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Consent Management System on Patient-Generated Health Data

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Abstract. We consent to many things in life, but sometimes we do not know what we consent to. When discussing data protection in Europe, consent has been associated with permission under the GDPR, and health data are highly sensitive. Patients cannot make an informed decision without being provided with the information they need upfront: no informed decision, no informed consent. This paper presents a consent management system for patient-generated health data stored with HL7 FHIR specification, tested on Type 1 diabetes synthetic data. This architecture, based on using FHIR as an unequivocal data exchange format, can lead to individuals (patients) taking control of their data, enabling potential data exchange and reuse of health data across countries and organisations, in line with the European Commission proposal of a European Health Data Space.

Keywords. Adoption and use of digital health standards, health information exchange, interoperability, privacy

1. Introduction

The sensitive nature of health data requires information systems to guarantee secure storage, access, and processing of Personal Identifiable Information (PII) [1]. To maximize the potential and value of health data, we need to improve access and compliance with relevant regulations, such as GDPR and then find ways to reuse or share the data. Thus, the patient's informed consent is an indispensable requirement.

This paper presents a consent management system using the HL7 Fast Healthcare Interoperability Resources (FHIR) with data obtained from a Diabetes continuous glucose monitor (CGM). Whilst FHIR defines health-related data exchange, unifying data access permissions, management, and usage across organizations remains a challenge due to the distributed nature of health data, which is often scattered across

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multiple entities such as healthcare systems, medical device producers, and third-party companies.

1.1. Objectives

We propose a system that unifies unify data access, governance and orchestration in order to facilitate informed data sharing by patients for primary and secondary use of their health data for specific purposes and periods of time.

Previous studies [2-5] have demonstrated how various software solutions can be applied to obtain patients' digital and paper-based informed consent when the FHIR standard for managing consent has been insufficient [3,5] or has been limited to the exporting of consent definitions previously defined [4].

2. Methods

2.1. Pilot and data simulation

The demonstration of this system requires at least two HL7 FHIR resources: Observation, which will store health data such as blood glucose level, and Consent, a resource that declares the "intent of use" in terms of action (e.g., collect, access) or scope (e.g., research, treatment) of the health data.

We generated synthetic data using a UVa/Padova simulator [6], which produced blood-related information and then profiled FHIR Observation resources to simulate data flow from patient devices. The FHIR Consent resources were designed in collaboration with a health domain expert from the Norwegian Diabetes Register for Adults to reflect a real-world scenario where patients are asked to provide time-limited consent for sharing their data to improve the quality of treatment for people with diabetes.

2.2. Developed solution

The system is built on top of open-source software, such as the Fybrik framework [7] and other open-source technologies, such as Kubernetes for container orchestration and Istio for service mesh implementation. Data access policies are defined via Open Policy Agent [8].

We have extended the Fybrik platform to allow for real-time decision-making about which data the requester can access based on policies and other contextual information provided by the FHIR resources. To configure this workflow, the patient defines their consent conditions through a Graphical User Interface (GUI). Organizational data policy is defined by an authority in the field, which typically would be the organization’s Data Policy Officer.

When a data requester (e.g., NOKLUS, Researchers) seeks data access through an FHIR request, the Fybrik platform assesses the request and applies data access policies based on the relevant FHIR resources (i.e., Observation, Consent) and requester identification. These data access policies can dictate redaction actions on specific FHIR resources or resource attributes, such as anonymization through statistical analyses or the redaction of PII (e.g., patient identifiers) from the data response while allowing other types of information to remain visible.

The high-level picture of the developed solution is presented in Figure 1.

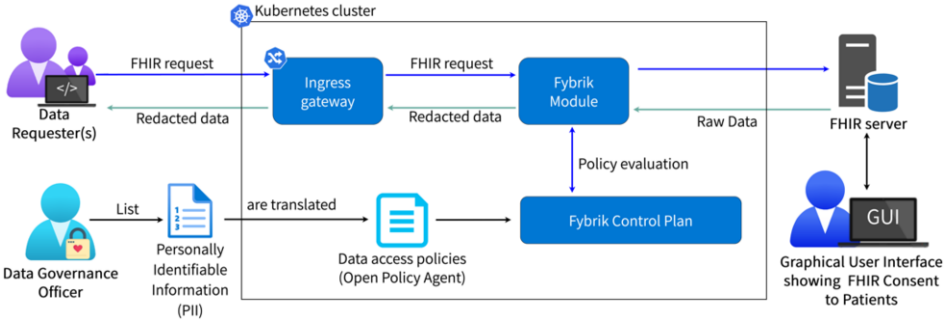

Figure 1. Consent management system - high-level architecture.

3. Results

3.1. Scenario and consent request

We simulated two weeks of Observations for each patient with diabetes, with a total of 4032 Observations and defined FHIR Consent for the different recipient(s) to perform one or more data redaction actions within a given data access policy.

Figure 2 displays how FHIR Consent resources are presented to patients.

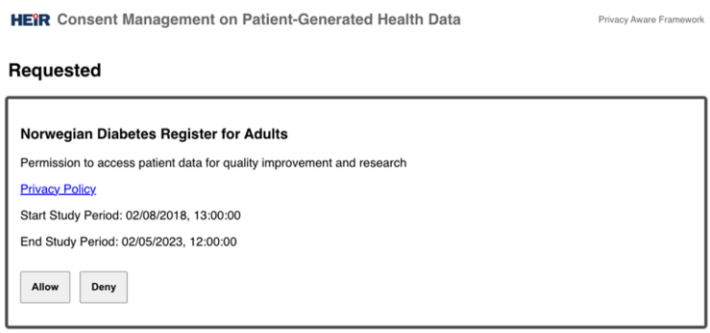

Figure 2. Consent request - patient perspective.

3.2. Observation returned according to the policy

As presented in Figure 1, a third-party entity may request data via a FHIR request. The Fybrik module passes the request to the backend server. It returns the Observation data according to the conditions enforced by the contextual information provided by the FHIR resources (i.e., Consent and Observation). Then it redacts the data by applying the policy.

The entire process is summarised in Figure 3.

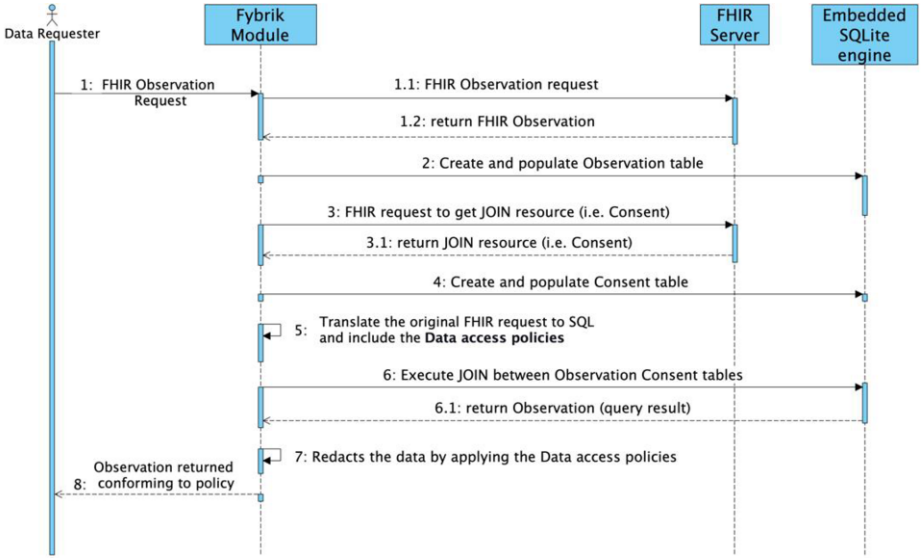

Figure 3. How FHIR Observation data are returned according to policies and FHIR Consent.

4. Discussion

4.1. Benefits of governance mechanisms for facilitating health data exchange

One of today's problems is the fragmented infrastructure where health-related data is stored in various formats, often owned by different entities, and not connected or interoperable. This fragmentation can result in challenges in health data reuse, leading to data access-, governance-, and orchestration challenges.

The proposed system unifies data access, governance, and orchestration. It ensures that data is available to the right individuals at the right time while maintaining appropriate security, privacy, and consent levels.

Adopting common data standards, such as FHIR, and establishing governance and orchestration mechanisms, like the consent management system presented, can facilitate the exchange and integration of health data, leading to better clinical decision-making, research, and patient outcomes. Additionally, the data access policies can contain more constraints [8] (e.g., geo-locational), allowing a cross-border exchange in line with the European Commission proposal of a European Health Data Space [9].

4.2. Limitations

A technical limitation is that all FHIR Observations are returned and then selected based on the constraints of the FHIR Consent. However, this approach could result in many Observations being returned, negatively impacting the system's memory usage.

Additionally, the idea behind this solution calls for the data owner (patients) to choose and evaluate with whom and why they share their data. It may require a high level of digital and health literacy. Thus, consent requests presented to patients should be reviewed by designated authorities.

5. Conclusions

The proposed system assumes the usage of HL7 FHIR. It allows data owners to share health data for the primary purpose (e.g., treatment) and secondary purposes (e.g., research) via the use of FHIR Consent and policy access rules designed by experts (e.g., Data Governance Officer). Furthermore, the system can be used for data access, governance, and orchestration. It can help ensure that health data is shared in a responsible and ethical manner, protecting the privacy and confidentiality of patients while enabling data reuse.

Future work will include exporting consent receipts and inspecting the use of consent to read data via an audit log, which is a record of all events. Additionally, the system presented will be evaluated using benchmarks and suitable evaluation criteria (i.e. usability, information quality) [10].

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