The Lower Saxony Bank of Health
Principles, Services, Organization and Architectural Framework

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Summary
Background:
Communication of information in health care between health care providers 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. Our objective is to report and explain (1) why this organization has been founded, (2) which basic principles have been set, (3) which services are provided, (4) which type of organization has been chosen and (5) which architectural framework has been selected.

Methods:
To report and discuss about how the intended objective has been achieved.

Results:
The LSBH was founded as an entrepreneurial company holding a self-understanding as a neutral third party information broker. The bank does not store medical documents itself but offers a document registry granting access to authorized health care providers. To implement our services we used established technical frameworks of the Integrating the Healthcare Enterprise Initiative as cross-enterprise document sharing (XDS). The rollout of the technical infrastructure has been accomplished. The integration and connection of the local components of the participating hospitals will follow soon.

Conclusions:
Different approaches of establishing health information exchange are in early stages or have failed in the past. Health Record Banking seems to be capable to address major challenges described in literature about HIE. Future will show if our provider-sponsored business model is sustainable. After reaching a stable network, additional HCPs, e.g. care homes or ambulance services, shall be integrated in the network of the LSBH.

* On the authors roles and responsibilities at time of publication:
   MP is LSBH's CEO. He 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 and MW is LSBH's technical 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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1 Introduction
Patient-centered care beyond one health care institution has been and is still remaining a major problem ([1], [2] sections 7 and 10). Depending on 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 [5] (see also [6] - [12]).

With this report we want to introduce the Lower Saxony Bank of Health (LSBH) to the international community. We want to report and explain
- why this organization has been founded (section 2),
- which basic principles have been set (section 3),
- which services are provided (section 4),
- which type of organization has been chosen (section 5),
- which architectural framework has been selected (section 6)
The LSBH is still in its establishing phase. We are aware of the fact that we cannot yet report sufficiently on the bank's impact on quality and efficiency of care. The reason to report already now is based on a number of requests to know more about our approach, and why we decided to found this bank of health. With this paper we want to share our knowledge and to report on our work until now. We also hope to get feedback from the international community.

2 Why founding the LSBH?
In 2009 a regional network initiative, called eHealth.Braunschweig, had been launched. The three year project took place in the Braunschweig region, aimed at overcoming barriers of institution-centered care towards patient-centered, shared care beyond institutions, including (home) nursing care and save living at home. Details on and further references of this project can be found in [13].

In this project it has been realized that - although there has been a considerable progress concerning patient-centered, shared care worldwide ([14], [15]), in Europe ([16], [17]) and in Germany [18] - there were still significant organizational deficits with respect to fragmented institution-centered care exists. In order to contribute to overcome these deficits as one of the outcomes of the eHealth.Braunschweig project it was decided to found a bank of health as an independent institution. With this decision initiatives like the German Telematic Infrastructure and the EU should be supported.

The eHealth.Braunschweig’s Advisory Board decided to found the ‘Lower Saxony Bank of Health’ (LSBH) as organization. Strategic decisions had been made on LSBH’s organizational structure, basic principles, services, type of organisation and its technical architecture on 13th of May 2011 [19]. In the following sections these points are addressed in more detail.
3 The LSBH’s basic principles

As mentioned, these basic principles have been decided by eHealth.Braunschweig’s Advisory Board, the bridging organization to support the eHealth.Braunschweig project management in establishing the LSBH. The original German text can be found in [19].

The LSBH pursue the business objective, to create added values for individuals and health care provider (HCP) during health care to make with these a contribution to a high quality and efficient health care. These added values shall arise especially when more than one HCP is involved in the health care of an individual. For this purpose the LSBH offers corresponding IT services. As company of the health care system with a professional organisational and operational structure the LSBH will face the 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 to these 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. **Only individuals respectively by him/her authorized HCPs should be able to access their medical data**: As a rule the access to the medical data of an individual should be restricted to a treatment context and limited in time. Who is able to access 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 gave 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 a usage of the data by third parties, which is not known by the affected individual or the affected HCP.

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

7. **The LSBH acts responsible and conscientious**: The main goal of the LSBH is to improve the health care. All entrepreneurial actions and all employees of the LSBH are bound in all conscience to this goal.

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

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1 In the context of the LSBH individuals are commonly, but not always, equate with patients. However individuals could for example also be healthy people, who attend prevention measures, or healthy people with age-related functional deficits.

2 In the context of the LSBH health care provider are commonly organisations like doctor’s offices, care homes for the elderly, hospitals, pharmacies or service provider like mobile nursing services. However in this connection the term health care provider shall be consciously understood in a broader way. So that for example caring relatives (resp. other persons of trust) or sport clubs could fall under this term, too.

3 In the context of the LSBH health care commonly stands for (outpatient or in-patient) patient treatment. But here, too, health care shall be understood in a more comprehensive way, for example in the context of prevention or caring of healthy people with age-related functional deficits.
The employees, the members of the committees and the shareholders of the LSBH pledge themselves to lead the LSBH as company respectively to adjust their work according to these basic principles. All of them consider the business success in close connection to the strict orientation to these principles.

4 Services

The services, which are offered by the LSBH, could 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 offers

TSL.1. monitoring, maintenance and support services for the underlying hard- and software components of the communication infrastructure.

This also includes

TSL.2. long-term archiving and backup of data stored in the LSBH to enable the services of the ASL.

On the ASL the LSBH offers services to allow directed and undirected communication of medical data between HCPs. Using the undirected communication the LSBH intends to implement a “virtual” 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. The LSBH will also support 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 with links to and metadata of available medical data within the network of the LSBH.

ASL.4. Provision and administration of an authorization system, which enforces role-based access restrictions and the individual’s informed consents.

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.

Building upon these services of the ASL the LSBH wants to offer services which support different use cases of the health care, health prevention and health management process. In the first step the LSBH plans to provide 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.

In further steps additional services shall be added to the service catalogue of the LSBH.

5 Type of organization

The LSBH was founded as an entrepreneurial company holding a self-understanding as a neutral third party information broker. It has been incorporated as subsidiary company of the Center of Informatics and Technology Braunschweig (Braunschweiger Informatik- und Technologiezentrum, BITZ [20]). As the success of health information infrastructure initiatives relies on diverse political, financial and technical conditions, its organizational structure aims to involve representatives of all tangled groups of stakeholders. Therefore, an Advisory Board 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 was constituted. Three additional members are entitled 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 is responsible to establish both a Technical Experts Committee and a Health Care Experts Committee. The Technical Experts Committee includes representatives from each participating data sharing organization. Central task of the committee is the continuous requirements management of LSBH's health information infrastructure. The Health Care Experts Committee brings together the expertise of providers’ health care professionals. As systems end-users, they will help to define requirements for a seamless integration of the LSHB services into their workflows.

6 Architectural framework

It was of importance for us to benefit from already successful routine installations [21] and progress in standardization. Major approaches in connecting health care ICT are driven by the Integrating the Healthcare Enterprise (IHE) [22] 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.

6.1 Application components

The LSBH-driven components are the backbone actors of an IHE Cross-Enterprise Document Sharing (XDS) ([23] - [27]) affinity domain comprising all local HCPs contributing or consuming data. These central components, combined in a so called Community Node (CN), are delivering 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;
3. An XCA Gateway for communication to other affinity domains;
4. A component for Audit Trail and Node Authentication (ATNA) for domain-wide logging.

Connected to this CN are several local HCPs, each providing their own local XDS components, referred to as Local Node (LN) and Application Node (AN). Local application systems, which are creating and providing or importing medical documents, are 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;
4. A Consumer Application integrable into local sub-systems for document retrieval;

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 provides direct communication between HCPs according to the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile and a Health Provider Directory (HPD). A complete component overview is shown by Figure 1
6.2 Document workflows

Main processes are wrapped around the core services of the LSBH. Documents provided by participating HCPs have to be registered in the central XDS Registry making them retrievable by other HCPs. According to a fine grained privacy concept, all patient data related processes have to be authorized by informed consent.

6.2.1 Informed consent process

Starting point is a consent form produced by a web based policy application. Apart from general information about provided services by the LSBH it 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 valid for 56 days and can be revoked or changed every time. After signing the consent form paper based, an electronic representation is created. This policy is sent to the LSBH Security Policy Administration module, which regulates access to all indexed documents. The paper-based form is 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 subsystems to retain user context and thus simplify workflows. Manual steps are reduced to a minimum due 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 the local flag for an existing patient consent is set a registration request is sent to the registry. The access itself is triggered from inside a connected consumer like a local EHR system. The HCP, logged in user context and selected patient are combined into 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 (ref. Figure 2).
Documents available can 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 web based Consumer Application runs in a web container of the consuming system a gapless transfer into the system is possible like taking over findings or laboratory data.

Figure 2 – Document registration and retrieval workflow

7 Discussion

7.1 Related approaches and state of the art

Some different approaches for the realization of HRBs exist. In 2012 a study [28] 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 [29]. The majority of the HRBs found in the study stores duplicates of provider generated documents as well as user entered data in one central repository. Roughly said, these HRBs can be grouped into approaches with focus on regional cooperation or focus on customer base. Approaches with focus on regional cooperation typically provide a personal health record (PHR) for a region or community. They 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 focus on customer base
mainly consist of an untethered PHR extended by open interfaces for data exchange with HCPs. The latter HRBs mostly operate nationally or internationally. From the findings of the study there is no indication that one of the approaches is superior to the other. Some HRBs of each kind ceased operation ([30], [31]), while others are operational and exchanging data ([32], [33]). The overall rate of HRBs, which ceased operation, was 8 in 17 (47%). Found financing models were patient paid accounts [34], employer-sponsored models [35] or mixtures. Most HRBs didn't make any statements concerning their financing model. One HRB planned to implement an app store/shopping mall model [36]. Two HRBs had plans to use their data for data mining ([36], [37]). Working implementations of one of these or other innovative approaches for generating added value could not be found. 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 HRBs of different kinds already exist, but they all lag behind the various HRB visions described in literature ([7], [9] - [12], [38]).

7.2 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. At first, the LSBH is 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 reveals which 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 similarities are missing, e.g. Tethered and Portal PHRs, national health portals and HCP networks with peer to peer communication. Having these core principles in common with other health banking approaches the main difference lies in LSBH's data storage approach. To take local HCP's interests into greater account the LSBH is not using a centralized data storage approach.

7.3 What has been achieved until now?

Based on results and established cooperation networks from the regional health care network eHealth.Braunschweig [13] the LSBH was founded at the beginning of the year 2011 as entrepreneurial company. After the constitution of the LSBH advisory board an Europe-wide call for competition was started to determine a suitable vendor of IHE compliant software components for the intended communication infrastructure and services. Subsequently system, interface and client concepts for the LSBH platform were developed in cooperation with the chosen vendor. In parallel data protection concepts were worked out for the LSBH to comply with European, German and Lower Saxon data protection laws. At the end of the year 2012 the central hard- and software components of the LSBH as well as the local components of the Braunschweig Medical Center and the hospital Wolfsburg were installed, configured and interconnected. For the start of the LSBH its central components were located in a separate logical and physical area of the BSI certified [39] computing centre of the Braunschweig Medical Center. To enable the communication platform to gather, store and enforce the two staged informed consent of the individual several software adaptions were performed with regard to IHE specifications. The integration and connection of the local components of the participating hospitals with their hospital information system, archive and PACS were conceptualized and shall be executed in midyear 2013.

7.4 Major barriers

In the past there have been several approaches to establish healthcare networks. While there has been put much effort into constitution of those networks, most of them have failed to develop sustainable business models. Lorenzi [40] describes varying reasons for Health Information Infrastructure Initiatives to fail reaching from technological to structural issues. It’s obvious that creating working and ongoing healthcare networks demands persistent commitment of all stakeholders and cannot be done short dated. In the process of planning we took into account that political and organizational aspects in establishing the LSBH might easily surpass technological challenges. The development of trust between
different organizational leaders plays a key role in the establishment of successful networks. A common understanding of the goals the LSBH had to be promoted among its stakeholders. In Germany, federal-state laws bear some obstacles concerning privacy and security requirements. Thus, pioneering work had to be done to make organizational form and technology match Lower Saxony medical data protection laws. Altogether, it took about three years to lay to foundation of a technical, financial, organizational and legal infrastructure. By adaption of established technology frameworks as IHE XDS and well-engineered software components we were able to benefit from experiences that already have been made in comparable HIE projects around the world. Consequently, rollout of the technical infrastructure has been accomplished without major problems.

As user adoption is critical for the success of the LSBH, we began to involve end-users in an early stage of development, taking into account professions' individual requirements. Especially measures to improve usability and enable seamless workflows have been focused in cooperation with clinicians and primary care providers. The employment of the Advisory Board and subordinated Experts Committees will help to counteract organizational issues as lack of communication and lack of consensus between different project stakeholders. It is crucial for the LSBH to bring network participants together and moderate competition among the healthcare providers. Therefore, the LSBH is planned as an unbiased third party entity outside of market competition.

Concerning financial aspects, we decided to start with a provider-sponsored business model as we expect those to gain highest cost savings. End users as clinicians and resident physicians will not be charged for using services. Furthermore, we plan to offer fee-based facilities as medical appointment scheduling software allowing hospitals to enhance referral doctor relationship and optimize processes. 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 bares major obstacles that need to be addressed ([41], [42]). There unquestionably will be the need to establish a routine in the use of electronic data exchange supported by a thoroughly planned change management. Else, a timely delivery of documents between healthcare providers is likely to fail to meet expectations. Evenly important is the need to address patient’s needs and create trust in the confidentiality and data security of the LSBH. We strongly need to obtain patients’ trust in the LSBH as benefits as cost savings and improved patient care will only occur with broad approval in the community.

7.5 Future plans

After the testing phase further HCPs of the south eastern Lower Saxony region shall be connected to the communication infrastructure of the LSBH. Especially to resident general practitioners and medical specialists the services of the LSBH shall 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 but its realization is seen critical. After this step additional HCPs, e.g. care homes or ambulance services, shall be integrated in the network of the LSBH.

Beneath this planned increase of the number of participants additional services shall 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 provision, information concerning donation of organs, an immunization card or information of the individual’s personal fitness training. Another planned service of the LSBH is the electronic support during the appointment scheduling. This should be possible for HCPs and patients.

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