The Lower Saxony Bank of Health*

Rationale, Principles, Services, Organization and Architectural Framework

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Summary
Introduction: This article is part of a Focus Theme of Methods of Information in Medicine on Health Record Banking.
Background: Poor communication of health care information between health care providers (HCP) is still a major problem. One recent approach is the concept of Health Record Banking.
Objectives: With this report we want to introduce the Lower Saxony Bank of Health (LSBH) to the international community. The main objective of this paper is to report and explain: 1) why this organization has been founded, 2) which basic principles have been set, 3) which services will be provided, 4) which type of organization has been chosen, and 5) which architectural framework has been selected.
Methods: To report and discuss how we plan to achieve the intended objectives.

Results: The LSBH was founded as an entrepreneurial company, regarding itself as a neutral third-party information broker. The bank does not store medical documents on its central servers but offers a document registry with links to documents stored at participating health care providers. Subject to valid patient consent, the LSBH grants access to these documents to authorized health care providers. To implement our services, we chose the established technical frameworks of the Integrating the Healthcare Enterprise (IHE) initiative using cross-enterprise document sharing (XDS).

Conclusions: Different approaches to establish health information exchange (HIE) are in early stages and some have failed in the past. Health Record Banking can address major challenges described in the literature about HIE. The future will show if our provider-sponsored business model is sustainable. After reaching a stable network, we intend to add additional HCPs, e.g., care homes or ambulance services, to the network.

1. Introduction

Accurate patient-centered care information beyond one health care institution has been and still remains a major problem ([1, 2] sections 7 and 10). Depending on the nation’s health care organization, different approaches to overcome this problem can be appropriate [3]. The approach to support shared care by so-called banks of health or health record banks (HRB) (i.e., “an independent organization that provides a secure electronic repository for storing and maintaining an individual’s lifetime health and medical records, obtained from multiple sources” [4]) is not new and goes back at least to work described by Dodd in 1997 [5] (see also [6–12]).

1.1 Objectives

With this report we intend to introduce the Lower Saxony Bank of Health (LSBH) to the international community. In this context, our aim is to report and explain 1. why this organization has been founded (section 2); 2. which basic principles have been set (section 3); 3. which services will be provided (section 4); 4. which type of organization has been chosen (section 5); and 5. which architectural framework has been selected (section 6).

The LSBH is in its preliminary phase of establishment. We are aware that we cannot yet report sufficiently on the bank’s impact on quality and efficiency of care. However, encouraged by a number of requests to...
know more about our approach, we decided to report on the present status. We will also discuss similarities and differences between existing HRBs and our approach, and we look forward to getting feedback from the international community.

1.2 Related Approaches and State of the Art

Diverse approaches for starting HRBs already exist. In 2012, a study [13] was conducted to investigate characteristics of planned and existing health record banks. It revealed that almost all HRBs pin their hopes on centralized data storage. A major promoter of this HRB approach is the Health Record Banking Alliance [14]. The majority of the HRBs found in the study store duplicates of provider-generated documents as well as user-entered data in one central repository. These HRBs can generally be divided into two groups: the first group with a focus on regional cooperation and the second group with a focus on customer base. Approaches with focus on regional cooperation typically provide a personal health record (PHR) for a region or community.

HRBs closely cooperate with local HCPs and local authorities in order to have the majority of health information on a single person stored in one PHR. HRBs with a focus on customer base mainly consist of an untethered PHR extended by open interfaces for data exchange with HCPs. These HRBs mostly operate nationally or internationally. From the study findings, there is no indication that one approach is superior to the other. Some HRBs of each kind never became operational [15] or ceased operation [16], while others are operational and exchange data [17, 18]. The overall rate of abandoned HRBs was 8 in 17 (47%) (A table listing the mentioned 17 HRBs can be found in the supplementary material).

We found financing models that were patient-paid accounts [19], employer-sponsored models [20] or mixtures. Most HRBs didn’t make any statements concerning their financing model. One HRB planned to implement an app store/shopping mall model [21]. Two HRBs had plans to use their data for data mining [21, 22]. We did not find working implementations of one of these or other innovative approaches for generating added value.

Further results of the study showed that the often-postulated sustainability of electronic health records is still a problematic issue. None of the HRBs assured a lifelong availability of the stored data or specified means to facilitate long-term availability. In summary, some different kinds of HRBs already exist, but they all lag behind the various HRB visions described in the literature [7, 9–12, 23].

2. Rationale for Founding the LSBH

A regional network initiative called eHealth.Braunschweig was launched in 2009. The three-year project took place in the Braunschweig region. The project aimed to overcome barriers of institution-centered care for patients and shared care beyond institutions (including home nursing care and safe living at home). Details on and further references of this project can be found in [24].

In eHealth.Braunschweig, there has been a considerable progress concerning patient-centered, shared care worldwide [25–27], in Europe [28, 29] and in Germany [30]. However, significant organizational deficits with respect to fragmented institution-centered care still exist.

For example, HCPs have not adapted sufficiently during the establishment of the Summary Care Record in England [31]. In the Netherlands, the Dutch government revoked funding of the National Electronic Patient Record due to problems concerning physician doubts about liability and quality of data [32]. However, encouraging results have been seen in particular initiatives in Austria and the USA [33, 34].

In order to help overcome these deficits, the scientific advisory board of the eHealth.Braunschweig project decided to start a bank of health records in 2011 based on the experiences from diverse HIE projects done so far. To our knowledge, our approach is the first to establish a HRB in Germany. By taking into account the hurdles that have been described in the literature, we aim to create a sustainable health information exchange with a regional scope.

3. Type of Organization

The establishment of successful health care networks requires trust between different organizational leaders in a competitive market. For this reason, LSBH was founded as an entrepreneurial company and a neutral third party information broker with no singular HCP taking the lead. The company has been incorporated as a subsidiary company of the Center of Informatics and Technology Braunschweig (Braunschweiger Informatik- und Technologiezentrum, BITZ [35]). Health information infrastructure initiative success relies on diverse political, financial and technical conditions, and its organizational structure aims to involve representatives from all groups of stakeholders. Therefore, an advisory board (Advisory Board) was started with members of the Lower Saxony federal state government, the Association of Statutory Health Insurance Physicians of Lower Saxony (representing all licensed general practitioners and medical specialists in Lower Saxony as members of this association), the Peter L. Reichertz Institute of Medical Informatics, the Medical Center Braunschweig and the Braunschweig City Council. Three additional members are added by the BITZ. The Advisory Board is responsible for the strategic management within the LSBH. It develops objectives for the consistent further development of network.

Moreover, the Advisory Board must establish both a Technical Experts Committee and a Health Care Experts Committee. The Technical Experts Committee includes representatives from each participating data sharing organization. The central task of the committee is continuous management of requirements for the LSBH’s health information infrastructure. The Health Care Experts Committee brings together the expertise of providers’ health care professionals. As system end-users, they will help define requirements for a seamless integration of the LSBH services into their workflows.

Concerning financial aspects, we decided to start with a provider-sponsored (e.g., hospitals, medical care units, rehabilitation clinics) business model as we expect
those to gain highest cost savings. Other end users like resident physicians and patients will not be charged for using the basic services. Furthermore, we plan to offer fee-based facilities such as medical appointment scheduling software that allows hospitals to enhance referral doctor relationship and optimize processes.

4. The LSBH’s Basic Principles

The eHealth.Braunschweig’s Advisory Board created the basic principles of the LSBH, the bridging organization to support the eHealth.Braunschweig project management. The original German text can be found in [36]. The basis for the formulation of these principles was the acquired prerequisites for a regional transinstitutional information system from the eHealth.Braunschweig project (see section 2). In addition to German and European data protection laws, a preferably good compliance of the patient and health care provider and results from comparable projects (e.g. [37]) were considered during their formulation.

The LSBH’s business objective is to create added value for individuals including health care providers during the health care process to make with this a contribution to high quality and efficient health care. This added value arises especially when more than one HCP is involved in the health care process. For this purpose, the LSBH wants to offer corresponding IT services. As a company of the health care system with a professional organisational and operational structure the LSBH will face competition. The LSBH employs qualified personnel and maintains a suitable IT infrastructure. The LSBH is oriented especially towards the following basic principles:

1. Medical data of individuals should still remain stored at the HCPs: As a rule the LSBH only wants to reference medical data. This is normally performed in the context of a treatment. If data concerning an individual is stored nevertheless in the LSBH, this is done in encrypted form. Decryption should only be possible by the affected HCPs or the individual him-/herself.

2. Medical data should only be accessed by individuals or HCPs authorized by them: As a rule the access to the medical data of an individual should be restricted to a treatment context and limited in time. Access to the data is regulated unambiguously and transparent.

3. The will of the individual has to be taken into account: Medical data regarding an individual respectively links to these data may only be saved and used in the LSBH, if the individual gives his/her explicit consent to it. This consent could be revoked at any time without giving reasons.

4. Services of the LSBH are verifiable and regulated unambiguously: All services of the LSBH are known to the respective individuals and HCPs.

5. The use of medical data of an individual is verifiable and regulated unambiguously: As a rule the data is used by a HCP for the health care of an affected individual. The LSBH will not offer or allow third party data usage that is not known by the affected individual or the affected HCP.

6. The LSBH works on trust of individuals and HCPs: The LSBH wants to support the cooperation between individuals and HCPs to aim for high quality and efficient health care. To guarantee the characteristic trust of the LSBH, appropriate committees were established and incorporated into its rules of order. The LSBH will be vendor-neutral – it will not enter into dependencies of soft- and hardware manufacturers or other companies. Regarding HCPs the LSBH will work balanced and not for the special interests of a certain HCP or branch.

7. The LSBH acts in a responsible and conscientious manner: The main goal of the LSBH is to improve health care. All entrepreneurial actions and all employees of the LSBH are committed to achieve this goal.

8. The LSBH assures quality and safety: Services of the LSBH are protocolled and verifiable. Where possible and reasonable, the offered services, as well as the personnel of the LSBH, its organisation and IT-infrastructure, are checked for quality and where applicable certified regularly by approved procedures. In particular, a high value is set on data protection, data security and data integrity. There will be service warranties for the services offered by the LSBH and international and national standards will be utilized.

The employees, the members of the committees, and the shareholders of the LSBH pledge themselves to lead the LSBH respectively and to adjust their work according to these basic principles. All of them consider business success in close connection to the strict adherence to these principles.

As stated in principle number five, medical data of an individual is used first for the health care of the affected individual. Other purposes of use – e.g., searching data for research or public health – must be explicitly permitted by the affected individual.

5. Services

The services, which will be offered by the LSBH, can be associated to three different service layers: technical service layer (TSL), administrative service layer (ASL), and functional service layer (FSL). These layers are built upon each other starting with the TSL. On this layer, the LSBH plans to offer: TSL1. Monitoring, maintenance and support services for the underlying

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The technical and software infrastructure to support the services on the TSL were built up during the last year.

On the ASL, the LSBH wants to offer services to allow directed and undirected communication of medical data between HCPs. Using the undirected communication, the LSBH intends to implement a lifetime electronic health record for the participating individuals. Exemplary services of the ASL to achieve this goal are:

ASL.1. Provision and maintenance of a master patient index (MPI) to enable the cross-institutional/intersectoral identification of an individual as well as data association.

ASL.2. Support of the manual merge process if an automatic match was not possible due to changes in multiple identification fields (e.g., simultaneous change of health insurance and last name).

ASL.3. Provision and maintenance of a document registry including links to and metadata of available medical data within the network of the LSBH.

ASL.4. Provision and administration of an authorization system, which acts according to the individual's informed consent and allows role-based access restrictions.

ASL.5. Provision and maintenance of a health care provider directory (HPD) for the identification and authorization of HCPs in the context of the LSBH.

ASL.6. Logging of all medical data communications and interactions within the network of the LSBH (e.g. HCP authentication or provision of an informed consent).

ASL.7. Provision of a gateway to other health care networks.

The central software components and the needed hardware to provide most of the services of the ASL are already setup by the LSBH. Building upon these services of the ASL, the LSBH wants to offer services that support different use cases of the health care, health prevention and health management process. In the first step the LSBH plans to offer the possibility to:

FSL.1. Register medical documents and images in the individual’s “virtual” health record for future retrieval by authorized HCPs.

FSL.2. Send discharge letters to the follow-up HCP.

FSL.3. Communicate a standardized nursing discharge summary.

FSL.4. Send structured information for a hospital admission.

FSL.5. Send structured information about hygiene relevant findings of an individual (e.g. MRSA, norovirus) to the follow-up HCP.

FSL.6. Communicate test results from a laboratory to the charging HCP.

FSL.7. Communicate radiological images for remote consultation during the treatment of poly-trauma patients.

These services and the interconnection to the existing information systems of the participating HCPs are currently in the implementation phase and should be finished at the end of 2013. In further steps, additional services will be added to the service catalogue of the LSBH.

6. Architectural Framework

Successful routine installations [34] and progress in standardization was important to us. Major approaches to connect health care ICT are driven by the Integrating the Healthcare Enterprise (IHE) [38] initiative. The IHE identifies health care related-use cases and defines respective integration profiles using established storage and communication standards. According to the basic principles of the LSBH, the architectural framework is implemented through these profiles.

Using IHE compliant software components as a basis for the communication infrastructure of the LSBH entails the following benefits:

1. Manufacturer independency: Exchangeable and reusable software components implementing IHE actors with well-defined interfaces.

2. Reusing LSBH’s network for national eHealth infrastructure: The upcoming German Telematic Infrastructure will support communication with IHE compliant domains.

3. Inter-network communication: Well-defined IHE gateways allow communication with other IHE domains or other existing medical networks.

4. Cross border communication: The main European eHealth interoperability project for electronic cross border communication of medical documents (epSOS [39]) is also using IHE profiles.

5. Data type independency: Due to CDA-encapsulated documents, all types of communication can be covered, reaching from structured laboratory data to unstructured PDF documents or image data reference objects.

6.1 Application Components

The LSBH-driven components will be the backbone actors of an IHE Cross-Enterprise Document Sharing (XDS) [40–44] affinity domain comprising all local HCPs contributing or consuming data. The basis for the software solution of the LSBH is the sensei® [45] product from the company ITHicoserve. This implementation of IHE actors proved productive in Austria for several years [34] and was extended to comply with German data protection regulations.

The central components, combined in a so-called Community Node (CN), deliver the main LSBH services. Respective sub-systems are:

1. An XDS Registry, collecting metadata for and links to local documents stored by the HCPs;

2. A Master-Patient-Index, allowing domain-wide patient referencing using demographic data (name, surname, gender and birthdate) as well as personal (health insurance ID) and institutional (ID of the patient in local information systems) identification numbers;

3. An XCA Gateway for communication to other affinity domains; and

4. A component for Audit Trail and Node Authentication (ATNA) for domain-wide logging.
To this CN several local HCPs that each provide their own local XDS components referred to as Local Node (LN) and Application Node (AN) will be connected. Local application systems that create, provide or import medical documents will be connected to the LN and AN using well-defined interfaces (e.g., web service calls, HL7 MDM messages, DICOM Send/Store). Respective sub-systems are:

1. An XDS Repository with locally stored documents;
2. A Source/Consumer Adaptor, which coordinates documents registration and fetching;
3. A Consent Application for creating personalized informed consent forms; and

An additional LSBH-Application Node (AN) encapsulates services provided for the entire affinity domain, e.g., accessing documents from an ambulatory service. Apart from XDS, the LSBH will provide direct communication between HCPs according to the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile and a Healthcare Provider Directory (HPD). A complete component overview is shown here in Figure 1.

### 6.2 Document Workflows

Main document processes are wrapped around the core services of the LSBH (see section 5, TSL and ASL). Documents, which will be provided by participating HCPs, have to be registered in the central XDS Registry making them retrievable by other HCPs. According to a developed fine-grained privacy concept, all patient data related processes have to be authorized by informed consent.

#### 6.2.1 Informed Consent Process

The starting point is a consent form, which will be produced by a web-based policy application. Apart from general information about provided services by the LSBH, the consent form specifies 1) the right of the issuing HCP for registering data at the domain specific registry, 2) the right for retrieving data with special refinements for a) the time since when data can be accessed, b) from which other HCPs data can be retrieved, and c) which medical document types can be accessed. The full consent is planned to be valid for 56 days. This time frame has been defined with clinical partners as the usual treatment duration. The reason for this time-based constraint is the yet unavailable technical treatment context verification mechanisms like an electronic health card. The consent can be revoked or changed at any time. After signing the consent form paper based, an electronic policy document is created. This policy is sent to the LSBH Security Policy Administration module, which regulates access to all indexed documents. The paper-based form will be archived locally for inspections of the LSBH on a random sample basis. This ensures existence of legally signed consents in addition to created digital policies.
6.2.2 Document Registration and Retrieval

The LSBH aims to provide in-depth integration into local health information systems to retain user context and thus simplify workflows. Manual steps in the planned procedure are reduced to a minimum to ensure security and reliability. Participating HCPs each defined a set of medical document types to be registered from a local EHR system. If a final (i.e., validated or signed) document is part of the specified typeset and if a local flag for an existing patient consent is set, a registration request will be sent to the registry.

Figure 2 Document registration and retrieval workflow
Access itself will be triggered from inside a connected consumer, like a local EHR system. The HCP, logged-in user context, and selected patient are combined into the GET parameter of a generated URL which is signed with a time-limited certificate. The URL calls the Consumer Application checking the signature and respective policy to ensure the right to access documents for this particular patient (Figure 2).

In the future productive phase of the LSBH, available documents could be obtained in raw format as previously provided by the source HCP or by special format handlers integrated into the Consumer Application (e.g., an LDT to PDF converter). Since the Consumer Application runs in a web container of the consuming system a gapless transfer of findings or laboratory data, for example, into the system will be possible.

7. Discussion

7.1 Similarities and Differences of the LSBH Approach to Other Bank of Health Approaches

The LSBH approach and other bank of health approaches have two core principles of health banking in common. First, the LSBH is structured as a neutral third party to avoid problems arising from conflicting interests of different stakeholders. Second, it fosters patient-control over data, i.e., the patient gets to decide to which HCP he/she reveals specified medical data for a certain timespan. It has to be noted that in the previously discussed related approaches, some other less closely related approaches for exchange of health information have not been considered. That is because one or both of these core principles are missing, e.g., Tethered and Portal PHRs, national health portals and HCP networks with peer to peer communication. With core principles in common with other health banking approaches, the main difference lies in LSBH’s data storage approach, which we chose for the following two main reasons. First, participating HCPs stated that they prefer to store the medical data they produced themselves. One reason is that they perceive the data as their data. Another reason is that German law has some regulations which ensure the privacy of a patient’s medical data even in case of prosecution, which could be lost if the data is stored by a third party. Secondly, centralised databases with all medical data about individuals within a region could trigger privacy concerns at the individual level and at the public level [10]. The national association of doctors in private practice clearly took up this position versus central data storage because of the enormous damage that even a small security gap could cause [46]. To the knowledge of the authors, there is currently no dedicated study investigating the motivations and attitudes of German HCPs or patients regarding different data storage models. However, there seems to be a common consensus versus central data storage. Not ignoring the fact that centralised data storage also has some potential benefits, to increase the compliance of local HCPs and to take into account privacy concerns, the LSBH is not using a centralized data storage approach.

7.2 Major Barriers

In the past there have been several approaches to establish healthcare networks. While there has been much effort into constitution of those networks, most of the networks have failed to develop sustainable business models. Lorenzi [47] describes varying reasons for health information infrastructure initiatives to fail progressing from technological to structural issues. It’s obvious that the creation of working and on-going healthcare networks demands persistent commitment of all stakeholders and cannot be done in a rushed manner. While being still in the planning process we can already confirm that political and organizational aspects in establishing the LSBH might easily surpass technological challenges. Continuous work needs to be done to achieve persistent commitment of all stakeholders and develop trust between participating organizational leaders and achieve a common understanding of the goals. As lack of communication and lack of consensus between different project stakeholders continues, the employment of the Advisory Board and subordinated expert committees has already shown to be helpful to counteract organizational issues.

As described in the introduction, user adoption is essential for the success of any health record bank. Therefore, we began to involve end-users in an early stage of development to be able to take into account individual requirements. Measures to improve usability and enable seamless workflows have been focused especially in cooperation with clinicians and primary care providers [48]. First results show that while the goals of health record banking are well anticipated by primary care providers, the usefulness of such systems is still seen skeptically. Provider’s attitude might be related to time constraints in German resident doctors. Compared to other European countries (10.7 minutes with a standard deviation of 6.7), consultations are mostly short and frequent in German general practices (7.6 minutes with a standard deviation of 4.6) [49]. Thus, specific workflows for the efficient use of health information exchange, like delegating access to the electronic health record to medical assistants, needs to be developed and established. Furthermore, the circumstances regarding when to use directed or undirected communication methods needs to be explored.

Data protection laws in Germany require an opt-in policy and written consent. Regarding management of patient consent, these constraints bear challenges in implementing fully computerized workflows. As described in section 6.2, today we are not able to circumvent to the use of paper-based consent forms. It seems unlikely to solve these challenges as long electronic signatures by patients and health care providers are not widely used in practice settings. While we do not know yet the impact of this less-than-ideal situation on provider’s acceptance of the LSBH, we expect a need to deliver on-site guidance and training for participants.

Certainly, the time after the “go live” will entail more barriers to come. Experience has shown that adoption of health technology, especially of health information exchange, in practice still includes major obstacles that need to be addressed [50, 51]. Unquestionably, there will be the need to establish a routine in the use of electronic health record banking.
data exchange supported by a thoroughly planned change management.

### 7.3 Future Plans

After the testing phase, further HCPs of the southeastern Lower Saxony region will be connected to the communication infrastructure of the LSBH. Especially to resident general practitioners and medical specialists, the services of the LSBH will be offered by using the eHealth Web-Portal or a standalone software client. A direct coupling with the existing information systems in the residential area is intended and this coupling is seen as critical. After this step, additional HCPs, e.g., care homes or ambulance services, will be integrated in the network of the LSBH.

Beneath this planned increase of the number of participants, additional services will be added to the service catalogue of the LSBH. In future the LSBH wants to offer for the individual the possibility to enter own data to his/her ‘virtual’ lifelong patient record. This could be, for example, a centralized medication plan, which is also editable by authorized HCPs, a patient’s caretaker, information concerning donation of organs, an immunization card or information of the individual’s personal fitness training. Another planned service of the LSBH is electronic support during appointment scheduling. This should be possible for HCPs and patients.

In the first stages of the LSBH, the provided medical data of an individual should only be used to support his/her health care process. Using existing medical data for research or other purposes by external service provider, must be explicitly permitted by the affected individual and will only be supported in future expansion stages of the LSBH. The postponement of this data usage by third parties to future stages was chosen in the first place to reduce patient’s concerns and fears of data misuse or leakage (see also section 4).

We intend to conduct a series of studies for system evaluation. This is not only of importance for upcoming projects in this field but also to iteratively monitor and readjust our project. Feasible study designs addressing use and impact of HIE have been described [51–53] and will be adapted to our specific setting.

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### Authors’ Roles and Responsibilities at Time of Publication

MP and MW are LSBH’s CEOs. MP has before been leading the eHealth.Braunschweig project. BH, JS and ET are as medical informaticists and information system architects involved in LSBH’s design and technical development. MR is LSBH’s organizational project manager. TB, Director of the Ambulatory Medical Care Center at Klinikum Braunschweig, is chairing LSBH’s Health Care Experts Committee. CS, CIO of Braunschweig Medical Center’s Ambulatory Medical Care Unit, is chairing LSBH’s Technical Experts Committee. TK, General Practitioner and Chairman of the Association of Statutory Health Insurance Physicians Lower Saxony, Braunschweig District, and HS, CEO of Braunschweig Medical Center are vice chairs of LSBH’s Advisory Board. RH, Director at Peter L. Reichertz Institute for Medical Informatics, is chairperson of LSBH’s Advisory Board. He has before been leading eHealth.Braunschweig’s Advisory Board and initiated LSBH’s foundation.

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