Decentralized Digital Health Services Caught Between the Pressure for Innovation and the Burden of Regulations

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Abstract. Multiple challenges await third-party digital health services when trying to enter the health market. Prominent examples of such services are clinical decision support systems provided as external software. Uncertainty about their challenges, technical as well as legal, pose serious hurdles for many innovations to be adopted early on. There are many options and trade-offs to provide digital healthcare solutions as a third-party service. This paper discusses them by referring to a pharmacogenetic decision support service. By providing best-practices, scenario descriptions and templates designed for third-party services with respect to legal and technical issues, obstacles and uncertainties can be reduced, which will have an impact on better diagnoses and treatments in the healthcare system.

Keywords. Privacy; Data Processing; Patient Empowerment; Digital Health Service; GDPR; Patient-Owned Storage System; Health-IT.

1. Introduction

Today's health IT start-ups are inspired by successful business models of IT-services from many different areas, for example from the financial industry. However, adaptation of these success stories in the healthcare sector are associated with additional hurdles compared to markets outside this sector, as it is far more regulated. For example, efforts to fulfill the requirements of the General Data Protection Regulation (GDPR) for personal and especially sensitive data, to which health data belongs, must be considered. In addition to that, the Medical Device Regulation (MDR) is relevant whenever a product is placed on the market or put into service as defined by MDR Art. 5 [1].

Prominent examples for third-party services are external clinical decision support systems (CDSS) or interpretation services [2,3]. Their main advantage compared to an incorporation into a clinical information system is the flexibility of integrating certain innovations into the healthcare process without investing too much in research and development. Even if healthcare providers are eager to integrate external services, both sides (the healthcare provider and the service provider) are in most cases uncertain about the corresponding technical and legal feasibility. This uncertainty is an obstacle for many innovations to be adopted early on.

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The options for processing data in a legally compliant and efficient way heavily depend on the characteristics of the data required by the third-party service. In the context of personalized medicine, especially genetic/genomic data are relevant, which are highly protected under the GDPR. However, it is not only conformity to regulations, e.g., receiving an MDR certification, which has to be achieved, but acceptance of healthcare providers as well as patients [4]. For the former, predictability of changes and risks are central, whereas empowerment for the latter plays an important role.

In the following, we will describe challenges for third-party digital health services with respect to uncertainties regarding the processing of health data. There are many options and trade-offs to provide digital healthcare solutions as a third-party service. These options are limited by regulations, but are not determined by them, as additional factors must be considered. As a use case, we will refer to a pharmacogenetic decision support service for adverse drug reaction prevention that uses SNP (Single Nucleotide Polymorphism) data [5].

2. Methods

We conducted a literature research using the PubMed database. We were only interested in studies that focused on integration from third-party services. The resulting articles were analyzed and categorized according to their relevance. The following combination of keywords were used:

- (third party service OR external service) AND health data
- (third party service OR external service) AND genetic data
- (third party service OR external service) AND data privacy
- (third party service OR external service) AND consent management
- (third party service OR external service) AND GDPR

From our use case, a service for adverse drug reaction prevention that uses SNP data, several challenges for entering the health market will be generalized together with the outcome of the literature research. Especially, non-regulative aspects are derived from this practical perspective.

3. Results

We did not find any scientific paper that goes beyond the discussion of the regulatory requirements (e.g., GDPR and MDR) for health IT start-ups, such as in [2,3]. From the perspective of the healthcare provider, considering using a third-party service, conformity to such regulations provides initial assurance. However, there are several further factors that contribute to the uncertainties about the risks and necessary steps for integrating the third-party service. For example, there are already blueprints for contracts between the healthcare provider and the health IT start-up, but those available are widely unknown and therefore rarely used. On a conceptual level, a contract has to clarify whether and how data of the patients are transferred and processed (e.g., using anonymized versus pseudonymized data, implementing a patient-owned storage system for exchanging data, etc.). This clarification process could also include activities for

obtaining the acceptance and consent of the patients in order to assure that they are empowered by using innovative services from outside [6].

Second, the concrete technological solution for integrating the third-party service into the healthcare context has to be determined. For a patient-owned storage system, for example, QR codes or NFC chips could be used. Again, it is crucial that the healthcare providers have confidence in the feasibility of the solutions without being forced to significantly change their usual processes, thereby reducing their uncertainty.

In order to concretize and summarize the central challenges for a digital health service to gain access into the health market, two scenarios for our use case are described: (i) the healthcare provider integrates the external pharmacogenetic decision support service (software provider) in the role of a data processor, and (ii) the patient is fully in control of her SNP data via a patient-owned storage system.

3.1 Healthcare Provider as Data Processor

In case the healthcare provider transmits patient data to an external software provider, the healthcare provider takes on the role of a 'data processor' according to GDPR. From a legal perspective, the processor may only forward data if a) there is an explicit consent, b) the data is anonymous or c) a corresponding legal basis exists (e.g., public interest outweighs personal interests) (GDPR Art. 6 (1)). In Figure 1, the following processing is depicted: the healthcare provider requests consent (1) prior receiving the patients' health information (2). The data is then either transmitted as personal or anonymized data (3). While personal data contains identifiable information (e.g., the patients name, birth date, address), anonymized data only contains the patients' non-personal medical data (e.g., liver insufficiency score, SNP signature etc.) and the intended drug prescription. For establishing her business model, the data processor has to decide whether she wants to establish a consent mechanism with all its burdens or whether to process the data anonymously, thereby reducing the possibility to create customer retention. Based on the processed data, the software provider delivers a case specific response (4) in order to prevent adverse drug reactions.
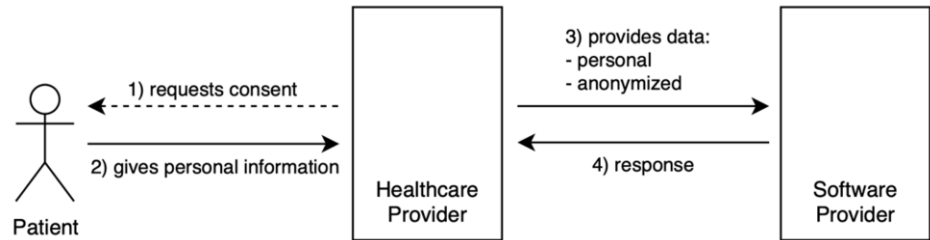

Figure 1. Healthcare provider provides data as data processor.

3.2 Patient-Owned Storage System

This scenario (depicted in Figure 2) is analogous to the situation where a general practitioner suggests further investigation by a specialist and hands out the EHR to the patient. The patient can decide whether he wants to follow this advice and which specialist (in this case, the software provider) he trusts. After requesting the corresponding consent (1), which is provided together with some patient information (2),

the patient receives the relevant laboratory (SNP) data, e.g., contained within a QR-code (3). In a next step, the patient provides data to the third-party software provider (4), gives the appropriate consent for data processing (5), receives the case specific response (6) and can then decide with which healthcare provider he wants to share his information. Even though this use case increases the overall complexity, it brings positive aspects such as patient empowerment and reduced responsibility for the healthcare provider.
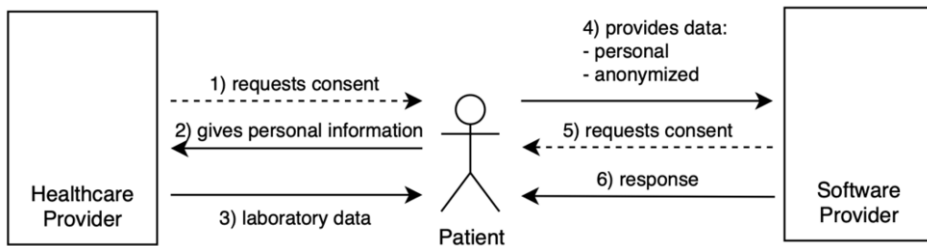

Figure 2. Data sharing via a patient-owned storage system.

4. Discussion

Regulatory requirements do not only constitute hurdles, but they are also associated with certain advantages, e.g., MDR certification protects innovations and deter competitors from adopting them without legal basis. In addition to that, uncertainties of healthcare providers are reduced by conformity to regulations. It will be beneficial for the practice to objectify the cost-benefit ratios by health economic evaluations [7].

Uncertainties related to non-regulatory challenges cannot only be addressed by referring to specific scenario descriptions; it is also important to develop templates for contracts, including the mechanisms for consenting, and to describe technical integration solutions that cover the entire chain of data processing between different institutions. Fast Healthcare Interoperability Resources (FHIR) are just the rails for the latter ones and should be the base for developing cross-institutional IHE profiles [8].

In conclusion, the challenges of start-ups in the health market can be highly deterrent, as the authors have experienced themselves. By providing best-practices, scenario descriptions and templates designed for third-party services with respect to legal and technical issues, obstacles and uncertainties can be reduced, which will have an impact on better diagnoses and treatments in the healthcare system.

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