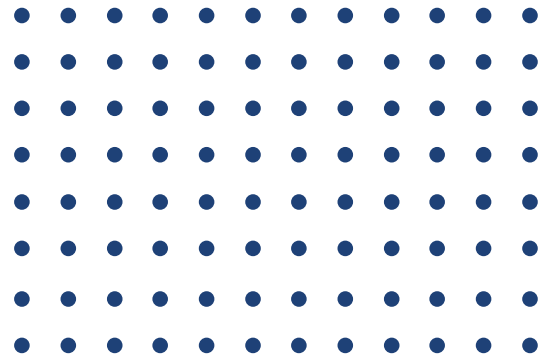# WHY IS THERE CURRENTLY NO UNIFIED PATIENT RECORD?

Lead Authors: Andrew Nguyen, Rita Gaspardi Baldoria and Shalini Trefzer

Contributors: Chuck Montague, Joseph McMenamin, Michael Kremliovsky, Stephen MacKinnon and Victoria Moy
Reviewers: Elaine Hamm, James Zanewicz, Maria Luisa Pineda, Mustaqhusain Kazi and Stacie Calad-Thomson

www.theaaih.org

Executive Summary

- The unified patient record provides a great opportunity to highlight many of the core questions and challenges in healthcare in general, given that patient-level data is an increasingly important aspect of AI in healthcare.

- However, there are key barriers to overcome before we have a unified patient record that everyone can benefit from. Not in the least, the lack of consistent best practices and recommendations across the board and the challenges that we are likely to face in the unification of records from systems and frameworks that are fundamentally very different.

- By shedding light on key reasons why the Unified Patient Record does not exist today, this paper paves the way to discuss the requirements for the patient-centric unified patient record concept of the future.

- The authors of the future papers might choose to: suggest innovative ways, discuss market incentives, and make recommendations to stimulate the adoption of a new model of unifying patient data in the US and elsewhere.

- A patient-centric framework is definitely disruptive of the current way of doing things, but the potential benefits for the healthcare market development and advancement of patient agency far outweigh the costs.

Why is there currently no Unified Patient Record?

A cancer survivor received radiation and chemotherapy as a young woman over 20 years ago. She still has medical problems and must deal with a large number of specialists, many of whom are new to her specifics, she has moved to a different state and as a result, the continuity of her records and care is broken. There is no system where she can log in and access her entire medical record. If a new doctor wants to see specific information about her past conditions, there is no place online where they can go to request this information.

A unified patient record is a critical step towards ensuring that all of the data of the fictitious patient above are easily accessible by herself and her medical providers and caregivers. In addition, for generations, state laws have seen medical records as the property of their authors, i.e. medical providers. This also necessitates that the technology is available to enable this level of access and eventually, patient ownership.

While acknowledging that there are commercial enterprises working on individual initiatives around unifying the patient record (e.g. from the perspective of the patient), there is a gap from a systemic perspective. Yet, in creating a unified patient record, we currently face many challenges which are summarized at the conclusion of this white paper.

Our research questions are: Firstly, what are the current challenges with creating a unified patient record for the delivery of efficient and effective healthcare services that put the patient front and center? Secondly, what are the challenges around data sharing that we need to address immediately?

What is a Unified Patient Record?

Let's first define what is meant by a "patient record". A "patient record" is a comprehensive collection of longitudinal information on a patient's medical history. Its purpose is to facilitate informed decision-making about a patient's disease treatment and prevention. In an AI-driven future, it is an important foundation for predictive and preventative healthcare.

In a patient record, you might find details such as the following (this is not an exhaustive list):

- Personal Information
- Visits/hospitalizations
- Medications
- Laboratory Results
- Immunization Records
- Treatments

Today, these records can be in the form of paper documents, electronic files, databases, etc. The goal would be to have all the necessary medical information centrally accessible, so any healthcare provider can quickly understand the patient's medical background and provide appropriate care. Too often, the onus to provide the patient record lies with patients, forcing them to be organized and proactive in a way for which they might not be prepared.

Imagine instead, the patient can provide a new medical provider with a QR code, giving them instant access to their entire medical history. We argue that such an arrangement would improve the effectiveness and efficiency of patient care.

While acknowledging that there are still systems in the world that are paper-based and also acknowledging that in some locations, the patients are barred from access to their own health data, we do not consider them in this white paper because creating a unified patient record intrinsically implies that we are working with a digitalized system.

Healthcare records, such as Electronic Health Records (EHRs) as currently implemented, are multipurpose. They contain important information about a patient's state of health and its development over time. They document the history of interactions between healthcare system stakeholders, including the patient's interaction with the providers and the providers with one another. The EHR plays the role of a connector between different care providers, payors, and the patient. As a result, the EHRs are generally designed and implemented by providers who then make data available to payors and patients. This results in fragmentation of data and difficulty in establishing a complete record for each patient. The completeness of the record, and its unified and holistic nature, are the foundation of an effective and efficient healthcare system.
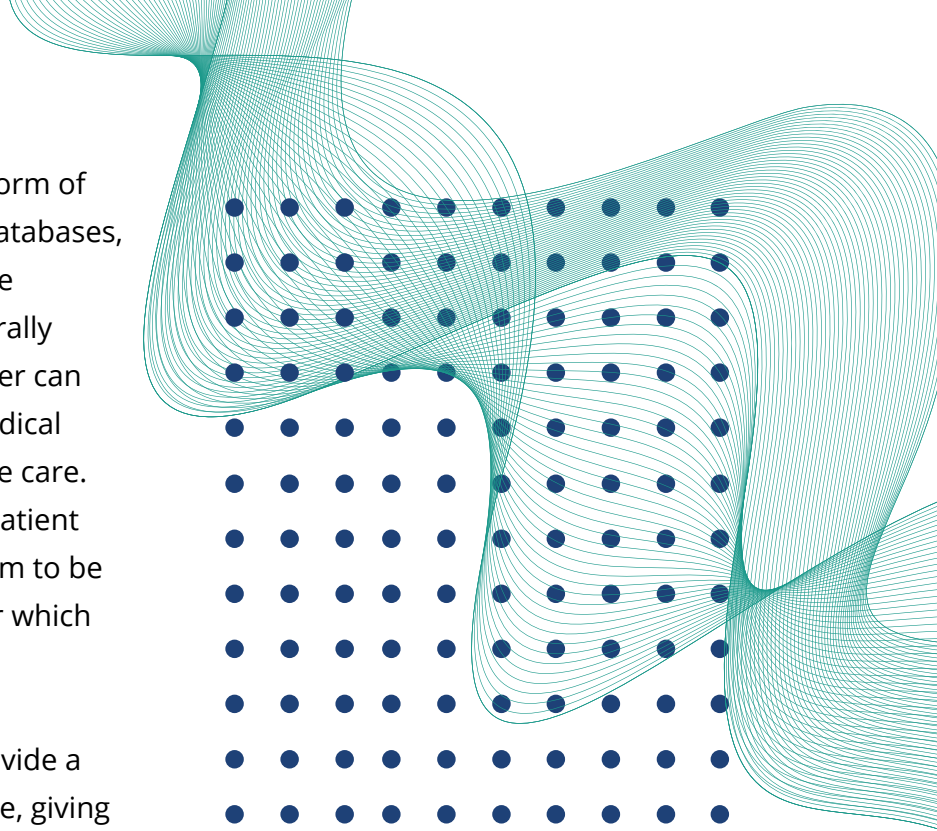
Current State

The patient is scurrying around, chasing after various institutions for their data. The patient is not in the center of this universe and is not being served with access to their health data in a comprehensive manner.

Here's what the future could look like, if the current challenges are met

The patient is truly in the center of this universe, being served by a unified patient record that holds their health data across providers, and eventually, across geographies. They have the agency to truly own and direct the use of their health data.

What prevents us from having a Unified Patient record for everyone?

In this paper, we list out the key challenges that prevent a Unified Patient Record from being realized currently because we believe that it's important to describe the problem as thoroughly and as realistically as possible first, before fitting potential solutions to it. We have grouped the key challenges into themes and provided a short description of each theme followed by a list of questions, considerations, or challenges.

1. Fragmentation

The patient record (currently EHR) is fragmented among care providers; often having different and incompatible technological platforms that are unable to communicate with each other (i.e. insufficient interoperability). Owing to that fragmentation, the EHR is inherently incomplete and often not accessible in a comprehensive manner to care providers and patients. Patterns that might reveal previously unrecognized risk factors for disease, or clues to its presence, or risks/benefits associated with particular therapies, are harder to discover.

- Who "owns" patient data given the legal and ethical complexities and differing legal frameworks from one jurisdiction to another?

- How do we uniquely identify patients from one institution to the next, even within the current system?

- How can we ensure that there is a holistic view across diagnoses and treatments that might have occurred at different institutions but are not isolated incidences, but rather interdependent?

- How do we recenter patient records around the patient?
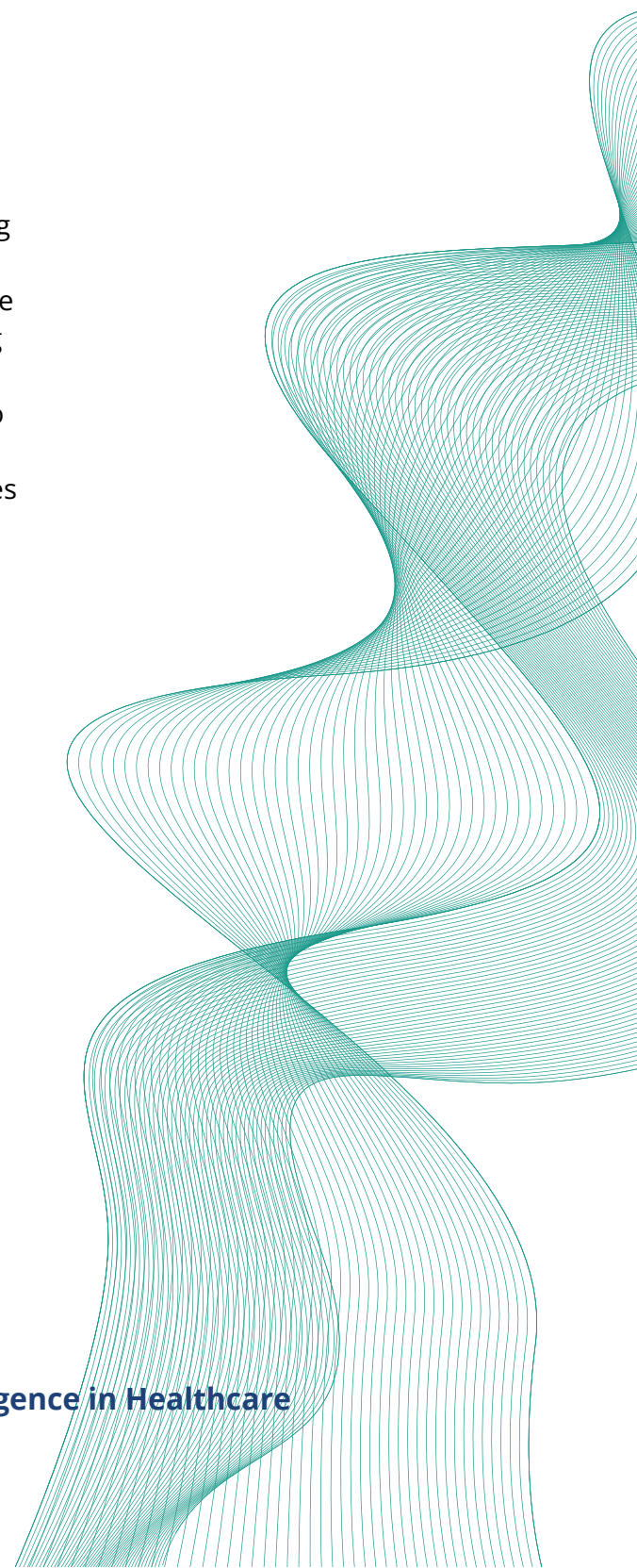
2. Technical Challenges

There is a saying that your AI is only as good as your Data. At the heart of the technical challenge around a unified patient record is the ability to access and leverage data to enable technology as a problem solver for us. These are complex and somewhat sticky problems that need to be solved by societies. Then comes a technical set of considerations, but this aspect is certainly generally available and only needs to be implemented correctly - encryption, access controls, and secure transmission protocols.

- How can we standardize data and create access to it?

- What will the common access point to the Unified Patient Record be?

- Who will develop and enforce universal standards for API endpoints and objects?

- How do we trust disparate systems sufficiently to build interoperability?

- Who and how will ensure data privacy? What happens if a data system is breached?

- Is the owner of the data, assuming this is the patient, sufficiently educated in the rules of safe and correct engagement with data and management of their data?

- If the patient is indeed the owner of their data, what mechanisms do we have on hand to discover where the patient actually has data?

3. Frameworks and Standards

In 1944, the Chicago Convention did something very important to make commercial air traffic safer for general use. Flight authorities across the world came together to agree on common rules and signed a contract, which included a crucial clause- a common form for incident reports, which would be shared. Since then, every crash or incident involving a commercial passenger plane has been investigated and reported; risk factors have been systematically identified, and improved safety procedures have been adopted worldwide. If we can take this collaborative approach for air traffic, can we also come together to develop common rules for structuring a record about and for the patient?

- How do we connect common APIs (Application Programming Interfaces) and all of the different sources of patient data (e.g., laboratory information management systems, pharmacy systems, electronic health records)?

- Why are we not seeing broader adoption of data governance frameworks, despite a growing number of potentially competing frameworks?

- How do we navigate the growing and layered web of interoperability and data-sharing standards (e.g., FHIR, OMOP, GA4GH, SNOMED, ICD-10)?

- How do standards keep up with our constantly evolving understanding of biology, physiology, and medicine?

4. Legal, Ethical, and Regulatory Challenges

The topic of AI is rising in both industrial and public discussion, and a wide variety of opinions exist about when and how it should be utilized. When we apply AI to healthcare it understandably has elicited quite strong responses, including advocacy for sometimes divergent positions. These responses are sometimes based on a sizable worry that regulatory response and action lag significantly behind technological advances in nearly every country in the world. Finally, the topic of patient ownership of data is akin to a "problem of the commons". Everyone wants it for their own benefit, but no one is willing to own it, maintain it, and most importantly, pay for it. Key challenges include:

- Who are the key players that need to come together in order to realize a shared legal framework that brings together policies, regulations, and penalties to govern the creation, maintenance, and evolution of an EHR?

- Should consent be treated as an absolute or contextual concept? e.g. off-label use is 100% contextual. Treatment is contextual. But a computer program is arguably absolute.

- What constitutes a robust patient consent policy? What provisions must be provided to accommodate the nuances that are inherently baked into this topic?

- How do we transition from the current system where the patient record is the property of the initiator i.e. individual or institutional provider to a framework where it becomes the property of the patient?

- How can we ensure that new, unified systems accurately represent existing agreements around patient consent, data sharing, research ethics approvals, etc. around existing medical record systems?

- How do we reach consensus on what information should be universally included and excluded from a unified patient record?

- What are the key legal and regulatory challenges that arise when attempting to create a unified patient record, such as data privacy and consent?

5. Cultural and Organizational Challenges

Though the discussion is about the unified patient record, we need to also consider the impact of the overarching cultural and organizational challenges of the healthcare industry. Regardless of the specific challenges and their solutions, there is a distinct need for good change management and a shift towards more collaboration across the continuum of care. However, we must also recognize the underlying business dynamics of the healthcare industry more broadly since these are baked into the existing organizational structures and cultures.

- How do current owners/controllers of data find the right incentives to unify the patient record despite being economic/professional competitors?

- Do we put the emphasis on the negative (i.e. lack of collaboration between and among healthcare providers) or employ resources to nurture the incentive?

- What frameworks and structures can be put in place to increase collaborations across the industry towards more effective data sharing?

- What changes do we need to implement to put the patient at the center?

Conclusion

Previously in the white paper, we talked about a Unified Health Record where the patient is truly in the center of this universe, being served by a unified patient record that holds their health data across providers, and eventually, across geographies. They have the agency to truly own and direct the use of their health data.

However, there are key barriers to overcome before we have a unified patient record that everyone can benefit from. Not in the least, the lack of consistent best practices and recommendations across the board and the challenges that we are likely to face in the unification of records from systems and frameworks that are fundamentally very different.

By shedding light on key reasons why the Unified Patient Record does not exist today, this paper paves the way to discuss the requirements for the patient-centric unified patient record concept of the future. The authors of the future papers might choose to: suggest innovative ways, discuss market incentives, and make recommendations to stimulate the adoption of a new model of unifying patient data in the US and elsewhere. A patient-centric framework is definitely disruptive of the current way of doing things, but the potential benefits for the healthcare market development and advancement of patient agency far outweigh the costs.

AAIH | ALLIANCE FOR ARTIFICIAL INTELLIGENCE IN HEALTHCARE