

ORIGINAL RESEARCH: PROOF OF CONCEPT/PILOTS/METHODOLOGIES

Clinical, Organizational and Regulatory, and Ethical and Social (CORES) Issues and Recommendations on Blockchain Deployment for Healthcare: Evidence from Experts

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Abstract

Objective: While existing research by our team has demonstrated the feasibility of building a decentralized identity management application (“MediLinker”) for health information, there are implementation issues related to testing such blockchain-based health applications in real-world clinical settings. In this study, we identified clinical, organizational and regulatory, and ethical and social (CORES) issues, including recommendations, associated with deploying MediLinker, and blockchain in general, for clinical testing.

Methods: CORES issues and recommendations were identified through a focus group with 11 academic, industry, and government experts on March 26, 2021. They were grouped according to their expertise: clinical care ($n = 4$), organizational and regulatory concerns ($n = 4$), and ethical and social issues ($n = 3$). The focus group was conducted via Zoom in which experts were briefed about the study aims, formed into breakout groups to identify key issues based on their group’s expertise, and reconvened to share identified issues with other groups and to discuss potential recommendations to address such issues. The focus group was video recorded and transcribed. The resulting transcriptions and meeting notes were imported to MAXQDA 2018 for thematic analysis.

Results: Clinical experts identified issues that concern the clinical system, clinical administrators, clinicians, and patients. Organizational and regulatory experts emphasized issues on accountability, compliance, and legal safeguards. Ethics and social-context experts raised issues on trust, transparency, digital divide, and health-related digital autonomy. Accordingly, experts proposed six recommendations that could address most of the identified issues: (1) design interfaces based on patient preferences, (2) ensure testing with diverse populations, (3) ensure compliance with existing policies, (4) present potential positive outcomes to top management, (5) maintain clinical workflow, and (6) increase the public’s awareness of blockchain.

Conclusions: This study identified a myriad of CORES issues associated with deploying MediLinker in clinical settings. Moreover, the study also uncovered several recommendations that could address such issues. The findings raise awareness on CORES issues that should be considered when designing, developing, and deploying blockchain for healthcare. Further, the findings provide additional insights into the development of MediLinker from a prototype to a minimum viable product for clinical testing. Future studies can use CORES as a socio-technical model to identify issues and recommendations associated with deploying health information technologies in clinical settings.

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Introduction

MediLinker is a prototype blockchain-based decentralized identity management system that is designed to provide patients autonomy and interoperability in managing personal health information.^{1,2} It was developed as a web application in 2020² and as a mobile application in 2021.¹ It features a digital wallet that contains six different types of credentials: health ID, insurance, medication, credit card, research consent, and medical power of attorney (MPOA). For patients to start using MediLinker, they need to present a valid physical identification card to the receptionist at a participating clinic (e.g., preferably a government-issued ID, such as passport, driver's license, or resident ID). The receptionist can then issue a digital identity on the blockchain. This blockchain-verified digital identity can then be shared by the patient with other participating clinics to verify their identity. After this, the patients do not need to show their physical identification card. With MediLinker, patients can share or revoke their medical information with clinics, have the option to allow information to be shared for clinical research, and allow a guardian or legal representative to act on their behalf to make health decisions through the issuance of a digital MPOA.

Field studies were conducted in 2020³ and 2021⁴ to test MediLinker's usability and identify participants' views on it. In both studies, university students were recruited to act as simulated patients of a simulated clinic where they navigated MediLinker's features using synthetic data. Both studies provided valuable insights that allowed us to improve MediLinker's usability. More importantly, these studies demonstrate that MediLinker has reached level four of the Technology Readiness Level (i.e., TRL4) since it has been tested and validated to be operational in a laboratory environment (i.e., simulated clinics).⁵ Although developed primarily to assess the maturity of outer space exploration technologies,⁶ TRL has been adopted as a means of measuring the maturity of technologies utilized for healthcare, such as blockchain.^{7,8} TRL has nine stages with TRL1 (i.e., basic principles observed and reported) being the lowest and TRL9 (i.e., actual system proven in operational environment) being the highest.⁵

Considering that MediLinker has reached TRL4, it is natural for us to set our sights on TRL5 (i.e., technology validated in relevant environment). A 2020 review⁸ of current blockchain use cases shows only one similar system⁹ like MediLinker that is also at TRL4. To reach TRL5, MediLinker needs to be tested and validated to be operational in a relevant environment. A relevant environment of interest for testing MediLinker would be primary care clinics since these facilities were simulated in earlier tests. Moreover, such testing requires the participation of primary care patients who will be using their actual personal health information instead of simulated patients who are using synthetic data.

To prepare for activities to reach TRL5, it is crucial to identify issues associated with deploying MediLinker in a clinical setting. Although the technical side of MediLinker has been dealt with by correcting multiple bugs and preparing a well-designed mobile application, there are several issues beyond these technical aspects that need to be recognized. In fact, MediLinker needs to be thought of not only as a technical system but as a socio-technical system^{10,11} because its deployment in clinics will involve the interaction of the technology with the clinics' relevant stakeholders as well as prevailing policies. The resulting interaction of these entities often produces issues that can have intended and unintended consequences that might cause harm.^{12,13} Therefore, there is a need to identify these issues and come up with potential ways of addressing them before deployment.

Previous studies suggest a myriad of issues associated with the use of blockchain for healthcare.¹⁴⁻¹⁹ In general, these issues can be classified into three main groups we refer to as CORES: clinical (e.g., uncertain health outcomes and patient information literacy),^{15,17} organizational and regulatory (e.g., accountability and legal compliance),^{14,18} and ethical and social (e.g., autonomy and trust).^{16,19} To date, such studies are in the form of literature reviews and focus on identifying clinical as well as organizational and regulatory issues^{14,15,17,18} with less emphasis on ethical and social issues.^{16,19} Although these reviews offer a good overview of relevant issues associated with deploying blockchain technologies for healthcare, additional research is needed to identify context-specific issues associated with deploying a specific blockchain-based health information technology, like MediLinker. Moreover, additional research is needed to identify potential solutions to address such issues. In general, this study aims to identify clinical, organizational and regulatory, and ethical and social (CORES) issues as well as corresponding recommendations that could address such issues.

Research Objectives

MediLinker is currently at TRL4 and moving it to TRL5 requires testing it in a relevant environment, such as clinics. However, before such testing, it is crucial for us to understand issues associated with deploying MediLinker in clinics. This is needed because deploying health information technologies in clinical settings often have intended and unintended outcomes that might be detrimental to patients, providers, and health administrators.^{12,13}

Guided by literature on the use of a socio-technical lens to identify unintended consequences of health information technologies,^{12,13} this study aims to achieve two objectives. First, it aims to identify CORES issues associated with deploying MediLinker in clinics. Second, based on identified CORES issues, the study aims to outline recommendations that could address these issues. Figure 1 shows a diagram that summarizes this study.

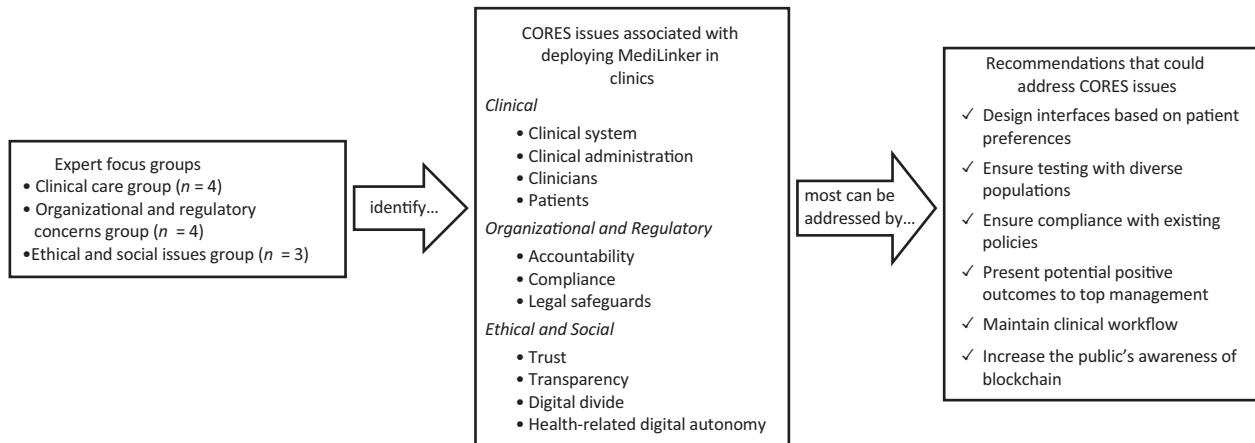


Fig. 1. Study summary. CORES: clinical, organizational and regulatory, and ethical and social.

Methods

Study Design and Ethics Approval

A qualitative research design was conducted through a focus group with domain experts. Previous research shows that expert focus groups are useful to obtain rich insights that can be used to identify issues and recommendations associated with the development and deployment of health information technologies.^{20,21} Prior to data collection, the study received exempt approval from the Institutional Review Board of The University of Texas at Austin.

Experts' Profiles

Potential experts from various academic, industry, and government organizations in the United States were invited to participate in a focus group. A total of 11 experts from different disciplines attended the focus group. Table 1 shows their profile. They were grouped according to their domain expertise: clinical care group ($n = 4$), organizational and regulatory concerns group ($n = 4$), and ethical and social issues group ($n = 3$).

Data Collection Procedure

A 90-min focus group was held virtually via Zoom on March 26, 2021. It was divided into four segments: introduction, small group discussion, overall discussion, and closing remark. Appendix 1 provides the segments of the focus group. The introduction segment provided experts with an overview and purpose of the study including a brief presentation of MediLinker's development and features. After the introduction, the experts were placed into small breakout groups that correspond to their expertise. Each small group is composed of three or four experts and a moderator. The purpose of the small group discussion was to identify issues associated with deploying MediLinker in clinics. Appendix 1 lists the guide questions asked by the moderators during

the small group discussion. Subsequently, the experts were reconvened in the main Zoom room to start the overall discussion where they discussed issues identified per group and propose potential recommendations to address such issues. Furthermore, the overall discussion allowed the experts to engage in intergroup discussion to identify overlapping issues and recommendations. The focus group ended with a closing remark where the moderators provided a summary of the focus group and thanked the experts for their participation.

Data Analysis

A video recording of the focus group was transcribed for qualitative analysis. The resulting transcriptions and meeting notes were imported to MAXQDA 2020 for thematic analysis. We used Tracy's guide in analyzing qualitative data for thematic analysis.²² First, primary-cycle coding was conducted by breaking down data into small analytical units through line-by-line open coding where codes were freely assigned to the data. Next, axial coding was performed during secondary-cycle by grouping primary-cycle codes to generate meaningful themes and sub-themes. Finally, the themes and subthemes were categorized whether they are related to issues or recommendations within specific CORES categories. Appendix 2 shows the coding tree.

In the entire coding process, memos were generated to provide a preliminary characterization of the themes. Likewise, the coding process was conducted in consultation with the research team to resolve disagreements and refine the themes. To ensure trustworthiness in qualitative research, we followed the principles of credibility (e.g., moderators established rapport and used iterative questioning), transferability (e.g., selecting participants that come from a variety of fields and disciplines), dependability (e.g., following the approved study protocol), and

Table 1. Experts' profile

Group/ID	Gender	Domain	Expertise
<i>Clinical care group</i>			
C1	Male	Academic	Accessibility of technologies for people with disabilities
C2	Male	Academic	Clinical informatics and systems engineering
C3	Male	Academic	Access, quality, and equity in healthcare
C4	Female	Academic	Aging, technology, and health
<i>Organizational and regulatory concerns group</i>			
OR1	Male	Industry	Application of blockchain in health and life sciences.
OR2	Male	Academic	Blockchain governance
OR3	Female	Academic	Corporate governance
OR4	Male	Government	Strategy development of prehospital medicine
<i>Ethical and social issues group</i>			
ES1	Male	Academic	Sociotechnical systems in healthcare
ES2	Male	Academic	Social and environmental processes that affect aging
ES3	Female	Academic	Medical sociology, social justice, and medical ethics

confirmability (e.g., presenting quotes that best represent themes or subthemes) in conducting the study.²³

CORES Issues

The following sections present CORES issues raised by experts. Aside from experts' insights, we discuss these issues in light of relevant literature.

Clinical Issues

Clinical issues associated with the deployment of MediLinker in clinics include those that concern the clinical system, clinical administration, clinicians, and patients.

Clinical System

Experts noted two clinical system issues associated with deploying MediLinker in clinics that are consistent with previous work.^{15,17} The first issue concerns the integration of MediLinker with existing clinical systems that are used in clinics. One expert explains why data integration is a crucial part of clinical systems:

“Thinking about integrating the data, it is nice to then have all of the personal and medical information show up within the software [MediLinker] at the clinic. But then, I imagine the first question would be ‘OK, how do we get that into the EHR [electronic health record]?’ We’re going to have someone copy and paste all that stuff in or what kind of integration would there be?” (C2)

Even when MediLinker is integrated in the clinical system of one clinic, another challenge is how to integrate it with other health institutions where heterogeneous clinical systems are used. This is a pertinent issue when scaling up MediLinker to work across clinics. One expert explains how this is a concern since health facilities often have different clinical systems:

“[Health institution A] uses Compass. [Health institution B] uses Athena. [Health institution C] use Next Gen and now transitioning to Epic. [Health institution D] uses their homegrown system that they don't share with anyone, then they're using Meditech now. [Health institution E] uses NextGen. So, there's no unified system.” (C3)

Clinical Administration

There is a consensus among experts that the success of deploying MediLinker in a health facility depends on clinical administrators' support. However, garnering their support would be challenging because of three relevant issues. Consistent with recent reports,^{24,25} experts noted that health organizations prefer to control patient data considering that they view such data as their property, and it serves as leverage for financial power. As a result, clinical administrators are less likely to support initiatives that would allow patients to have full control of their data (e.g., such as MediLinker).

“I think hospitals and health systems, they view that their patients' data belongs to them and that's power. There's financial power there. There's financial gain to it. So, this notion that it seems so obvious that patients' data should belong to patients is completely at odds with how health systems operate.” (C3)

Another deterrent in obtaining support from clinical administrators is the uncertainty associated with blockchain technology. Although blockchain has been used by some early adopter hospitals in the United States to improve health services and outcomes,²⁶ for the majority, it is a relatively new and immature technology that clinical administrators may be hesitant to integrate with their clinical systems.²⁷ One expert noted that clinical administrators could deliberately

avoid adopting blockchain as part of their systems by justifying strict adherence to the Health Insurance Portability and Accountability Act of 1996 (HIPAA)²⁸:

“Organizations could easily use HIPAA as a way [to avoid blockchain implementation in healthcare] ... I mean, you’re trying to use blockchain to say that we can protect patients’ data. Sure. But organizations may not just understand, or they may not want to understand, and they just want to use HIPAA as a weapon to go against this new technology.” (C4)

In situations where clinical administrators agree to deploy MediLinker as part of their clinical systems, one pertinent challenge to be considered is the time and financial costs associated with its implementation. One review considers this issue as one of the major challenges of implementing blockchain for healthcare.¹⁵ One expert provides a clear explanation of this issue:

“The frustrating thing that we’ve experienced with sharing of data across organizations is that organizations are not demonstrating that they are willing to commit the initial cost and initial work of adoption and implementation with their own systems to get that savings down the road. I guess you really have to make a case that this is either going to save them significantly or make them money somehow.” (C2)

Clinicians

Aside from integrating MediLinker with existing clinical systems, experts also pointed out another facet of integration that has been described also in blockchain literature^{15,17}: workflow integration for clinicians. Research shows that even for existing health information technologies, such as electronic health records, workflow issues among clinicians are associated with stress and burn-out.^{29,30} Thus, emphasizing workflow integration is important because this could reduce clinicians’ workload when incorporating new technologies:

“People really don’t want to have that [new technology] added to their workflow. Are we integrating this as a part of the workflow or is this an additional piece? [The latter] would require tremendous amount of time, especially on nurses who would probably end up having to enter the data. Which brings up the point of not just the patients who would need to work with the system, it’s also the clinicians.” (C4)

Patients

Since MediLinker is also designed to be used by patients (or their guardians) for health information management, experts pointed out several issues associated with its use. First, experts emphasized the need for appropriate safeguards within MediLinker to ensure appropriate

information disclosure because not everyone has the same level of eHealth literacy to navigate complex information for decision making. For instance, options within MediLinker can be added to show patients less information or more information, depending on how medically inclined they are. As one expert noted, inappropriate information disclosure can lead to patient misinformation.

“Let’s assume that you get these medical institutions on board with adopting this application [MediLinker]. The trick would be to ensure that whoever is entering the data makes it understandable to the patient. Because if you have a low level of eHealth literacy and you get a piece of information pushed to your phone and you can’t understand what it is, and you go to WebMD ... all of a sudden you think you’re dying of cancer, and then you could have a whole bunch of misinformation problems.” (C1)

The second patient-related issue that experts noted is usability. Since MediLinker’s usability has only been evaluated in a study involving university students (young and well-resourced) who were acting as simulated patients,² there is a need to test its usability among other population groups so that additional usability issues can be uncovered. As noted by one expert, asking vulnerable patient groups to use technologies for healthcare presents several challenges:

“As soon as you start moving out from a young, equipped, and well-resourced student population, whether it’s the older population or population with disabilities... I work with the homeless or any of the other vulnerable populations, these technologies potentially breakdown because they don’t know how to use it, or they don’t have the phones, or they don’t like it. It’s a myriad of different reasons.” (C3)

The third patient-related issue that experts noted is accessibility. Although smartphones are already widely available, there is a need for MediLinker to be accessible in both new and old smartphones and in different operating systems while achieving the same level of security across versions. According to one expert, this is particularly important among older adults who are likely to use old smartphones and are typically hesitant to perform updates:

“I know of older individuals that have an old smartphone. For example, an iPhone and they don’t update the iOS at all. To make the program [MediLinker] universally usable, you’d have to consider if the population isn’t as technically literate. What can we do to build in legacy support for older versions of phone operating systems to ensure that the system works as intended and we have the same level of security and usability of the program?” (C2)

The final patient-related issue that experts noted is the verification of the patient's identity in the absence of identity documents. Since MediLinker relies on the presentation of a government-issued identity document to create the patient's account,² those who are not able to present such a document would not be able to use MediLinker and that would contribute to the proliferation of inequitable healthcare.³¹ One expert provides an explanation for this:

“My patients often don't have their original vital documents. For [undocumented] immigrant populations, obviously this is a major issue. So, overcoming just that sort of simple barrier of having to prove who you are without using archaic paper, plastic cards, and paper documents time and time again, I think, it's a big win.” (C3)

Organizational and Regulatory Issues

Organizational and regulatory issues associated with the deployment of MediLinker in clinics include accountability, compliance, and legal awareness and safeguards.

Accountability

Although blockchain provides a secure means of storing data for patients,¹⁷ experts noted that it is unclear how organizations will be accountable with health information that is stored on blockchain, especially during a data breach.¹⁴ One expert noted the complexity of accountability when data on the blockchain is handled by multiple entities:

“We have organizations that are going to be represented on the blockchain, right? For those transactions to take place, what is the representation of a clinic on a blockchain? Will the clinic specify whether is it the front desk person, the CEO, or somebody else who is just assigned for this function? And the same is true for a payer [insurance] who has to approve these claims. If we were to test this in the real [clinical] environment, how would organizations assign their persona on the blockchain?” (OR1)

Aside from mapping out organizational entities that are accountable for patient-related data on the blockchain, one expert also highlighted the need for organizations to be familiar with device identity¹⁴ since devices are part of the ecosystem by which information passes to and from the blockchain:

“There's also a lot of groups looking at different standards and identity. Not only identity of individuals and patients, but identity of providers, identity of organizations, and then even down to identity of Internet of Medical Things and identity of a particular device that may be contributing information to this system... the information being tracked via blockchain.” (OR4)

Compliance

There is a need to work with the clinics' administrators to ensure MediLinker's compliance with existing regulations and standards.^{14,17} Although this may seem to be straightforward, one expert noted that the challenge to achieve full compliance is that regulators are still in the process of interpreting existing laws whether it is applicable for blockchain:

“With many of these regulations, they're not set for blockchain. Yet they're still being interpreted for it. The healthcare regulators don't know this technology, so it's a very slow conversation.” (OR4)

While compliance can be attained by complying with laws that are in place,^{14,17} experts noted the need to be mindful of relevant laws where MediLinker will be deployed. In the United States, aside from federal laws such as HIPAA and Federal Trade Commission Act, MediLinker's deployment requires compliance with state laws also. To illustrate this, if MediLinker will be deployed in a clinic in California, it needs to comply with the California Consumer Privacy Act (CCPA). As one expert noted:

“Generally, we have federal rules, but also since I assume we are going all over the country, so we also need to think about the relevant states and there are states with different rules. For each state, we add something that opens the door to more compliance.” (OR3)

Legal Safeguards

Considering that blockchain technologies are relatively new and regulators are still in the process of providing guidance toward full compliance,¹⁴ experts pointed out the difficulty of legally safeguarding the software (i.e., MediLinker) and the organization (i.e., the clinic). One expert highlighted the difficulty of setting up MediLinker's terms and conditions in the absence of clear legal guidance:

“If something goes wrong, if there is a dispute, we need to protect the program. For an example, legislators and lawyers have to think about what happens if things don't go well. What if there is a glitch or something was not properly recorded? In case we are negligent, what do we do with the problem? How do we resolve it? What type of indemnification? We are trying to limit the [organizational] liability in situations like that.” (OR3)

Experts also highlighted the need to legally safeguard clinicians when patients deliberately withhold health information that prevents clinicians from providing appropriate services.³² One expert asks who will be liable in such a situation:

“What if patients start censoring some of the data that they share, which could give a totally different picture because they want to hide their addiction? There is information that they [the patient] think is not relevant, but actually the physician thinks it’s very relevant. Who has the liability for that?” (OR1)

Ethical and Social Issues

Ethical and social issues associated with the deployment of MediLinker in clinics include trust, transparency, digital divide, and health-related digital autonomy.

Trust

New health information technologies are usually met with skepticism and obtaining people’s trust is a strong driving force for acceptance and adoption.^{33,34} Although blockchain is essentially a technology meant to protect people’s data,^{14,17} persuading people to use a technology that they are not familiar with can result in trust issues (e.g., will it really protect my data from hacking? Is this another scheme to secretly collect my data?). One expert emphasized the need to overcome trust issues, especially among oppressed groups:

“How do you overcome suspicion or trust issues? We pointed out that there are specific populations [African Americans, Hispanics, rural people, and older people] that have been abused by surveillance and law enforcement and other mechanisms of society. So how do we not reiterate those kinds of abuses in the technological tools that we make.” (ES1)

Transparency

Experts have pointed out that people’s tendency to distrust technologies may be rooted in the lack of transparency on how such things are developed and utilized.³⁵ This is particularly true for blockchain where most people might have not heard of it, especially on how it can be used for healthcare.³⁶ For one expert, there is a need for developers and implementers to explain how blockchain stores and protects data to demonstrate transparency:

“[Sharing a perspective of a potential user of MediLinker] I might be a slow adopter in some ways because I’m concerned about where my original data that I’m going to share actually lives. I’m not comfortable with my credit card being on here [MediLinker] and doing this.” (ES3)

Digital Divide

Another ethical and social issue associated with deploying MediLinker in clinics is the digital divide. As MediLinker requires an Internet-connected smartphone, those who do not have such a device will be left behind which then contributes to inequity in health.^{37,38} One expert shares the link between the digital divide and inequity:

“Not everyone has a cell phone or a cell phone that’s capable of mobile data. My experience at the VA [Veteran Affairs health facility] was they have a lot of veterans that are vulnerable. They don’t have any kind of Internet access or mobile phones. Has there been any thought to using this system [MediLinker] without owning a mobile phone?” (ES1)

Health-Related Digital Autonomy

Experts have raised the issue of health-related digital autonomy (i.e., health-related decisions of individuals in the digital context)³⁹ when patients decide to share information with clinics and institute an MPOA through MediLinker. Although the Chapter 166 of the Texas Health and Safety Code⁴⁰ approves the use of digital or electronic signatures, especially when signing an MPOA, certain institutions may prefer that patients sign forms using a wet signature rather than a digital signature that is created within an application. As such, patients’ health-related digital autonomy may not be fully acknowledged by institutions when using MediLinker. As one expert noted:

“Our default is still relying on signing paper forms [with wet signatures] and faxing them between institutions. If you had a tool [MediLinker] that allowed for a quick ‘yes, I grant access’, there will be hurdles with getting the organizations to accept patients’ authorization that doesn’t include a handwritten signature.” (ES2)

Recommendations to Address CORES Issues

Experts pointed out several recommendations to address CORES issues associated with deploying MediLinker in clinics. Table 2 summarizes applicable recommendations that could address specific CORES issues.

Design Interfaces Based on Patient Preferences

Experts noted that for MediLinker to have good usability as a health information management application, it is important to design its interface that even those with limited eHealth literacy can use it. This means that its design must be based on accommodating multiple patient preferences that can contribute to reducing the digital divide. For example, allowing patients to set their preferred amount of control to their data (from little to full control) not only fosters good usability but also digital autonomy. One expert emphasized how MediLinker’s interface should accommodate various user’s configuration regarding the control of data:

“Maybe you can make different types of interfaces or different gradients of interfaces so that people can have some control of their data and then move to maximum control of data depending upon how they want or how they graduate to that. About 20% of patients

Table 2. CORES issues to be addressed by the recommendations

Recommendation	Issues to be addressed by the recommendations		
	Clinical	Organizational and regulatory	Ethical and social
1. Design interfaces based on patient preferences	<ul style="list-style-type: none"> ✓ eHealth literacy ✓ Usability 		<ul style="list-style-type: none"> ✓ Health-related digital autonomy ✓ Digital divide
2. Ensure testing with diverse populations	<ul style="list-style-type: none"> ✓ eHealth literacy ✓ Usability 		<ul style="list-style-type: none"> ✓ Digital divide
3. Ensure compliance with existing policies	<ul style="list-style-type: none"> ✓ Accessibility 	<ul style="list-style-type: none"> ✓ Accountability ✓ Compliance ✓ Legal safeguards 	<ul style="list-style-type: none"> ✓ Trust ✓ Transparency ✓ Digital divide
4. Present potential positive outcomes to top management	<ul style="list-style-type: none"> ✓ Uncertainty with blockchain 	<ul style="list-style-type: none"> ✓ Compliance 	
5. Maintain clinical workflow	<ul style="list-style-type: none"> ✓ Workflow integration 		
6. Increase the public's awareness of blockchain	<ul style="list-style-type: none"> ✓ Uncertainty with blockchain 		<ul style="list-style-type: none"> ✓ Trust ✓ Transparency

right now want control of their data. 30% would move there if the interface is pretty good or there's an incentive. 50% are like 'let my kids deal with that or my doctor deal with that, I don't want to do it'." (C4)

Ensure Testing with Diverse Populations

To be able to design MediLinker that has good usability (regardless of the user's eHealth literacy and type of device owned) and to be able to predict most, if not all, issues associated with deploying it in clinics, experts highlighted the need to conduct testing with diverse populations. To date, MediLinker has only been tested by university students on a simulation-based field study.^{2,3} Although the results of that study³ uncovered important user-related issues that can improve MediLinker's usability, experts noted that testing beyond university students is needed because actual patient populations have different needs and preferences. As one expert noted:

"It would be really helpful to broaden up the testing base. You should test on users with diverse backgrounds, needs, skills, and preferences because that will be really helpful to make the technology usable by everyone." (C4)

Ensure Compliance with Existing Policies

Although there is still unclear regulatory guidance on the use of blockchain in healthcare, experts noted that, at the very least, we should anticipate all issues of its implementation and determine which standards or regulations will such an issue be covered. For example, it would be a good start if MediLinker can attain accessibility compliance based on Section 508 of the US Rehabilitation Act of 1973.⁴¹ Although Section 508 only applies to federal government-owned or funded information and

communication technology, Section 508 has been used as a benchmark by institutions to determine whether their technologies (e.g., websites and mobile applications) are accessible for people with disabilities. Attaining such a compliance would promote accountability, minimize the digital divide, facilitate consumer trust, and promote transparency. One expert summarizes the need to be forward thinking in terms of how compliance should be attained:

"You need to figure out how it would be interpreted by any of the governing bodies, not just how you interpret it, which is sometimes the shortcoming of new technologies. The people who developed them are thinking all the good things, but the regulators think of all the bad things that could happen. So, you need to kind of put yourself in those shoes [regulator's mindset] as well." (OR1)

Present Potential Positive Outcomes to Top Management

Top management support is needed for MediLinker to be deployed in clinical settings. As experts noted earlier, garnering top management support for its deployment is a challenge mainly because of the perceived uncertainty and lack of clear guidance with using blockchain for healthcare. To overcome these barriers, there is a consensus among the experts that we should engage in a dialogue with the top management to identify and address context-specific issues associated with MediLinker's deployment. One expert noted that:

"You've done a lot of work on the end user side. You need to start having focus groups and interviews with the C-suite executives and the administrators who we're all assuming may be opposed to this for financial

reasons or for data control reasons. And maybe we're wrong or it's an oversimplified assumption.” (C3)

In that dialogue, we should lay out potential positive outcomes of its adoption to garner support. These outcomes should not only emphasize positive health outcomes (e.g., reduced length of stay or mortality), but more importantly, positive organizational outcomes (e.g., reduced operation cost or positive public image). As one expert noted:

“If you could make a case to say, ‘by introducing our technology, we can help you save in XYZ’. I think that would be a great way to present... Also think about the potential changes in the organization’s image. If you are able to put out this new sort of technology-based image to show your patients that you are cutting edge, that might potentially bring in patients who might be going after that.” (C4)

Maintain Clinical Workflow

Experts emphasized the need to integrate MediLinker with clinical systems that are already being used in target clinics. Such integration is needed to achieve the smallest possible disruption in the clinical workflow. This would ensure that the deployment of MediLinker in clinics will not be a source of burden for clinicians who will be using it. Moreover, since blockchain runs in the background when using MediLinker, it is possible to maintain the clinician’s workflow. As one expert noted:

“The best answer will be nothing changes for the people doing the work and this is an infrastructure in the background that is facilitating what we want to happen. The transactions that happen on the chain happen between parties and these parties can be individuals, organizations, devices, and we leave that up to the parties. And we simplify the definition of the transactions as being derived from the workflow as it happens. We can’t think of it these things as we do traditional IT systems.” (OR2)

Increase the Public’s Awareness of Blockchain

Considering that most people are unaware of what blockchain is, let alone its use for healthcare purposes,³⁶ experts recommend using MediLinker as a means to educate people on what blockchain is and how it can enhance health data privacy. Experts hoped that with more people getting familiar with the role of blockchain in healthcare, such familiarity would reduce uncertainty, foster trust, and inculcate transparency. As one expert noted:

“I think there’s going to have to be a fair amount of education and even advocacy around this. Blockchain is still like this scary unknown novel crazy thing to most people. There’s going to have to be a fair amount of education to patients, providers, of system leaders,

of administrators on what it is, what it isn’t, and the security aspects.” (C3)

Conclusion and Future Work

This study identified a myriad of CORES issues associated with deploying MediLinker in clinics. Moreover, the study also uncovered several recommendations that could resolve CORES issues and mitigate the occurrence of negative consequences (e.g., becoming a source of high clinician workload and contribution to the digital divide). In general, the findings raise awareness of CORES issues that should be considered when designing, developing, and deploying blockchain for healthcare. With these findings, we can further improve MediLinker from a prototype to a minimum viable product for clinical testing and make appropriate preparations for clinical testing to reach TRL5.

Aside from the practical contributions of the study, it also contributes to theory by demonstrating the usefulness of utilizing a socio-technical perspective when uncovering blockchain-related issues. Although a socio-technical perspective has been used to identify issues surrounding blockchain in general,^{11,42} this is the first study that explicitly used such a perspective to uncover issues and recommendations associated with deploying blockchain for healthcare. Hence, future studies can use CORES as a socio-technical model to identify issues and recommendations associated with deploying health information technologies in clinical settings.

The study has several limitations that will guide future work. First, the study involved a focus group of 11 experts only. Although we were able to obtain rich insights from these experts, future work can be geared toward inviting more experts. Second, because of the first limitation, we were able to allocate experts in three groups only (i.e., clinical care, organizational and regulatory concerns, and ethical and social issues). Future work can invite more experts so that there will be five expert groups that represent each aspect of CORES (i.e., clinical care, organizational concerns, regulatory concerns, ethical issues, and social issues). Third, the focus group was conducted within 90 min only because of scheduling constraints. It would have been ideal if this event was conducted as a full-day workshop so that the experts could have more time to brainstorm ideas within and outside their designated group. Finally, although experts provide a unique perspective towards issues and recommendations associated with deploying MediLinker in clinics, future work can also involve groups that are represented by lay people since their perspective can provide consumer insights in designing and deploying MediLinker in clinics.

Competing Interests

The authors have no relevant financial or nonfinancial interests to disclose.

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Contributors

Drs. Khurshid and Harrell conceptualized the study and obtained funding. Drs. Bautista, Meyer, and Khurshid designed the study. Drs. Bautista, Harrell, Meyer, and Khurshid collected data. Dr. Bautista and Mr. Usman performed data analysis. Dr. Bautista and Mr. Usman wrote the draft of the manuscript. All authors edited and approved the final version of the manuscript.

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Appendix I. Focus group segments

1. Introduction (10 mins)
 - Introduction to MediLinker and project motivation
 - Overview of MediLinker application (video presentation)
 - Current research findings
 - Discussion instructions and questions from participants
2. Small group discussion (30 mins)
 - Move experts into three groups with three to four people each for detailed discussion.
 - Moderator: in final 10 min, ask each group to come up with actionable next steps.
 - Questions for each expert group:

Clinical Care Group

Moderator: You have seen the project so far. We would like to get your expert views on which of the issues that we have not yet addressed (and there are many) are TOP priorities as this project moves forward. You have been invited because you have expertise in real-world clinical settings and the experience of patients. We would like this group to focus particularly on issues relating to:

- What parts of the clinician and patient experience and information needs would a system like this help or alternatively make more difficult?
- What elements might be attractive or off-putting for particular types of patients, caregivers, and providers?
- What sort of messaging might make this appealing to patients and their providers? What might turn people away?
- What challenges that you experience have NOT been discussed, but that you hope a system like this might be able to help with?

Organizational and Regulatory Concerns Group

Moderator: You have seen the project so far. We would like to get your expert views on which of the issues that we have not yet addressed (and there are many) are TOP priorities as this project moves forward. You have been invited because you have expertise in the law, regulations, governance, health organizations, and related areas. We would like this group to focus particularly on issues relating to:

- What regulations might influence a system like this, positively or negatively?
- Are there legal or regulatory barriers to a system like this?
- What are the organizational practices and governance issues that might influence the implementation of this system?
- What challenges that have NOT been discussed should we be thinking about?

Ethical and Social Issues Group

Moderator: You have seen the project so far. We would like to get your expert views on which of the issues that we have not yet addressed (and there are many) are TOP priorities as this project moves forward. You have been invited because you have expertise in social and ethical issues around data and information. We would like this group to focus particularly on issues relating to:

- What does your knowledge of social behavior and ethics tell you would be either appealing or likely to find resistance to patients, citizens, organizations, or society more generally?
- What social and ethical issues are most crucial to address?
- What privacy issues are most important to understand?
- Are there equity issues that are particularly apparent or important?
- What challenges that have NOT been discussed should we be thinking about?

3. Break (10 mins)
4. Overall discussion (30 mins)
 - Convene all groups for an overall discussion

- Each group will be given 5 min to present their top priorities and issues as MediLinker moves from a minimum viable product to a product for real-world clinical testing.
 - Facilitate intergroup discussion to identify overlapping issues and recommendations.
 - Moderators: in the final 10 min, ask experts to come up with actionable next steps or recommendations
5. Closing remark (10 min)
- Moderators provide a summary of the discussion and additional messages to the experts (e.g., potential discussions in the future).
 - Thank participants for their time.

Appendix 2. Coding tree

1. Issues
 - 1.1. Clinical issues
 - 1.1.1. Clinical system
 - 1.1.1.1. Integration with clinical system
 - 1.1.1.2. Heterogenous systems among health institutions
 - 1.1.2. Clinical administrators
 - 1.1.2.1. Health institutions' preference to control data
 - 1.1.2.2. Time and financial costs
 - 1.1.2.3. Uncertainty with blockchain
 - 1.1.3. Clinicians
 - 1.1.3.1. Workflow integration
 - 1.1.3.2. Clinician workload
 - 1.1.4. Patients
 - 1.1.4.1. eHealth literacy
 - 1.1.4.2. Usability
 - 1.1.4.3. Accessibility
 - 1.1.4.4. Identity verification
 - 1.2. Organizational and regulatory issues
 - 1.2.1. Accountability
 - 1.2.1.1. Organizational entities
 - 1.2.1.2. Device identity
 - 1.2.2. Compliance
 - 1.2.2.1. Regulators are still in the process of interpreting existing laws
 - 1.2.2.2. Compliance with existing federal and state laws
 - 1.2.3. Legal safeguards
 - 1.2.3.1. When clear legal guidance is absent
 - 1.2.3.2. When patients deliberately withhold health information
 - 1.3. Ethical and social issues
 - 1.3.1. Trust
 - 1.3.1.1. Because of technology skepticism
 - 1.3.1.2. Among oppressed groups
 - 1.3.2. Transparency
 - 1.3.2.1. Rooted from technology distrust
 - 1.3.2.2. Unfamiliarity with the use of blockchain for health
 - 1.3.3. Digital divide
 - 1.3.3.1. MediLinker requires an Internet-connected smartphone
 - 1.3.3.2. Inequity
 - 1.3.4. Health-related digital autonomy
 - 1.3.4.1. Sharing information with clinics
 - 1.3.4.2. Medical power of attorney
2. Recommendations to address CORES issues
 - 2.1. Design interfaces based on patient preferences
 - 2.2. Ensure testing with diverse populations
 - 2.3. Ensure compliance with existing policies
 - 2.4. Present potential positive outcomes to top management
 - 2.5. Maintain clinical workflow
 - 2.6. Increase the public's awareness of blockchain