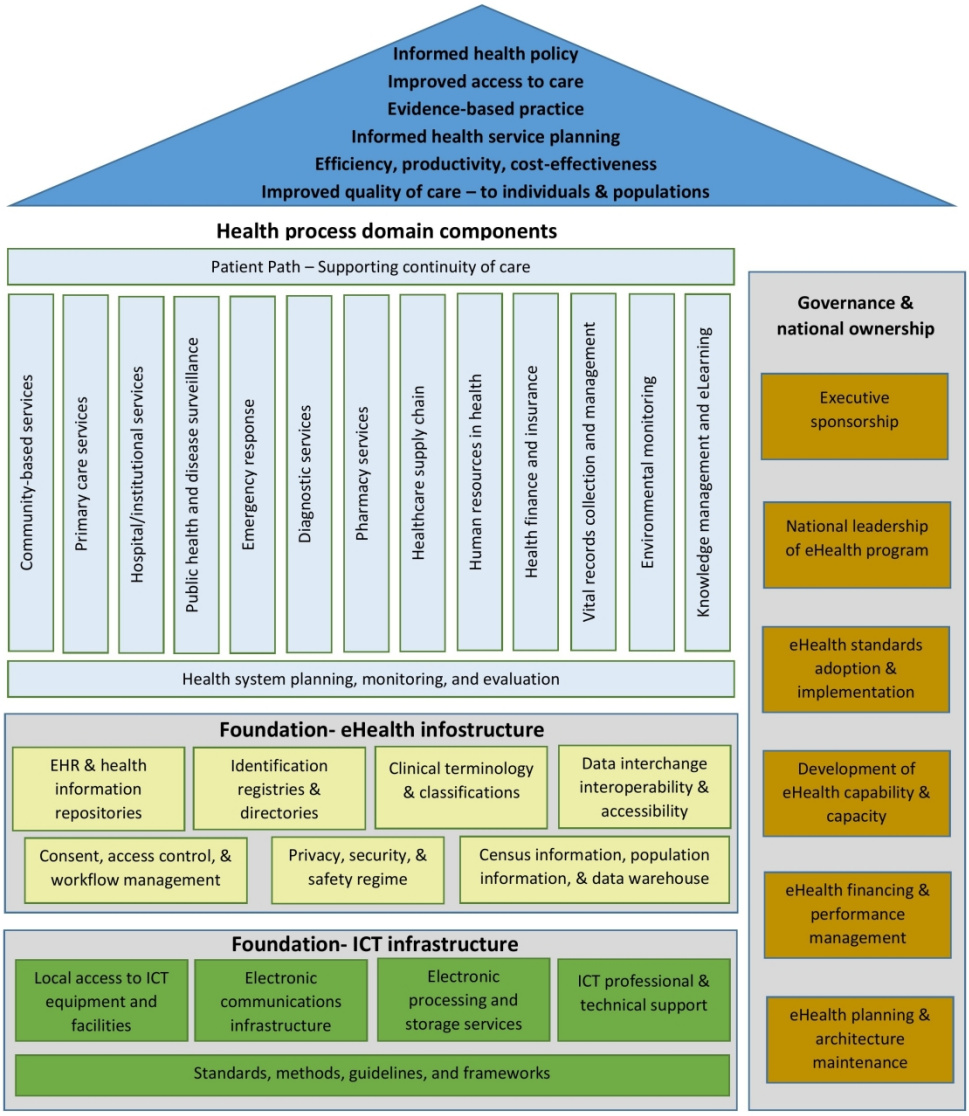


Figure 1. Breakdown of research phases

210x148mm (300 x 300 DPI)



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697x788mm (96 x 96 DPI)

Appendix

Table 1. Description of four categories of eHealth architecture model

Categories	Description	Components
Governance and national ownership	This is an important category of the eHealth architecture model since it represents the organizational and governance aspects of eHealth, including the financing, performance management and the development of local capability and capacity in Health Informatics.	1) Executive sponsorship; 2) National leadership; 3) eHealth standards adoption and implementation; 4) Development of eHealth capability and capacity; 5) eHealth financing and performance management; 6) eHealth planning and architecture maintenance.
eHealth infostructure	It includes those foundation components that exist at the national level or in some instances, the state/province level or both, acting as "cornerstone" resources that provide interoperability, both functional and semantic, plus related consent, privacy, and security controls for the transmission and broad sharing of data from various point-of-service systems, including repositories of domain data. These components also provide data processing and analytic capability supporting the secondary use of aggregate data.	1) EHR and health information repositories; 2) Identification registries and directories; 3) Clinical terminology and classifications; 4) Data interchange interoperability and accessibility; 5) Consent, access control, and workflow management; 6) Privacy, security, and safety regime; 7) Census information, population information, and data warehouse.
ICT infrastructure	It encompasses the core IT technologies including networking, servers, software, and IT human resources. In general, this is the most commonly found category in any country, all underpinned by relevant standards, methods, guidelines, and frameworks.	1) Local access to ICT equipment and facilities; 2) Electronic communications infrastructure; 3) Electronic processing and storage services; 4) ICT professional and technical support; 5) Standards, methods, guidelines, and frameworks.
Health process domain components	It addresses the various health process domains that comprise the set of services and processes delivered across the healthcare continuum. These processes generally involve both patients seeking and accessing healthcare services and providers offering these services. The health domains encompass a broad range of services intended to address clinical (provider) assessment of health problems coupled with diagnostic (test) assessments, therapeutics and related components such as payment for services and evaluation of services, provider and patient education and knowledge management, essentially the spectrum of patient-provider experiences that span the continuum of care.	1) Community-based services; 2) Primary care services; 3) Hospital/institutional services; 4) Public health and disease surveillance; 5) Emergency response; 6) Diagnostic services; 7) Pharmacy services; 8) Healthcare supply chain; 9) Human resources in health; 10) Health finance and insurance; 11) Vital records collection and management; 12) Environmental monitoring; 13) Knowledge management and eLearning; 14) Health system planning, monitoring, and evaluation

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Title Page

Design and Validity of a Questionnaire to Assess National eHealth Architecture (NEHA): A Study Protocol

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Keywords: Instrument development; eHealth; eHealth architecture

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ABSTRACT

Introduction: eHealth is critically important to build strong health systems, and accelerate the achievement of sustainable development goals (SDGs), particularly universal health coverage (UHC). To support and strengthen the health system, the eHealth architecture needs to be formulated and established prior to the implementation and development of any national eHealth applications and services. The aim of this study is to design and validate a standard questionnaire to assess the current status of national eHealth architecture (NEHA) components.

Methods and analysis: This study will use a mixed-methods design consisting of four phases: 1) item generation through review of evidences and experts' opinions, 2) face and content validity of the questionnaire, 3) determination of a range of possible scenarios for each item included in the questionnaire, and 4) evaluation of reliability. This questionnaire is expected to generate critical and important information about the status of NEHA components that will be useful for monitoring, formulating, developing, implementing and evaluating NEHA. Our paper will contribute, we envisage, to establishment of a socio-technical basis upon which governments and other relevant sectors can compare the policy interventions that boost the availability and utilization of eHealth services within their settings.

Ethics and dissemination: The Ethics Committee for Research at the Tehran University of Medical Sciences approved the study protocol. We will obtain informed consent from each participant and collect data anonymously to maintain confidentiality. The translation of the findings into future policy planning will include the production of a series of peer-reviewed articles, presentation of the findings at relevant eHealth conferences, and preparation of policy reports to the international organizations aiming to strengthen national capacity for better-informed eHealth architecture.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will propose, following a robust and mixed-method design, a validated instrument with focus on the national eHealth architecture (NEHA).

- The findings will advance the existing knowledge about the status of NEHA components in different countries, which can create an evidence-based platform to learn from both achievements and mistakes for improving practices.
- The latter will help develop eHealth architecture prior to the implementation, scale up and development of any national eHealth solution, which can help improve the efficiency of health systems.
- The number of items are relatively high in the questionnaire, which may compromise participants' compliance.
- Although the questionnaire is comprehensive and applicable to all settings, it might overlook some contextual factors that might affect the process across different settings.

INTRODUCTION

Health systems have great opportunities to alleviate the healthcare resource constraints and reduce costs. These can be realized through investment in technology to help better healthcare coordination and move all functions of public health management into the service economy (1). As an umbrella concept, eHealth is defined as the combined use of information and communication technologies (ICT) in the health sector for clinical, educational, and administrative purposes. The eHealth solutions, i.e. telehealth, mobile health, electronic health records (EHR), electronic prescription (EP), etc., are considered as cost-effective applications for improving equity in access and patient safety, enhancing quality of healthcare delivery, implementing change management in healthcare organizations, and promoting the exchange of information and quality of health data (2-13). eHealth also plays a critical role in building the foundation for a robust health system towards universal health coverage (UHC), which builds the fundamental component of sustainable health development (14). eHealth technologies and their successful implementation in the health systems have been well-known for a long time (15).

The enhanced insight about eHealth has led the policy makers in many countries to expand their investment in various eHealth products (16). Like other settings, eHealth has become fundamental in managing the limited available resources to achieve more health for money and better quality of care in low and middle-income countries (LMICs) (17). Nevertheless, due to poor infrastructure, limited resources, and lack of political commitment and support, the implementation of ICT has been challenging in the LMICs (18). Concerns and

expectations from eHealth in high-income countries differ from the LMICs (19). Hence, the LMICs can benefit from transferrable lessons for investing and adopting the eHealth solutions. This is a crucial step for successful transformation of healthcare systems in the LMICs (20).

Being aware of various descriptions of the concept, we define eHealth architecture as structure of eHealth components, their functions and inter-relationships, as well as the principles and guidelines that govern their design and evolution over time (21). Before any attempt for production, implementation, and scaling-up eHealth solutions, healthcare systems require the development of a national eHealth architecture (NEHA) based on a clear understanding of their needs and expectations. This may pave the way to accommodate the appropriate IT solutions that are tailored to countries' needs (22, 23). An evidence-informed NEHA is the backbone of eHealth system to design and implement eHealth solutions.

Our experience suggests that many countries have been implementing eHealth solutions into their healthcare settings. However, in advance development of a tailored (22, 24) eHealth architecture at the national level has not taken place in many countries. To promote successful adoption of national eHealth policies, it is crucial to assess the current status of NEHA. This study is motivated since hitherto there is no validated instrument with a focus on the NEHA components. Our research aims to bridge this gap through designing and validating a questionnaire to understand NEHA. Through firstly painting a clearer picture of the existing situation, and secondly creating a platform to compare the status of eHealth architecture across various settings, our findings can contribute to, we hope, improve the increasing initiatives in adopting meaningful eHealth solutions anywhere.

METHODS

This study will employ a mixed-methods design to construct and validate a questionnaire on the status of NEHA. Our work will have four sequential phases: 1) item generation through review of the evidences and experts' opinions, 2) evaluating the face and content validity of the questionnaire to gain consensus regarding the relevancy and clarity of items, 3) determination of a range of possible scenarios for each item of the questionnaire, and 4) evaluation of reliability. The flow of the study is described in Figure 1. To the best of our knowledge, e.g. through discussions with global experts in the field, currently there is no comprehensive validated questionnaire for evaluating the eHealth architecture components. Our study will provide fundamental information about the construction of the eHealth

architecture, which may be used to guide the formulation of tailored NEHA in different settings.

The conceptual model

We will use the eHealth informatics- capacity-based eHealth architecture roadmap, developed by the International Organization for Standardization (ISO) [Figure 2] (25), as the main framework to construct the NEHA questionnaire. The framework comprises the following four general categories: 1) Governance and national ownership, 2) eHealth infostructure, 3) ICT infrastructure, and 4) Health process domain (Appendix 1).

The planning committee

We have established a planning committee of six members: three experts in health policy and management, plus three experts in eHealth and health informatics. The committee holds regular meetings, physical and mostly virtual, to design the research protocol, formulate various phases of study, and approve the required material for data collection. The research phases have been prepared and approved, through consensus, by the planning committee. We anticipate that data collection will be completed by December 2018.

Patients and public involvement

We will not involve patients and any member of public during the development of this study protocol.

Phase 1: item generation

The first phase of the instrument development process will be generating a comprehensive list of items that can represent the various aspects of each component. The most important sources for item generation will be evidence review and experts' opinions.

Source one: Evidence review

Reviewing the available evidence will enable us to identify the core items to inform the consensus-seeking process. Through discussions, the planning committee recommended three international documents for identification of the potential relevant items: 1) The eHealth Informatics-Capacity-Based eHealth Architecture Roadmap developed by the ISO (25); 2) The National eHealth Strategy Toolkit developed by the World Health Organization (WHO) - International Telecommunications Union (26), and 3) The National Health Information System: An Assessment Tool, developed by the WHO (27). These documents were carefully examined and reviewed using the evaluation criteria for applicability and relevancy. Applicability refers to the extent to which the chosen items apply to eHealth architecture at

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The panel of experts will be used as a second source of item generation and selection. The expert panel is a practical method for obtaining opinions on a given question. This procedure will help experts develop a broad range of items for each component. Using purposive sampling technique, we will recruit four eHealth international experts from academic, policy, and clinical background, from both high income countries and LMICs, who have in-depth knowledge and experiences in health informatics and eHealth policy.

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Table 1. Criteria to apply to items in making judgements in the face validity step

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Ambiguity	The extent to which an item is not open to more than one possible interpretation.
Relevancy	The extent to which an item would be relevance to its component.
Difficulty	The extent to which an item would be easily understood by readers.

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Table 2. Response scales used by the experts for rating the relevancy, clarity, and missing items

Relevancy		Clarity		Any missing item for each component?	
Description	***Scale***	***Description***	***Scale***	***Description***	***Scale***
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A member of planning committee (SMM) will independently scrutinize and transcribe data from the Limesurvey into IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. The median score for all items will be calculated. For each item rated as "quite relevant/quite clear" or "highly relevant/highly clear", a value of 0.79 or above will be given. We will collate free text comments and conduct directed content analysis (30) to capture the opinions expressed at the end of each questionnaire.

Phase 3: Determination of a range of possible scenarios for each item

After the completion of analysis, we will convene a panel of experts to determine a range of possible scenarios for each item that is included in the questionnaire. The scenarios will be a descriptive example for each item under each of the four situations (high, medium, low, and not at all), which will meet the gold standard of the conceptual model and will allow us to gather more complete and reliable information on the current status of NEHA within selected countries.

The selection process of the experts will be purposively congruent with this phase's aims. The planning committee will design preliminary possible scenarios for each item. This will create inputs for the panel of experts to give their views about various scenarios for the situation relevant to each item. We will set an 80% agreement as an indication of acceptable consensus for each item.

Phase 4: evaluation of reliability

The final phase in designing and validating the questionnaire is evaluating the reliability, and doing so will allow us to start the development and implementation phase. In doing so, we will estimate the internal consistency by calculating Cronbach's alpha coefficient, ranges from 0.0 to 1.0, with the cutoff point at 0.70, more than which is generally considered as an acceptable level for internal consistency (31).

DISCUSSION

This will be the first and most comprehensive study to design and validate the questionnaire on NEHA using the mixed-methods design. The findings are anticipated to be useful for all countries and international organizations who intend to assess, formulate, develop, implement, and evaluate eHealth architecture. The findings will help establish a socio-technical basis, upon which governmental and others concerned bodies can compare the policy interventions that boost the availability and utilization of eHealth services. It is also valuable for governments to design and develop strategies and policies that could facilitate the adoption of eHealth and guide the use of ICTs toward the achievement of the desired goals.

Finally, this questionnaire will enable national evaluators to examine the extent to which the governments develop various components of eHealth architecture anywhere. Therefore, our study will contribute to the growing body of research that aims to create insights into the current status of eHealth architecture and identify the areas in need of improvement. As such, we hope that this study will open up further avenues to assess the status of eHealth architecture in different settings.

FOOTNOTES

Division of contributions: AT was responsible for conception, design, implementation, analysis, drafting the manuscript and supervision of the whole process of this study. He is principal investigator and guarantor. SMM is the principal researcher, who was involved in conception, development, implementation, data collection, analysis, and writing of this manuscript. SMT is member of research team and responsible for intellectual development of manuscript as well as technical consultation for validating the questionnaire. All authors read and approved the final manuscript.

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Patient consent: Not required.

Ethics approval: The Ethics Committee for Research at the Tehran University of Medical Sciences approved the study protocol (Ref: IR.TUMS.SPH.REC.1396.3998).

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FIGURES' LEGEND

Figure 1. Breakdown of research phases

Figure 2. eHealth Architecture Model (eHAM) according to ISO TR 14639 - Capacity Based eHealth Architecture Roadmap

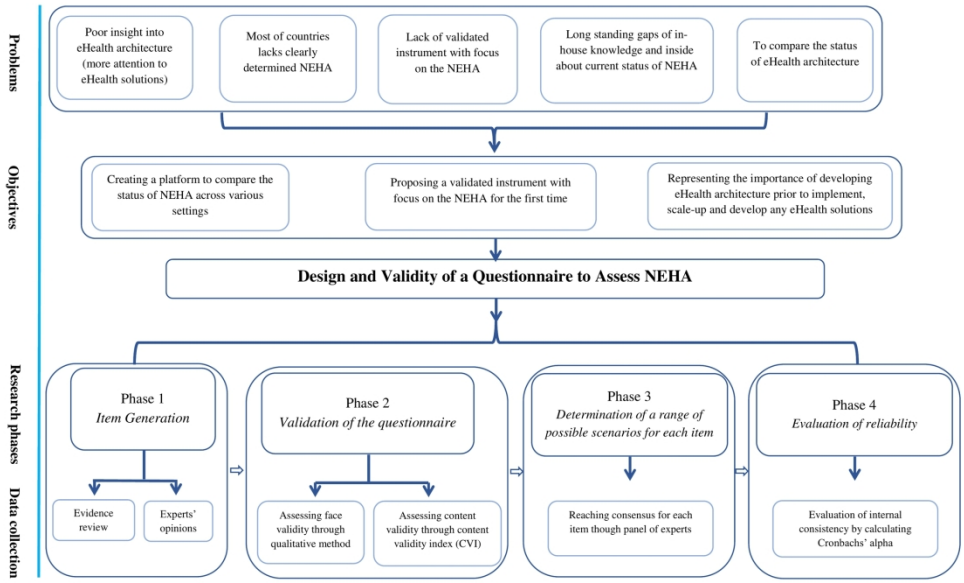

Figure 1. Breakdown of research phases

210x148mm (300 x 300 DPI)

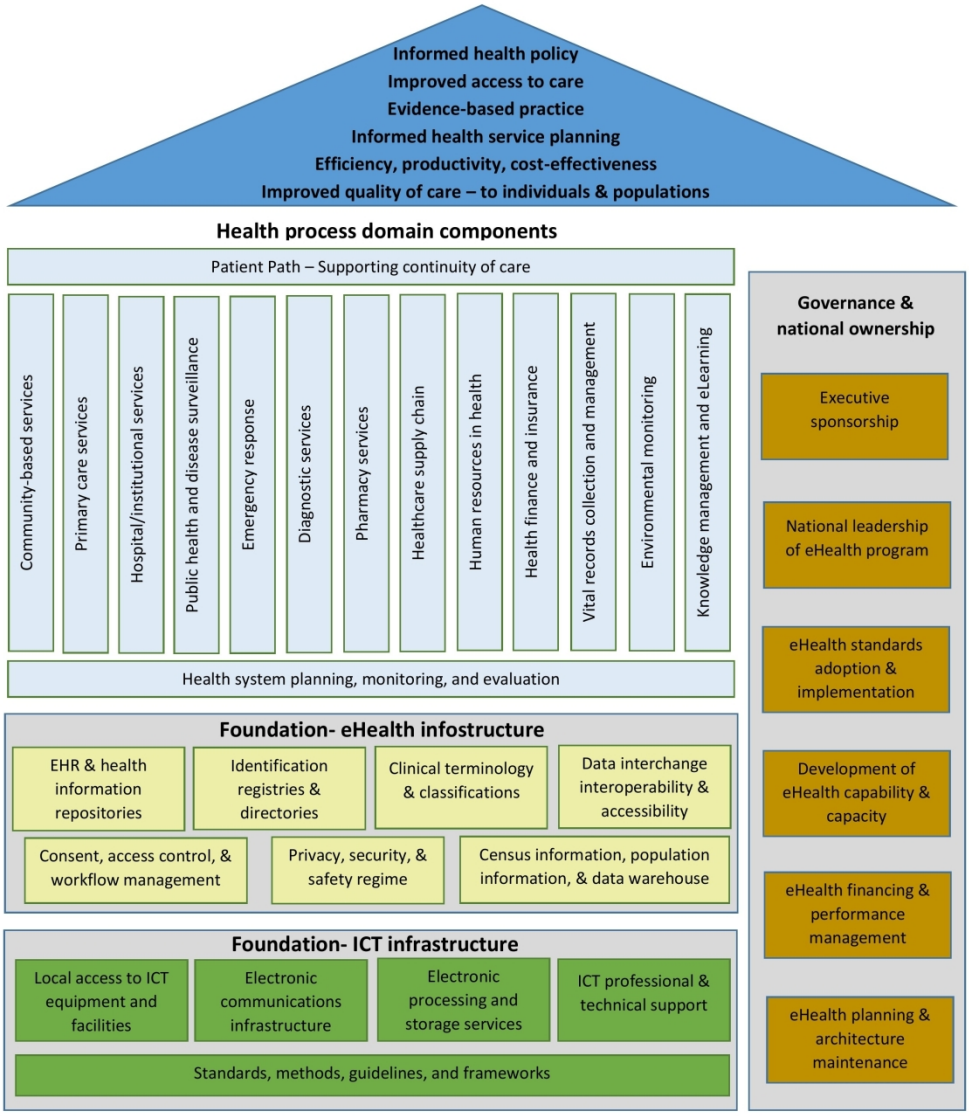

Figure 2. eHealth Architecture Model (eHAM) according to ISO TR 14639 - Capacity Based eHealth Architecture Roadmap

697x788mm (96 x 96 DPI)

Appendix

Table 1. Description of four categories of eHealth architecture model

Categories	Description	Components
Governance and national ownership	This is an important category of the eHealth architecture model since it represents the organizational and governance aspects of eHealth, including the financing, performance management and the development of local capability and capacity in Health Informatics.	1) Executive sponsorship; 2) National leadership; 3) eHealth standards adoption and implementation; 4) Development of eHealth capability and capacity; 5) eHealth financing and performance management; 6) eHealth planning and architecture maintenance.
eHealth infostructure	It includes those foundation components that exist at the national level or in some instances, the state/province level or both, acting as "cornerstone" resources that provide interoperability, both functional and semantic, plus related consent, privacy, and security controls for the transmission and broad sharing of data from various point-of-service systems, including repositories of domain data. These components also provide data processing and analytic capability supporting the secondary use of aggregate data.	1) EHR and health information repositories; 2) Identification registries and directories; 3) Clinical terminology and classifications; 4) Data interchange interoperability and accessibility; 5) Consent, access control, and workflow management; 6) Privacy, security, and safety regime; 7) Census information, population information, and data warehouse.
ICT infrastructure	It encompasses the core IT technologies including networking, servers, software, and IT human resources. In general, this is the most commonly found category in any country, all underpinned by relevant standards, methods, guidelines, and frameworks.	1) Local access to ICT equipment and facilities; 2) Electronic communications infrastructure; 3) Electronic processing and storage services; 4) ICT professional and technical support; 5) Standards, methods, guidelines, and frameworks.
Health process domain components	It addresses the various health process domains that comprise the set of services and processes delivered across the healthcare continuum. These processes generally involve both patients seeking and accessing healthcare services and providers offering these services. The health domains encompass a broad range of services intended to address clinical (provider) assessment of health problems coupled with diagnostic (test) assessments, therapeutics and related components such as payment for services and evaluation of services, provider and patient education and knowledge management, essentially the spectrum of patient-provider experiences that span the continuum of care.	1) Community-based services; 2) Primary care services; 3) Hospital/institutional services; 4) Public health and disease surveillance; 5) Emergency response; 6) Diagnostic services; 7) Pharmacy services; 8) Healthcare supply chain; 9) Human resources in health; 10) Health finance and insurance; 11) Vital records collection and management; 12) Environmental monitoring; 13) Knowledge management and eLearning; 14) Health system planning, monitoring, and evaluation