Development and evaluation of a conceptual model with an electronic medical record system for diabetes management in Sub-Saharan Africa

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Summary

Diabetes mellitus is today the cause of an important and expensive health crisis in Sub-Saharan Africa (SSA). Scientific publications and research reports of the World Health Organization (WHO) and the International Diabetes Federation (IDF) have pointed out that more than 18 million diabetes patients will live in Africa in the next 20 years. This represents an increase of diabetes prevalence of up to 80% in SSA by 2025 exceeding the worldwide forecast of 55% in the same year. For a strategic plan with regard to this health challenge, decisions makers need reliable data which are so far not easily accessible in a large part of this region. Researchers and clinicians have long recognized the important role of ehealth based solutions for a better diabetes management. Unfortunately, such solutions are not commonly used for diabetes in SSA.

To meet this challenge, a new approach for the management of diabetes in SSA was developed and validated. This approach exploits the experience of an economically viable electronic medical record system (EMRS) used for the support of human immunodeficiency virus/ acquired immune deficiency syndrome (HIV/AIDS) and multiple-drug resistance tuberculosis (MDR-TB) therapy, in accordance with the diabetes guideline recommendations of the IDF Africa.

An analysis of the situation of diabetes management in Africa was conducted and publications on computer-based diabetes management solutions were reviewed. The analyses included a need assessment conducted in SSA and a process-oriented analysis of diabetes care in SSA using the unified modelling language method. Based on these analyses, a new conceptual model making use of an economically viable EMRS as well as the pyramidal healthcare referral system common in SSA was designed and requirements for the EMRS prototype were specified. New application modules for the demonstrator build on an open source EMRS were derived, modelled, and developed applying the methodology of the three-layer graph meta model. Finally, the new approach was discussed during an international workshop in Abidjan Côte d'Ivoire (Africa) and evaluated by SSA experts.

The described conceptual model fosters a collaborative and problem-oriented approach to diabetes management processes in urban SSA. The prototype EMRS demonstrates options for the coordination of care, a patient portal, and a simulation tool for education of health professional and diabetes patients in SSA. Results of the validation workshop and experts evaluation highlighted a clear satisfaction of SSA experts and patients with the new approach.

The local efficiency and sustainability of the solution will, however, depend on training and changes in work behaviour.

Keywords:

Computerized medical record, diabetes, business process analysis and conceptual model, information management, information system, ehealth, information and communication technology, developing region, Africa

Zusammenfassung

Diabetes mellitus verursacht heutzutage wichtige und teure Gesundheitsprobleme in Subsahara-Afrika (SSA). Nach Informationen aus wissenschaftlichen Publikationen sowie Forschungsberichten der Weltgesundheitsorganisation (WHO) und der „International Diabetes Federation (IDF)“ werden mehr als 18 Millionen Diabetes-Patienten in den nächsten 20 Jahren in Afrika leben. Diese Prognose entspricht einer Steigerung der Diabetes-Prävalenz von bis zum 80% im Jahr 2025 in SSA und ist damit höher als die Prognose in der Weltbevölkerung (55%) im gleichen Jahr. Für eine strategische Planung in Hinblick auf diese Gesundheitsherausforderung brauchen Entscheidungsträger zuverlässige Daten, die zurzeit in dieser Region nicht einfach zugänglich sind. Zudem haben Forscher und Kliniker die wichtige Rolle der ehealth-basierten Lösungen für ein besseres Diabetesmanagement längst erkannt. Dennoch werden solche Lösungen für Diabetes in SSA kaum angewandt.

Um diese Herausforderung zu bewältigen, wurde eine neue Vorgehensweise für das Diabetesmanagement in SSA entwickelt und validiert. Diese Vorgehensweise nutzt, unter Betrachtung der Diabetes-Leitlinien des IDF-Afrikas, die Erfahrung einer zur Unterstützung der „Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome“ (HIV/AIDS) und multiresistente Tuberkulose (MDR-TB) Therapie eingesetzten wirtschaftlichen elektronischen Patientenakte (ePA) aus.

Eine Situationsanalyse des Diabetesmanagements in Afrika wurde durchgeführt und Publikationen über Computergestütztes Diabetesmanagement wurden studiert. Die Analyse beinhaltet eine in SSA durchgeführte Feldforschung sowie eine unter Benutzung der Unified-Modelling-Language-Methodik prozessorientierte Auswertung der Diabetes-Versorgung in SSA. Auf der Basis dieser Analyse wurde ein neues konzeptionelles Modell entwickelt. Dieses Modell integriert die Benutzung einer wirtschaftlichen ePA sowie das oft in SSA genutzte pyramidale Gesundheitssystem. Anforderungen der ePA wurden spezifiziert, neue Applikationsmodule für den auf einer open Source ePA basierten Demonstrator abgeleitet und unter Betrachtung der Drei-Ebenen-Metamodell-Methodik modelliert sowie entwickelt. Die neue Vorgehensweise wurde schließlich im Rahmen eines internationalen Workshops in Abidjan – Côte d’Ivoire (Afrika) von SSA Experten diskutiert und evaluiert.

Das beschriebene konzeptionelle Modell fördert eine kollaborative und problemorientierte Vorgehensweise für den Diabetes-Managementprozess in urbanem SSA. Der ePA-

Demonstrator beleuchtet Optionen für die Koordination der Versorgung, ein Patientenportal und ein Simulationstool für die Bildung bzw. Weiterbildung der Heilberufler und Patienten in SSA. Ergebnisse des Validierungsworkshops und Expertenevaluation haben eine deutliche Satisfaktion der SSA-Experten und der Patienten mit der neuen Vorgehensweise hervorgehoben.

Die lokale Effizienz und Nachhaltigkeit dieser Lösung hängt dennoch von der Ausbildung und Änderung in Handlungsweise ab.

Schlüsselwörter: Elektronische Patientenakte, Geschäftsprozessanalyse und Modellierung, Diabetes, Informationsmanagement, Informationssystem, eHealth, Information und Kommunikation Technologie, Entwicklungsregion, Afrika

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Contents

1. Introduction

1.1 Motivation: the ehealth-trend and the improvement of the health situation in SSA

The important role, influence, and impact of information and communication technology (ICT) in all sectors of our society have long been recognized [1-7]. In the health sector, ICT-tools are increasingly being developed, recommended, and used to improve the quality of work in administration, care delivery, health services, and research [8-10]. During the nineteen-eighties, at the inception of the use of ICT-tools in most developed countries, the use of ICT-tools were not an issue or at best a matter of low priority in less developed countries (LDC) [11]. Cost of hardware, economic constraints, limited infrastructure, and investment priorities were some of the major factors responsible for the difference. Over the years, opinions have changed and several authors, publishers and institutions like the World Health Organization (WHO) have recognized the necessity to introduce ICT-tools in the health sector of LDC and have placed great importance on it [7, 11, 12]. This use of ICT in the health sector is commonly referred to as "ehealth" (Figure 1).

The WHO defines ehealth as *the cost-effective and secure use of ICT in support of health and health-related fields including healthcare services, health surveillance, health literature, health education, knowledge and research [13]*.

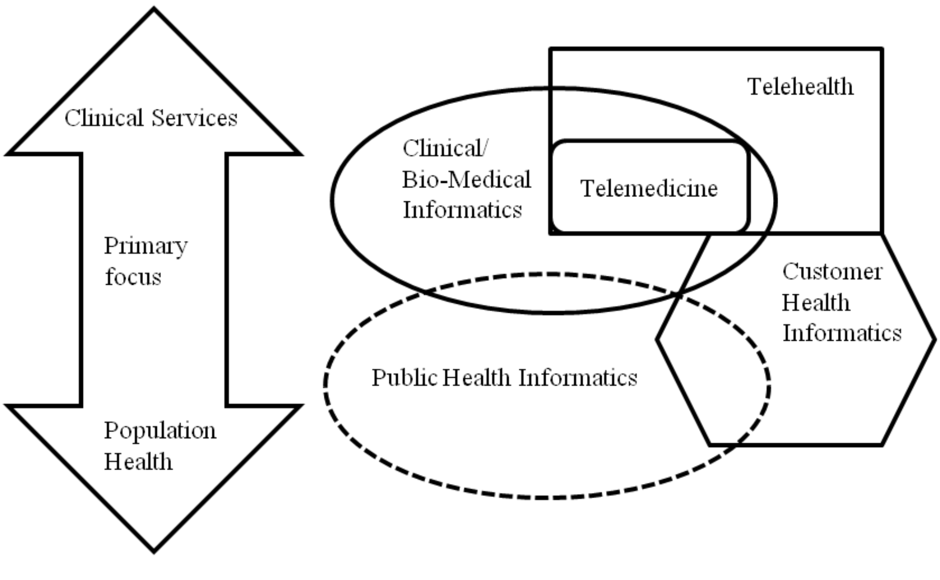


Figure 1: Areas covered by ehealth [14]

This means that ehealth-tools should be implemented and used in any health system of the world and is therefore not a luxury for countries in Sub-Saharan Africa (SSA) -i.e. countries of Africa south of the Sahara desert- but more a needed technology to improve the healthcare delivery system of each country in this region.

Telehealth is the use of electronic ICT to support long-distance clinical healthcare, patient and professional health-related education, public health and health administration [15].

Telemedicine is the delivery of healthcare services, where distance is a critical factor, by healthcare professionals using ICT for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of care-providers, all in the interest of advancing the health of individuals and their communities [16].

The ehealth-trend started thirty years ago in academic research centers with imaging application and laboratory automation and focused on health professional and diseases [17]. This approach has changed over the years and the new trends are patient-oriented and focus much more on health and the citizen – empowering him with information to maintain his health where ever he may be [17].

The WHO has published ehealth strategies with the aim of strengthening health systems in countries, support capacity building, promote the use of norms and standards, foster public-private partnership, and promote better understanding of ehealth. Tools identified as either very useful or extremely useful instruments for changing and improving the health system itself and therefore achieving these strategies include electronic health records (EHR), patient information system (PIS), hospital information system (HIS), national electronic registries, national drug registries, decision support system (DSS), geographical information system (GIS), and telemedicine, among others [18].

Some of the tools above have been successfully used in SSA. The important areas of implemented ehealth projects in SSA were: telemedicine, tele-education, DSS, electronic data exchange, electronic patient registration, EHR, electronic medical record (EMR), and medical imaging [19]. The motivation behind these projects was principally to provide a better work environment to health workers of these countries in order to contribute to the fight against the principal or most known health crisis in this region that threatens the lives of millions of people and kills most of them: human immunodeficiency virus/ acquired immune deficiency

Syndrome (HIV/AIDS), multi-drug resistant tuberculosis (MDR-TB), onchocerciasis [20], and malaria [19].

The use of telemedicine-tools where distance is a critical factor provides major improvements in care delivery. These projects mostly reduced the difficulties faced by health workers in both rural and sub-urban areas and improved treatment delivery and outcomes in these environments [21-23]. The main realizations are: north-south tele-education, web-casting of scientific conferences, south-south tele-education, south-north tele-education, north-south tele-consultation, south-south tele-consultation, and south-north tele-consultation [21].

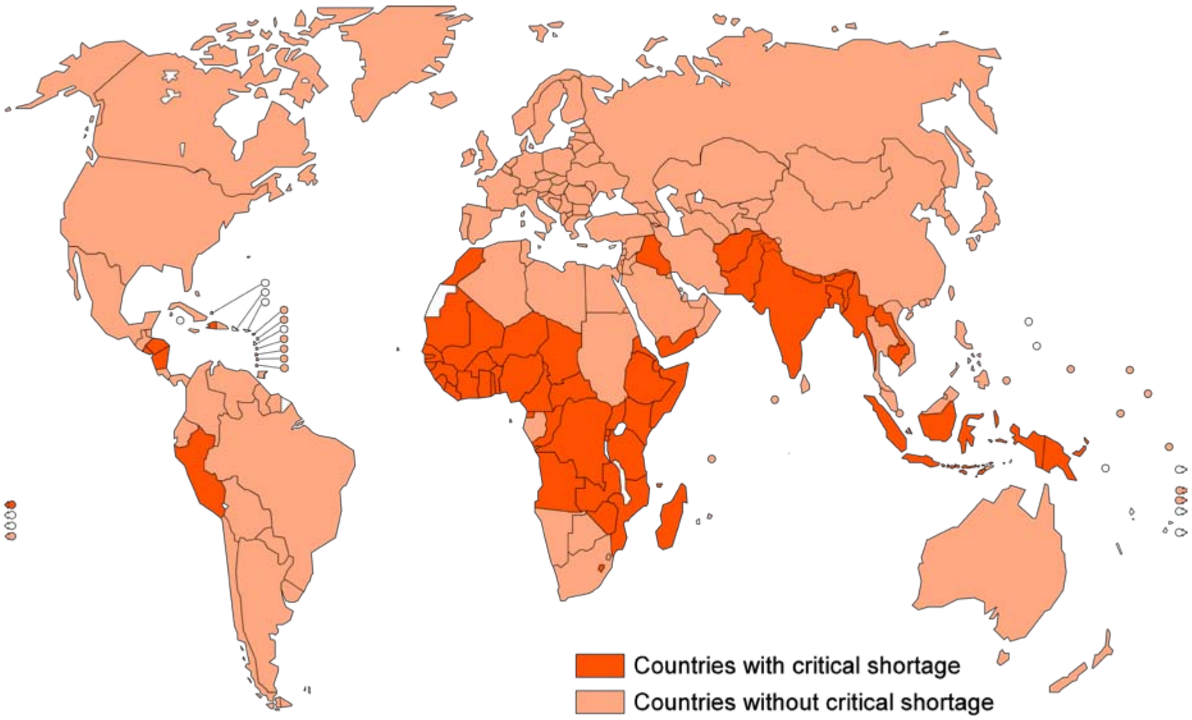
According to the implementation of EMR, major improvements have been achieved in HIV/AIDS and MDR-TB control and adherence to care as well as clinical and epidemiological research that therefore helped to cross the digital divide [24-26]. The Lilongwe Computer-based Order Entry (COE) team remarked after their implementation that COE enabled elimination of errors in medication dosage calculations by clinicians and elimination of the requirement for nurses to transcribe orders [27]. The use of personal digital assistant (PDA) (Figure 2) in Uganda, Kenya, and Ghana for the collection of health data of HIV/AIDS patients to be later synchronized with personal computer (in case of no internet connection) for data transfer and analysis bring a scientific significance in the control of these diseases [28].

Figure 2: An innovative home-care programme using hand-held computers. Ms. X, who is living with HIV and is trained as an outreach worker, interviews Mr. Y, 52, at his home in Captarit village and records his answers [28]

Other notable initiatives of WHO are: the Health Internetwork Access to Research Initiative (HINARI) that provides health professionals in SSA with free or affordable online access to top scientific journals in the health field; the health metrics network and the African health infoway which is a system to support the collection of sub national health data and statistics for analysis, dissemination and use to support decision making in health, and strengthen capacity of African countries to use information in decision making [29]. HINARI strongly contributes to help local health professionals know what they need to know for consideration in the care delivery [20].

1.2 Problem identification and Objectives

The first health report of the WHO African region published in 2006 presents an overview of major SSA health problems as well as current solutions approach. The report highlights that people living in SSA are more exposed to a heavy and wide-ranging burden of disease partly because of SSA's unique geography and climate. This explains why malaria is more intractable in SSA than in the rest of the World. Although malaria kills more, HIV/AIDS remains however the main concern for many countries in the region. This disease has killed a large proportion of the economic active population in SSA. Another infectious disease that needs to be confronted is tuberculosis which has re-emerged and being fueled by the HIV epidemic. Furthermore, diabetes and other chronic diseases (non communicable diseases) are becoming increasingly prevalent in SSA and are to date a severe burden in this region, while the complication of pregnancy and childbirth as well as child health problems takes millions of lives every year. These severe burdens of diseases with the critical shortage of care-providers (Figure 3) (4% of health workers and 25% of global burden of diseases) [30], which does not facilitate access to healthcare hamper social progress and economic development in many African countries.



Data source: World Health Organization. *Global Atlas of the Health Workforce* (http://www.who.int/globalatlas/default.asp).

Figure 3: Global Atlas of the Health Workforce [30]

The rapidly increasing number of people with diabetes worldwide is recognized as a serious, costly, but underestimated health problem [1-5]. Estimates published by the WHO and the International Diabetes Federation (IDF) shows that diabetes will affect up to 400 million people by 2030 in the world [1, 3, 6-8]. This represents an increase of approximately 55% in worldwide prevalence between 2000 and 2030. Furthermore, recent studies indicate global mortality due to diabetes being similar to that of HIV/AIDS [1, 3, 8].

The situation is alarming in low and middle income countries, particularly in East Mediterranean and SSA countries. The expected increase in prevalence of diabetes in SSA (80%) is higher than the global average (55%) [1, 3, 8]. Diabetes complications - nephropathy, retinopathy, neuropathy, stroke, and heart diseases - are also increasing. The probability of death from diabetes in SSA is higher than in developed countries [1, 3, 8, 9]. In addition to this, diabetes and other non-communicable diseases tend to affect the economically active population in SSA [9]. This means that diabetes and its complications contribute to poverty, thereby hindering the economic development of SSA [6]. A study conducted by the WHO estimated a total economic loss attributable to diabetes in the year 2000 in the African region at Int$ 25.51 billion, i.e. $3633 per patient with diabetes [10].

Int$ “International Dollars” is a unit of monetary value, similar to US$, but which takes into account purchasing power parity as well as the exchange rate between a local currency and US$

Due to a lack of reliable local data, diabetes has not been a priority for policy and decision makers of the health sector in countries of this region for a long time [1, 9, 11, 12]. In this respect, Beran and Yudkin [3] presented key areas to be addressed if diabetes is to be addressed in SSA: (1) organization of the health system, (2) prevention, (3) data collection, (4) diagnostic tools, (5) infrastructure, (6) drug procurement and supply, (7) accessibility and affordability of healthcare workers, (8) adherence issues, (9) patient education and empowerment, (10) community involvement, and (11) positive policy environment.

Many of these key areas can be improved using information technology (IT) [19, 31-35]. However, economically viable implementations of IT-systems are extremely rare in developing regions. Therefore, the proof of an economically viable solution based on an electronic medical record system (EMRS) to support tuberculosis treatment in Peru was a significant improvement [36]. A similar solution developed to support HIV/AIDS and MDR-TB is used as a model in many resource-poor regions including SSA [24, 37-40]. As diabetes shares several common factors with HIV/AIDS and MDR-TB it should be possible to develop economically viable IT-systems to support the treatment and management of diabetes in SSA following experiences with EMRS solutions in Latin America.

Firstly, this research work identified diabetes as a potential major health problem in SSA which is similar to HIV/AIDS and MDR-TB, being a business case for the use of IT-based solutions in the health system of SSA countries. Secondly, it is aimed at identifying problems encountered in the care and management of this disease. Thirdly, assess the Needs and Remedies to the situation. Fourthly, derive a conceptual model for the treatment and management of this disease in SSA with the use of a specialized economically viable EMRS, fifthly to demonstrate its functionality with a prototype, sixthly to validate the model, and lastly to address the role of health informatics programs towards a sustainable development of health informatics in SSA. To this effect, the following research questions will be answered:

- Is diabetes at the moment a health problem beside HIV/AIDS and MDR-TB which is expensive to the African health system?
- Which problems are encountered in the care and management of this disease?

- What are the Needs and Remedies to the situation?
- How could the management of this health problem be improved using an economically viable EMRS?
- What are the possible impacts of the conceptual model on the applied care environment?
- Is the conceptual model right and generalizable in SSA?
- Are the incorporated EMRS functionalities appropriate for the purpose described?
- What is the impact of the implementation of it-based solutions such as EMRS in SSA on the local education and training of health professional and computer science students?

2. Background

2.1 Diabetes

Diabetes mellitus is a disease of carbohydrate metabolism in which the individual cannot properly utilize the sugar and starch in food. If not diagnosed or not properly treated and controlled, it can lead to acute and irreversible complications such as: blindness, kidney failure, heart attack, stroke, amputation, erectile dysfunction, neuropathy, nerve damage [41].

There are three main types of diabetes – type 1 diabetes, type 2 diabetes, and gestational diabetes. In addition to these, there are other specific types of diabetes, which are less common and involve genetic disorders, infections, and diseases of the exocrine pancreas, endocrinopathies or as a result of drugs [42].

Type 1 diabetes is an autoimmune disease characterized by the destruction of the insulin-producing beta cells in the islets of the pancreas. Type 1 diabetes patients are mostly young people and children who require insulin for survival.

Type 2 diabetes is characterized by insulin resistance and relative insulin deficiency. This type of diabetes is mostly known as a life style disease and it also has a genetic component. It is the most rampant diabetes type in the world. Due to the insidious nature of the disease, it is often diagnosed with features of diabetes complications.

Gestational diabetes is carbohydrate intolerance of variable severity which appears, recognized or diagnosed for the first time in pregnancy. If not treated or poorly controlled, it can lead to an increased prenatal mortality and maternal complications at birth and therefore, lead to a poor pregnancy outcome.

Diabetes patients generally require detailed dietary advice and self care education tailored specially to their type of diabetes and their personal circumstances. The level of care to provide requires a multidisciplinary approach comprising medical, nursing, dietetic and podiatric staffs that have specific training in diabetes management and self care education. This level of care in many SSA countries is provided almost exclusively on an outpatient ambulatory care basis thus saving costly inpatient services [41].

Tertiary prevention refers to the prevention or management of diabetes complications. The presence of co-morbidities adds significantly the complexity of diabetes management and requires care by health professionals with specialized training and access to the necessary equipment and supplies. This level of care in SSA is only available in some referral hospital of the tertiary level of the local care structure.

2.2 Information and communication technology use in SSA: overview

The International Communication Union (ITU) began the publication of information on the penetration of ICT in SSA in 1990. Data from this institution shows that SSA ICT penetration rates were insignificant in 1990 and the environment was not ready for networked solutions [43]. Since 2000 ICT use in SSA has been increasing permanently and SSA is in terms of ICT growth one of the most dynamic regions in the World (Figure 4).

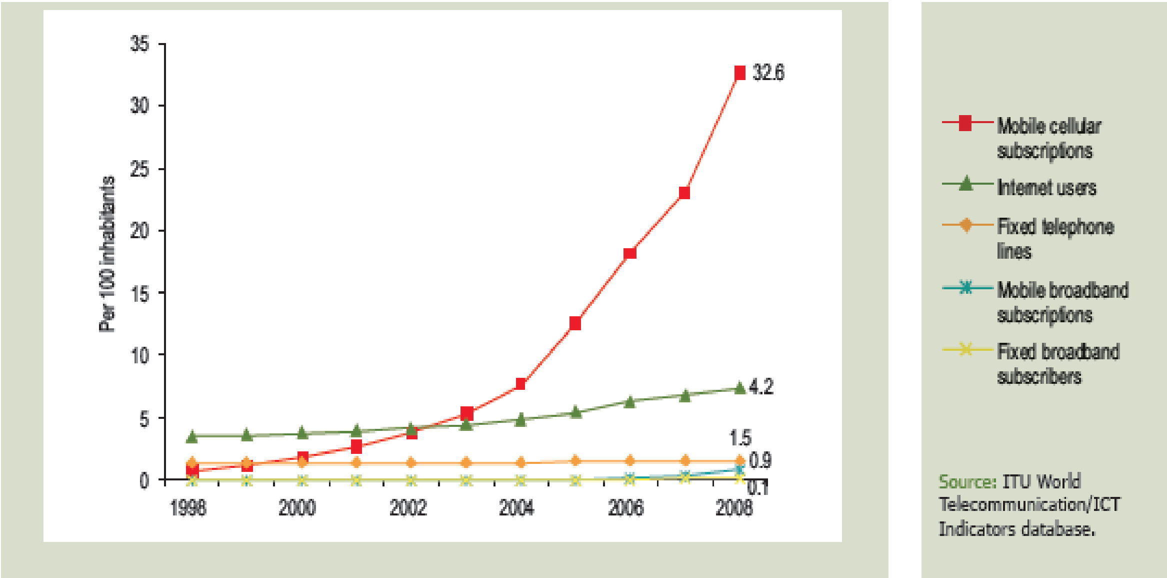


Figure 4: ICT development in Africa – penetration rate between 1998 and 2008 [44]

A substantial increase in the rate of expansion and modernization of fixed networks is observed, along with an explosion of mobile networks that provided in the last years more connectivity to rural localities in SSA (Figure 5) [43-45]. According to ITU data, over 40 percent of rural inhabitants in SSA were covered by a mobile signal in 2006 [45].

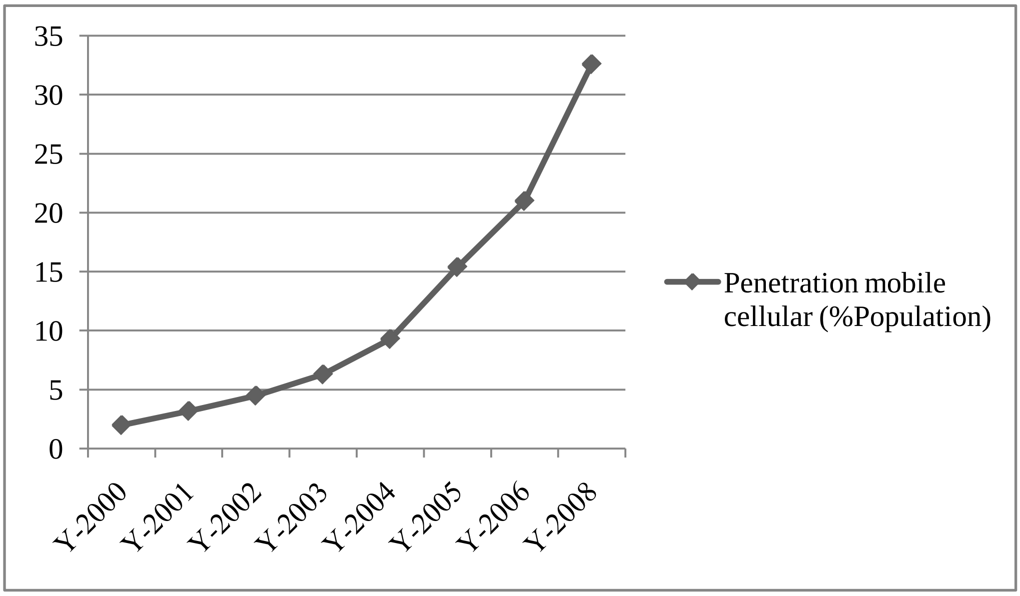


Figure 5: Mobile cellular penetration rate in Africa between 2000 and 2008 [44]

The increase of internet availability is also remarkable across SSA. Latest data shows that all the countries are connected to the internet with a local population penetration of 8.7 % that represents 4.8 % of users in the World (Figure 6) [46]. It is also important to point out that the total internet user growth in Africa between 2000 and 2009 is 1,809.8 % and is more than four times that of the World (399.3 %). More than half of the available lines are however located in the capital and large cities [47, 48].

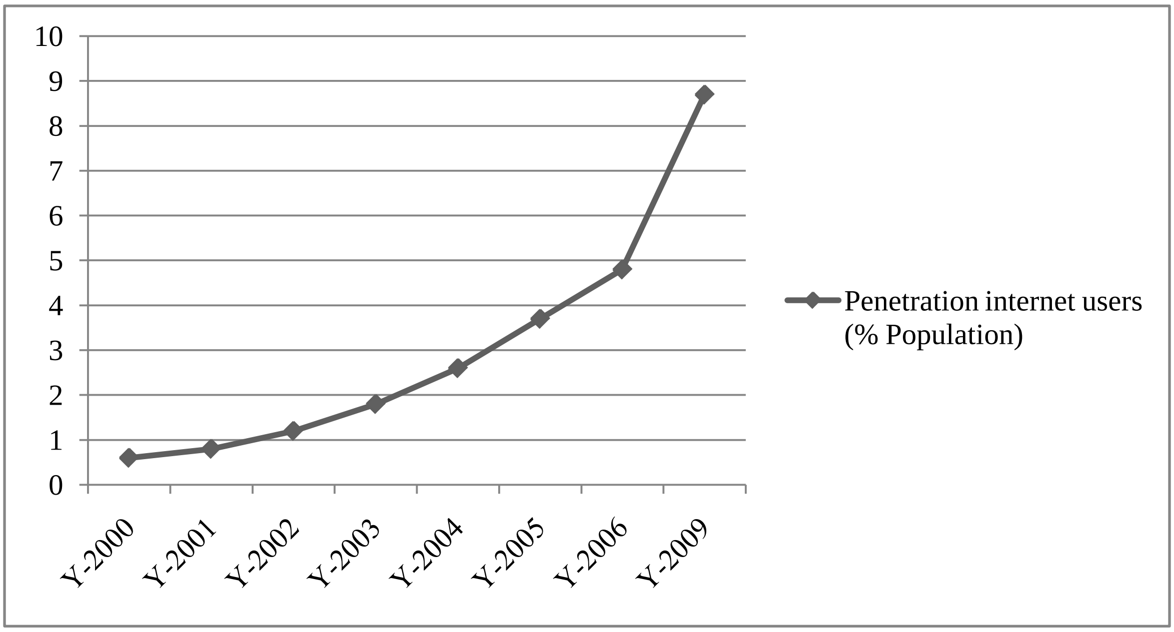


Figure 6: Internet users penetration in Africa between 2000 and 2009 [44]

Despite this positive data, electricity availability still remains low in SSA rural localities (about ten percent in rural household). The availability of internet and computers in rural localities is negligible [45] and represent a digital divide between rural and urban SSA [48]. To face this situation in rural areas, international partners and local governments have initiated projects to foster greater access to ICT. The development of e-government and digital villages in SSA provide rural inhabitants with electronic access to government services. This base can be used to extend other services in the rural localities. Although Africa has made impressive gains, it remains far behind the ICT penetration levels of the World and even those of developing countries (Figure 7) [43, 44].

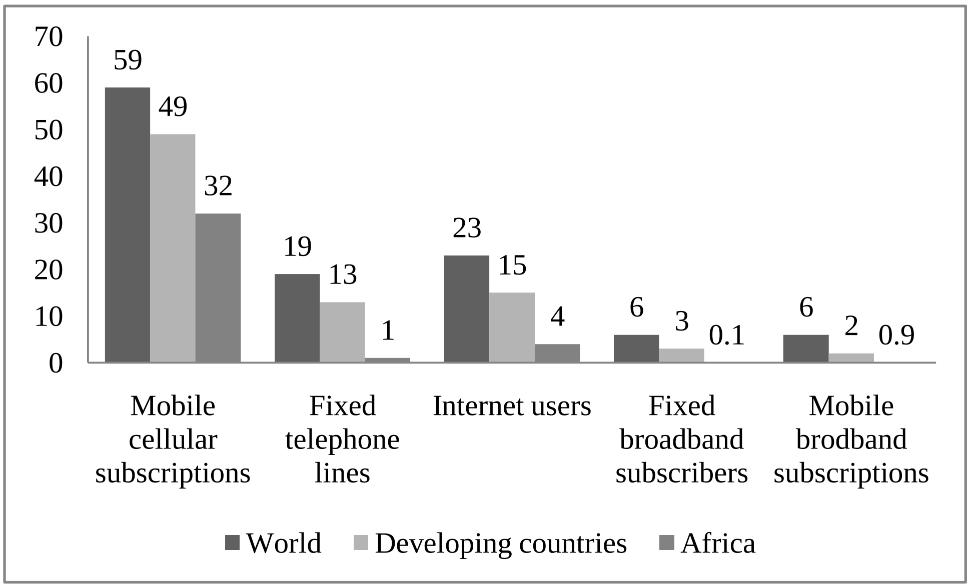


Figure 7: ICT uptake in Africa, developing countries, and the World, 2008 [44]

2.3 Electronic medical record system: overview

Five centuries before Christ, medical records were influenced by Hippocrates who advocated two main goals: it should accurately reflect the course of disease, and it should indicate the possible cause of disease. An example of medical records described by Hippocrates shows that he recorded his information in a purely chronological order [49]. This corresponds to a time-oriented medical record. From the time-oriented medical record, further medical records orientations were developed including: the patient-centered medical record and the problem-oriented medical record both first introduced by Florence Nightingale in 1850 and Larry Weed in 1960 respectively.

The increasing demand for well-structured and easily accessible patient data and the development in computer sciences sparked a great interest in the development of electronic or computer-based patient record [49]. The first virtual records in medicine began to emerge in the 1970’s. Among them the Problem Oriented Medical Information System (PROMIS), the Computer Stored Ambulatory Record (COSTAR), and the Regenstrief Medical Record System (RMIS) [50, 51]. These first systems were focused on capturing patient data, retrieving patient data, and supporting business and administrative functions [51] which have proven to improve the quality of care by helping care-providers consistently apply medical knowledge at the point of care [52]. Since 1990’s new acronyms of virtual medical records are interchangeably used in research, business, and political areas, among them: EHR, EMR, and personal health record (PHR) [50, 51, 53, 54]. While these three terms are strongly interchangeably used, some authors pointed out differences that need to be considered in the concept of each term [53, 55]

EMR is an electronic healthcare information system regarding one patient within a healthcare enterprise [55, 56].

A healthcare enterprise may be a health center (HC), a district hospital (DH), a reference hospital (RH) or other healthcare settings. A pre-requisite to the EMR is to create interoperability among all systems of the enterprise by harmonizing incompatible or disparate systems into a comprehensive EMR that includes all documentation of care given to a specific patient within the enterprise [53].

EHR is an electronic health information system belonging to an individual that reflects the entire health history of the individual across his or her lifetime and not limited to a specific healthcare enterprise [53-55].

The information is entered, accessed, and managed by care-providers at the point of care.

PHR is a health information system belonging to an individual and managed by him or her. It includes health information entered directly by the individual and/or other (with individual permission), automatically from outside sources [52, 53].

The outside sources may include hospital EMR or EHR, commercial pharmacies and laboratories, and even machines in a health club linked to record information at the time of specific exercises. PHR brings more patient empowerment in the healthcare information management [52].

2.4 The Three-layer Graph-based Meta Model

The Three-layer Graph-based Meta Model ($3LGM^2$) is a meta model for modeling information systems. $3LGM^2$ defines ontology to describe the static and dynamic architecture of HIS. It had been primarily designed to support information managers in enterprise architecture planning and monitoring, quality assessment of information processing in hospitals, and the systematic management of health information systems [57, 58]. It combines a functional meta model with technical meta model and is represented in unified modeling language (UML) notation. $3LGM^2$ distinguishes three layers of information systems.

- A domain layer
- A logical or application layer
- A physical layer

These layers provide a framework for describing on the one hand information processes at the domain layer and communication paths between application components at the logical layer as well as inter-layer relationships to build integrated models of information system on the other. These $3LGM^2$ concepts may be formalized using algebraic structures that are relevant for their definition and the mapping of information processes to communication paths [59].

An appropriate $3LGM^2$ tool had been developed on the ontological basis of the meta model $3LGM^2$ to assist information managers in creating $3LGM^2$ models similarly as computer aided design tools support architects. The tool provides a graphical representation of the most important concepts of $3LGM^2$, ensures that only the $3LGM^2$ concepts can be modeled and that only those association can be specified which are defined by the $3LGM^2$, displays the three layers of a HIS model separately but also can be represented in a multi-layer view together with the inter-layer relationships, helps to manage even large models by supporting sub-models for various views, provides means for analyzing a completed model, and provides means for documenting all needed properties of functions, entity types, application components, and physical data processing components [60].

2.4.1 Domain layer

The domain layer is focused on enterprise functions that have to be performed in order to accomplish the required aims of the information system. To accomplish an aim, each enterprise function needs to interpret or update specific information of a certain type about physical or virtual entities of the healthcare facility. These types of information are represented as entity types. An example of an instance of the domain layer is shown in the result section. The dynamic aspect of the domain layer is described through information processes. An information process in $3LGM^2$ is defined as a sequence of enterprise functions using and/or updating information about entity types.

The formal description of the relationship between enterprise functions and entity types as well as of an information process using algebraic structure is as follow [59, 61]:

Let $\underline{EF} := \{ef_1, \ldots, ef_P\}$ *be a set of enterprise functions* $P > 0$, $\underline{ET} := \{et_1, \ldots, et_Q\}$ *be a set of entity types* $Q > 0$, *and* $ACC := (acc_{p,q})_{p = 1 \ldots P,\, q = 1 \ldots Q}$ *be a two-dimensional matrix describing how enterprise functions access entity types.*

It shall hold that $acc_{p,q} \in \{0, i, u, iu\}$ *and* $acc_{p,q} := 0$ *if enterprise function* ef_P *neither interprets nor updates entity type* et_Q, $acc_{p,q} := i$ *if enterprise function* ef_P *interprets entity type* et_Q, $acc_{p,q} := u$ *if enterprise function* ef_P *updates entity type* et_Q, *and* $acc_{p,q} := iu$ *if enterprise function* ef_P *interprets and updates entity type* et_Q.

A tuple $(ef_1, \ldots, ef_p)$, $ef_i \in \underline{EF}$ *defined below is called* $3LGM^2$ *information process if, and only if* $ef_i, i = 1 \,..\, p\text{-}1: \quad (ef_i, et', u), (ef_j, et'', i) \quad ACC: et' = et''$.

Example

Given

$\underline{EF}$:= {patient admission, order entry, creation and dispatch of results, receipt and presentation of results}, $\underline{ET}$:= {order, result, patient, case}, ACC := {(order entry, order, u), (creation and dispatch of results, order, i), (creation and dispatch of results, result, u), (receipt and presentation of results, result, i)}

The tuple IP := (order entry, creation and dispatch of results, receipt and presentation of results) is a $3LGM^2$ information process.

2.4.2 Logical layer

The logical layer describes the application components that support enterprise functions of the domain layer. Application components in 3LGM[2] may be paper-based or computer-based. Paper-based application components are implementations of an organizational plan that describes how people use paper-based data processing. These components may file their documents in a document collection. Computer-based application components are controlled by application programs, which are adapted software products. These components may have a local database system to store data. Communication interfaces ensure the communication among component interfaces and communication links can be defined as relation between application components. An elementary communication path defined as a sequence of communication links between application components, necessary to satisfy the information needs given by an information process [59]. Therefore application components are responsible for the processing, storage, and transportation of data representing entity types in document collections respectively database systems. This is possible using the inter-layer relationship that will be explained later on. An example of an instance of the logical layer is shown in the result section.

The formal description of the relationship between enterprise functions and application components, entity types and application components, and between applications components using algebraic structure is as follow [59, 61]:

Let $\underline{EF} := \{ef_1, \ldots, ef_P\}$ *be a set of enterprise functions* $P > 0$, $\underline{AC} := \{ac_1, \ldots, ac_N\}$ *be a set of application components* $N > 0$.

The relationship between enterprise functions and application components is defined as *a two-dimensional matrix* $SUP := (sup_{p,n})_{p=1 \ldots P, n=1 \ldots N}$ *with* $sup_{p,n} \in \{0, 1\}$ *such that*

$sup_{p,n} := 1$ *if the function* ef_p *is supported by the application component, and*

$sup_{p,n} := 0$ *else.*

Formal description of an elementary communication path:

Let $\underline{AC}$ *be a set of application components,* $\underline{CI}$ *a set of components interface,* $\underline{CL}$ *a set of communication links, and owns a function that denotes the application component, which owns a certain component interface.*

A tuple $(Cl_1, .. , cl_n)$, $cl_i = (ci_1^{cli}, ci_2^{cli}, \{et_1^{cli}, …, et_n^{cli}\}) \in \underline{CL}$, $i := 1..n$; $n, m \in IN$ *is called elementary communication path if and only if*

$cl_j, cl_{j+1} \in CL, j := 1..(n-1) : owns(ci_2^{clj}) = owns(ci_1^{clj+1})$ [59]

The description expresses that for each pair of communication links cl_j, cl_{j+1} where cl_{j+1} is the direct successor of cl_j, the receiver of cl_j must be owned by the same application component as the sender of cl_{j+1}. This condition ensures the inner connectivity of the communication path which is guaranteed by the application components. The communication matrix that describes the communication among application components may be defined as follow:

Let $\underline{ET} := \{et_1, …, et_Q\}$ *be a set of entity types* $Q > 0$. *For each entity type* $et_q \in \underline{ET}$,

let $R_q := (r^q_{n,m})_{n=1..N, m=1..N}$ *be a communication matrix for* et_q *such that*

$r^q_{n,m} := 1$ *if* ac_n *can send data representing information about* et_q *to* ac_m, *and*

$r^q_{n,m} := 0$ *else.*

Each communication matrix R_q is an adjacency matrix of a directed, labeled graph of application components and communication links being able to exchange data about et_q.

The formal representation of the data storage may be described as follow:

Let $STORE := (store_{q,n})_{q=1..Q, n=1..N}$, *be a data storage matrix,* $store_{q,n} \in \{0, s, m\}$ *such that for data concerning entity type* et_q *and an application component* ac_n

$store_{q,n} := 0$ *if the data is not stored in* ac_n,

$store_{q,n} := s$ *if the data is stored in can, and*

$store_{q,n} := m$ *if* ac_n *is master for* et_q.

A master application component is defined to better manage the redundant storage of data. If the application component ac_n is master for the entity type et_q, then only ac_n can create or update data of et_q, and, therefore, in case of redundant data storage, contains the current data.

2.4.3 Physical layer

The physical tool layer describes physical data processing components that are needed to operate the application components described on the logical layer. These components can be human actors (such as care-providers, hospital managers), paper-based physical tools (such as paper-based patient records, books), or computer systems (such as personal computers, servers) which can be physically connected via data transmission connections (e.g. data wires). An exemplary instance of this layer is illustrated in the result section.

2.4.4 Inter-layer relationships

A particularity of $3LGM^2$ is it capability to describe and graphically illustrate the dependencies or relationship between concepts and components of the domain layer and logical layer as well as between concepts and components of the logical layer and physical layer.

Among elements of the domain layer and the logical layer, the inter-layer relationships describe which application components are needed to perform what function, and which database systems respectively document collections store what entity types [58]. The matrix SUP and STORE described above (sub-section 2.4.2) highlight the formal representation of the inter-layer relationship.

There is a relationship between application components of the logical layer and physical data processing components of the physical layer that is represented by the data processing component configuration [58]. A data processing component configuration contains all physical data processing components which are needed in collaboration with each other to install an application component completely [60].

2.5 Security Assertion Markup Language

The Security Assertion Markup Language (SAML) is an Extensible Markup Language (XML) based framework, developed by the security services technical committee of the Organization for the Advancement of Structured Information Standards (OASIS), for communicating user authentication, entitlement, and attribute information. Major drivers behind the adoption of SAML standard include: multi-domain web single-sign on (SSO), federated identity, and web-services [62].

The past versions v1.x have been used or adapted by other standards and initiatives such as the liberty alliance, the internet2 shibboleth project, and the OASIS web services (WS) security. The current version v2.0 allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner institution within a care network or another enterprise application. The development of this version built on the success of the past versions and on functionality found in the liberty alliance and shibboleth [62-64].

Beside the improvement of the traditional SSO capability of the SAML versions v1.x, SAML v2.0 includes features for session management, pseudonym and encryption purpose, and support for mobile devices. The basic components of SAML (Figure 8) that permit to transfer identity, authentication, attribute, and authorization information between autonomous organizations that have an established trust relationship include [63]:

- Assertions

  An assertion is a package of information that supplies one or more statements made by a SAML authority. SAML authority can create three different kinds of assertion statements: authentications, attributes, and authorization decisions.

- Protocols

  Protocols are generalized frameworks that allow SAML participants to communicate (request/response message).

- Bindings

  Bindings are mapping from SAML request-response message exchanges into standard messaging or communication protocols.

- Profiles

  SAML profiles define constraints and/or extensions in support of the usage of SAML assertions, protocols, and bindings for a particular application, the goal being to enhance interoperability in the implementation of the application.

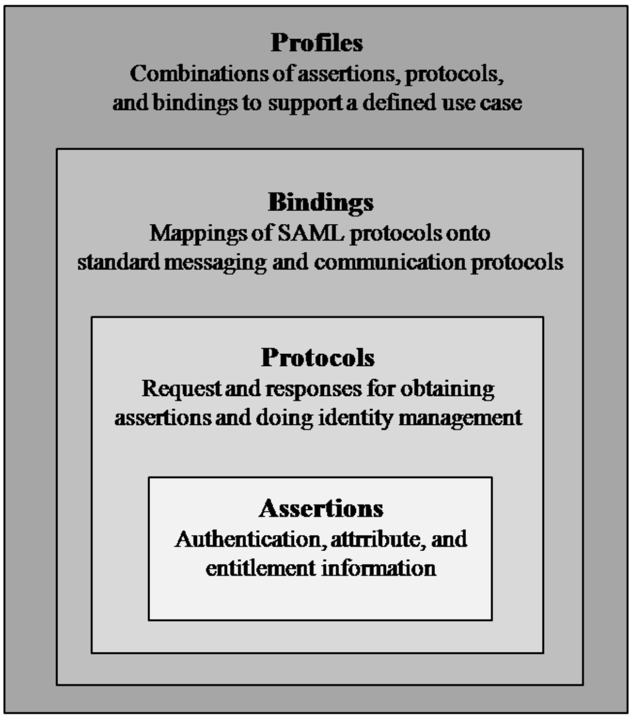


Figure 8: Basic SAML components and their relationship [63]

The most important use case for which SAML standard is applied is the SSO. This use case allows a user after one authentication to get access to local applications and applications located by partner institutions. SSO describes a typical federated identity management model in which users of member institutions of a care network can authenticate locally but globally act within the defined federation depending on their role.

A user is said to have federated identity when partners have establish an agreement on a common, shared name identifier to refer to the user in order to share information about the user across the organizational boundaries [63].

To support SSO, SAML defines the roles of identity provider (IdP) and service provider (SP).

The IdP is responsible for: managing users and their identities, issuing credentials (user name and password), handling user administration, authenticating the user, and vouching for the user's identity with the SP [63].

The SP is responsible for: controlling access to services, validating the asserted identity information from the IdP, providing access based on asserted identity, and managing only locally relevant user attributes, not an entire user profile [63].

SSO increases security by eliminating multiple credentials and reduces the phishing opportunity by eliminating the number of times a user has to log-in for using different services. It also simplifies and reduces the cost of the implementation of the collaboration between different trusted organizations.

The use of SSO therefore presents the risk of overworked care-providers, to forget the termination of some opened sessions. The SAML profile for single logout (SLO) that allows a global termination of opened sessions from a unique browser can be applied to solve this problem [63]. SAML 2.0 SLO was inherited from the liberty alliance's identity federation framework.

3. Methods

3.1 Literature analysis

The first part of the literature search performed focused on health problems encountered in SSA. The main inclusion criteria for this part were documents describing health problems that contribute to the hinderance of the economic development of this region and/or which are recognized as severe by local governments and international funding agencies. Having identified diabetes as the health problem to be addressed in this thesis, a literature search focusing on options for ICT in diabetes care in SSA was performed in November 2006 and progressively updated. Medline and Google scholar were used. WHOLIS and Google were used for the search of non-peer-reviewed articles. The following medical subject headings (MeSH) were used during the search: diabetes, register, prevalence, insulin, blood glucose, management, computerized patient record, Africa, developing countries. These terms were combined as follows: diabetes management Africa, diabetes prevalence Africa, diabetes prevalence in developing countries, blood glucose management Africa, insulin management Africa, diabetes register Africa, computerized patient record and diabetes in Africa, computerized patient record and diabetes, and information technology and diabetes. Inclusion criteria for the literature search were: English and French reviews or articles highlighting the situation in SSA. Letters were excluded. For the part focusing on the use of ICT in diabetes, the inclusion criteria were: articles describing the development and implementation of a diabetes information system preferably in resource-poor areas, articles highlighting the role and impact of ICT in diabetes care and management. Exclusion criteria were: experiences not adaptable to resource-poor areas, letters, and editorials. Experiences considered inadaptable to resource-poor areas refer to solutions not economically viable. Open-sources based solutions that have been successfully used and evaluated in resource-poor regions and are being used by local stakeholders are preferred. To be efficient, review articles were first analyzed and were sometimes helpful to determine further search combinations. Abstracts were used to select pertinent papers and their references were used to identify additional papers. Furthermore, relevant literature addressing EMRS experiences with HIV/AIDS and MDR-TB in SSA were taken into account.

3.2 Need assessment

Taking into account the results of the literature search on the use of IT-systems in diabetes care in SSA, it became obvious that a field survey had to be conducted. The survey should examine local requirements and the importance local experts and decision makers attribute to the role of EMRS/EHR in diabetes care and management. It should also facilitate the involvement of local experts and decision makers in the solution development process. The unstructured interview survey method was adopted because of its flexibility and the possibility to gain more information from interviewees. Also it is easier in SSA to gain information through interviews than via questionnaires because of the high role of oral communication within the cultural behavior of people in SSA. To prepare the survey, discussion topics were selected, profiles of individuals to be interviewed (Table I) were set up, and potential participants were identified through an internet search of relevant institutions and persons as well as author’s and main supervisor’s networks. In addition the main criteria for the selection of individuals to be interviewed were: work experience (ideally at least five years) and/or a leadership position for at least one year in an institution which deals with the discussion topic. To facilitate interview guidance and analysis, different aide memoires were arranged depending on each profile (Table I). However, the interview method based on open topics provides the possibility to address topics which are not on the aide memoire depending on the kind of discussion.

Experts, decision and policy makers from Mali, Senegal, and Cameroon were identified, formally contacted, and meetings were organized. More experts from other African countries (Burkina Faso, Congo Democratic Republic, Ghana, Niger, Nigeria, and South-Africa), as well as from developed countries (France, Switzerland, United States of America (USA)) with experiences in developing regions were targeted and interviewed during international and national conferences and workshops. These included: the Health Informatics in Africa Conference 2007 (HELINA 2007) in Bamako (Mali), the 2007 implementers meeting of the Open Medical Record System (OpenMRS) in Cape Town (South Africa), the expert ehealth workshop - addressing strategies for strengthening capacities in the collaborative production of online medical contents with a special focus on diabetes in SSA, and the Cameroonian Medical Informatics Conference 2007 in Yaoundé (Cameroon).

Table I: Topics discussed in the needs analysis depending on interviewees backgrounds

Legend: (1): health problems (2): challenges in care delivery (3): disease management (4): role of IT-based solutions (5): introduction of health informatics (6): sustainability of projects (7): impact of the computerization on the health system and curricula

CIO: chief information officer HC: health Center

MoH: ministry of health MoT: ministry of telecommunication

Profile/position/work area	**Topics**						
	(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**
Physician working with diabetes patients	X	X	X	X		X	
Nurse working with diabetes patients	X	X	X	X		X	
Hospital or HC manager		X	X	X	X	X	
Researcher/lecturer (medicine, informatics)	X			X	X	X	X
Decision maker (MoH)	X	X	X	X	X	X	X
CIO (MoH)	X	X	X	X	X	X	X
CIO (MoT)				X		X	
Health minister	X	X	X	X	X	X	X
Head of department or dean of faculty				X	X	X	X
Leadership position in health or ehealth organization	X	X	X	X	X	X	X

Totally, 44 persons (5 females and 39 males) were interviewed (with some occupying double functions: 4 nurses, 15 physicians, 5 CIO from the MoH and from the MoT, 10 researchers/lecturers, 2 health ministers, 4 decision makers from MoH, 5 hospital/HC managers, 7 heads of departments or deans of faculties, 7 leaders of health or ehealth nongovernmental organizations). Interviews were digitally recorded, when possible, or notes were taken by the co-facilitator and in this case a consensual summary was made directly after the interview. Absolute confidentiality and privacy of interviewees were guaranteed to acquire valid answers. The interview data were manually analyzed using a thematic analysis approach [65]. Interview data were segmented, coded, and assigned to the main interview topics presented in Table I.

3.3 Business process analysis of the diabetes care in SSA

The business process analysis of the current diabetes care in SSA is a pre-requisite to the development of the new conceptual model. This analysis helps to better understand, evaluate, and suggest potential improvements of the current diabetes care state by answering questions such as [66]:

- Which activities are executed with regards to the diabetes care in SSA?
- Who is responsible and which tools are used in given diabetes care process?
- Which activity is the pre- or post-condition for a given activity?
- What are the weak-points of the diabetes care process that need to be improved?
- How can these weak-points be improved?

To perform the analysis, business process meta-models that focus on a dynamic view of information processing during diabetes care in SSA are designed. The elements used are activities and their chronological and logical order. Different perspectives are distinguished during the analysis [66]:

- Functional perspective: what activities are being performed during the diabetes care in SSA and which data flows are needed to link these activities?
- Behavioral perspective: when are the activities being performed during the diabetes care in SSA, and how are they performed?
- Organizational perspective: where and by whom are activities being performed during the diabetes care in SSA?

- Informational perspective: which entity types or entities (e.g. documents, data, and products) are being produced or manipulated during the diabetes care in SSA?

This analysis is performed based on a model designed using activity diagrams with the modeling technique of the UML of the Object Management Group. The sequence of processing diabetes care in SSA using activities, branching, conditions, and entities are described. The diagram descriptions are based on the literature review, the need assessment including the diabetes strategy for Africa from the African region of the IDF and WHO. The process analysis led to the identification of common critical issues and needs for improvement of diabetes care and management to SSA countries. Then a list of processes to be improved was derived and improvement elements specified.

3.4 Conceptual model and development of a prototype

Based on the list of processes to be improved, a conceptual model was designed using an EMRS as instrument to support the improvement of the diabetes challenges in SSA. In the next step, the main functionality-requirements for the EMRS inferred from the conceptual model were compared to existing functionalities of the open source platform OpenMRS, which had been successfully used in resources-poor regions [24, 37, 38, 40]. After that a functional and technical design of a prototype solution was derived, modeled applying the $3LGM^2$ methodology for modeling of HIS [57, 60], and developed. A demonstrator was implemented at the Department of Medical Informatics of the University Medical Center of Goettingen to serve for validation purposes. This demonstrator also includes a simulation tool based on the Lehmann/Deutsch simulation model used by the AIDA freeware educational simulator program of glucose-insulin interaction and insulin dosage and dietary adjustment in diabetes mellitus [67-69]. The diabetes-team of the Department of Gastroenterology and Endocrinology of the University Medical Center of Goettingen provided twenty anonymized patient records which facilitated the functional test of the demonstrator as well as the demonstration of the medical functionality of the prototype before, during and after its validation in Abidjan 2009 (Côte d'Ivoire).

3.5 Validation of approach

The validation workshop took place on April 17th 2009 in Abidjan Côte d'Ivoire, during the 6th Health Informatics in Africa Conference - HELINA 2009 -. Twenty-two persons attended the workshop. Their profiles were: patients (members of a local diabetics association), nurses, medical doctors (clinicians, researchers, lecturers, and public health experts), sociologist, and medical students. The main questions were: is the concept right and generalizable in SSA? Are the incorporated OpenMRS functionalities appropriate for the purpose described?

Seven senior experts from Côte d'Ivoire, Senegal, Switzerland, and USA representing different end user groups evaluated the conceptual model realized in the OpenMRS environment: 2 health informatics experts, 3 clinicians, 1 public health expert, and 1 patient representative. The two health informatics experts from Switzerland and USA have many years of experiences in ICT-based solutions in SSA and currently supervising ehealth research projects in SSA. These two experts were important for an assessment with regard to the state of the art in general. The clinicians from Côte d'Ivoire represent the primary, secondary, and tertiary level of the pyramidal healthcare structure. The patient representative is president of a diabetes patients' association in Côte d'Ivoire. Each expert received:

- A summary of the conceptual model and its graphical representation.
- A detailed oral presentation of the conceptual model.
- A live demonstration of the OpenMRS functionalities based on a diabetes management scenario.
- A user-id and password to access the system currently in test at the Department of Medical Informatics of the University Medical Center of Goettingen in Germany.
- Some relevant screenshots of the OpenMRS use for diabetes.
- Questionnaires for evaluation of the proposed conceptual model for the diabetes management in SSA (Appendix-Table I), and for evaluating the OpenMRS prototype used for visualizing the conceptual model (Appendix-Table II).

4. Results

4.1 Literature analysis

4.1.1 Diabetes as an expensive health problem in SSA

The literature analysis presented in the motivation session shows that diabetes is a worldwide health problem that threatens the live of millions of people. The increase of diabetes prevalence and its complications in SSA is one of the most important health issues worldwide [8, 70]. The impact of this health problem on the SSA economic development has rarely been evaluated. Some authors who however began performing such studies in SSA came to the conclusion that diabetes is a fatal disease for African countries [71]. Following analysis made by Chale et al., subsequent analysis have also pointed out that diabetes and its complications is one of the major threats to the economic development of SSA which is likely to take a devastating human, social, and financial toll in Africa [10, 22, 41, 72]. An estimate of the direct cost of childhood diabetes in Sudan showed that families pay a considerable part of their income to sponsor the health of their diabetic children and receive little support other than that from relatives and friends [72].

A recent broader analysis focused on the economic burden of diabetes in the WHO African region provides an actual view of the situation in SSA [10]. This analysis employs the cost-of-illness approach which is based on the estimate of direct costs, indirect costs, and intangible costs. The direct costs include the health system costs such as diagnostic test, medicines, device for injecting insulin, and hotel costs. The indirect costs results from productivity losses due to patient disability and premature mortality, time spent by family members accompanying patients when seeking care. Intangible costs refer to psychological and physical incapability of the family. Therefore the total cost (TC) to be estimated can be expressed as

$TC = DC + IC + ITC$, where DC is direct cost, IC is indirect cost, and ITC is intangible cost.

Estimate of this study shows that the 7.02 million cases of diabetes recorded by countries of the WHO African region in 2000 resulted in a total economic loss of Int$25.51 billion. This loss means $3633 per patient with diabetes. In this analysis, due to lack of information on diabetes complications, the authors were not able to directly estimate the economic loss of diabetes complications in this region. They therefore agreed that by disregarding these important factors their estimate will only reflect a part of the economic burden of diabetes in the WHO African region. Knowing that diabetes complications are mostly costly chronic diseases - nephropathy, retinopathy, neuropathy, stroke, and heart diseases -, it is clear that the economic burden of diabetes presented here will be considerably different, if the treatment costs of these complications are included.

4.1.2 Option for IT support of the diabetes management

This part of the literature search highlighted the absence of any relevant information describing the use of ICT-based solutions in diabetes care in SSA. However, when not limited to SSA, results of this part showed that the complexity in diabetes care delivery and management can ideally be supported and enhanced using IT [73-78]. Electronic registers, EMR, laboratory result ordering and reporting, clinical decision support systems (CDSS), automated phone systems, electronic diary tools, electronic glucometers, and other telemedicine tools have demonstrated significant improvement potentials for diabetes care and management [32, 33, 74, 75, 79-82]. These tools have been used to improve the process of care [83] and to prevent development of diabetes complications [73], to enhance subjects' knowledge of diabetes [78], to improve the accuracy of clinicians' blood glucose prediction [84] as well as the generation and transmission time for an expert opinion [85], to prevent or delay development of diabetes complications [2, 74, 81], to generate cost-saving [74] and an objective measure of the completeness/currency of diabetic clinical management information [86], to enable remote monitoring and efficiency of communication [33, 79, 80, 82, 87], to reduce foot amputations, to improve physician performance and quality of diabetes care [32, 73], and to serve for modifying ordering behavior [83] as well as for epidemiological purposes [1, 88]. Electronic registers and EMR, for example, help to track and manage patients and their diabetes-specific information, to support diabetes surveillance and evaluation [2, 3, 73], to provide and monitor comprehensive and structured care [33], to ameliorate HbA1c, blood glucose level, and low density lipoprotein cholesterol level (LDL-cholesterol) [2, 89]. Furthermore, they are important in the organization structure for integrated care and its coordination [32, 73, 74, 88], and are used for increasing adherence to standards of care by prospectively tracking patients requiring assessments and/or treatment modifications [90]. The uses of CDSS and laboratory result ordering and reporting with EMR help to eradicate delays in medical intervention [74] and loss of laboratory data [33]. They further help to track potential errors and also to generate alerts about them [87]. However, none of these possibilities are currently implemented in SSA.

4.1.3 EMRS used in SSA

The development or adaption of EMRS solution in SSA is no more a luxury today. Many SSA countries have experienced the use of EMRS in care delivery. As mentioned before, the terms EMRS is mostly interchangeably used with other acronyms (EHR, EPR, PHR, etc) [53]. Therefore this sub-section highlights major EMRS projects related to the different acronyms used in this area in SSA.

Mosoriot Medical Record System (MMRS), Eldoret, Western Kenya

MMRS is a computer-based patient record for a primary healthcare center in rural Kenya which has been operating since February 2001 [25, 91]. This was the result of collaboration between the Moi University Eldoret Kenya and the Indiana University School of Medicine USA. The implementation place (the Mosoriot rural HC) provides all primary healthcares to a surrounding community of 40,000 persons with minimal financial means. The MMRS consists on module programmed in Microsoft Access (MA) and a paper form encounter [92]. The modules include registration, encounter data, reports, and data dictionary. Project evaluation highlighted a high patient satisfaction with the system, considerable time saving, the use of report generated for clinical and community-based public health research purposes [93].

In 2002 MMRS was extended for prospective investigation of acute respiratory illnesses with the use of PDAs as data entry instrument. The use of PDAs enabled a home follow up of patients in the village and therefore improved the efficiency in the clinical research [28].

Lessons learned: patient registration and clear patient identification were not easy to manage because of the absence of national unique personal identifier. Multiple redundant back-up systems were implemented and solar-powered battery was used to face the unreliable local electric power. Cultural stigma due to HIV/AIDS had to be overcome so as to capture more accurate data. The evaluation shows that the “digital divide” could be crossed using a simple, inexpensive EMRS and mobile devices despite significant logistical, and cultural barriers [28, 93].

AMPATH Medical Record System (AMRS), Eldoret, Western Kenya

The Academic Model for Prevention and Treatment of HIV/AIDS (AMPATH) was established by the Moi University Eldoret Kenya and the Indiana University School of Medicine USA in collaboration with the Moi Teaching and Referral Hospital Eldoret [37]. AMRS being an improvement of the MMRS is focused on the enhancement and management of the care of HIV/AIDS patients. Its evaluation shows a standardized patient data collection, an evidence-based decision-making for patient encounters and for the health system and therefore a better management of HIV/AIDS patient in the pilot environment [40].

Medical Electronic Data base and Comprehensive Application for Medical Cabinet (MEDCAB)

MEDCAB was a prototype EHR developed in Cameroon for use in primary healthcare (PHC) as a means to improve providers' performance, quality and continuity of care, and the availability of routine outpatients' consultation data [94]. Major constraints before implementation included limited institutional framework and political commitment, work overload, insufficient training, low motivation, intensive medical shopping with a patient consulting more than one provider for a single episode of care, and an unfavorable culture to data collection from both patient and providers.

MEDCAB was developed in a Microsoft environment using visual basic and MA for stand-alone application. The functionalities include among others: medical encounter, appointment management, and report generator. After implementation, a great acceptance of users was highlighted as well as an improved patient management [94].

Lessons learned: lack of well organized paper-based documentation increased the difficulty to design the EHR. Instability of trained personnel and management staff, hardware breakdown, and departure of main investigators led to a massive dropout of MEDCAB users after 14 months. This sustainability issue could be overcome if end-users involvement and capacity building were addressed at the early stage of the development process.

Lilongwe EMR

This patient management information system was developed and implemented as instrument to support order entry in the Pediatric Department of the Lilongwe Central Hospital in 2001. After implementation, it was highlighted that the use of this platform contributed to the elimination of errors in medication dosage calculations made by clinicians and the requirement for nurses to transcribe orders [27].

CareWare

CareWare is a stand-alone EMR originally developed by the health resources and services administration within the department of health and human services for entering, collecting, and reporting demographic, service, and clinical information in USA. An international version focused on the treatment and management of HIV/AIDS patient was developed and implemented in Uganda, Kenya, Zambia, Tanzania, and Nigeria [95]

Open Medical Record System (OpenMRS)

OpenMRS is an open source EMRS for developing countries. Originally, it is an improvement of the AMRS [96] with major adaption of work made in this area in the Regenstrief Institute of Indiana in USA. The first version of OpenMRS implemented in Eldoret was therefore focused on managing information to facilitate treatment and management of HIV/AIDS patients [97]. The successful used of this EMRS for the treatment and management of HIV/AIDS patients led to its adaption for the management of MDR-TB in SSA. The OpenMRS foundation is based on the collaborative effort between Regenstrief Institute and the non philanthropic organization Partner in Health (PIH) in Boston which later on included the Medical Research Council in South Africa. This collaborative effort led to major technical improvements of the first system including a new core application programming interface, a framework for a web-based application, a patient-centric data model, and the integration of the Health Level Seven (HL7) standard representations. The development environment is based on open source and free technologies [24, 36, 38] used in a three layers architectural environment (Figure 9) [96].

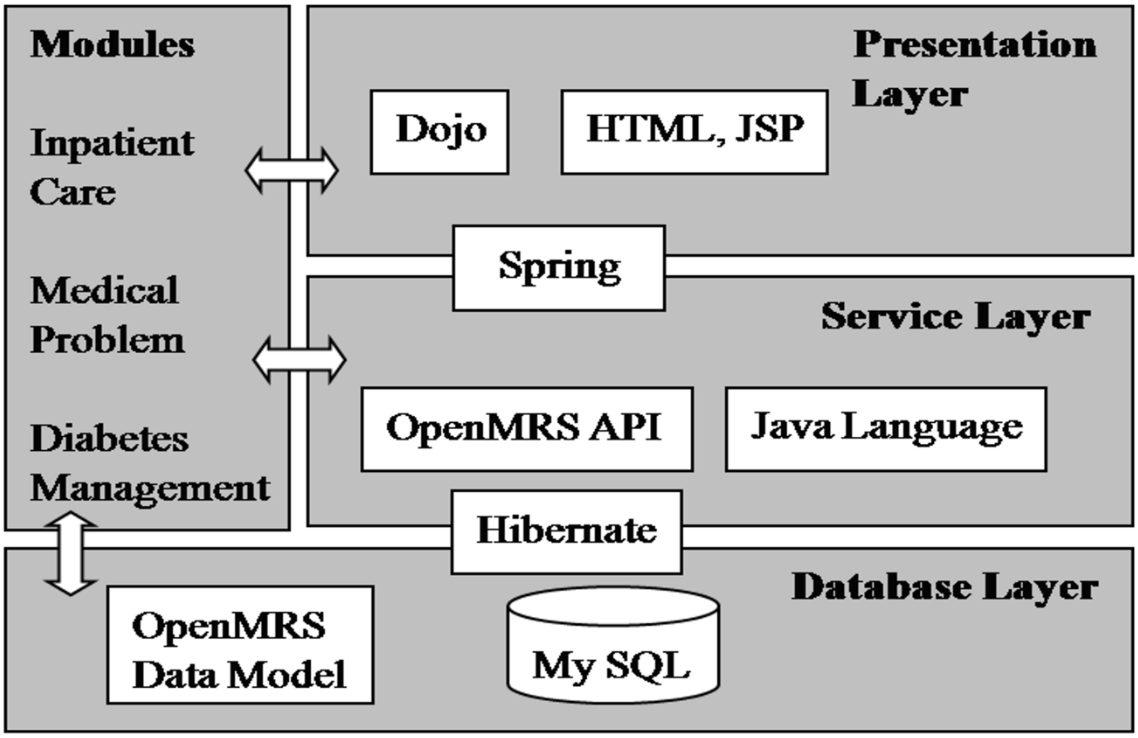


Figure 9: OpenMRS architecture. New modules (e.g. 'Inpatient Care', 'Medical Problem', and 'Diabetes Management') can be used to extend the web application, the application interface, and the data model. 'Dojo' facilitates the dynamic web application development

Today, OpenMRS is implemented in many SSA countries as an instrument for the improvement of the care delivery and management of HIV/AIDS, MDR-TB [97], and mother-child health [98].

4.1.4 Selection of an economically viable EMRS as technical key component

The framework for EHR system analysis highlights important aspect to be taken into account in the selection process (Table II). Taking this framework into account, one can say that the EMRS used in SSA presented above are all single model types with a consolidated distribution of data. They provide a retrospective and concurrent view of patient healthcare and have an episode-oriented organization. They are used to support healthcare delivery, research, and the work of public health expert and policy makers.

Table II: Framework for EHR system analysis [99]

Views	Choices				
Model types	Single model	Two-level modeling			
Distribution of data	Consolidated (warehouse)	Federated (virtual)	Materialized		
Objectives (*)	Improve patient safety	Improve efficiency	Deliver effective care		
Temporal (*)	Retrospective	Concurrent	Prospective		
Functionality (*)	Administrative processes	Results management	Order entry	Health information and data	Patient support
Organization	Specialty-oriented	Episode-oriented	Problem-oriented	Neutral	
Uses (*)	Deliver health care	Personal EHR	Research	Public health and policy	
Interoperability	Not interoperable	Functional interoperability	Semantic interoperability		

(*) are multiple choice dimensions

OpenMRS was chosen in 2007 for implementation [38] because of its scalability, multi-layered architecture, flexibility, adaptability, the use of open or accessible standards such as XML and HL7, the mapping possibility to standardized vocabularies such as LOINC, ICD-10, SNOMED [98, 100], and its non dependence on web applications. OpenMRS can, therefore, exchanges information with other systems if these are also standard-based and the structure of data to be exchanged agrees. Such a functional interoperability example has already been made with the district health information system and further initiatives are projected. Regarding its flexibility, the concept dictionary of the data model has flexible semantic relationships and significant context-dependent metadata that is used in various ways throughout the application and facilitate the customization of OpenMRS for other care environment [96]. The scalability has been proven in many implementation sites where millions of data are managed. Since the development of data entry interfaces on the basis of Hypertext Markup Language (HTML) and open standard-based XForms, the platform can totally be implemented, customized, and used on the basis of technologies freely available to anyone [101].

Furthermore another very important assessment parameter to be considered in the selection process of open source software is the organizational background and the dynamic nature of the community surrounding this [102]. According to this point, the OpenMRS consortium is very organized and supported by a growing, strong, and very dynamic community and institutions around the world (Kenya, Rwanda, South-Africa, Zimbabwe, Lesotho, Malawi, Uganda, Tanzania, Gabon, Senegal, Mali, Ghana, Nigeria, Peru, Chili, USA, Haiti, Pakistan, Germany, and India) that constantly improves the platform. This consortium is today in this area an example of successful south-south, south-north, and north-north collaborations [103].

4.2 Need assessment

4.2.1 Interview outcomes

Looking at the sample of interviewees recruited (sub-section 3.2), apart from the patient group, all the main end user groups (leaders of strategic and operational groups) were represented. Health professionals of all levels of the pyramidal healthcare structure common in SSA (nurses, non-specialists, and specialists physicians) were represented. Among diabetes specialists some occupying leadership position in international diabetes association, were main actors in the African strategy development group against diabetes in WHO Africa. All interviewees were mostly experienced people in their areas of expertise in their countries with a broader knowledge of the diabetes situation in SSA.

The thematic analysis of the interviews led to the following categorization and quantification: Health professionals in SSA expressed the wish to use EHR to improve their work. All interviewees recognized the importance of information systems in the management and improvement of diabetes care if properly used. All interviewees recognized the importance of EHR or EMRS for the treatment and management of HIV/AIDS and TB. 80% recommended the consideration of EHR or EMRS in the management and treatment of new health challenges like cancer, diabetes, and hypertension. 84% pointed out that the sustainability of an open source based EMRS solution depends on the involvement of local stakeholders, local financial backing, training, and education. 86% highlighted the importance to preserve privacy and security. 11% considered the use of information system not to be a priority for SSA countries. Further results obtained from the interviews led to the identification of issues to be considered in the conceptual model: (1) support of the communication structure of urban care delivery and care processes (because the diabetes prevalence is higher in urban environments of SSA countries than in rural areas), (2) shortage of well trained diabetes care-providers, (3) concentration of well trained care-providers at facilities of the tertiary level, (4) support of care-providers of the primary level, (5) improvement of patient involvement and education, (6) derivation of data for planning and surveillance, and (7) support of epidemiological and clinical research. Since arguments stated for the issues (2) to (7) are also highlighted in other sessions, only a summary of the issue (1) is highlighted here.

According to (1) for example, the chief medical officer and manager of a reference HC, which includes seven other HC, of the capital city of a SSA country visited during the need assessment highlighted the impact of the poor management of medical information on the quality of care of chronic and co-morbid patients such as diabetics in his district. This situation was related to the poor organization and the absence or inadequate use of communication infrastructures available in the HC he is managing. The critical aspect of the organizational view was the fact that, in the ambulatory care, care-providers record their observations and make their prescriptions into a notepad brought by the patient (Figure 10). Since patients go home with their notepad after the encounter, this clinic manager explained that there is a considerable rate of patients (mostly old patients living in under-literate families) who come to the next appointment without their notepad. In this case, the care-providers have no possibility to know what has been done so far. They are therefore obliged to restart the care process, which is not particularly easy with patients who mostly are not able to explain their problems. This leads to a poor quality of care, a considerable time lost for the care-provider and the patients as well as to an increase of the treatment cost for the patients who mostly have no insurance and are financially dependent on families and friends' solidarity.

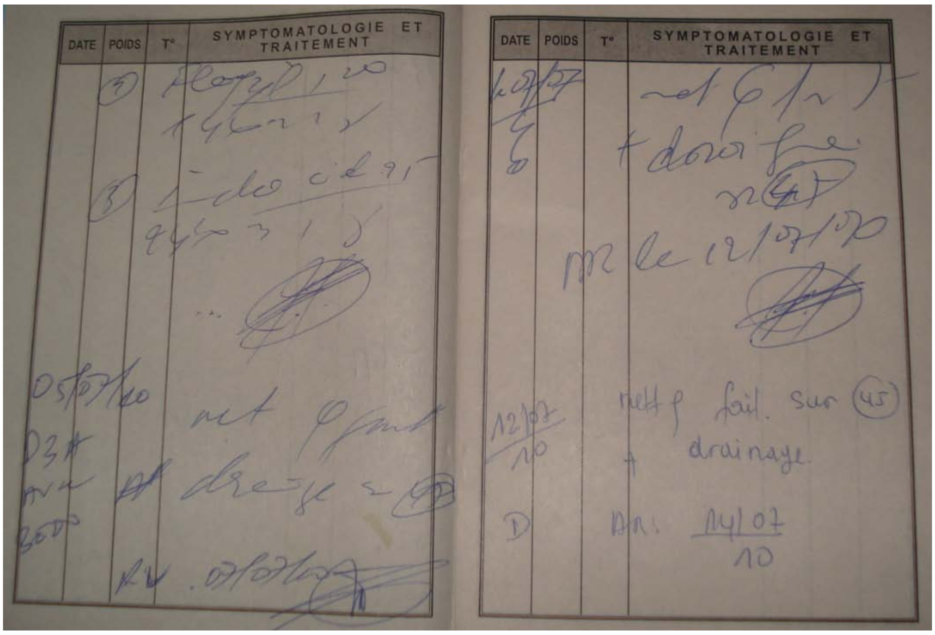


Figure 10: Example of notepad with observations and prescription of a care-provider

Another example of the organizational view deals with the medical record of hospitalized patients. After the discharge of these patients their data are locally archived. The chief medical officer explained that there are not enough places for an organized archive. That is why medical records of already discharged patients are sometimes found in the bureau of care-providers or at other unauthorized places accessible to all (Figure 11).

Figure 11: Patients medical records stapled on and under the table of a care-provider in SSA. On the other side of the room, there is a consultation table

In the will to show how places reserved for archives look like, the chief medical officer discovered another problem (Figure 12) and asked the interview team: “which overworked care-providers will have the time to search old medical records in such archives even if they wish to do so?” Consequently care-providers mostly do not take into account the treatment of former hospitalized patients even if these patients came back into the clinic after a short interval of time like 3 months.

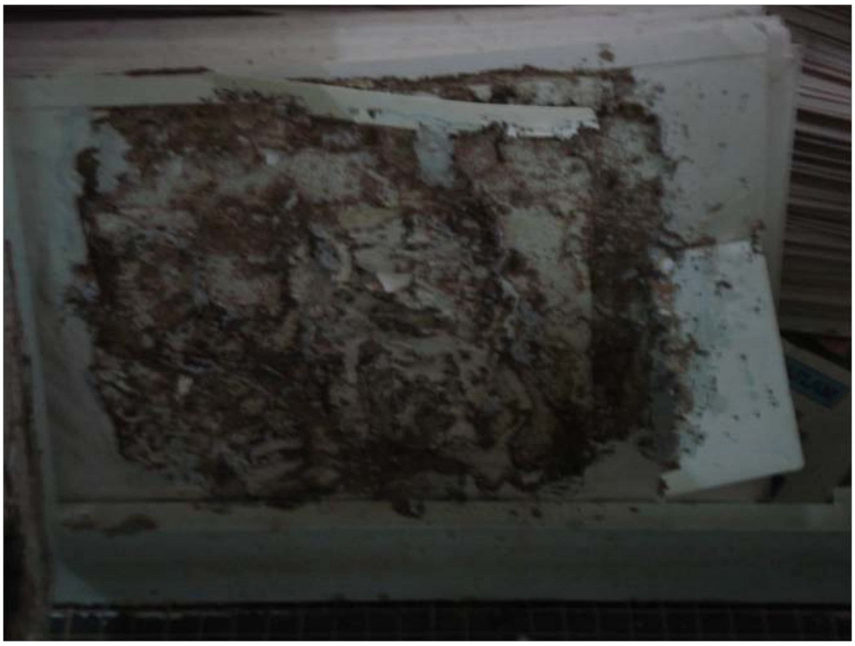


Figure 12: Archived patients medical record. Patient charts are stapled without clear structure in an armoire. Due to a termite attack, a part of the records are destroyed

Something however curious was the availability of IT infrastructure with internet availability in many urban HC (Figure 13). These were often used neither for medical purposes nor for administrative ones. The clinic manager by presenting these, explained that these infrastructures with adequate applications, will provide to his personnel the ability to share and collaborate on research, to participate in chronic patients tracking, and to consult with colleagues and medical experts.

Figure 13: IT-infrastructure in the bureau of a care-provider in an urban SSA HC. This being connected to internet is neither used for medical nor administrative purposes

4.2.2 Process analysis of the diabetes care in SSA

Processes related to the issues highlighted in the interview, the SSA diabetes guideline, and literature outcomes were mapped into a scenario to improve diabetes care and management in urban settings of SSA countries. The focus is on urban environment because urban residents have a higher prevalence of diabetes compared to rural residents [104].

Diabetes patients can receive care at all facilities in urban cities in SSA - for example Yaoundé in Cameroon or Dakar in Senegal. It is common in the SSA region, that patients go to a laboratory for a lab test and carry their lab-results to care-providers at their next appointment. Care-providers of the primary and secondary care level often need the assistance of well trained health professionals from the tertiary care level. Also, complicated cases from the primary and secondary care facilities are often being referred without a referral letter to the tertiary level for multi-disciplinary expertise and/or inpatient treatment. Experts of the tertiary level, in absence of medical history, laboratory report, medication history, and care plan of the patient, mostly order the same lab test and medication again. These dynamic care environments are informal and usually lack epidemiological data for planning of resources and are costly for patients who in most cases have no health insurance.

Before starting with the main process analysis, it is important to highlight the general healthcare organizational structure in SSA.

The healthcare system common in SSA is the pyramidal healthcare referral system (Figure 14). The organizational care structure in this system is built around the main facilities of each level of the pyramid:

a. The bottom of the pyramid constitutes the primary level where care is mostly provided or supervised by HC
b. The middle of the pyramid constitutes the secondary level where care is mostly provided by DH
c. The top of the pyramid constitutes the tertiary level where care is mostly provided by RH which are also mostly teaching hospitals

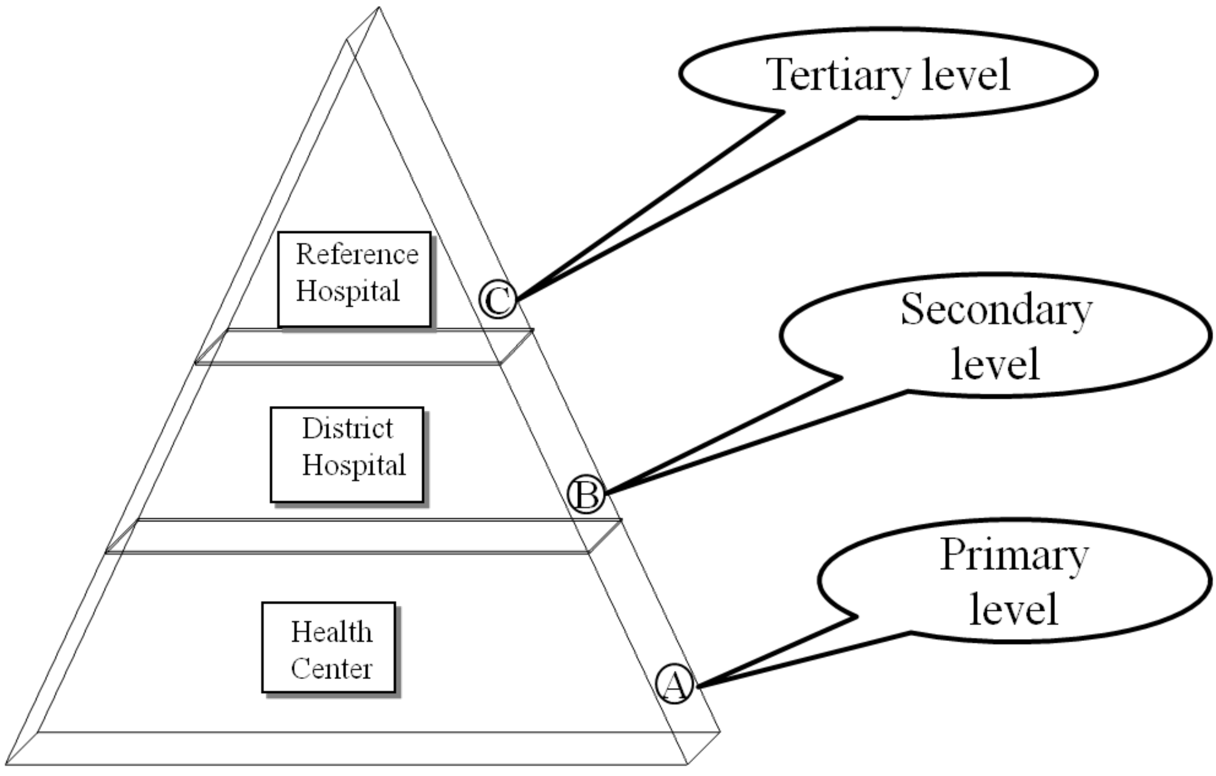


Figure 14: The pyramidal healthcare referral system common in SSA

In HC, the main actors are patients, nurses, lab-personnel (mostly lab-assistants), educators, medical assistants, and normally primary care physicians. In DH, actors of HC are available and added to these there are primary care physicians (with specialists in some urban areas) and pharmacists or assistants. In RH, in addition to actors of the DH there are physicians' specialist, pharmacist, lab-experts, researchers, etc.

Figure 15 highlights the model designed using activity diagrams of the UML with regards to the scenario above. The main actors presented in this model are patients, lab technicians, care-providers of the HC, DH, and RH. Management staff and other actors of the normal care process are abstracted here. The model describes therefore an abstract view of the SSA diabetes care process and distinguishes processes performed within HC, DH, and RH. The care process starts with the patient who decides, if he/she is going to receive treatment or to attend a diabetes education session in a HC, DH or RH. The end of both the education session and treatment process at all care levels leads to the start of a new care process, because of the chronic character of diabetes which requires a long term treatment. The patient examination process at each facility is described in additional models. To avoid duplication of content in description of other sub-cases, it is preferable to highlight the major difference between the different cases. Also, the sub-model presenting the patient examination processes at the DH and RH are in the appendix section.

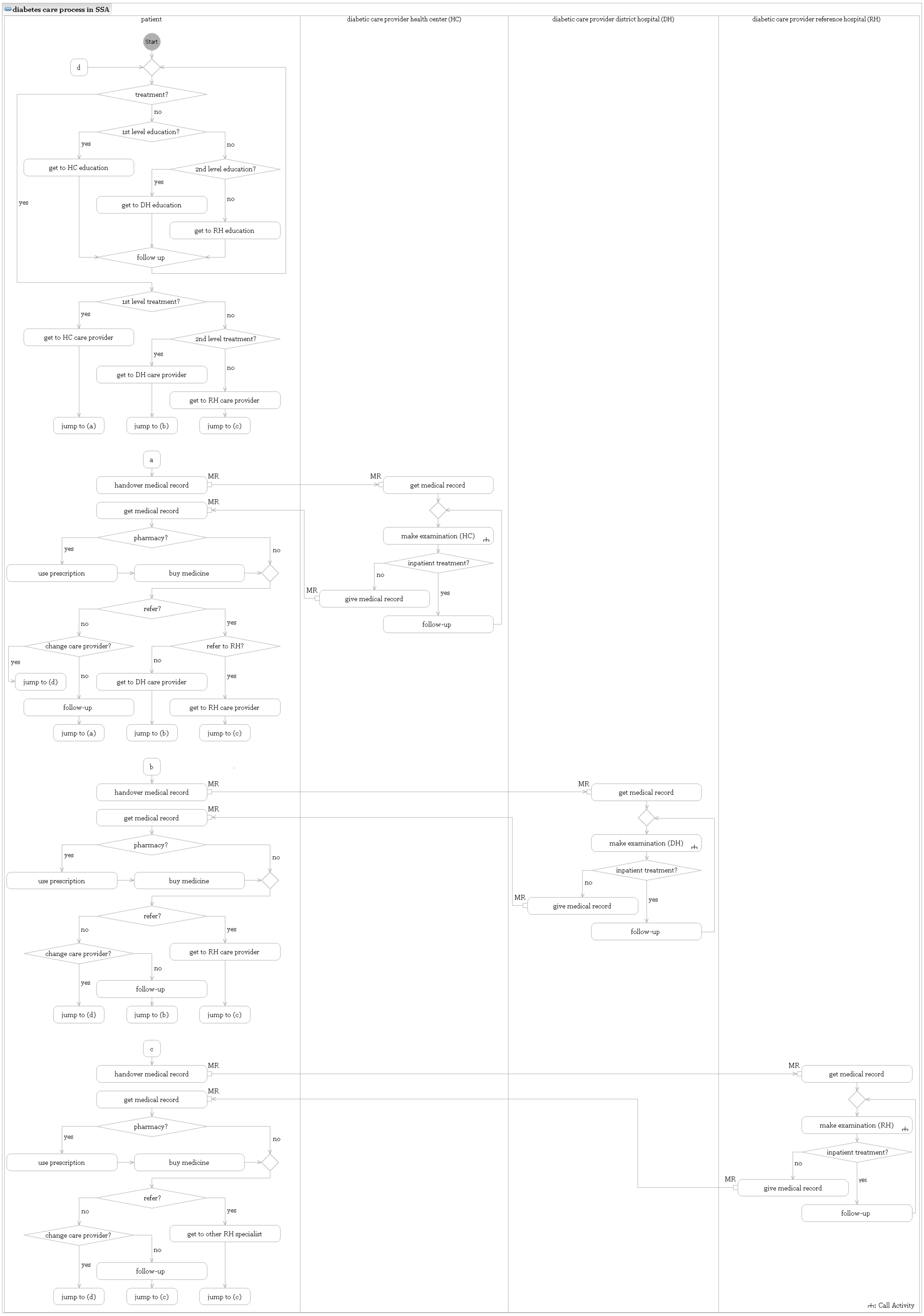


Figure 15: Current diabetes care process in SSA

4.2.2.1 Case 1: patient begins care at the primary level of the care structure

After having decided to receive treatment at a primary level facility (e.g. HC), the patient goes to the HC. After the fulfilling administrative procedures, not represented in this workflow, the patient hands over his/her medical records contained in a notepad to the care-provider. The care-provider starts the examination process (Figure 16). At the middle of the process, the care-provider often have to refer the patient to other facilities (e.g. RH) for either eye examination in case of initial or annual visit or specialized lab test. When the patient comes back with the results, the care-provider analyzes these and, in complicated cases, may seek support from experienced care-providers in other facilities before finalizing the diagnosis and set up the treatment with a new medicine if necessary. The care-provider plans the continuum of care (Figure 17) before ending the examination process with further documentation which may include: compile medical record, write discharge letter, and perform statistical analysis for example the internal quality of care assessment, the health ministry, and the national diabetes program.

After the examination process, the patient may be hospitalized, should an inpatient follow up be needed, otherwise the care-provider gives the patient back the notepad containing his/her medical records. The patient goes to the pharmacy, if medicine is prescribed. Finally the patient can decide to either follow the continuum of care recommendation (Figure 17) made by the care-provider or elide this and change the care-provider.

The figures 15, 16, and 17 highlight the main activities performed during the diabetes care process in SSA. These workflows show that the work of care-providers strongly depends on the capability of the patient to take care of his/her medical records. Since diabetes is a chronic disease, medical records of past consultations are very important for the continuity of care. What happens if the patient comes to the next appointment without the medical records? The efficiency of the support requested from experts of the secondary or tertiary level of care as highlighted in the make examination process (Figure 16) may increase the quality of care at this level. Interviewed experts mentioned however that, the inefficiency of this collaboration, due to the kind of communication medium used, led to an increased number of patients referred to other care levels (DH, RH). Since access to care-providers working in RH is not easy, many patients came back to HC without having encountered the specialist. This situation raises some very important questions. How can this important sub-process be improved? How can the reference of not really complicated cases be avoided? From the patients' perspective, how can they avoid double prescription? How to reduce unnecessary costs? At the end of the examination process (Figure 16), some parallel documentation activities are highlighted. According to some experts interviewed, the report to be sent to the health ministry, researchers, and other organizations as well as the result of the quality of care assessment are mostly not reliable due to the poor quality of data recorded and the absence of analysis tools. Also in case of hospitalization, the content of discharge letters is mostly very poor and consequently not helpful for the next encounter. This situation is partly due to the high density of patients to be managed by the care-provider. How can this situation as well as the documentation of co-morbid diabetics during the outpatient care be improved?

Taking into account the economic situation of the majority of patients receiving care in HC, a strategy that could help to reduce the number of patients to be referred will be helpful, because it may also contribute to the reduction of the treatment cost. The EMRS functional requirements should therefore be part of the daily practice of care-providers and patients.

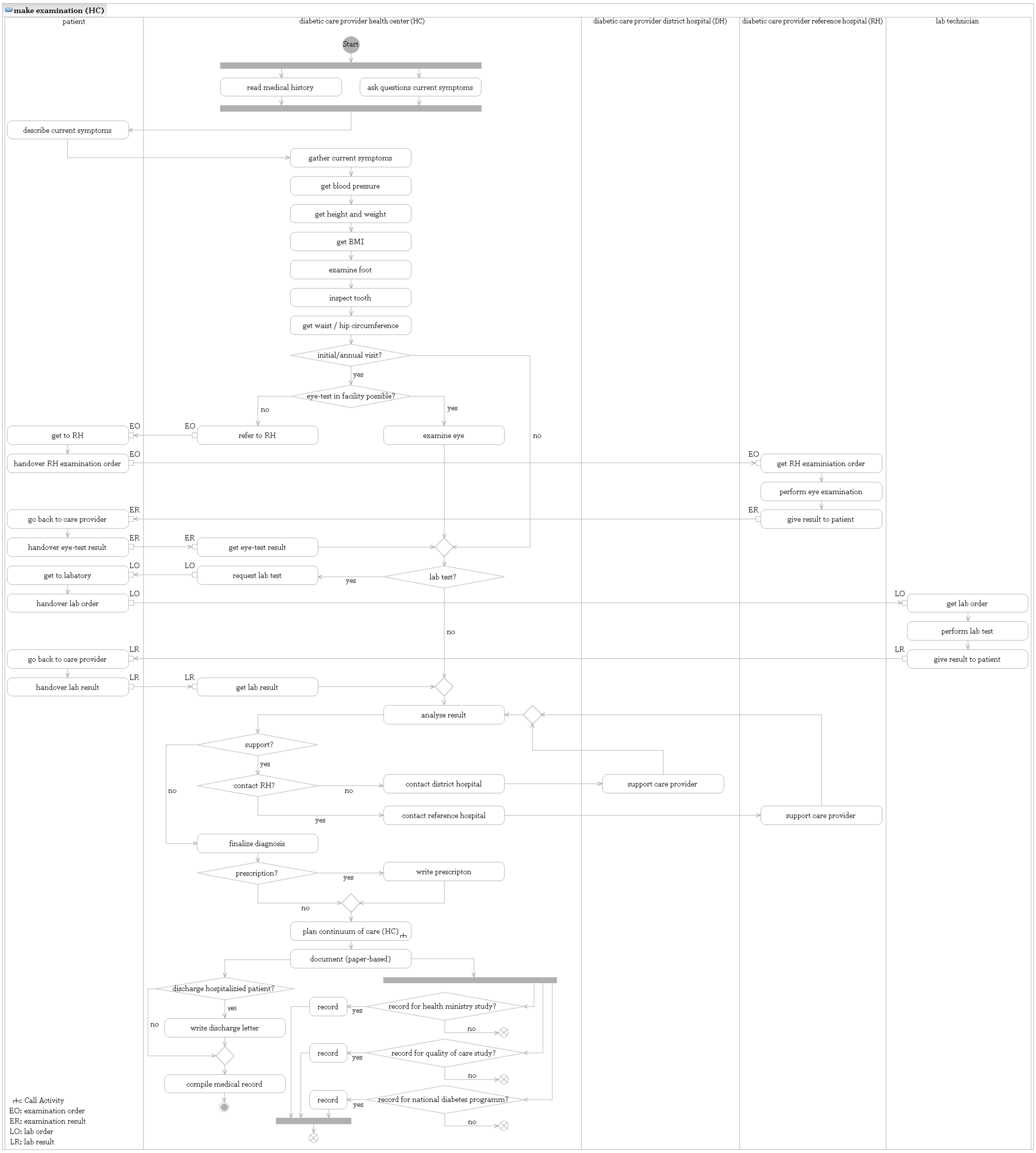


Figure 16: Current diabetes examination process in SSA HC

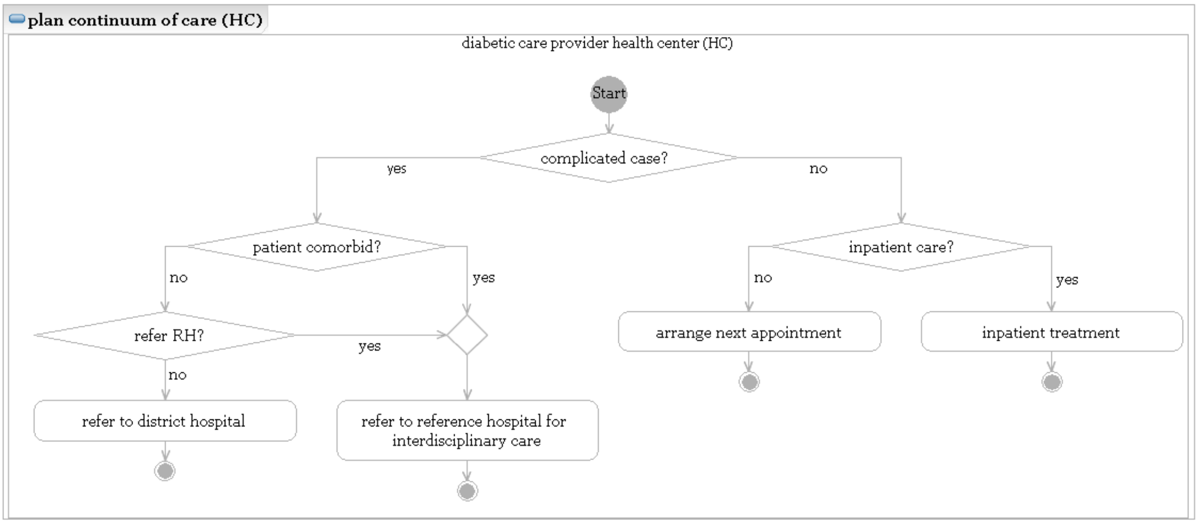


Figure 17: Continuum of care process of a diabetic at a HC in SSA. After having finalized the diagnosis, the care-provider checks if the case is complicated for him. If it is a complicated case, the patient is referred either to DH or to RH. Otherwise the care-provider arranges the next appointment, if the patient does not need an inpatient treatment

4.2.2.2 Case 2: patient begins care at the secondary level of the care structure

According to the abstract view of the SSA diabetes care process at the DH highlighted in Figure 15 (b) the main difference to the HC Figure 15 (a) is the number of patient reference possibility. This is derived from the continuum of care process at the DH (Figure 18). The sub-model highlighting the examination process at the DH (Appendix-Figure 1) also shows a reduced number of activities, should support from experienced care-providers be considered. This is because care-providers at this level are more experienced than those at the first level. Therefore support can only be acquired from the RH.

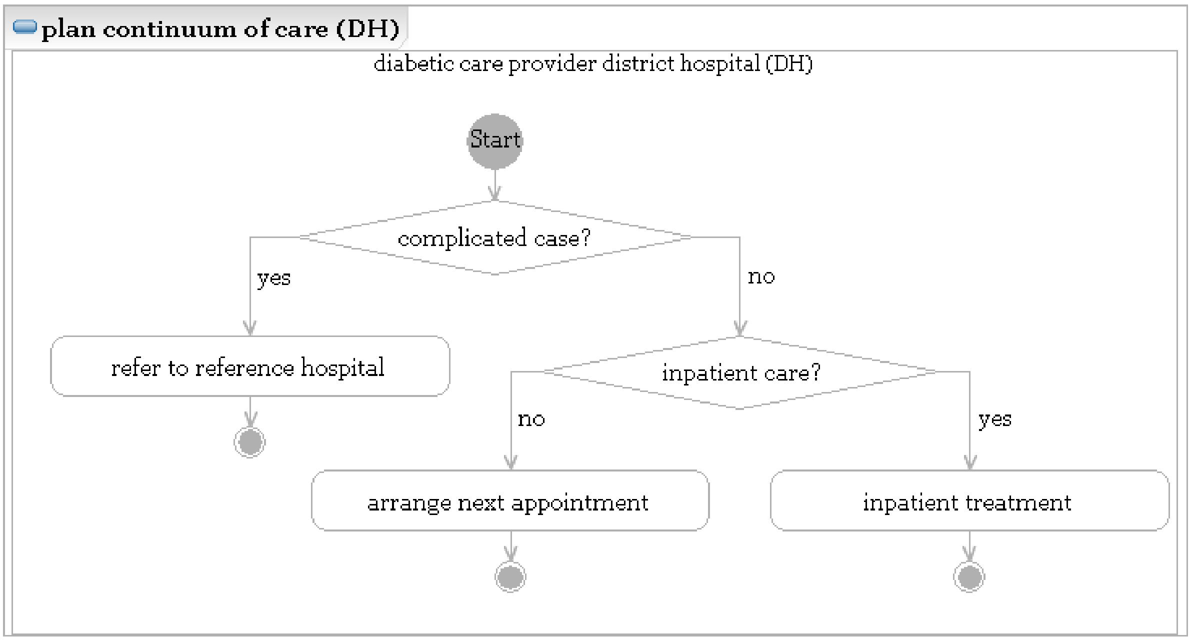


Figure 18: Continuum of care process of a diabetic at a DH in SSA. After having finalized the diagnosis, the care-provider checks if the case is complicated for him. If it is a complicated case, the patient is referred to a RH. Otherwise the care-provider arranges the next appointment, if the patient does not need an inpatient treatment

4.2.2.3 Case 3: patient begins care at the tertiary level of the care structure

According to the abstract view of the SSA diabetes care process highlighted in Figure 15 (c), the main difference in comparison to the other cases is the reference within the same facility. This is a result of the continuum of care process at a RH Figure 19. The sub-model highlighting the make examination process at a RH (Appendix-Figure 2) shows that, the whole examination process can be done within this facility. There is no need to interrupt the process and refer the patient for eye examination elsewhere. Lab test are also often performed within the same facility. In addition, patients with further complications such as co-morbid patients most often receive interdisciplinary care within the same facility. This reduction of sub-activities within the workflow and concentration of different specialties at this level may increase efficiency in the care process at this level.

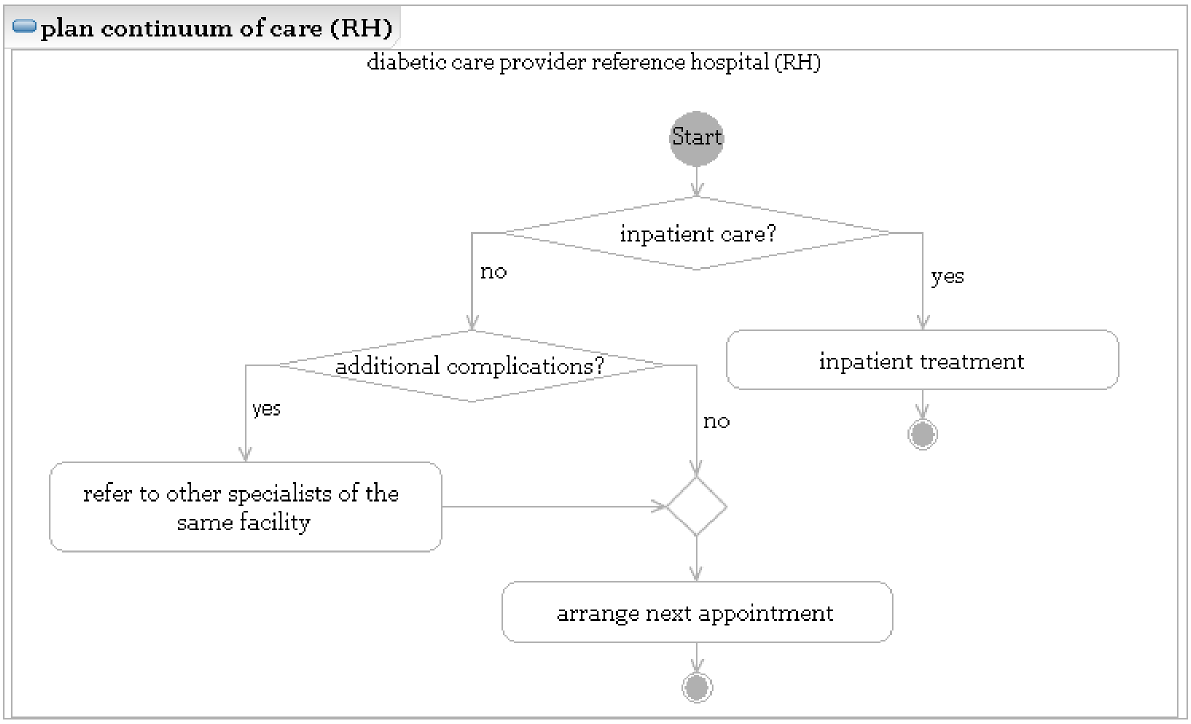


Figure 19: Continuum of care process of a diabetic at a RH in SSA. After finalizing the diagnosis, the care-provider checks if the patient needs an inpatient treatment or the expertise of other specialists, then refers him/her to the respective service. Otherwise the care-provider arranges the next appointment

4.2.3 Functional requirements for an EMRS prototype

Following the process-oriented analysis above, a list of functional requirements for the EMRS that will be used to optimize information flow and facilitate the collaboration between the different levels of the healthcare structure was specified (Table III). Some functions are specific to diabetes and others are globally valid for information processing within a health facility. Let’s explain, for example, how some weak-points of the current SSA diabetes care processes are related to some processes in Table III.

Number 1 *“Diabetes data entry form (as recommended in the clinical guideline of IDF Africa)…”* deals with the computerization of a standardized clinical documentation during the whole diabetes care process. This is related to problems encountered during the diabetes examination process at all levels of the SSA care structure.

Number 2 *“Review the patient’s problems list, problem status”* deals with better information management of co-morbid patients. It is therefore a globally valid requirement. This is related to problems encountered during the whole care process. Care-providers often need to know what problems the patients have and what treatment progress have been achieved so far?

Number 3 *"Get patient history details"* deals with problems encountered by care-providers at the beginning of each examination process. The computerization of medical records is helpful in this case since care-providers are no longer dependent on the patient notepad as highlighted in all the sub-models dealing with the current SSA diabetes examination processes.

Number 4 *"Track and manage patients and their diabetes-specific information"* deals with better information management of the long care process and the assistance of diabetes patients during this process.

Number 5 *"Provide simulation tools for inexperienced health professionals…"* deals with the assistance of care-providers at the primary level. This is related to the fact that many patients are referred to the secondary or tertiary level with no real complicated problems.

Number 6 *"Allow patients to use their portal to enter observations relevant to their diseases"* deals with the involvement of patients into the care process. This is related to the fact that diabetes patients regularly have to check basic clinical parameters which can be sent to care-providers for appreciation.

Number 13 *"Generate discharge letter …"* deals with the optimization of discharge letter process and content. It is related to the fact that overworked care-providers are often not able to provide consistent discharge letters after patient hospitalization.

Table III: List of processes to be improved using the EMRS as result of the literature review and the need assessment ranked according to priority

1.	Diabetes data entry form (as recommended in the clinical guideline of IDF Africa): record results of lab tests and other diabetes important investigations
2.	Review the patient's problems list, problems status
3.	Get patient history details
4.	Track and manage patients and their diabetes-specific information
5.	Provide simulation tools for inexperienced health professionals: simulate a 24-hour profile of glucose-insulin interaction for diabetes patient
6.	Allow patients to use their portal to enter observations relevant to their diseases
7.	Allow patients to simulate their daily data for education purpose
8.	Provide access to each problem detail
9.	Get encounters details, observations details, and regimens details
10.	Track patients requiring assessment (planned visit)
11.	Simulate responses to glucose equivalent of carbohydrate intake and different type of insulin injection
12.	Allow altering regimens and running another simulation, as well as displaying differences in glucose and insulin curves between current and previous runs
13.	Generate discharge letter after an inpatient hospitalization
14.	Follow results of a test or investigation over time
15.	Display a graphical timeline of the encounters for the last six months
16.	List inpatient care encounters
17.	Provide a restricted access for patients to the EMRS
18.	Provide reliable data for diabetes surveillance and evaluation
19.	Display comparative graphs of relevant clinical data of diabetes patient
20.	Generate report for the monitoring of quality of care as recommended in the clinical guideline of IDF-Africa
21.	Produce data reviews for specific patient groups
22.	List existing location (location, department, specialty, room) and allow a location restricted view of patient data

4.3 Conceptual model of the solution

Based on the literature research results and the need of assessment, a conceptual model was designed for urban regions using OpenMRS to improve processes and outcomes. The concept is based on the pyramidal healthcare referral system common in SSA in which the care process should start from the bottom of the pyramid to the top. However, in reality patients decide where to receive their care. To accommodate this, the conceptual model defines diabetes care networks within the existing healthcare structure and distinguishes between three cases: (1) patients who receive care at the primary level, (2) patients who receive care at the secondary level, (3) and patients who receive care at the tertiary level of the pyramid. The collaboration within a diabetes care network is built on trust relationships based on a federated trust approach between the members of the network. These trust relationships are created using business and legal agreements between the institutions that are members of the network. Furthermore a formal patient agreement is required before any patients information is transferred within the care network. These agreements are prerequisites to the use of the EMRS as described below.

The regulation document of the network called “Governance of the diabetes care network” must refer the establishment of some or all the business agreements including amongst all: the diabetes care network goals, requirements needed to become members, the rights and obligations of each network member, and the relationship and liability management between members of the network. In addition, the above governance document of the diabetes care network should include an ICT-governance part that specifies the aims and policies of the use of EMRS and other ehealth components within the network with respect to local regulations. It should also invoke the management of infrastructures necessary for establishing cryptographic trust, and user identifiers or attributes across security and policy domains to enable more seamless cross-domain business interactions in the internet environment. This governance document of the diabetes care network must be accepted by each partner before the beginning of the collaboration.

4.3.1 Case 1: patient begins care at the bottom of the pyramid

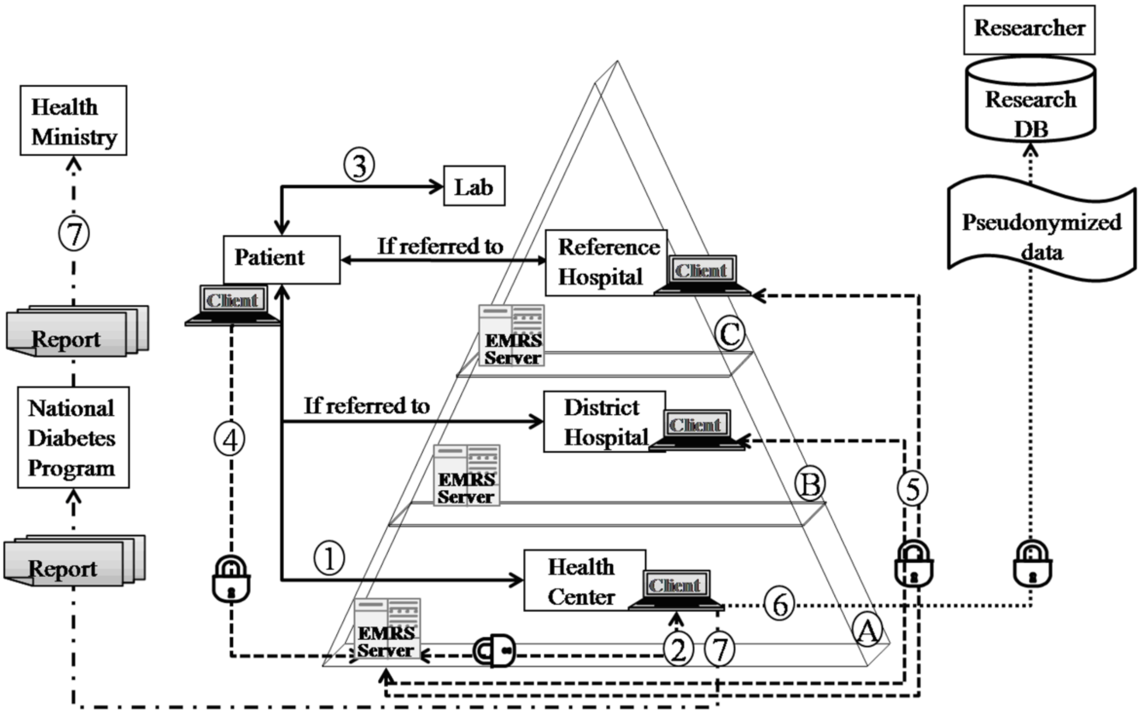


Figure 20: Conceptual model for diabetes care and management. The proposed solution is based on the fact that patients start their care-process at the bottom of the pyramidal healthcare structure: A primary level, B secondary level, and C tertiary level. The processes 1 to 7 are explained in the text

Figure 20 shows at the bottom of the pyramid (A) a healthcare facility of the primary level i.e. HC, in the middle (B) a healthcare facility of the secondary level i.e. DH, and at the top (C) a healthcare facility of the tertiary level i.e. RH. Although each facility has a laboratory, patients can decide to go to an external laboratory. This concept images the following processes: (1) patients go to health facilities of the primary level to receive care; in case of reference, patients go to care-providers of the secondary, or tertiary level; (2) care-providers get access to their patients' data through the EMRS and can update them; they can use the EMRS-capabilities to facilitate different data analysis including the quality of care assessment recommended by the IDF; inexperienced care-providers can also use the integrated simulation tool for education purpose; (3) patients go to an external laboratory with the lab order and carry their lab-result to the next appointment; (4) patients can get secure access to the EMRS to simulate their daily glucose and insulin records for education purposes and discuss the results with health professionals or diabetes-educators; they can also record their prior lab results; (5) experienced care-providers from the secondary and tertiary levels use a secured connection for secured online access to patients' data of facilities which require their expertise; care-providers collaborate with colleagues from other settings or from other departments within their facility; (6) only pseudonymized data are exported for research purposes; (7) reports adaptable to local requirements for decision making and planning generated at the healthcare facility using the EMRS are sent to the regional diabetes program of the MoH and data is exported to a regional register which also uses a master patient index.

The idea behind steps (4) and (5) is to facilitate the collaboration, connectivity, and alignment between inexperienced diabetes care-providers of the primary level and experienced care-providers of the secondary level or diabetes experts of the tertiary level as well as between multi-disciplinary specialists within a facility of the tertiary level. For example, each diabetes-specialist of the tertiary level will serve as a consultant in a facility of the primary level and as a mentor of the primary care-provider in diabetes care management. Thus, a user-profile for the specialist in the local EMRS of the primary care facility will be defined. In public sector facilities, this will enhance the work of care-providers who already work in separate facilities of the organization structure.

Technically there is no data transfer between the EMRS of different institutions. It was preferred in this concept, looking at the environmental situation of the region, not to use a solution based on a central database. This has been adopted in order to avoid a system paralysis in case of no internet connectivity. The advantage here is that each institution has control over its local EMRS and does not depend on internet availability. This decision allows avoidance of interoperability problems between the possible heterogeneous EMRS used within a care network. Furthermore, the secured connection mentioned above is based on the secure sockets layer (SSL) / transport layer security (TLS) protocols.

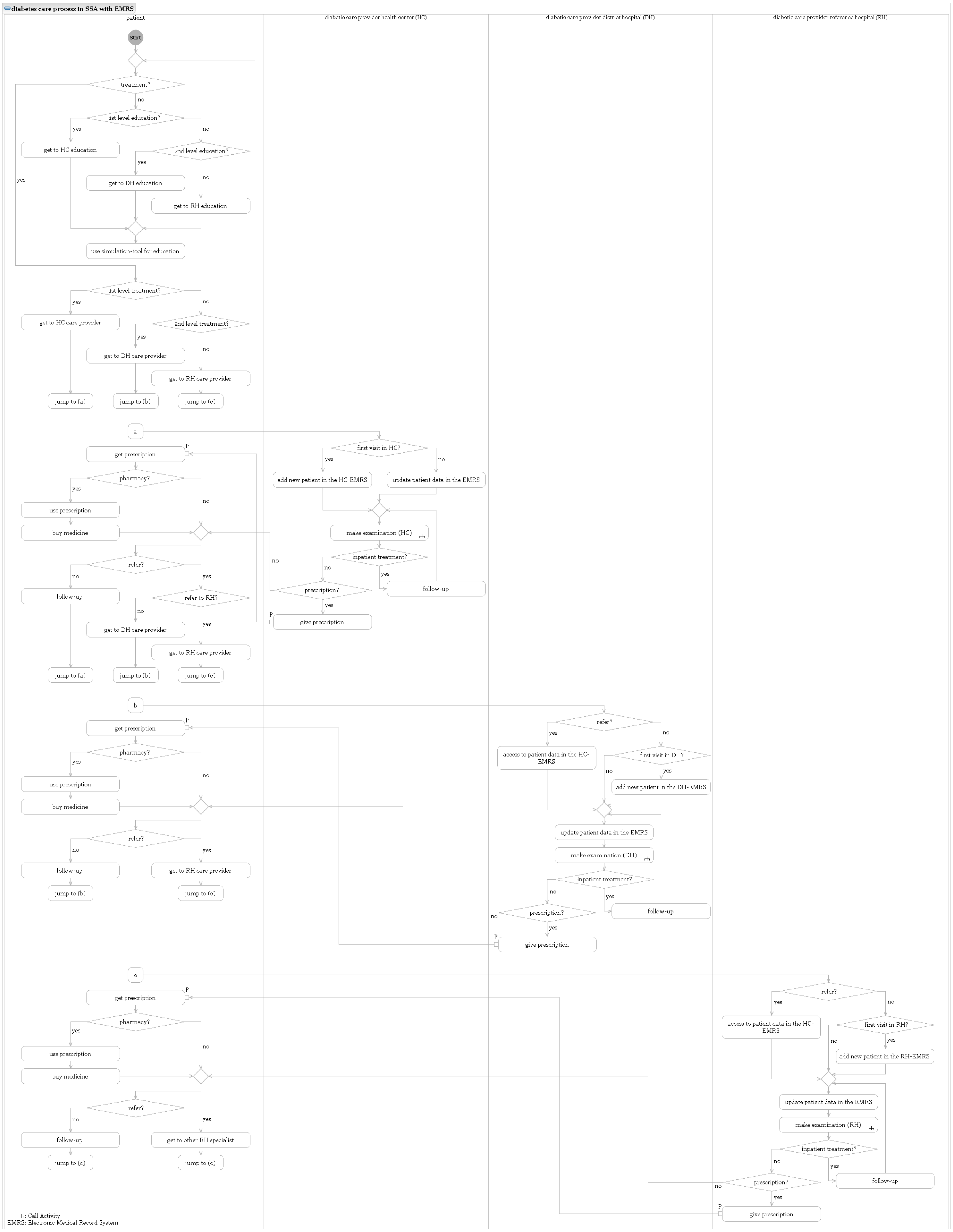


Figure 21: The new SSA diabetes care process with the use of an EMRS

Figure 21 presents a UML-model highlighting major processes of the new SSA diabetes care processes derived from the conceptual model above. The main actors remain the same like in the model describing the current care process (Figure 15). The care process starts with the patient who decides, if he/she is going to receive treatment or to attend a diabetes education session in HC, DH or RH.

In case patients attend an education session, they may use, independently of the facility level, the simulation-tool integrated into the EMRS for education purpose. Under supervision of a diabetes educator, the patient can simulate responses to glucose equivalence of carbohydrate intake and different type of insulin injections.

In case the patient goes to the care-provider at the HC (Figure 21) (a)), the care-provider or an assistant checks the EMRS and either add the patient data in the EMRS, if it is his/her first visit at the HC, or update existing patient data in the EMRS. The examination process (Figure 23) starts with some parallel activities of the care-provider: reading patient medical history in the EMRS, open the form entry, asking current symptoms to the patient. While the patient describes his/her current symptoms, the care-provider gathers these in the EMRS. After the measure of basic parameters, the care-provider fills-out the opened form entry. In case of initial or annual visit, eye examination is needed. The patient is referred to the RH with an examination order, if it is not possible to perform the test at the HC. When the patient comes back with the test result, the care-provider updates the EMRS. If a lab test is needed, the patient goes to the laboratory with the lab order. The lab result is given to the patient who takes it to the care-provider. The patient can either enter the result in the EMRS or give it to the care-provider who updates the EMRS. The care-provider can visualize (including graphically) the results in the EMRS and then analyze these. If there is a need of expertise from DH or RH care-providers, they may provide these using the HC EMRS. They access the HC EMRS, check the patient data, and provide their expertise. After this, the HC care-provider can finalize his diagnosis and write the prescription if necessary. It should be mentioned that the process remains within the same established diabetes care network. Within the network and with respect of the network governance document, diabetes experts from DH and RH stated above receive automatically authentication and authorization credentials to access the HC EMRS, should the HC care-providers make a request.

The continuum of care is planned (Figure 22) and the patient is referred to DH or RH experts of the diabetes network, should the case be complicated.

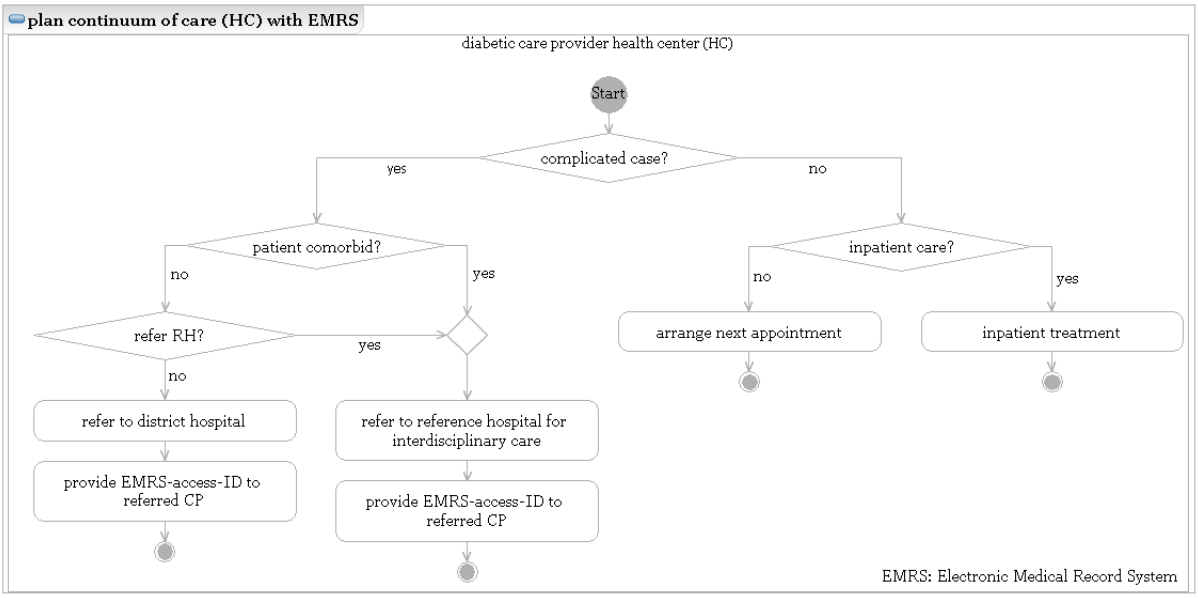


Figure 22: The new continuum of care process at the HC

The care-provider then updates the EMRS and may generate the discharge letter using the new function of the integrated EMRS as well as perform the different studies using the EMRS functions adapted for these (Figure 23).

After the examination process (Figure 23), the patient may be hospitalized (Figure 22), should an inpatient follow up be needed, otherwise the care-provider gives the patient the prescription order (Figure 21), if new medicine is needed. Finally the patient must follow the continuum of care recommendation (Figure 22) made by the care-provider in order to remain member of the diabetes care network. The collaboration between the care-providers and patients within the diabetes care network is facilitated via EMRS functions that present the right information to the right user based on its role within the network. This is also a key element for the SSA diabetes care optimization in general and particularly in primary level where patient often need expertise from DH and RH care-providers.

To avoid replication in the model explanation, the figures highlighting the conceptual model (Appendix-Figure 3, Appendix-Figure 4) and the detailed examination processes (Appendix-Figure 5, Appendix-Figure 6) at the secondary and tertiary level of the SSA care structure are in the appendix session. These models can be explained by adapting the text described above.

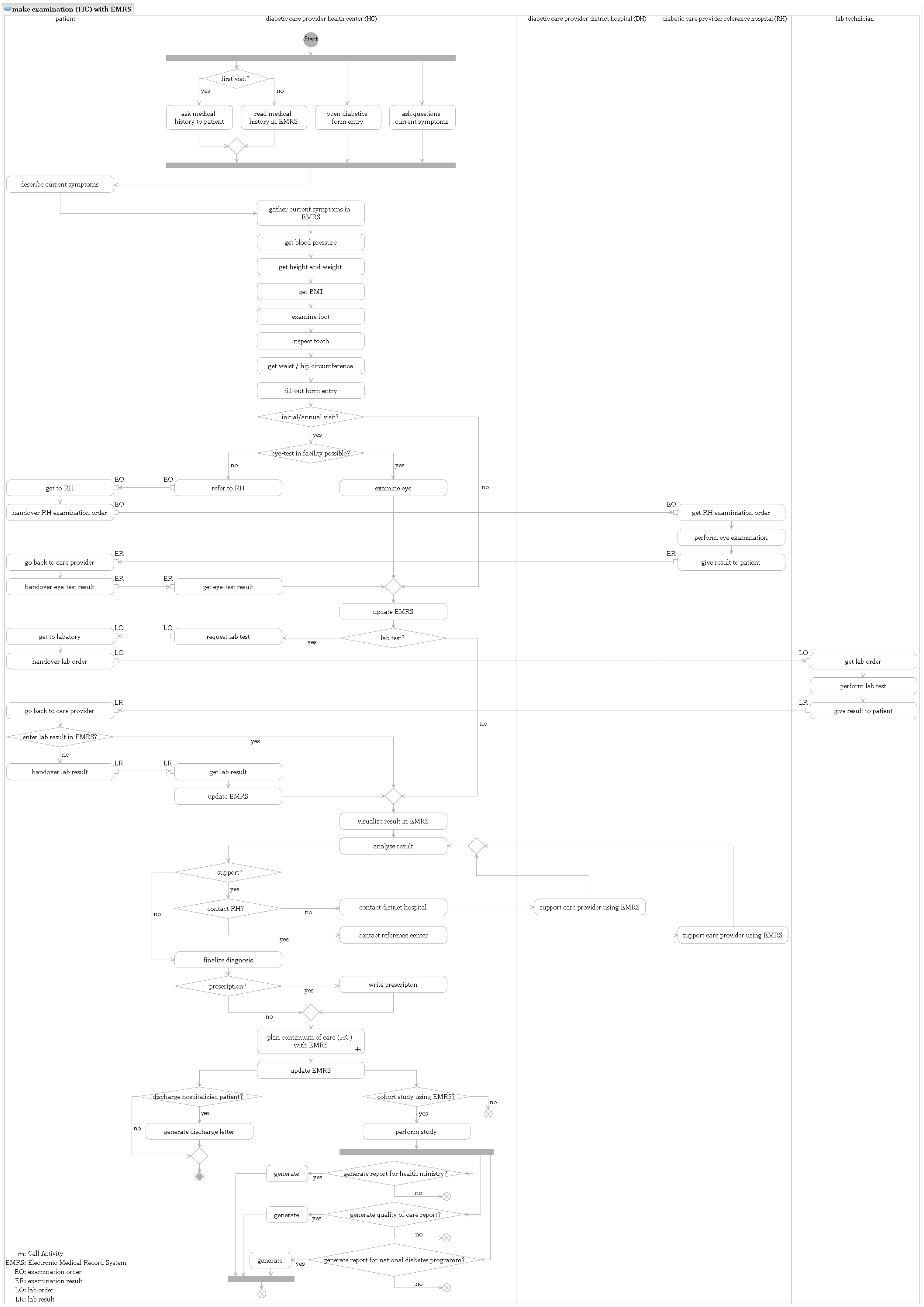


Figure 23: The new patient examination process with an EMRS at the HC

4.3.2 Alternative access to patient data within the diabetes care network: the single-sign on

Case one presented above specified that care-providers from DH and RH have access to patient data of the HC. This means that profiles for DH and RH care-providers have been defined in the HC EMRS. This approach however, means that well trained care-providers from DH and RH, who will be consultants in different HC will have to manage many different authentication and authorization credentials (user name and password). This approach presents security and phishing risks, because the users are rarely able to manage different authentication and authorization credentials.

To overcome this situation, a SSO service for the EMRS applications of each network member is needed. Applying SSO model to case one, the HC acts as the SP and the DH and RH are IdP. In order to access patient data at the HC (in this case SP), care-providers from DH and RH (in this case IdP) only need to authenticate locally and then, depending on their role, they are able to access EMRS applications of the HC (Figure 24). The abstract view of the SSA diabetes process with EMRS and SSO services is highlighted in the appendix session (Appendix-Figure 7).

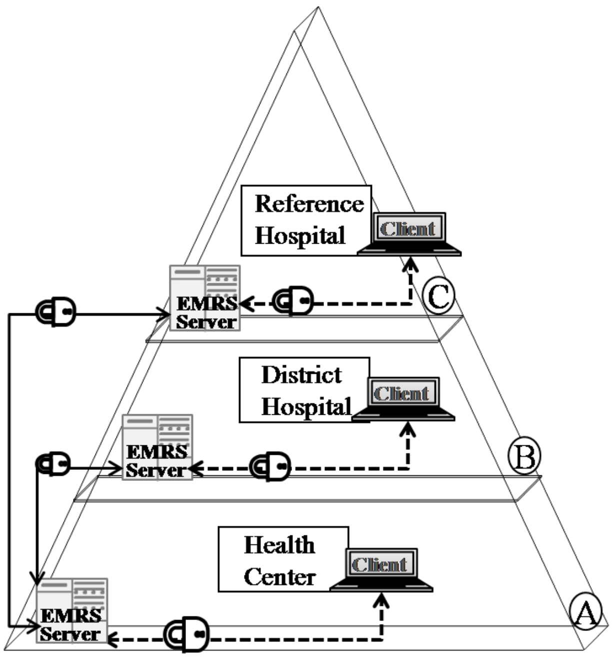


Figure 24: SSO service at each level of the care structure within the diabetes care network. Care-providers (clients) from DH and RH do not need different authentication credentials to access application of the EMRS at the HC

Technologies used for implementing SSO services such as SAML protocol, liberty alliance, shibboleth, XACML, WS-security, Microsoft passport system, and WS-* kerberos offer, in addition to the SSO functionality, supports for managing the trust relationship and cryptographic between members of a federation like the diabetes care network. Since most of these technologies use the SAML standard and considering the fact that the SAML 2.0 incorporates approaches of other solutions like the liberty and shibboleth projects and is a non-proprietary solution [63], there is a tendency to internationally adopt SAML 2.0 for SSO purposes [64, 105]. Therefore SAML 2.0 is used here to illustrate the SSO functionality across the diabetes network.

In case 1, from which the care process begins at the primary level, the partner institutions (DH and RH) being the IdP and the HC the SP. In this use case, the message flows between the HC and the DH or between the HC and the RH. The message flows can be initiated by each of them (HC, DH, RH). To execute web-based SSO scenarios two SAML messages "Authentication Request message" (<AuthnRequest> message) and "Response message" (<Response> message) are used. These messages are associated to the following HTTP protocol: HTTP Redirect, HTTP POST, and HTTP Artifact bindings.

Scenario 1: message flows initiated by the DH or RH (identity provider)

A care-provider of the RH (IdP) has a login session on the website of the RH and can access local secured resources on this website. From this web site he selects a link to request access to the EMRS of the HC (SP) in order to provide his expertise to colleagues of the HC, thereby requesting the SSO service of the RH. The RH asserts to HC that the care-provider is known, has authenticated to it, and has the identity attributes "physician". Since there is a trust relationship between the RH and the HC as stated in the "Governance of the diabetes care network", the HC trusts that the care-provider is valid and properly authenticated. It therefore creates a session on the HC website for the care-provider of the RH. Figure 25 illustrates the processing that describes a HTTP POST Binding <Response> message used to deliver the SAML message containing the assertion to the HC.

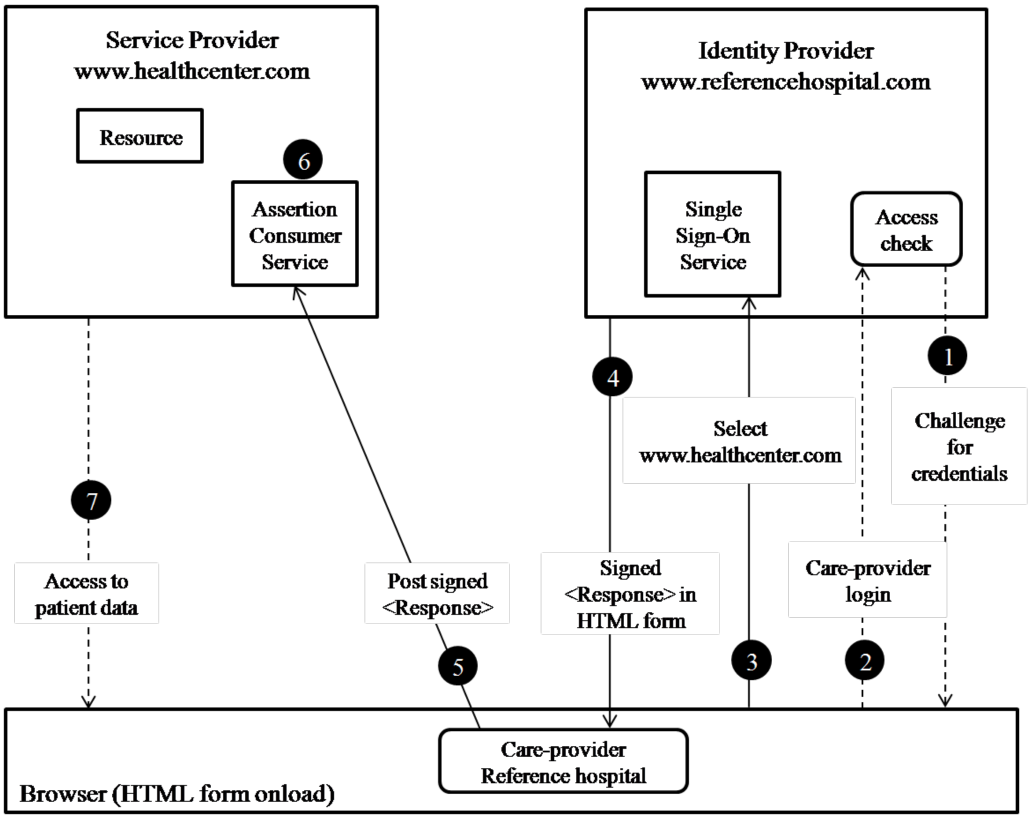


Figure 25: RH (IdP) initiated SAML 2.0 SSO with HTTP POST Binding (Adapted from [63])

1. To get access to secured application of the RH, the care-provider of the RH is required to supply his credentials to the website of the RH (IdP).

2. The care-provider provides valid credentials and a local logon security context is created for him at the RH.

3. Applications locally hosted or hosted by the DH or the HC are proposed on the RH website with respect to the user profile. The care-provider selects the link of the HC website to request access to the EMRS located at the HC.

4. The SSO service of the RH builds a SAML assertion representing the care-provider's logon security context. If the "Governance of the diabetes care network" requires a digital signature for SSO service, the assertion will be digitally signed before it is placed within a SAML <Response> message. The <Response> message is then placed within an HTML FORM as a hidden form control named SAMLResponse. (If the convention for identifying a specific application resource at the HC is supported at the RH and the HC, the uniform resource locator (URL) at the HC is also encoded into the

form using a hidden form control named RelayState.) The SSO service of the RH sends the HTML form back to the browser in the HTTP response.

5. The browser, due to either a care-provider action or execution of an “auto-submit” script, issues an HTTP POST request to send the form to the HC’s website, precisely the assertion consumer service. The HC’s assertion consumer service obtains the <Response> message from the HTML FORM for processing.

6. The digital signature on the SAML assertion, if used in step 4, must first be validated and the assertion contents processed in order to create a local logon security context for the care-provider at the HC. Once this is completed, the HC retrieves the RelayState data (if used in step 4) to determine the desired application resource (not shown). An access check is made to establish whether the care-provider of the RH has the correct authorization to access the EMRS at the HC.

7. If the access check goes through, then the care-provider gets access to the EMRS otherwise the login panel of the HC will be shown or he will be redirected to the RH.

Scenario 2: message flows initiated by the HC (service provider)

A care-provider of the RH, without a log in session on the website of the RH (IdP), who attempts to directly access the EMRS at the HC through the HC website (SP). Since the care-provider is not logged in at the HC, before it allows access to the EMRS, the HC sends the care-provider to the RH for authentication. The RH builds an assertion representing the care-provider’s authentication at the RH and then sends the care-provider back to the HC with the assertion. The HC processes the assertion and determines whether to grant the care-provider access to the EMRS.

Figure 26 illustrates the processing of an HTTP Redirect Binding used to deliver the SAML <AuthnRequest> message to the IdP (RH) and the HTTP POST Binding used to return the SAML <Response> message containing the assertion to the HC.

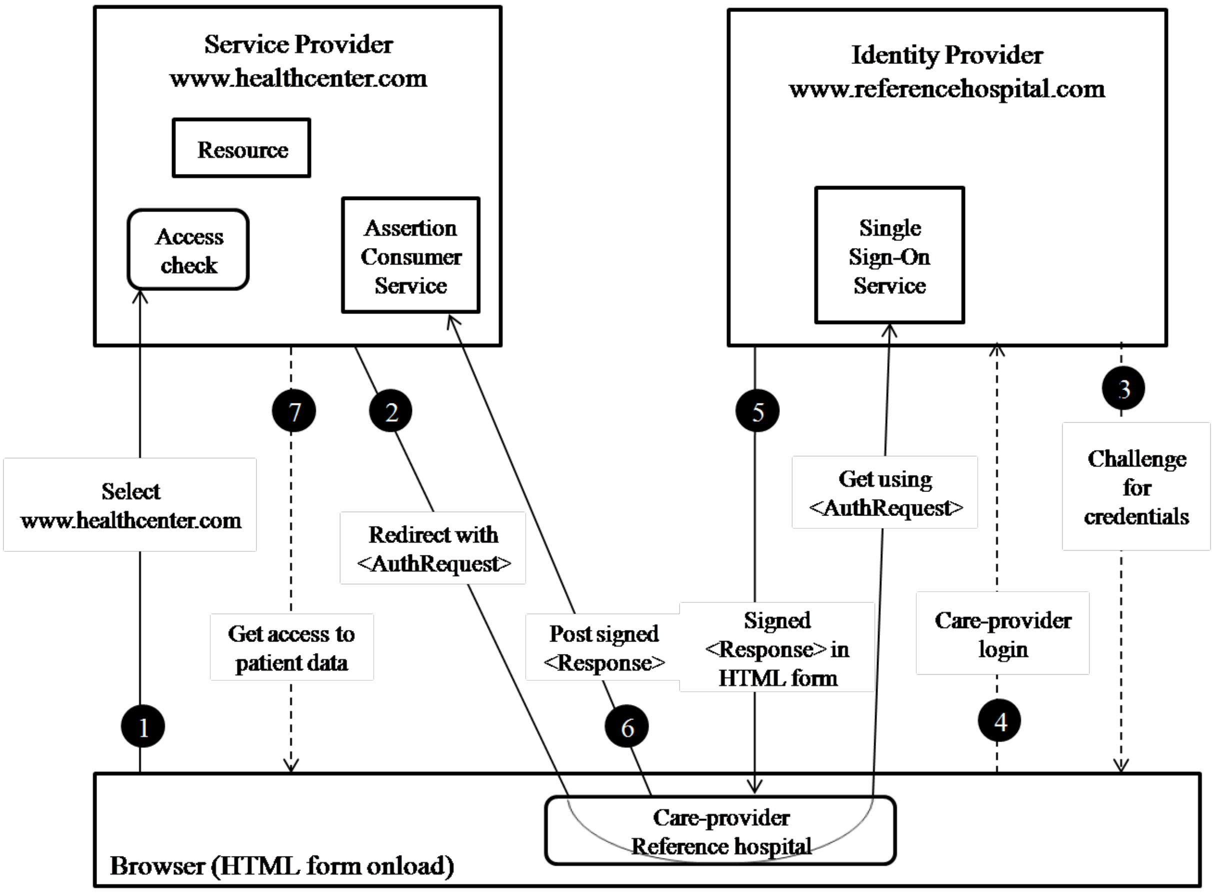


Figure 26: HC (SP) initiated SSO with Redirect and POST Bindings (Adapted from [63])

1. A care-provider of the RH aims at getting access to the EMRS located at the HC (SP) and accessible through its uniform resource identifier (URI) address. The care-provider does not have a valid session on the website of the HC. The HC saves the requested URL resource in local state information that can be saved across the web SSO exchange.

2. The HC initiates the SAML authentication protocol by sending the browser of the care-provider an HTTP Redirect Response directed to the RH (IdP). The HTTP header location contains the URI destination of the sign-on service at the RH and an authentication request <AuthRequest> message with a unique identifier string of the request.

   The browser processes the redirect response and issues an HTTP GET request to the RH's SSO service with the SAMLRequest query parameter.

3. The SSO service of the RH interacts with the browser to challenge the care-provider to provide valid credentials.

4. The care-provider provides valid credentials and a local logon security context is created for him at the RH.

5. The RH SSO service builds a SAML authentication assertion containing the unique request identifier of step 2, the care-provider's logon security context, the URI address of the RH, and the URI address of the HC. If the "Governance of the diabetes care network" requires a digital signature for SSO service, the assertion is digitally signed and then placed within a SAML <Response> message. The <Response> message is then placed within an HTML FORM as a hidden form control named SAMLResponse. If the RH received a RelayState value from the HC (in step 2) it must return it unmodified to the HC in a hidden form control named RelayState. The SSO service sends the HTML form back to the browser in the HTTP response. For easy-use purposes, the HTML FORM typically will be accompanied by script code that will automatically post the form to the HC website.

6. The browser, due to either a user action or execution of an "auto-submit" script, issues an HTTP POST request to send the form to the HC's assertion consumer service. The HC's assertion consumer service obtains the <Response> message from the HTML FORM for processing. The digital signature on the SAML assertion, if available, must first be validated and then the assertion contents are processed in order to create a local logon security context for the care-provider at the HC. Once this is completed, the HC retrieves the local state information indicated by the RelayState data to recall the originally-requested EMR URL. It then sends an HTTP redirect response to the browser directing it to access the originally requested EMRS (not shown).

7. An access check is made to verify whether the care-provider has the correct authorization to access the EMRS. If the access check goes through, then the patient data is returned to the browser.

4.3.3 The single logout in the diabetes care network

The care-provider who uses a SSO service of his local identity provider to access EMRS application at other healthcare facility has at least two open sessions. He therefore needs to go through all the visited websites to terminate the sessions opened. This exercise in the SSA healthcare context is very difficult to achieve because care-providers are mostly overworked.

To reduce the risk of forgetting to close all opened sessions and leaving sensible patient data accessible to unauthorized persons, the care-provider can globally terminate all the sessions he has opened by using a SLO from an opened session. To this effect SAML logout messages are synchronically communicated using the “SOAP Binding” or asynchronically communicated using the “HTTP redirect binding”, the “HTTP post binding”, or the “HTTP artifact binding”. Let’s adapt the SP-initiated SLO SAML specification to the case one of the conceptual model.

A care-provider of the RH locally authenticated by the IdP is interacting with the EMRS application of the HC through a SSO service of the RH. He decides to globally log out of all sessions opened. Figure 27 illustrates the SAML SLO processes initiated by the care-provider from the HC (SP).

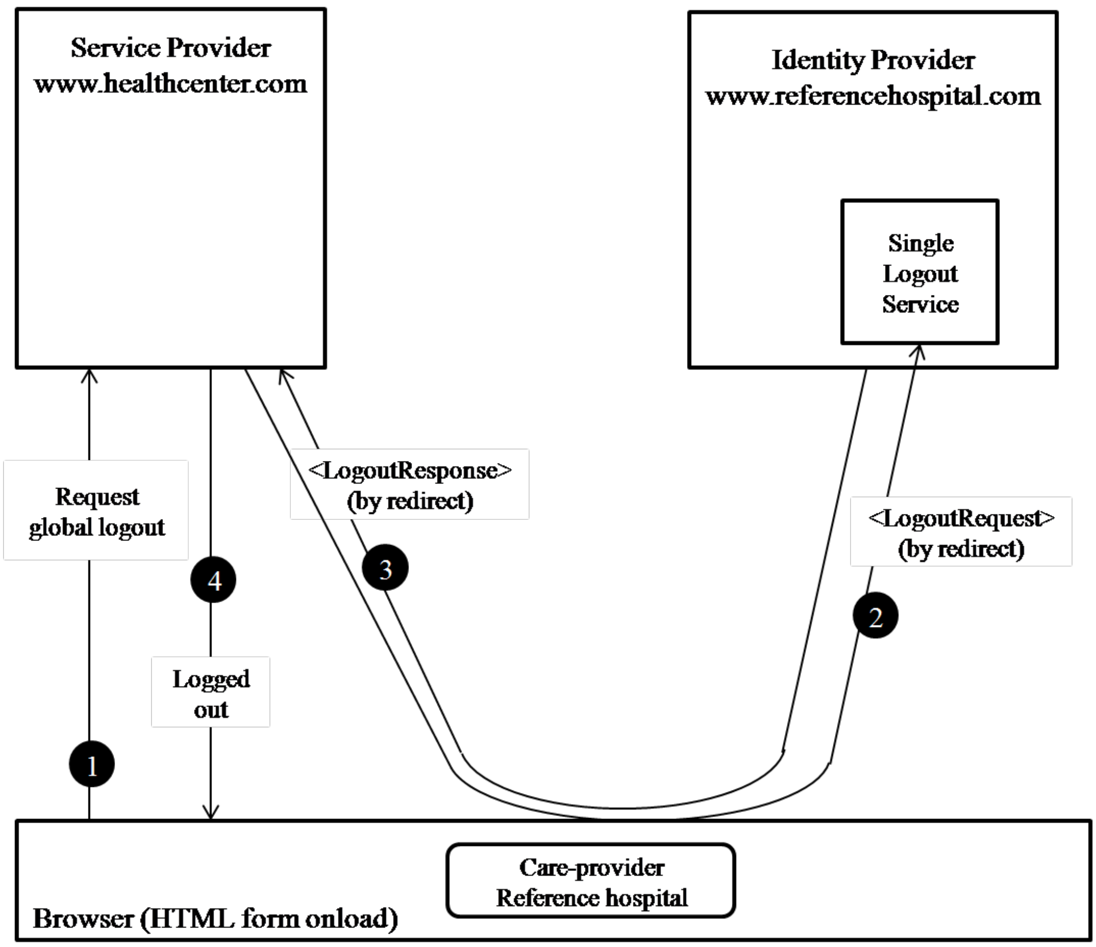


Figure 27: SLO process initiated at the HC (adapted from [63])

The processing is as follow:

1. The care-provider of the RH decides to globally logout and selects an appropriate link on the website of the HC that initiates the global logout request.

2. The HC destroys the local authentication state for the care-provider and then sends the RH a SAML <LogoutRequest> message requesting that the care-provider's session be terminated. The request identifies the principal to be logged out using a <Name ID> element, as well as providing a <SessionIndex> element to uniquely identify the session being closed. If the "Governance of the diabetes care network" requires a digital signature for SLO service, then the <LogoutRequest> message will be digitally signed and then transmitted using the HTTP Redirect binding. The RH verifies the <LogoutRequest> message originated from the HC. The RH processes the request and destroys any local session information for the care-provider.

3. The RH returns a <LogoutResponse> message containing a suitable status code response to the HC. If the "Governance of the diabetes care network" requires a digital signature for SLO service, the response is digitally signed and returned using the HTTP Redirect binding.

4. Finally, the HC informs the care-provider that he is logged out of all opened sessions.

4.4 Design of the EMRS prototype

In regard to the list of tasks to be improved (Table III) as inferred from the literature and the need assessment, a functional and technical analysis of OpenMRS was performed. This analysis came to the conclusion that those tasks dealing with the problem-oriented data aggregation (for example reviewing the patient's problem list and problem status), with the management of inpatient care events (for example generating the discharge letter after an inpatient hospitalization), with the pseudonymization of research data, and with the simulation issue of insulin and glucose levels cannot be achieved without an extension of the platform. This fact led to the design and development of two new modules: "Medical Problem" and "Inpatient Care" besides the "Diabetes Management" module. A pseudonymization service will be integrated in the application service later on. Each module is developed and used in the context of the conceptual model designed for the diabetes purpose in SSA. The conceptualization of three modules instead of one massive new diabetes module was preferred in order to give other OpenMRS users the possibility to separately adapt or use the new modules for their purposes [106]. For example, a site using OpenMRS for HIV/AIDS or MDR-TB patients can also use the “Medical Problem” and “Inpatient Care” modules without using the “Diabetes Management” module which only related to diabetes. However, the module “Medical Problem” is a prerequisite for the module “Diabetes Management” because of the importance of problem-oriented data aggregation in the management of co-morbid patients such as diabetes patients.

4.4.1 Module “Medical Problem”: problem-oriented data handling

The module provides the possibility to aggregate and display patient data in a problem-oriented way and also provides a quick access to patient problems with a causal mapping of problems and their details (encounters, observations, and programs). It provides functions (Table IV) necessary for recording problems, and for displaying all recorded patient problems (both resolved and unresolved), as well as the list of unresolved patient problems. It also includes functions for the management of patient problems and related medical data which can be used for example to define the relationship between existing and new problems. These functions will be very important for the management of co-morbid diabetes patients. In addition, the module provides a patient panel which is a portal page for limited patient access to the EMRS. The functions of this module cover the items 2, 3, 6, 8, and 9 of the list of processes to be improved (Table III).

Table IV: Functions and purposes of the module "Medical Problem"

Module name	Function	Purpose
Medical Problem	„Problems“ tab on the patient dashboard	- Displays all of recorded problems for the patient (both resolved and unresolved) in a similar way as the encounters tab, which can be then accessed individually
		- A “Problem” is a new data type that aggregates encounter, observation, and program records in order to provide a problem-oriented view;

	„Current Problems List“ box on the patient dashboard „Overview“ tab	- Lists all currently unresolved problem records for the patient
	“Patient Panel”	- Portal page for patients for limited system access (such as adding own observations); further functionalities have to be provided by other modules
		- Introduces new privileges for limited access to the user's own patient data, to be used in a "Patient" role
	additional graph servlets	- An improved JFreeChart servlet for observation graphs with different colors for the value ranges
		- JFreeChart graph servlet for displaying Map data written as serialized files
	“Manage Problem”	- This function has following sub-functions: “Add Problem”, “View/Edit Problem”, “Related Problem”, “Add related Problem”, and “Find Problem” as well as call the functions “Programs”, “Add Existing Programs”, “Encounters, “Add existing Encounter”, “Observations, and “Add Existing Observation”

4.4.2 Module: “Inpatient Care”: management of inpatient care data

This module extends the currently existing location hierarchy in OpenMRS data model by adding ‘department’, ‘specialty’, and ‘room’, as well as the ‘encounter‘ data [101, 106]. It provides functions and sub-functions (Table V), which facilitate the management of inpatient data, of departments, specialties, and rooms of a healthcare facility as well as generate discharge letters. Further functions allow a location-based provider role with restricted data access, and list inpatient care encounters. A graphical encounter timeline in the patient overview dashboard provides an access to specific past encounters. The functions of this module cover the items 3, 9, 13, 15, 16, 17, and 22 of the functional requirement (Table III) that improve some of the coordination of care processes described above.

Table V: Functions and purposes of the module "Inpatient Care"

Module name	Function	Purpose
Inpatient Care	*extension of the Location hierarchy*	- Add new subsets to the Location data type (Location->Department->Specialty->Room)
		- basic data structures similar to Location
		- Room also has a capacity field for calculating currently available capacity
	"Manage Department/Specialty/Room"	- Lists of existing departments, specialties, and rooms, as well as pages for adding/editing existing ones
	extension of the Encounter data type	- Add an encounter date time end field to the "Encounter" data type, allowing to record a duration for encounters (for inpatient care)
		- Add a hierarchy to encounter records: inpatient care *(parent)* records can have multiple *(child)* records as a subset (representing the duration of inpatient care as well as encounters and processes during the inpatient care)
		- Add a "room_id" field to encounter records for recording a more precise point of care including the bedroom during inpatient care
		- Display a list of currently hospitalized patient for each bedroom, specialty, department, and location
	"Inpatient Care" tab on the patient dashboard	- Lists and provide access to inpatient care encounters (parent and child encounters)

	„Encounter Timeline“ box on the patient dashboard „Overview“ tab	- Display a graphical timeline for the last encounters (using an own graph drawing servlet)
		- Use different colors to specify encounter types (outpatient, inpatient, visitation)
	“Discharge letter”	- Create a discharge letter dataset for inpatient care encounters (as a XML and PDF document)
	“Location-restricted view”	- Add a department-based provider role with restricted data access (i.e. a care-provider of a specific department may only access records of patients that have had at least one encounter at the department)
		- A care-provider may belong to many departments
	“Manage Encounter”	Another function that manages inpatient care encounters is „Manage Encounter“. It has sub-functions like: “Add Encounter”, and “Find Encounter”. Under the function “Inpatient Care” of the dashboard the sub-function “View” give a list of encounters within the hospitalization time, and the sub-function “Edit” calls the function “Manage Encounters” with the sub-functions: “Encounter Summary”, “Generate Discharge letter”, “Child Encounters”, “Add new Child Encounter”, “Observations”, and “Add Observation”.

4.4.3 Module: “Diabetes Management”: optimization of diabetes care and management process in SSA

The designed module provides functions (Table VI) which help to manage relevant clinical data for diabetes care, to generate graphs for visualization of clinical diabetes data, and to manage the insulin type. The data entry form has been designed using information of the diabetes clinical practice guidelines for SSA recommended by the IDF Africa [42]. Existing reporting functions in OpenMRS have been used in order to generate the report recommended by IDF Africa. Furthermore, the module offers a glucose-insulin metabolism simulation. This simulation model is for inexperienced care-providers, patients, and students for educational purposes [107, 108] and possibly for research [109, 110]. The simulation is based on the following parameters: patient's weight, time, and carbohydrate intake, type and dosage of insulin injections, values for kidney threshold and function, and values for liver and peripheral insulin resistance. The result set consists of the graphs for plasma glucose and plasma insulin, as well as a graphical representation of the meals and insulin injections entered into the input fields prior to the simulation run. The functions of this module with the core clinical and cohort building functions of OpenMRS cover the items 1, 4-7, 10-12, 14, and 18- 21 of the functional requirements list (Table III) that include processes of the coordination of care, strategic planning, patient involvement, and support of diabetes research described above. The validation demonstrator mimics this functionality.

Table VI: Functions and purposes of the module "Diabetes Management"

Module name	**Function**	**Purpose**
Diabetes Management	"Graphs of Relevant Observations"	- Display a page of relevant diabetes related observation graphs (use the observation graph servlet provided by the Medical Problem module)
	"Glucose-Insulin Simulation"	- Simulate a 24-hour profile of glucose-insulin interaction for a type 1 diabetes mellitus patient (based on the Lehmann/Deutsch model)
		- Simulate responses to glucose equivalents of carbohydrate intake and different types of insulin injections
		- Allow altering regimens and running another simulation directly afterwards; display the difference in glucose and insulin curves between current and previous runs

		- Link the simulation page in the „Patient Panel“
	Observation entry pages for patients	- Add observation entry pages in the "Patient Panel" (added by the Medical Problem module)
Other functions	*Diabetes care data form entry*	- Add diabetes specific data entry forms (conform to the IDF Africa Recommendation); forms should be in html and MS Infopath
	“Diabetes Care Reports”	- Add XML templates for reports recommended by the IDF African Region
		- Include the existing “Report Template module” to be used to export the generated XML-based reports as Excel style sheets, thus allowing to calculate incidence percentages (as requested by the IDF African Region)
	“Configure Relevant Concept”	- This function provides the possibility to remove or add concepts to the existing list of diabetes concept of the EMRS.
	“Manage Insulin Types”	- This function provides the space for adding new insulin type or deleting existing one.

4.5 Modeling the new modules with $3LGM^2$ -tool

Applying the methodology of the $3LGM^2$ each module described below was modeled. The enterprise functions of each module and their associated entity types were modeled in the domain layer. Each function interprets or updates entity types which are part of the OpenMRS data model. Figure 28 for example shows an instance of the domain layer of the module “Medical Problem”.

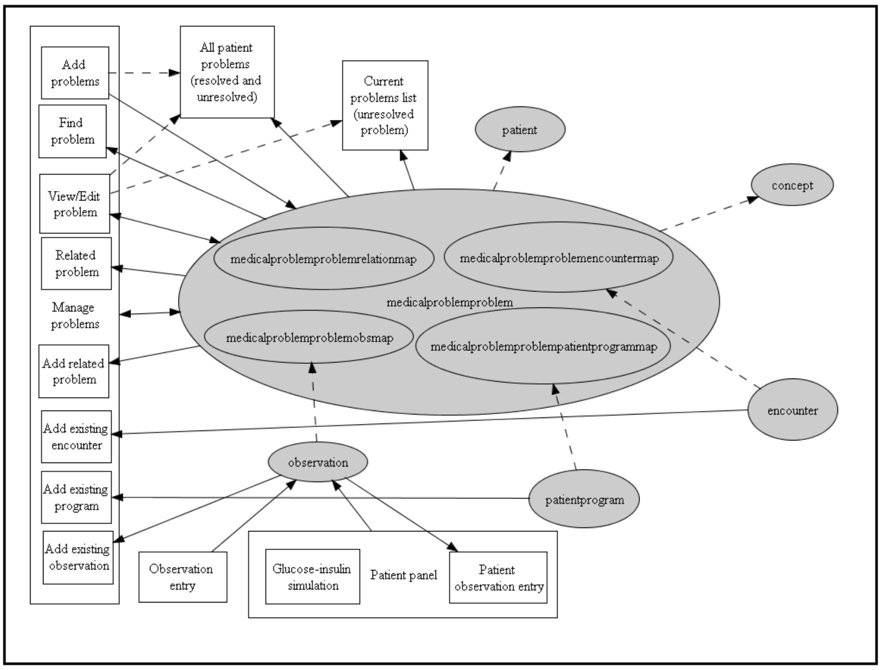


Figure 28: The domain layer of the medical problem module. Enterprise functions are depicted as rectangles, entity types as ovals, interpretation as an arrow pointing to a function, and update as an arrow pointing to an entity type. The meaning of dashed arrows is explained within the text

The association between the function "Manage problems" and the entity type "medicalproblemproblem" (expressed by the bidirectional arrow) denotes that "Manage problems" does not only use information about "medicalproblemproblem", but also updates information. The enterprise functions (e.g. "Add related problem") designed inside the enterprise function "Manage problems" and the dashed arrows denote the 'is_part_of' relation between functions as well as between the entity types.

The concepts illustrated in Figure 28 can be formalized using algebraic structure as explained in 2.4.1 Domain layer. Let:

- EF := {ef_1, …, ef_{15}} denotes the set of enterprise functions as follows: ef_1 = "Add problems", ef_2 = "Find problem", ef_3 = "View/Edit problem", ef_4 = "Related problem", ef_5 = "Add related problem", ef_6 = "Add existing encounter", ef_7 = "Add existing program", ef_8 = "Add existing observation", ef_9 = "Manage problems", ef_{10} = "Problems", ef_{11} = "Current problem list", ef_{12} = "Observation", ef_{13} = "Patient panel", ef_{14} = "Patient observation entry", and ef_{15} = "Glucose-insulin simulation";

- $\underline{ET}$:= {et_1, …, et_{10}} denotes the set of entity types as follows: et_1 = "medicalproblemproblem", et_2 = "medicalproblemproblemrelationmap", et_3 = "medicalproblemproblemencountermap", et_4 = "medicalproblemproblemobsmap", et_5 = "medicalproblemproblempatientprogrammap", et_6 = "observation", et_7 = "patient", et_8 = "patientprogram", et_9 = "encounter", and et_{10} = "concept";

- and ACC := $(acc_{p,q})_{p=1\ldots15,\ q=1\ldots10}$ be a two-dimensional matrix describing how enterprises functions access entity types. It shall hold that $acc_{p,q} \in \{0, i, u, iu\}$ and $acc_{p,q}$:= 0 if enterprise function $ef_{p\ (1 \le p \le 15)}$ neither interprets nor updates entity type $et_{q\ (1 \le q \le 10)}$, $acc_{p,q}$:= i if enterprise function $ef_{p\ (1 \le p \le 15)}$ interprets entity type $et_{q\ (1 \le q \le 10)}$, $acc_{p,q}$:= u if enterprise function $ef_{p\ (1 \le p \le 15)}$ updates entity type $et_{q\ (1 \le q \le 10)}$, and $acc_{p,q}$:= iu if enterprise function $ef_{p\ (1 \le p \le 15)}$ interprets and updates entity type $et_{q\ (1 \le q \le 10)}$. The matrix can be seen in Table VII.

Table VII: Two dimensional matrix describing how enterprises function access entity types

$acc_{p,q}$		Entity types q = 1, …, 10									
		et_1	et_2	et_3	et_4	et_5	et_6	et_7	et_8	et_9	et_{10}
Enterprise functions p = 1, .., 15	ef_1	u	0	0	0	0	0	i	0	i	i
	ef_2	i	i	i	0	0	0	i	0	i	i
	ef_3	iu	i	i	i	i	i	i	i	i	i
	ef_4	i	i	i	0	0	0	i	0	i	i
	ef_5	i	i	i	0	0	0	i	0	i	i
	ef_6	i	0	0	0	0	0	i	0	i	i
	ef_7	i	0	0	0	i	0	i	i	0	i
	ef_8	i	0	0	i	0	i	i	0	0	i
	ef_9	iu	i	i	i	i	i	i	i	i	i
	ef_{10}	i	0	0	0	0	0	i	0	i	i

	ef_{11}	i	0	0	0	0	0	i	0	i	i
	ef_{12}	i	0	0	i	0	iu	i	0	i	i
	ef_{13}	0	0	0	0	0	0	i	0	0	0
	ef_{14}	i	0	0	0	0	u	i	0	0	i
	ef_{15}	0	0	0	0	0	0	0	0	0	0

Application components such as ‘ProblemService’, ‘ObsService’ are represented in the logical (application) layer Figure 29.

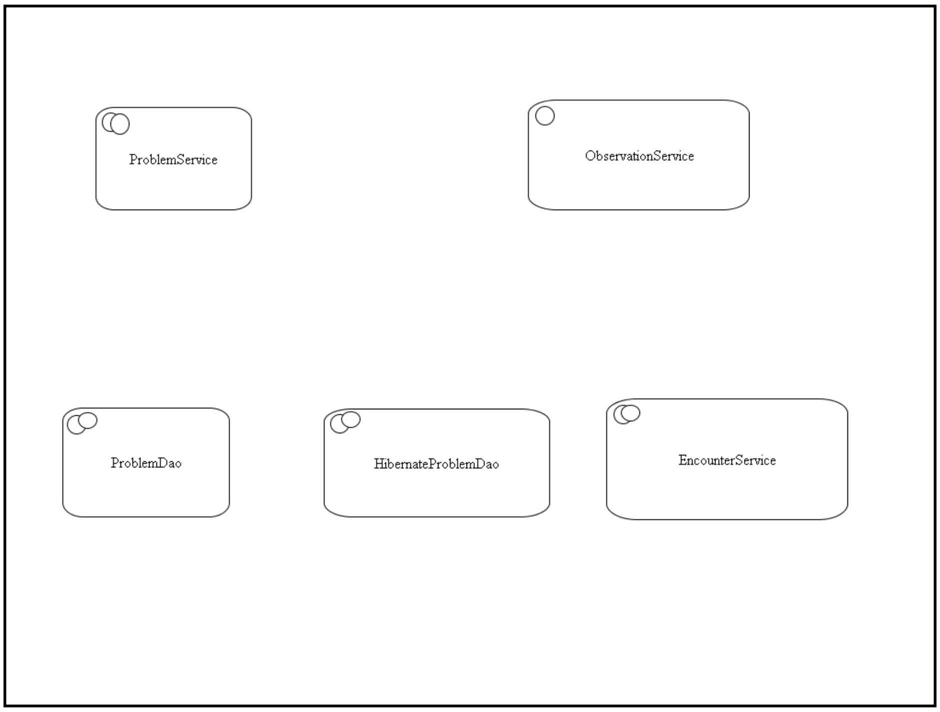


Figure 29: The logical layer of the medical problem module. Application components depicted as rounded rectangle support enterprise functions of the domain layer. The circles denote communication interfaces such as “ProblemDao” and “HibernateProblemDao” which are used for the communication with the database

These application components are linked to their corresponding functions and entity types from the domain layer. The linkage describes for example which application components are needed to perform what functions. The ontology of this relation is as follow:

- let <u>EF</u> := {ef_1, …, ef_{15}} be the set of enterprise functions of the domain layer;

- let <u>AC</u> := {ac_1, ac_2} be the set of application components as follows: ac_1 = "ProblemService", ac_2 = "ObservationService"

- and let SUP := $(sup_{p,\ n})_{p\ =\ 1...15,\ n\ =\ 1,\ 2}$ be a two dimensional matrix describing the relationship between enterprise functions and application components, such that $sup_{p,\ n} \in \{0, 1\}$ and $sup_{p,\ n}$:= 1, if the function ef_p is supported by the application components ac_n and $sup_{p,\ n}$:= 0 else. This matrix can be seen in Table VIII.

Table VIII: Two dimensional matrix describing the relationship between enterprise functions and application components

$Sup_{p,\ n}$		Application components n = 1, 2	
		ac_1	ac_2
Enterprise functions P = 1, …, 15	ef_1	1	0
	ef_2	1	0
	ef_3	1	1
	ef_4	1	0
	ef_5	1	0
	ef_6	1	0
	ef_7	1	0
	ef_8	1	1
	ef_9	1	1
	ef_{10}	1	0
	ef_{11}	1	0
	ef_{12}	1	1
	ef_{13}	1	0

	ef_{14}	1	1
	ef_{15}	0	0

Three healthcare facilities, each representing a facility of the pyramidal healthcare referral system (HC, DH, and RH), are represented at the physical layer which images the place of use of the system as well as the data storage place (Figure 30).

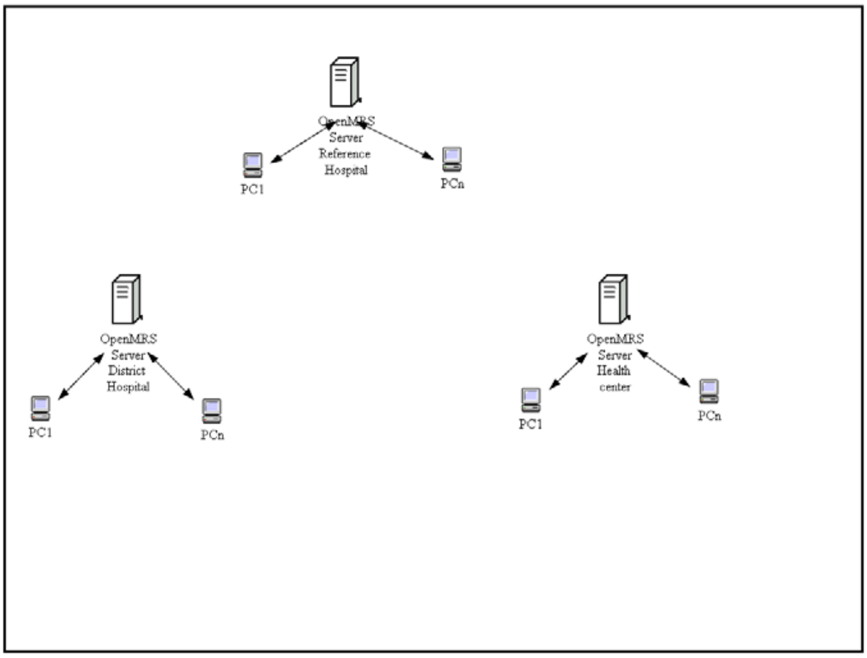


Figure 30: The physical layer of the medical problem module

Figure 30 images however an abstract view of the physical data processing components used in each healthcare facility of the established network. To enhance the security in each facility, the use of different servers for the database and the applications as well as firewall is recommended. The physical data processing components are linked to the application components of the logical layer. The inter-layer representation is highlighted in the appendix-section (Appendix-Figure 8).

4.6 Prototype development and test

The development environment of the open source EMRS (Figure 9) selected as application platform was used to develop the demonstrator. For each module described above, an entity-relationship diagram (ER-diagram) was designed with regard to the existing OpenMRS data model. For each new function, existing or new application interfaces and web applications were used or developed. Since the whole data model of OpenMRS has been explained in many papers, it will not be repeated here [24, 96-98, 100].

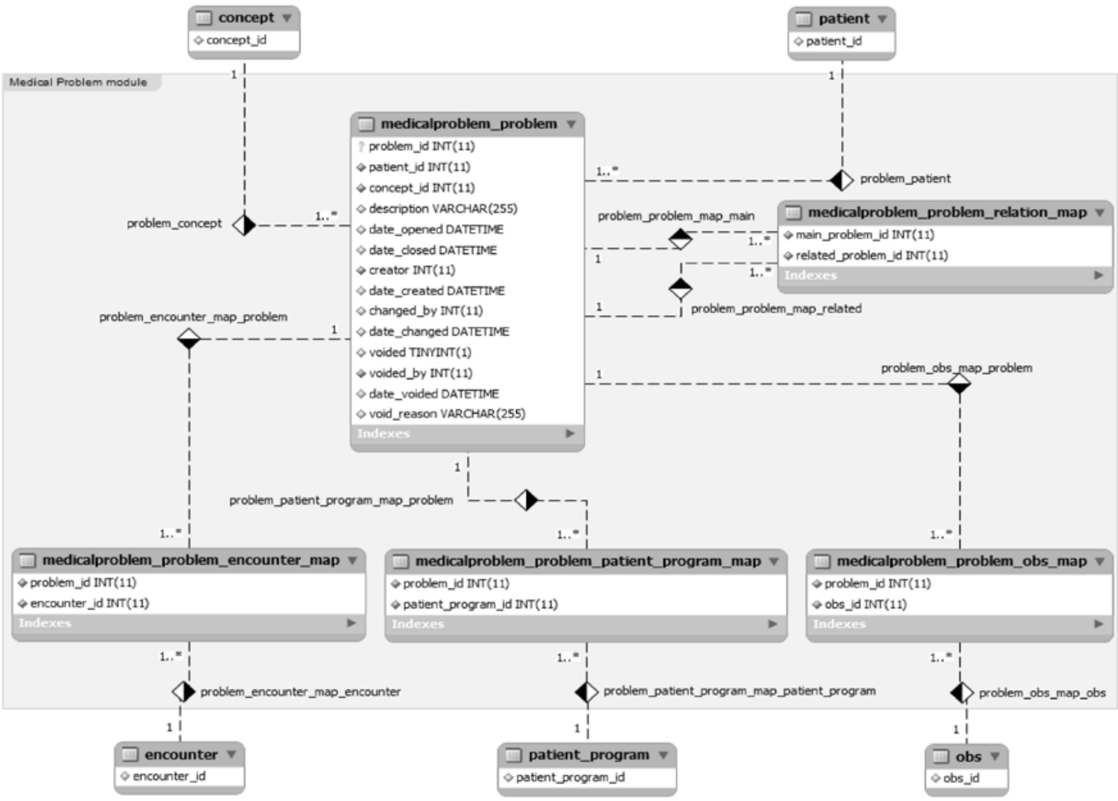


Figure 31: Entity-relationship diagram of the "Medical Problem" module. The diagram is explained in the text

Figure 31 shows for example the ER-diagram of the medical problem module. This diagram shows the tables of this module and their relationships. The module's main table "medicalproblem_problem" for example displays fields that include important attributes such as 'problem_id' (unique ID of the record), 'patient_id' (references in the patient table), 'concept_id' (references in the concept table), and 'description' for a short description of the care-provider with respect to the mentioned problem. Patients' medical problems are defined as concepts that can be clearly identified and used for other purposes including data analysis.

The attribute ‘concept_id’ contains the ID of the concept that describes the type of patient problem (e.g. diabetes mellitus type 2). This concept is defined like most data in OpenMRS, using the concept dictionary and being stored as coded concepts to allow easy information linkage, retrieval, and analysis. All patient data relevant to a specific medical problem are captured through attributes of the tables ‘encounter’, ‘observation’, and ‘patient_program’ that are linked to the table ‘medicalproblem_problem’. The concept dictionary includes terms for questions and potential answers [96].

Twenty anonymized diabetes patient details of the Department of Gastroenterology and Endocrinology of the University Medical Center of Goettingen were used for test purpose. The black box test performed shows that the demonstrator fulfills the functions designed with a limitation in the simulation tool. Figure 32, for example, shows a screenshot of the new patient overview page. This page illustrates the current problem list of the patient and an encounter timeline. The tabs “problem” and “inpatient care” link the care-provider to all patient problems and to inpatient care encounters. Further ER-diagram’ figures and screenshots of the demonstrator developed are available at:

http://openmrs.org/wiki/Inpatient_Care_Module_User_Guide
http://openmrs.org/wiki/Medical_Problem_Module_User_Guide
http://openmrs.org/wiki/Diabetes_Management_Module_User_Guide

Results of the experts validation section provide more insight into the demonstrator’s evaluation [111].

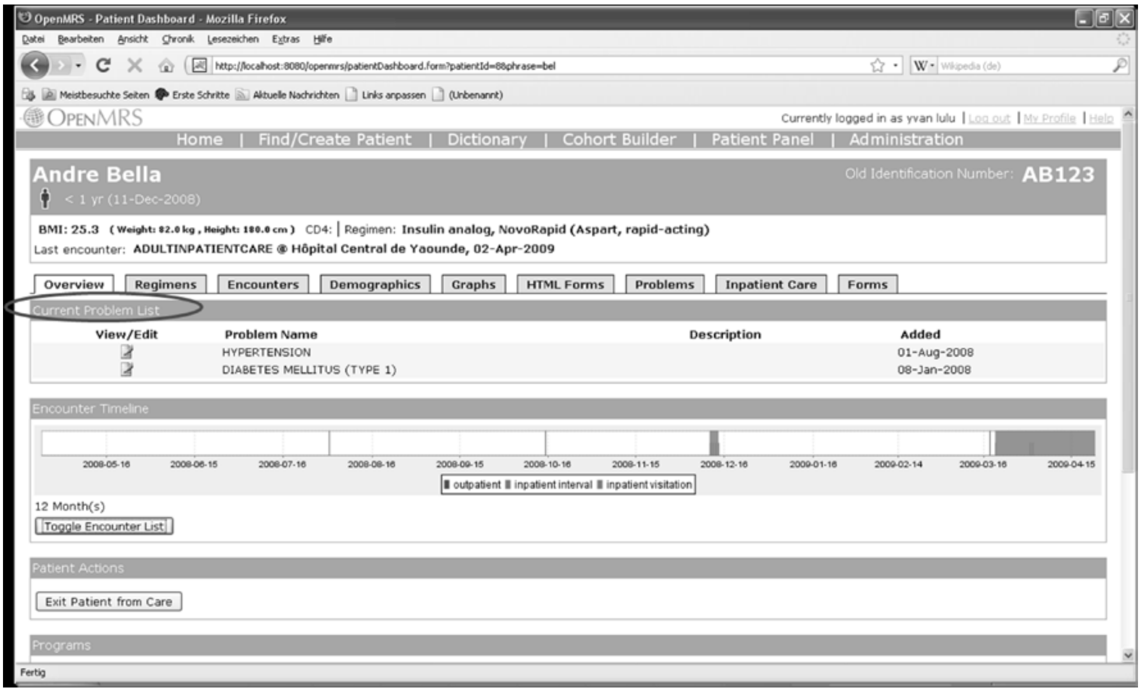


Figure 32: Patient dashboard with a view of the current problem list, the encounter timeline, and the tabs to further functionalities of the problems and inpatient care

4.7 Potential impact of the conceptual model on diabetes care and management in SSA

4.7.1 Coordination of care and interdisciplinary teamwork

The organizational key improvements of the approach are: (1) access to patients’ information by care-providers at different sites, and (2) avoidance of double test ordering and drug prescribing and improvement of collaboration.

By offering access to patients’ data to care-providers of other departments or settings, the concept designed (Figure 20, Figure 21) provides a framework for sharing patients’ information that is important for coordinated care. This framework is particularly important in SSA countries for an efficient and effective use of the limited number of well-trained care-providers available. A problem-oriented aggregation and presentation of data (encounters, observations, programs, and related problems) of the EMRS will support the multi- and interdisciplinary teamwork needed for co-morbid diabetes patients.

Considering the fact that the majority of patients in SSA countries have very low income and no health insurance, a closely-knit teamwork of care-providers with the EMRS decision support tools will help to avoid or at least reduce duplication of services, double test ordering and drug prescribing which increases the costs of treatment. These services lead to time saving and treatment cost reduction. Additionally, the growing use of modern mobile phones in SSA may facilitate the communication and collaboration between health professionals of different settings as well as between health professionals and patients as presented in the models highlighting the examination processes.

4.7.2 Strategic planning and diabetes surveillance

The key treatment improvements are: (1) diabetes report generation and transmission, and (2) the assessment of the quality of care.

The EMRS in the conceptual model will allow health professionals to generate different reports (Figure 21) including population-based ones which are important for the strategic planning and diabetes surveillance. These reports will be electronically transmitted to the different institutions. Such services also lead to time savings. In case of a roll out in all diabetes centers of a region, it will facilitate the work of regional diabetes programs and healthcare decision and policy makers, and will support the work done by the WHO, the IDF, and other institutions active in this area in Africa.

The EMRS in the model will also facilitate the assessment of indicators for a periodic monitoring of the quality of care of diabetics in SSA recommended in the “Type 2 Diabetes clinical practice guidelines for SSA” by the IDF-Africa [42]. As explained in this guideline, the regular assessment of quality of care indicators helps to identify deficiencies, which are important for the development of change strategies needed, to improve the quality of healthcare delivery and its outcome.

4.7.3 Patient involvement

The model provides an option which allows patients to access the EMRS. This includes a tool for simulating patients’ daily insulin and glucose levels, and a function which allows patients to send lab results to care-providers. In a long-term view these services could improve the communication processes between care-providers and patients as well as the motivation of patient self-care education. The self-care education should be coordinated by diabetes educators and should be a complementary component to the current education session organized by diabetes centers in the countries visited.

4.7.4 Support of diabetes research in SSA

Local clinical and public health researchers could address research topics using population-related and medical data collected at the point of care. Indeed the problem-oriented record of patient data as specified in Table IV will facilitate diabetes studies. By using the EMRS for example to support care delivery and management of diabetes and HIV/AIDS patients, it could provide a framework to support research addressing the impact of HIV on diabetes prevalence. However, it would be important to develop a module for pseudonymizing research data, in order to preserve privacy.

4.8 Validation of the proposed approach

4.8.1 Validation workshop

The validation workshop based on problems encountered in diabetes management in Côte d'Ivoire proved that the approach presented here was also applicable in countries which were not visited during the need assessment [111]. The local situation presented by the president of the national program against metabolic diseases of Côte d'Ivoire correlated well with problems identified in the literature and during the need assessment. This senior expert agreed that his vision of a strategic approach correlated well with the approach of the conceptual model or could be improved by it: the creation of diabetes HC with collaborating local clinics to reduce the workload of the few available diabetes experts. In the case of Côte d'Ivoire for example, there are only two diabetes centers in the country (both based in Abidjan). At the end of the workshop, some participants suggested that the solution should be extended to the use of mobile phones for the follow-up of patients at home and in remote areas. This issue could be improved by adopting for example the home blood pressure tele-management system described in [79] for a use in OpenMRS – when the OpenMRS community will have reached the level of the mobile version. In addition, the data security problem was also addressed by many participants.

4.8.2 Outcome of the SSA experts evaluation

The evaluation of the conceptual model (Figure 20) by the experts was focused on 4 sub-topics: coordination of care and multi- and interdisciplinary teamwork, strategic planning and diabetes surveillance, support of diabetes research in Africa, and patient involvement. These four topics which are presented in sub-section “4.7 Potential impact of the conceptual model on diabetes care and management in SSA” as proof of concept have been validated by all seven experts.

Coordination of care

All experts validated the proposed four statements (Appendix-Table I, part 1) that describe the possible impact of the conceptual model on the coordination of care of diabetes patients with at least “slightly agree”. While five of seven experts validated the statements with “agree”, two of seven experts validated these with “strongly agree”. The result of the assessment of this sub-part of the conceptual model seems to illustrate the need and the importance to introduce this approach for the improvement of the multi-disciplinary and interdisciplinary care in SSA. This can also be attributed to the key role that organizational aspects play in the effectiveness of chronic disease care improvement and management.

Strategic planning and diabetes surveillance

While two of seven experts evaluated the first statement of this sub-part (Appendix-Table I, part 4) with “strongly agreed”, five of seven experts validated this with “agree”. The second statement was validated with 3 “strongly agree”, 3 “agree”, and 1 “slightly agree”. The evaluation results of this sub-part of the questionnaire appear to confirm that the conceptual model will help to improve processes of the quality of care-delivery as well as to facilitate the work of all actors active in the strategic planning such as decision and policy makers.

Patient involvement

While the first statement of this sub-part (Appendix-Table I, part 3) was validated with 1 “strongly agree”, 4 “agree”, 1 “slightly agree”, and 1 “neutral”, the second statement was validated with 1 “strongly agree”, 3 “agree”, 1 “slightly agree”, and 2 “neutral”. One expert who remains neutral added: “I think the overall strategy of incorporating patient data is good, but likely to be unachievable in many SSA settings for a while.” The evaluation results of this sub-part seems to confirm that the patient access in the EMRS is a complementary component to the education session already organized by diabetes centers in SSA that could also help to improve the communication between patients and health professional.

Support of diabetes research

While the first statement of this sub-part (Appendix-Table I, part 2) was validated with 4 “strongly agree”, 1 “agree”, and 2 “slightly agree”, the second statement was validated with 1 “strongly agree”, 3 “agree”, 1 “slightly agree”, 1 “neutral”, and 1 “disagree”. The third statement was validated with 4 “strongly agree”, 2 “agree”, and 1 “slightly agree”. Although this sub-part result confirms the possible impact of the model on diabetes research in SSA, it also illustrated disagreements of two experts with two statements formulated. One expert believed that the expansion of OpenMRS to diabetes does not provide a framework supporting research on the impact of HIV on diabetes development in SSA. Another expert highlighted that a module for pseudonymizing research data is not absolutely necessary for SSA. This expert believes that privacy should not be a barrier to the implementation of EMRS in SSA, and added that the focus should be on the improvement that can be obtained with the solution. One of the four experts who strongly agreed with the statement on the importance to pseudonymize research data in SSA commented that it is very important to apply pseudonymization not only for research purposes, but also for monitoring and evaluation.

Summary conceptual model

Three experts evaluated their satisfaction with the conceptual model as “very good” while four found it “good”. This expert validation demonstrates that requirements elaborated after the evaluation of the literature result and the need assessment have been well interpreted and incorporated in the conceptual model that could improve the situation of diabetes care and management in SSA.

Summary significance of EMRS functions

Table IX: Expert assessments of the EMRS functions deducted from the conceptual model

Function	Assessment				
Review the patient's problems list, problem status	Non significant	Slightly significant	Neutral	Significant	Strongly significant
	0	0	0	2	5
Provide access to each problem details	Non significant	Slightly significant	Neutral	Significant	Strongly significant
	0	0	0	4	3
Follow results of a test or investigation over time	Non significant	Slightly significant	Neutral	Significant	Strongly significant
	0	0	0	0	7
Diabetes data entry form (as recommended in the clinical guideline of IDF Africa): result of lab tests and other diabetes important investigations are recorded	Non significant	Slightly significant	Neutral	Significant	Strongly significant
	0	0	0	2	5
Get encounters details, observation details, and regimens details	Non significant	Slightly significant	Neutral	Significant	Strongly significant
	0	0	1	4	2
Get patient history details	Non significant	Slightly significant	Neutral	Significant	Strongly significant
	0	0	0	4	3
Produce data reviews for specific patient groups	Non significant	Slightly significant	Neutral	Significant	Strongly significant
	0	0	0	5	2

Generate discharge letter after an inpatient hospitalization	Non significant 0	Slightly significant 0	Neutral 3	Significant 1	Strongly significant 3
Display comparative graph of relevant clinical data of diabetes patient	Non significant 0	Slightly significant 0	Neutral 0	Significant 4	Strongly significant 3
Track and manage patients and their diabetes-specific information	Non significant 0	Slightly significant 0	Neutral 0	Significant 3	Strongly significant 4
Track patient requiring assessment (planed visit)	Non significant 0	Slightly significant 0	Neutral 0	Significant 2	Strongly significant 5
Provides reliable data for diabetes surveillance and evaluation	Non significant 0	Slightly significant 0	Neutral 0	Significant 3	Strongly significant 4
Generate report for the monitoring of quality of care as recommended in the clinical guideline of IDF Africa	Non significant 0	Slightly significant 0	Neutral 0	Significant 4	Strongly significant 3
Simulation tools for inexperienced health professionals Simulate a 24-hour profile of glucose-insulin interaction for diabetes patient	Non significant 0	Slightly significant 0	Neutral 2	Significant 1	Strongly significant 4
Simulate responses to glucose equivalent of carbohydrate intake and different type of insulin injection	Non significant 0	Slightly significant 1	Neutral 1	Significant 3	Strongly significant 2

Allows altering regimens and running another simulation directly afterwards, displaying differences in glucose and insulin curves between current and previous runs	Non significant 0	Slightly significant 1	Neutral 1	Significant 3	Strongly significant 2
List existing location (location, department, specialty, room) and allow a location-restricted view of patient data	Non significant 0	Slightly significant 1	Neutral 2	Significant 1	Strongly significant 3
List inpatient care encounters	Non significant 0	Slightly significant 1	Neutral 2	Significant 3	Strongly significant 1
Display a graphical timeline of the encounters for the last six months	Non significant 0	Slightly significant 0	Neutral 2	Significant 2	Strongly significant 3
Provide a restricted access for patients to the EMRS	Non significant 0	Slightly significant 1	Neutral 2	Significant 2	Strongly significant 2
Patient can simulate their daily data for education purpose	Non significant 1	Slightly significant 2	Neutral 0	Significant 3	Strongly significant 1
Patient can use their portal to enter observation relevant to their diseases (eg. blood glucose)	Non significant 0	Slightly significant 1	Neutral 1	Significant 3	Strongly significant 2

5. Discussion

5.1 Main findings

This research work aimed at, firstly, to identify a major health problem which is similar to HIV/AIDS and MDR-TB, being a business case for the use of IT-based solutions in the health system of SSA countries. Secondly, it is aimed at identifying problems encountered in the care and management of this disease. Thirdly, assess the Needs and Remedies to the situation. Fourthly, to propose new management approach with the use of economically viable EMRS and lastly to address the role of health informatics programs towards a sustainable development of health informatics in SSA. The detailed results have been presented in the previous sections and the mains findings are discussed below.

1 "Identify a major health problem which, similar to HIV/AIDS and MDR-TB is a business case for the use of EMRS in the health systems of SSA countries"

HIV/AIDS and MDR-TB have been considered here as a business case for the use of EMRS in the health system of SSA countries because, firstly these two diseases affect greatly the economically active population in SSA, secondly they are highly communicable, thirdly they are costly for patients and for the local health system, and finally they have a direct impact on the local economic development. In this case, the use of economically viable EMRS has proven to be efficient for clinical and planning purposes with an indirect cost saving for the health system. For example in countries like Peru [36, 112, 113], Kenya [25, 37, 40], Malawi [27], and Ruanda [24]. These facts can explain the increasing acceptance of local SSA government and international funding agencies to support the implementation and use of economically viable EMRS for improving the quality of treatment and management of HIV/AIDS and MDR-TB in SSA. This acceptance and support by the local governments and stakeholders is an important prerequisite for the sustainability of ICT-based healthcare projects and for a long term planning of a multi sectoral introduction of IT-infrastructure in countries of this region. Therefore, the use of IT-based solutions in the SSA health care system should be focused first on health problems that contribute to hinder the economic development of this region or/and which are recognized as severe by local governments and international funding agencies. This approach takes into account the difficult economic situation of SSA countries which are not able to afford IT-infrastructure, IT-systems, and to engage adequate personnel for the use at all levels of their health system, especially, where the impact of this use cannot be easily proven.

In this work, diabetes has been identified as a costly, chronic, incurable and underestimated health problem in SSA which, similar to HIV/AIDS and MDR-TB, is a business case that also demands the use of IT-based solution such as EMRS.

Results obtained from the literature review and the assessment of the Needs show that SSA faces other severe burdens of diseases in addition to HIV/AIDS and MDR-TB that handicap the local economic development. The most dangerous diseases mentioned among all are: non communicable diseases such as cancer, diabetes, heart diseases, and stroke, as well as maternal, new born and child health. From this list diabetes has been preferred because it is a costly chronic disease, and the economic active population is the most affected. In most cases, patients are co-morbid and they generate severe complications like amputations, blindness, heart diseases, stroke, end-stage kidney disease, and nerve diseases to which treatment is usually expensive. Furthermore, the estimated increase of diabetes prevalence in SSA is alarming.

It is worth mentioning that the estimated augmentation of diabetes prevalence for SSA presented in the literature highlighted in this work does not take into account facts like the level of urbanization, the change of life style, overweight, and obesity in today's SSA population which are on the increase. These factors are well recognized drivers of the epidemic of type 2 diabetes [1, 114]. The increasing number of obesity can be attributed to the societal tendency of SSA population to see overweight and obesity as a sign of good health in comparison to AIDS and TB patients. The urbanization and change of life style can be attributed to the industrialization and globalization respectively.

The study conducted by authors working at WHO Africa, analyzing the cost of diabetes in SSA health system highlights significant total cost of diabetes [10]. This shows that diabetes is costly for the patients, relatives (family, neighbors, friends), and imposes a substantive economic burden on SSA countries. The study, however, does not consider the costs of diabetes complications because there is no valuable information to assess their impact on medical costs and productivity. Taking the treatment costs of diabetes complications into account can considerably enhance their current estimate. The lack of information on the number of diabetes patients with complications such as heart diseases, nephropathy, retinopathy, foot ulcers, kidney problems, etc is being stated as a cause. This situation can be improved using EMRS at the point of care [115].

Knowing that the risk of TB increases when hyperglycemia is uncontrolled [116-119], and that some anti-retroviral drugs are suspected to augment the risk of diabetes [9, 120-125], SSA countries need to develop parallel strategies to tackle these pathologies -MDR-TB, HIV/AIDS, and diabetes. The parallel rise of diabetes, MDR-TB, and HIV/AIDS prevalence in the active population of SSA enhances the need of such initiatives in SSA. Consequently, addressing HIV/AIDS and MDR-TB without seriously taking diabetes and its complication into account could be dangerous for the future of SSA health systems and the economic development of SSA. Furthermore, a management concept for diabetes with EMRS has an impact on the management of the above specified associated pathologies. Therefore, this will facilitate a progressive adoption and use of the EMRS based management concept for diabetes complications. All these make the choice of diabetes as a business case for the use of ICT-based solutions such as EMRS in the health system of SSA countries consistent with the literature and the local reality. Consequently the first and second aims of this work have been achieved.

2 ”Model a new management approach for diabetes using an economically viable EMRS”

The main innovation of the conceptual model that describes the new management approach is the integration of diabetes care networks in the pyramidal healthcare referral system common to SSA urban cities associated to the use of economically viable EMRS adapted for the diabetes management purposes. The adapted EMRS makes patient data available through secure Web-based interface. This model advances the state of the art of the diabetes care and management in SSA and it is consistent with the diabetes strategy for SSA [41]. It is also consistent to the chronic care model adopted in many developed countries for improvements in diabetes care, education, and management [126-128]. Benefits of the new approach for diabetes management in SSA include:

- In the short term, cost saving through a reduction in duplication of services, avoidance of unnecessary lab test (redundancy) and same medication prescription, optimization of some clinical processes (e.g. review of patient medical history, generate discharge letter), support collaboration within the referral care system, and facilitate access to experts’ knowledge.

- In the medium term, generate reliable data for decision makers, support diabetes clinical research.

- In the long term: cost savings from avoided complications, reduced referral healthcare service utilization through avoided complications. Avoided complications means lower unnecessary hospitalization and imply a reduction of the workload of limited well trained health professionals, and a dynamization of the economy through workplace productivity gains.

The conceptual model developed in this work provides a set of solutions to problems identified as major challenges. These problems must be dealt with so as to improve the care and management of diabetes in SSA. These challenges include the organization of the health system and the lack of well trained diabetes care-providers or health professionals, who are capable of initiating or adapting treatment of a life-long condition [1, 3, 41, 129]. Other challenges include: the collection of data for surveillance, the inadequate patient record keeping, the poor communication between staff, the evaluation and transmission of key information to decision makers, the management of clinical information and the assessment of the quality of care, and the patient education and involvement [3, 9, 41, 129, 130].

The two main aspects of the conceptual model can be summarized as follow:

1. Organizational aspect: optimization of the current care and management process usually applied in SSA. Definition of diabetes care networks supervised by diabetes experts in each SSA urban city.

2. Technological aspect: the adaptation and use of economically viable EMRS as instrument for the success and efficiency of the work within a referral care system and the information management of chronic patients.

Concerning the improvement of the organization of the health system, this model suggests the creation of specialized diabetes care centers at the primary and secondary level of the healthcare structure. These centers are networked to a specialized center of the tertiary level. The care process is collaborative and integrated. Patients belong to a specific network, and patients' data are recorded and managed with the EMRS. This model adopts and optimizes the recommended care process structure described in the diabetes guidelines for SSA [42] and it is in agreement with the diabetes strategy for Africa [41].

To overcome the problem of limited number of well trained diabetes care-providers or health professionals capable of initiating and adapting treatment of a life-long condition, the model presented here suggests that diabetic patients should belong to a specific care network supervised by a diabetes expert. In each network, care-providers of diabetes centers of the primary and secondary healthcare level are coached by experienced care-providers of a diabetes center of the tertiary level. The permanent coaching system supported by the use of the EMRS and the simulation tool integrated in the EMRS can provide in a short term more confidence to care-providers of diabetes centers of the primary and secondary healthcare level in their daily contact with patients. This approach enhances the communication between staff and can also contribute to increase the number of experienced or empowered diabetes care-providers at the primary and secondary level of the SSA healthcare structure in a long term. Therefore, this new model can contribute to reduce the number of non significant cases currently referred to specialists of the tertiary healthcare facility and to improve the care provided at the primary level of the healthcare structure. Participants to the validation workshop including the president of the national diabetes program of Côte d'Ivoire, patients, and care-providers were committed to this approach [111]. The result of the validation workshop also confirms the need of an integrated approach for improving the management of chronic diseases such as diabetes in low-income and middle-income countries [111] as suggested in the literature [3, 131-133] and in the diabetes strategy for Africa [41]. Care-providers suggested during the validation workshop, however, that a teleteaching module could optimize the coaching concept. Since the focus of this work was to improve the management of diabetes in SSA with an EMRS, the teleteaching aspect was not included into the concept. Nonetheless, it is important to recognize that a teleteaching module can definitely optimize the solution proposed here. Low-bandwidth and economically viable teleteaching solutions adapted to SSA conditions are currently successfully used in SSA [19].

The use of EMRS for collecting and managing diabetes patient data (at least clinical and demographic data) can enhance the quality of diabetes management and also improve the speed of communication between decision makers of the ministry of health for example and the staff at the point of care. This is confident to the approach used for HIV/AIDS and MDR-TB in SSA that proof to be efficient for the strategic planning and the surveillance of these diseases [24, 25, 37]. This point contributes to resolve the problem of inadequate diabetes patients' record keeping, the evaluation and transmission of key information to care-providers, decision and policy makers, the management of clinical information, and the support of the strategic planning and surveillance of diabetes in SSA. This is confident to the diabetes strategy for Africa and correlates with the view of WHO and the literature which specify that better information led to the improvement of health system management, planning, and research [18, 20, 29, 99, 134].

Concerning the quality of care within a network of specialized diabetes centers, it is evaluated by the experienced care-provider of the network. The evaluation process in this model is facilitated by using the cohort study function of the EMRS. SSA diabetes experts specified in their clinical guideline that the regular assessment of the quality of care indicators helps to identify deficiencies, which are important for the development of strategy changes needed for the improvement of the quality of healthcare delivery [42]. The integrated cohort study can also be used for a comparative analysis of diabetes patients involving clinical and epidemiological research criteria [40, 135, 136]. Considering these, an improvement of the evaluation processes as it is the case in this model means an indirect improvement of the quality of care. Therefore, this model can contribute to improve the quality of care and the management of diabetes patients in each healthcare facility part of a diabetes care network. This can also be inferred from the result of the expert assessment of the significance of the EMRS tasks used in the conceptual model. While 3 of 7 experts assessed the use of EMRS for generating report for the monitoring of quality of care as very significant, 4 experts found this task significant. Indicators to assess the quality of diabetes care such as the level of HbA1c have also been indicated in the literature to be improved with the EMRS [42, 137, 138]. However, some authors find the use of EMRS not necessary for the improvement of these indicators [139]. Other authors think that the use of EMRS alone cannot improve the quality of care [140]. This divergence of view on the impact of the use of EMRS on the diabetes quality of care can be attributed to the strategies used prior to the EMRS development and implementation for the diabetes management as well as to the healthcare environment. The impact of the EMRS on the quality of care merely depends on the end-user involvement and the quality of the patient - care-providers interaction, and on the way the technology is integrated in the healthcare structure. The good evaluation of the expert with regard to the quality of care can be inferred to the bottom up and flexible methodology used for developing the conceptual model. This approach led to the identification of problems encountered by the end-users of the model and to a close contact during the conceptual model and demonstrator development. The validation results proved that the requirements derived from the need assessment and mapped in the conceptual model and the demonstrator are in agreement with local strategies and with the literature result presented in this work.

Considering the patient education and involvement, the model includes a portal page that provides access to application such as an insulin simulation tool for education purpose and a portal for recording lab and daily insulin test results for patients. This aspect of the model can also improve the communication between patients and care-providers. It was highly accepted and supported by patients and care-providers during the validation workshop. Patients were happy to be taken in consideration and to be involved as active partners in their care. Their availability to foster this aspect of the model within their association in case of an implementation shows their commitment to the approach. This commitment can also be helpful to face a challenge like the computer literacy of patients that can be improved through training. It is important to mention that patients personally did not find that their current incapability to use and understand computer based solutions should be a barrier to the implementation of this model. Their focus was more on the impact the technology and the organization suggested could have on their live long care. Speculating on this view of the patients, one can say that computer literacy of patients may be taken into account in the whole strategy but should not be a barrier to the implementation of this solution. Patients recognize in this case that the model provides a complementary component to the education session already organized by diabetes centers in SSA and could also help to improve the communication between health professionals and them. Their involvement in the development process and before the final implementation certainly plays an important role in their appreciation. This eventually shows that communication with end-users can help to overcome or at least reduce possible implementation barriers.

The fact that 3 of 7 experts have, however, not absolutely supported the role of the patient portal shows that a particular focus should be given to this in case of implementation. These differences of views were attributed to the feasibility of this aspect of the model in SSA because of the financial and infrastructural barriers. However the hardware cost is decreasing in SSA [36, 95] while the internet and ICT penetration rate are increasing [44]. Even if the average income of the population is still low, patients' feedbacks during the validation workshop show that, if implemented, this solution will be used. Patients who attended the validation workshop were aware of their financial situation, but were prepared to make more sacrifice for a better care. However, local government and funding agencies can certainly play an important role in this issue. Furthermore, experts who assessed this aspect negatively did not attend the validation meeting and were consequently not aware of the patient views highlighted above. But following this, one can ask how representative these patients were? Many comparative evaluations in different pilot implementations in SSA could help to objectively clarify these differences of views. The use of the WHO approach for the cost effectiveness analysis on the national level could also be helpful for a return on investment evaluation of this approach [141].

Concerning the technological view, the model designed described a way to adequately introduce and use economically viable and standard based EMRS in the diabetes management in SSA. The EMRS prototype modeled and developed adapts a successful outpatient EMRS and paves the way for use of this platform in an integrated and inpatient care environment. To this end, the design and development of the inpatient care and medical problem modules beside the diabetes management module were important. The module specifications were derived from the need assessment and the lessons learned from the literature. The modules extend the different layers (presentation, service, and database) of the open source used for the prototype development (OpenMRS) by using standard based languages such as JAVA and XML. To remain in an open source spirit and avoid any isolation all the modules respect the community recommendation. Furthermore, the ”Inpatient Care” module and ”Medical Problem” module are being used/adapted in other OpenMRS settings independent of the ”Diabetes Management” module.

The descriptive analysis of the detailed task-oriented validation of the prototype EMRS (Table IX) adapted in the conceptual model showed that each task received at least one “strongly significant” from an expert. This may illustrate the high significance of most of the functionalities inferred from the need assessment and the literature review added to the OpenMRS environment for prototype development. These include: problem list, problem status, inpatient care functionalities, graphical timeline of the last encounters, patient portal and its functionalities, etc.

However, one expert evaluated the task “patients can simulate their daily data for education purpose” as “non significant” and two other experts evaluated it as “slightly significant”. Six other tasks (“simulate responses to glucose equivalent of carbohydrate intake and different type of insulin injection”, “allows altering regimen and running another simulation directly afterwards, displaying differences in glucose and insulin curves between current and previous runs”, “list existing location (location, department, specialty, room) and allow a location-restricted view of patient data", "list inpatient care encounters", "provide a restricted access for patients to the EMRS", and "patient can use their portal to enter observation relevant to their diseases") were evaluated only once as "slightly significant". These critical evaluations are not directly tied to the technical design and extension of the EMRS but to the impact of these functionalities on the diabetes management in SSA. This view was discussed in the sub-section above.

The location extension and other inpatient care and medical problem functions such as the "discharge letter", the "restricted access for patients to the EMRS", and the "problem list" among others are being, however, adopted as core of the open source EMRS used for the prototype development (OpenMRS). This adoption of the community can be attributed to the capability of the new functionalities to respond to the expectation of the community and to pave the way to a broader use of the platform around the world. It is also the result of a good collaboration with the OpenMRS core team of the Regenstrief Institute in Indianapolis.

While four experts assessed their satisfaction with the total set of EMRS-functions used in the conceptual model as very good, three found these functions good. This validation illustrates that the technological extension reflected by the functions assessed correlate with the expectations described by experts of the need assessment. It further reflects that the adequate use of the EMRS for diabetes management in SSA may notably contribute to improve the current situation.

The above discussion shows that the new management approach (conceptual model) based on an adaptation of an opensource EMRS (OpenMRS) for diabetes and a collaborative and integrated care process, has the potential to serve as master version for a diabetes production module which can improve the coordination and quality of care delivery, the management, and the outcome of diabetics in SSA.

5.2 Patient data security

The discussion of patient privacy and security of patient data was a concern for 86% of interviewees during the need assessment and for a few participants at the validation workshop. The physical security issues are managed in OpenMRS by the use of a role-based access control (RBAC) approach for authentication and authorization [142] within the application. In case of patient data access via internet, the SSL/TLS protocol is used as specified in the conceptual model. This allows the establishment of an authenticated and encrypted connection between a client used by a care-provider from outside the healthcare facility and a server of the healthcare facility. Further, within this secured connection, data transferred are also encrypted and their integrity checked.

The use of network-based security such as virtual private network that offers the possibility to build a private network in each diabetes care network is certainly better than only the application-based security. Network-based security and certificate of commercial certification authority have however not been adapted in the conceptual model presented here because of the economic constraint of countries in SSA.

The model proposed here extends the current use of the RBAC in OpenMRS and paves the way to more patient privacy and limited access to sensitive patient data in OpenMRS. The ”Inpatient Care” module of the prototype includes a location restricted view of patient data which is also implemented in the diabetes production module. A location can be: hospital, department, specialty, room. In the prototype, an example for a department restricted view of patient data was developed. This application can be adapted according to local policies and requirement made in the trust document “Governance of the diabetes care network”. For research purposes patient data should be anonymized or pseudonymized using SAML 2.0 protocol.

Many interviewees as well as participants at the validation workshop mentioned the necessity of antimalware programs and multiple backup strategies. To increase the security across a diabetes network, the network system of each health facility should be distributed and the access to the application and database layers can be protected by firewalls. A specification of anti-malware methods, anti-virus programs, and backup strategies to address the high number of power loss should be made in the ICT-governance part of the “Governance of the diabetes care network”. Even if this recommendation means more cost for the user-organizations, it implementation can significantly contribute to reduce the physical security risks that seems to be particularly high in SSA. Furthermore, renewable energy can be adapted in future implementation.

The introduction and use of the SAML SSO and SLO protocol facilitate the management and the coordination of user authentication and authorization credentials within each created diabetes care network or within different networks. This approach facilitates the collaborative work of care-providers within the established diabetes care network. It enhances the security and privacy issue by reducing the number of authorization credentials to be used and by providing the possibility to close all opened session from a unique link independent of the website visited. The use of a security transport mechanism such as: HTTP over SSL 3.0 at least or TLS 1.x to preserve message integrity and message confidentiality is also recommended in the SAML security specification [63]. The capability with SSO to however track user's movement on a system – from application to application can be viewed as a privacy risk [143]. Since captured audit data could be used for other purposes than compliance, it will be important to specify their use within the trust document of the network.

5.3 Deployment strategy

An English version of the system demonstrator is currently running in Goettingen. The validation workshop during HELINA 2009 led to the creation of a network of potential end users groups in SSA countries that expressed the wish to implement a product solution. Because the design of the demonstrator was orientated towards urban environments in SSA it would be preferable to start a pilot product also in an urban area of an English speaking country. It will be necessary to deploy the production system also to a few primary and secondary healthcare facilities so that the installation can be evaluated.

5.4 Language barrier

The current demonstrator is in English and the core of OpenMRS has been developed in English. However, the OpenMRS community has launched French and Portuguese versions of OpenMRS which need to be strongly improved in order to be competitive to the English version. This very important language aspect is currently a drawback of the prototype and could certainly be an adoption problem in non English-speaking countries in SSA.

5.5 Feasibility of the approach in urban SSA

The feasibility of this new approach for diabetes management in SSA is certainly a challenging task but not an impossible one. Looking at the approach described here and knowing the difficulties faced by developed countries in implementing similar models, a major question to be answered is why the approach would be feasible in urban SSA environment?

Even if in developed countries the application of integrated care associated to variable ICT-based solution is rarely successful, the SSA context is however strongly different to the one in developed countries. Firstly, in the SSA environment, diabetes patients have mostly no choice and are thankful when they can receive diabetes care from a qualified care-provider. This example is one amongst others which proves that the biggest challenge in SSA is to coordinate the provision of healthcare more efficiently and to deliver healthcare interventions to the people who need them most as stated by the WHO regional director [144]. This is naturally not the case in most developed countries where patients have a considerable number of well trained diabetes care-providers available. Secondly, since the majority of SSA diabetes patients have no health insurance like European patients for example, the high costs of care are supported by patients, their families, and their friends. Consequently, making clear to SSA diabetes patients that the cares given at each level of the pyramidal healthcare structure follow the standardized guideline of the created diabetes care network and that care-providers within the network collaborate will facilitate the acceptance of patients. The possibility to receive good care at each level of the care network has for example an impact on direct costs related to treatment such as diagnostic tests, consultation fees, and transport. This means an impact on the financial situation of patients, their family, and their friends. That is why all patients during the validation workshop accepted the model and wished an implementation in their country.

For SSA diabetes care-providers, an implementation of the model means in a medium term the reduction of the number of patients that regularly solicit their interventions for cases that could be resolved at the primary care level. This view was recognized by local diabetes key stakeholders from Côte d’Ivoire during the validation workshop and therefore explains their adherence to the model and their wish to see the model implemented in their work environment. This need in improvement was also recognized by African leaders (political, health professional, patients, and scientist) as specified in the diabetes strategy for Africa published in 2006 [41].

The wish to adopt the model in a productive system by key local diabetes leaders in a SSA indicates that the model provides a new approach and an adequate IT-support that can help to challenge problems identified during the need assessment. This is an important requirement for the operative and strategic feasibility of the model. Since the prototype EMRS is an adaptation of a successful open source EMRS implemented in many SSA countries, the system feasibility is not the major problem. The fact that the model avoids a data transfer between EMRS but provides a secure web access to data to each care-provider overcomes the problem of system interoperability and terminology issues which are so far not standardized and mostly differ from a country to another.

The financial and human resources constraints remain however unanswered. The human resource constraint is discussed in section 6. The experience in SSA shows however that the support of political leaders doesn't mean an immediate financial support of the government to a project. This statement is absolutely not made to minimize this political support very important for a project implementation in SSA but to emphasize the fact that the financial support are mostly provided by international funders [19]. To gain the support of funding agencies for a broad rollout, the approach should be implemented in a real environment and evaluated. If the evaluation in a productive environment confirms how powerful the approach is improving the management of diabetes care in SSA then the resources will certainly follow. This view correlates with the relationship between investment in health and improved economic growth demonstrated by Saunders et al. in [144]. Economic development is impossible without major investments to apply tried-and-tested healthcare interventions that work. The severe burden of diseases hampers social progress and economic development in many African countries. There are positive indications that things are changing as SSA countries and their partners continue to demonstrate the will to address poverty and development by bringing health issues to the forefront [144].

5.6 Extend the solution to mobile phone capabilities

The importance of the mobile phone in SSA has been highlighted in sub-section "2.2 Information and communication technology use in SSA: overview". The high number of mobile phone users in SSA need to be taken into account. Participants at the validation workshop of the solution proposed in this thesis expressed the wish to see mobile phones capabilities incorporated into the current solution. The extension of the model presented here to the use of mobile phone capabilities will allow a broader involvement of diabetes patients. Mobile phones have been successfully used in diabetes environment in developed countries and have been stated as an important device for the use of diabetes management applications by patients. In SSA, mobile phone devices have been used for survey purpose as well as for medical data transfer in projects related to HIV/AIDS and MDR-TB [28].

The open source EMRS used for the prototype of the conceptual model is also being adapted by the community for the use in mobile phone environment. This means that a mobile phone version of the applications developed for the diabetes management prototypes could be adapted as soon as the OpenMRS community is more acquainted with the development of the mobile phone environment. This should however be restricted to the use of web-based applications for information transfer from patients to care-providers. The use of short message service (SMS) in the conceptual model was strategically avoided during the modeling step because of privacy concerns. The major concern was to make sure that SMS that include sensible data should only be read by authorized persons.

Furthermore, a detailed inclusion of mobile phone solutions for the management, monitoring, and report transmission of diabetics data was not the main focus of this thesis and therefore avoided. This important topic may be addressed in further works.

5.7 Sustainability and role of health informatics program in SSA

The lack of well educated and trained personnel in health informatics in LDC was identified as a major constraint to the sustainable development of information systems and IT in the health sectors of these countries [16, 145-149]. In 1980, after an evaluation of medical information systems in South-Africa, Rienhoff et al. recommended "South-Africa to institute without delay training programmes for professionals who will be required to organize and staff such systems [19]. Decision makers at the Medical School, University of Cape Town recognised this assessment and established in 1985 the first postgraduate education programme in Medical Informatics in SSA [148]. But this clear recognition of the need for health informatics programmes seems not to be the case in SSA in general. In 1996, at the second HELINA Conference in Johannesburg, South Africa, Ball and Douglas reminded the participants of the significance to attain certain basics which are frequently and most regrettably overlooked before entering the telematics world. They stated that, technology gives us tools, but does not provide us with the wisdom and the skill to use them [149]. In 1998, Shortliffe pointed out what role computer literacy and knowledge of the role that computing and communications technologies could and should play in the healthcare system are different [150]. Haux specified that, through an improved education of healthcare professionals, and an increase in the number of well-trained health and medical informatics specialist, this lack of knowledge and associated skills could be reversed [151]. During the assessment of this thesis, similar views were expressed by interviewees who recognized the necessity to provide more training and education to health workers in order to enable them to efficiently and effectively use the new technology. They also recommended firstly, the education of a clinical workforce before furthering the implementation of ehealth solutions in SSA.

For SSA these therefore mean that major efforts should be made in the area of curriculum development in order to successfully and sustainably solve the problem of the shortage of health informaticians in this region. Such efforts may produce appropriate and well trained local health informaticians in SSA, which will be able to model, develop, and implement appropriate IT-strategies, as well as choose, evaluate, and manage local IT infrastructure in the health sector of these countries [19, 152]. Furthermore, in our global world, well trained health informaticians will strongly contribute to the improvement of the economic situation of their countries by acting as a pulling factor for ICT outsourcing from the developed countries. Examples of Asian countries like India and China are proof enough of the importance to get well trained stakeholders in a country.

The prototype diabetes EMRS follows the concepts of those application systems used for HIV/AIDS and MDR-TB in Latin America and later in SSA which could prove economic viability [36, 38]. The sustainability of the African solution for diabetes will depend on local adoption (ownership), financial and training possibilities, and knowledge of local manpower [19].

5.8 Conclusion

The management of diabetes in SSA has been recognized worldwide as an important issue to be addressed. Research results in this area and efforts made by the international community to challenge this critical situation led to many commitments. In 2006, it led to the development of an integrated strategic plan for diabetes and related health risks in SSA. The implementation of this strategy should improve the management of diabetes in SSA.

This thesis reviews the efforts stated above and investigates the role and impact of an EMRS in the diabetes management in SSA. To the best of my knowledge, it is the first research work that investigates the use of an EMRS in diabetes care process and its impact on the care improvement and strategic management in the whole SSA. The methodology used to address the research questions points out clearly understanding of the situation and provides very adequate solutions in many cases from the experts' assessment viewpoint. While the literature review permits to gain major information, the need of assessment performed in some SSA countries plays a key role in the research process. The interviewing of local SSA experts as well as experts from Europe and USA also working in SSA provided great insight into the work environment and enabled the set up of a network of experts who continue to answer questions during the business process analysis of the current situation and the development of the new approach.

The new conceptual model derived from the current SSA diabetes management investigation and from the 2006 diabetes strategic plan, adapts an economically viable EMRS already successfully used to support HIV/AIDS and TB treatment for diabetes management in SSA. The report of the validation workshop organized in Abidjan, Côte d'Ivoire, and results of the seven senior experts' validation of the model and its demonstrator highlighted a significant satisfaction of participants and evaluators with regards to the coordination of diabetes care, the strategic planning and diabetes surveillance. Some health professionals and patients leaders in SSA expressed the wish to implement the model with the demonstrator in their country. Such an implementation in a country will need a customization of the model to the country's requirement before an introduction in the live system. This will also offer the opportunity to perform a long-term evaluation of the model and derive the effective impact on diabetes management in a country.

The thesis therefore outlines and demonstrates the road map for real work applications based on a new conceptual model, which has the chance to reach a positive economic evaluation in SSA context. Discussions related to sustainability issues have however shown that African countries cannot fully reap the benefits from progress in ICT in healthcare delivery if both infrastructure and adequate research and education structures are not in place. African governments and the international community should therefore raise funds in order to achieve these particular and strategic objectives which can help to achieve SSA scientific diabetes challenges and to meet up with the UN millennium development goal of halving poverty by 2015.

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Acronyms

A

AIDS	Acquired Immunodeficiency Syndrome
AMPATH	Academic Model for Prevention and Treatment of HIV/AIDS

C

CDSS	Clinical Decision Support Systems
CIO	Chief Information Officer
COE	Computer-based Order Entry
COSTAR	Computer Stored Ambulatory Record

D

DC	Direct Cost
DH	District Hospital
DSS	Decision Support System

E

EHR	Electronic Health Record
EMR	Electronic Medical Record
EMRS	Electronic Medical Record System

G

GIS	Geographical Information System

H

HbA1c	Hemoglobin A 1c

HC	Health Center
HELINA	Health Informatics in Africa
HINARI	Health Internetwork Access to Research Initiative
HIS	Hospital Information System
HIV	Human Immunodeficiency Virus
HL7	Health Level Seven
HTML	Hypertext Markup Language
HTTP	Hypertext Transfer Protocol
I	
IC	Indirect Cost
ICD	International Classification of Diseases
ICT	Information and Communication Technology
IDF	International Diabetes Federation
IdP	Identity Provider
Int$	International Dollars
IT	Information Technology
ITC	Intangible Cost
ITU	International Communication Union
L	
LDC	Less Developed Countries
LDL	Low Density Lipoprotein
LOINC	Logical Observation Identifiers Names and Codes

M

MA	Microsoft Access
MDR-TB	Multi-Drug Resistant Tuberculosis
MEDCAB	Medical Electronic Data base and Comprehensive Application for medical Cabinet
MeSH	Medical Subject Headings
MMRS	Mosoriot Medical Record System

O

OASIS	Organization for the Advancement of Structured Information Standards
OpenMRS	Open Medical Record System

P

PDA	Personal Digital Assistant
PHC	Primary Health Care
PHR	Personal Health Record
PIH	Partner in Health
PIS	Patient Information System
PROMIS	Problem Oriented Medical Information System

R

RBAC	Role Based Access Control
RH	Reference Hospital
RMIS	Regenstrief Medical Record System

S

SAML	Security Assertion Markup Language
SLO	Single Logout
SMS	Short Message Service
SNOMED	Systematized Nomenclature of Medicine
SOAP	Single Object Access Protocol
SP	Service Provider
SSA	Sub-Saharan African
SSL	Secure Socket Layers
SSO	Single-Sign On

T

TB	Tuberculosis
$3LGM^2$	Three-Layer Graph-based Meta Model
TLS	Transport Layer Security

U

UML	Unified Modeling Language
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
USA	United State of America

W

WHO	World Health Organization
WHOLIS	World Health Organization Library Information System
WS	Web Services

X

XML	Extensible Markup Language

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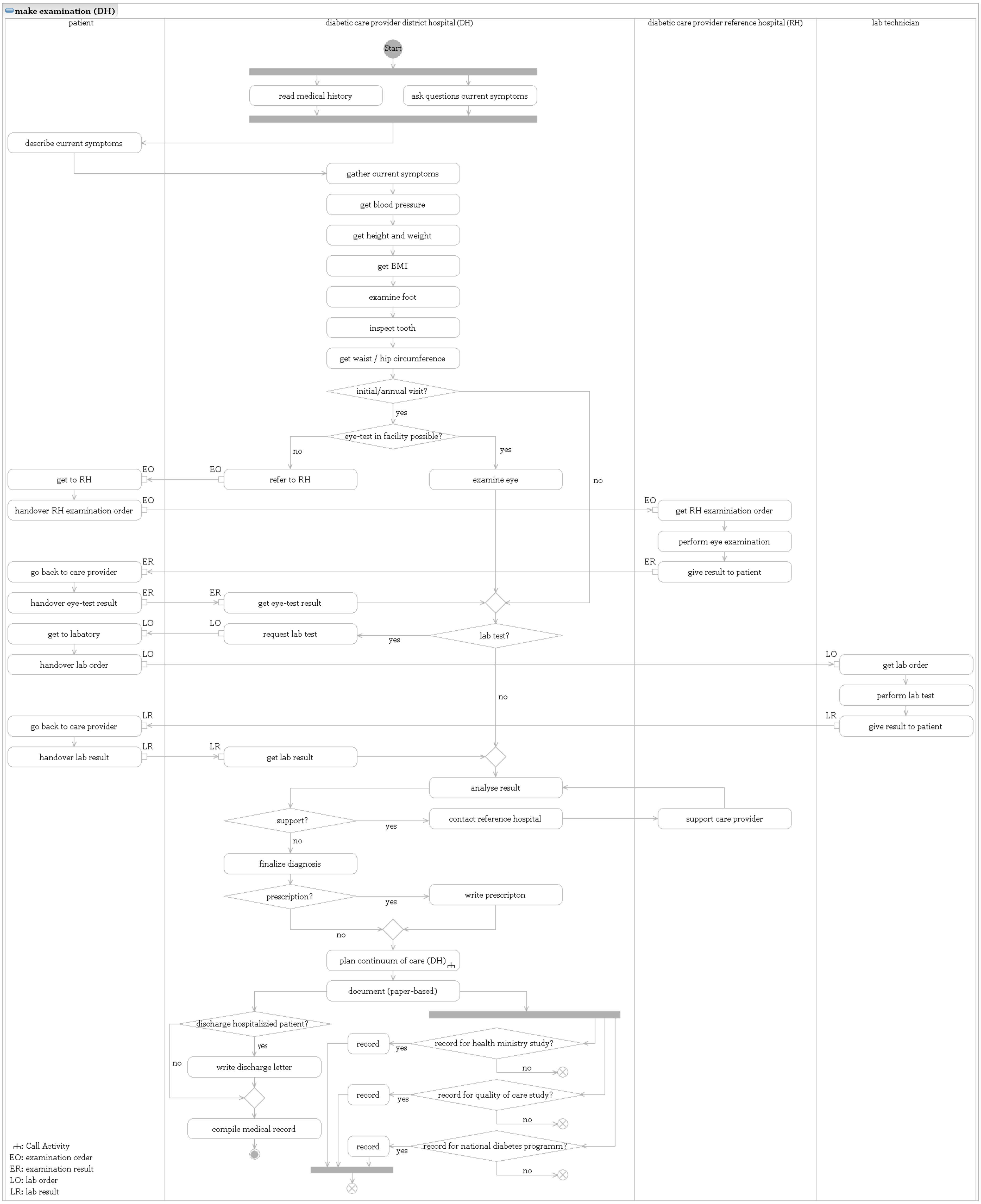
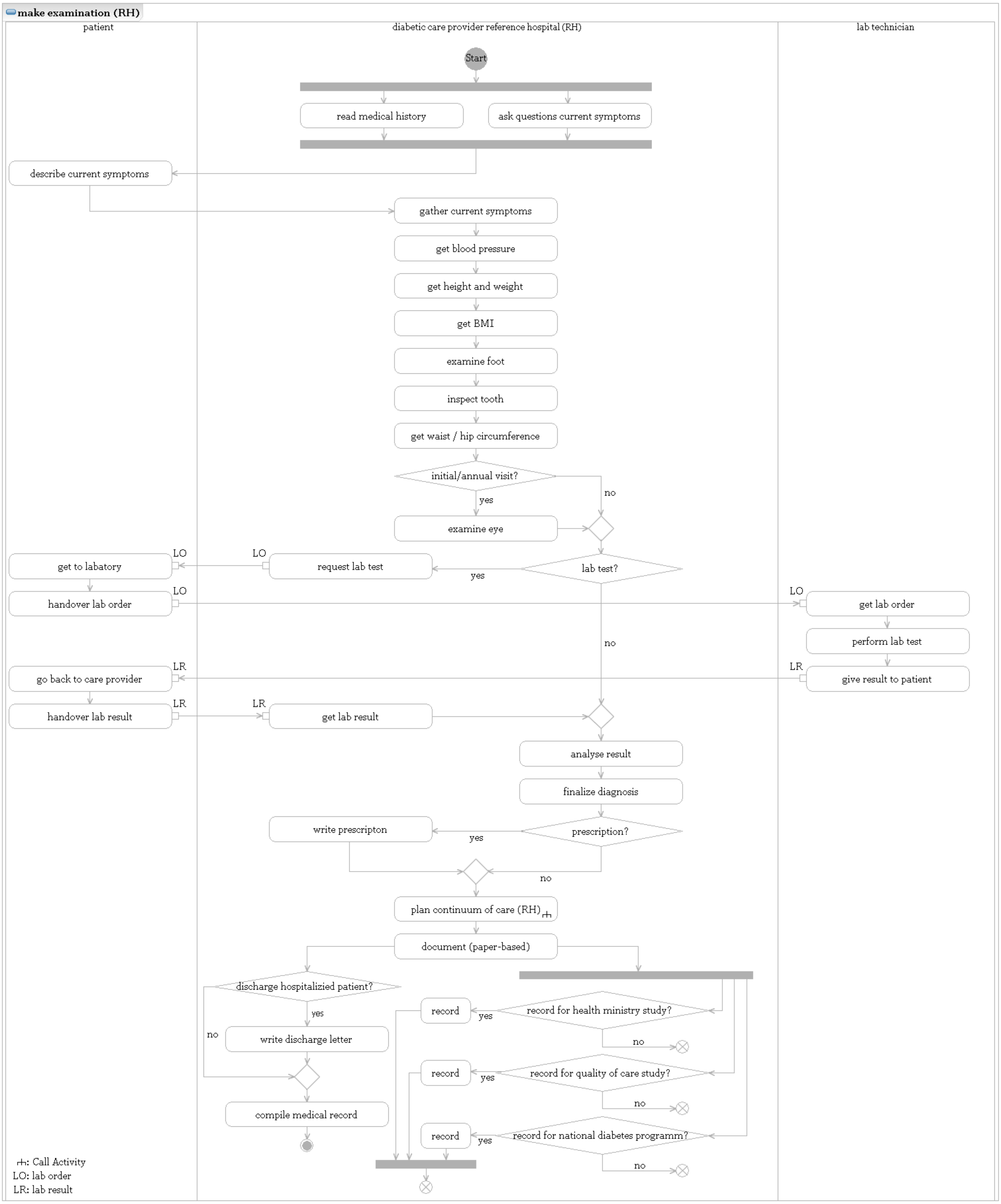
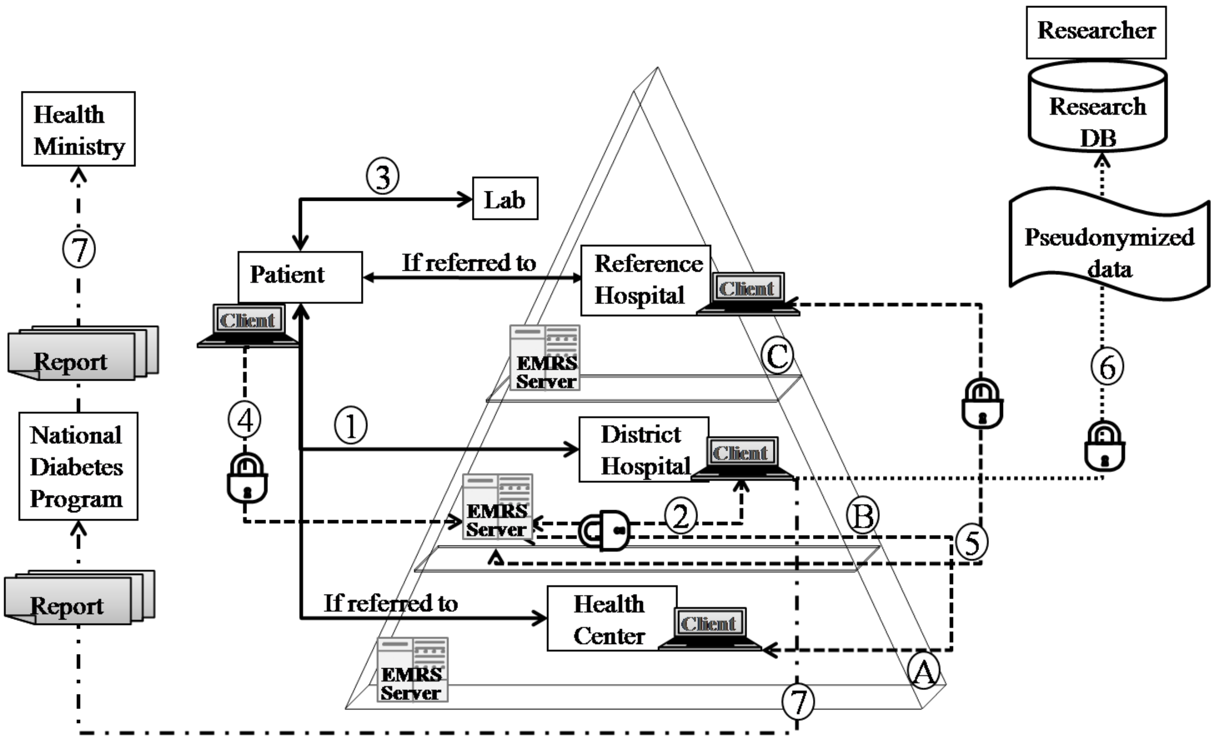
Appendix



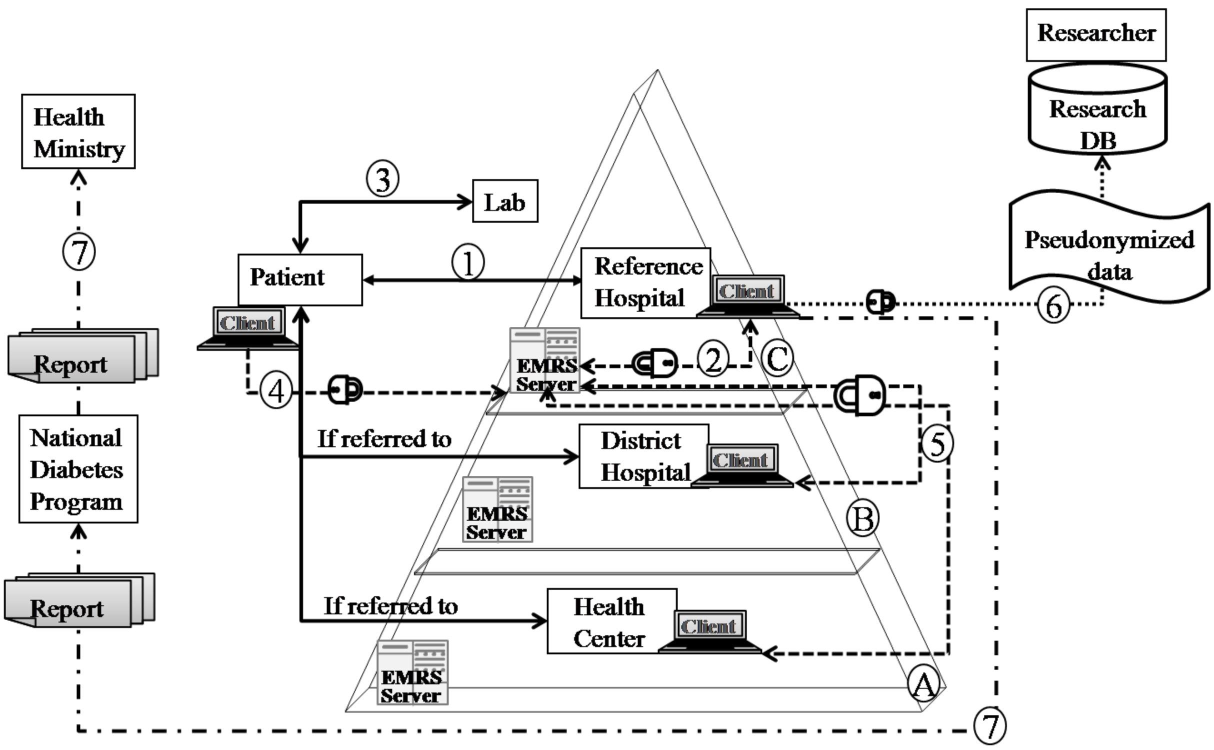
Appendix-Figure 1: The current examination process at the DH



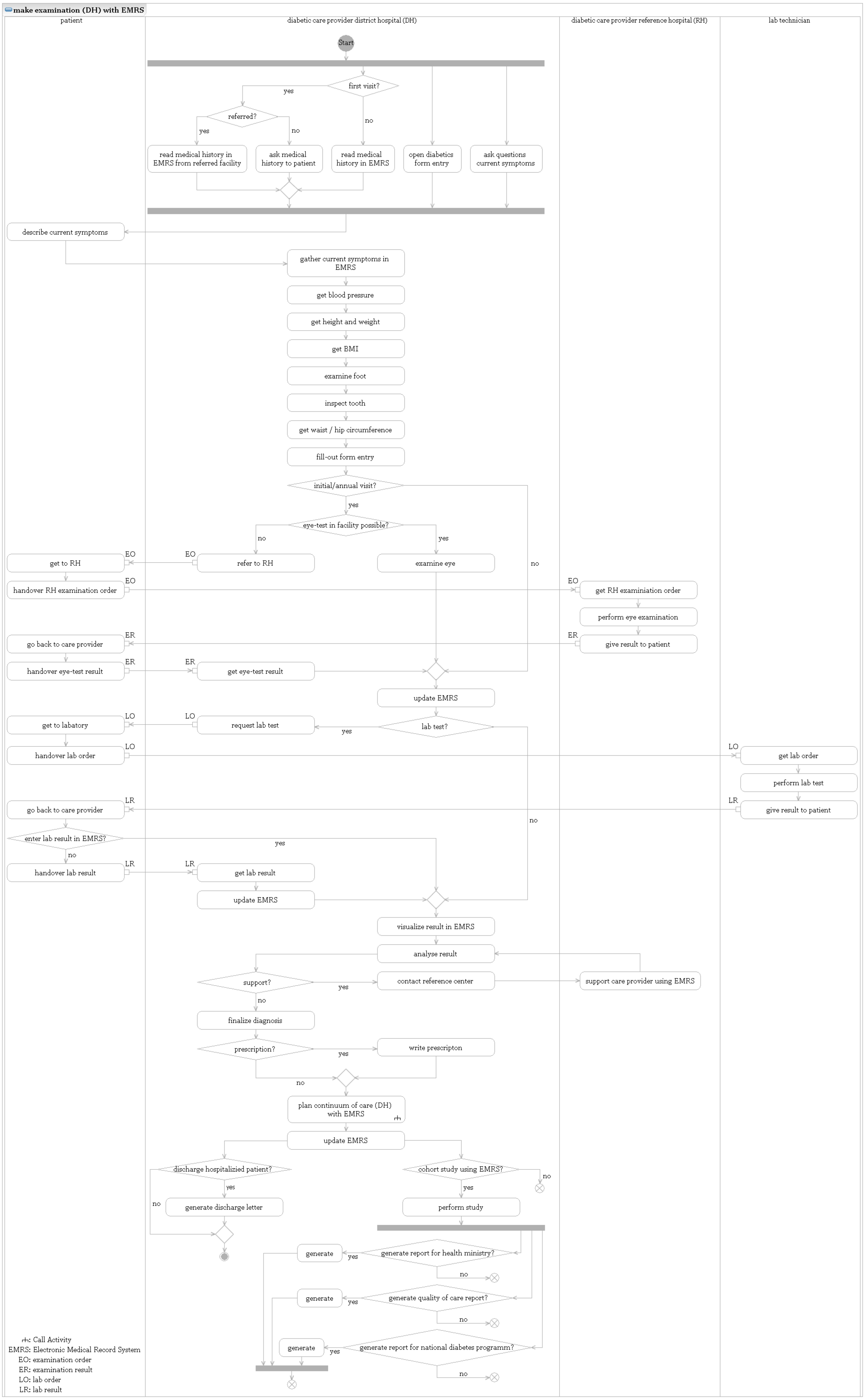
Appendix-Figure 2: The current examination process at the RH



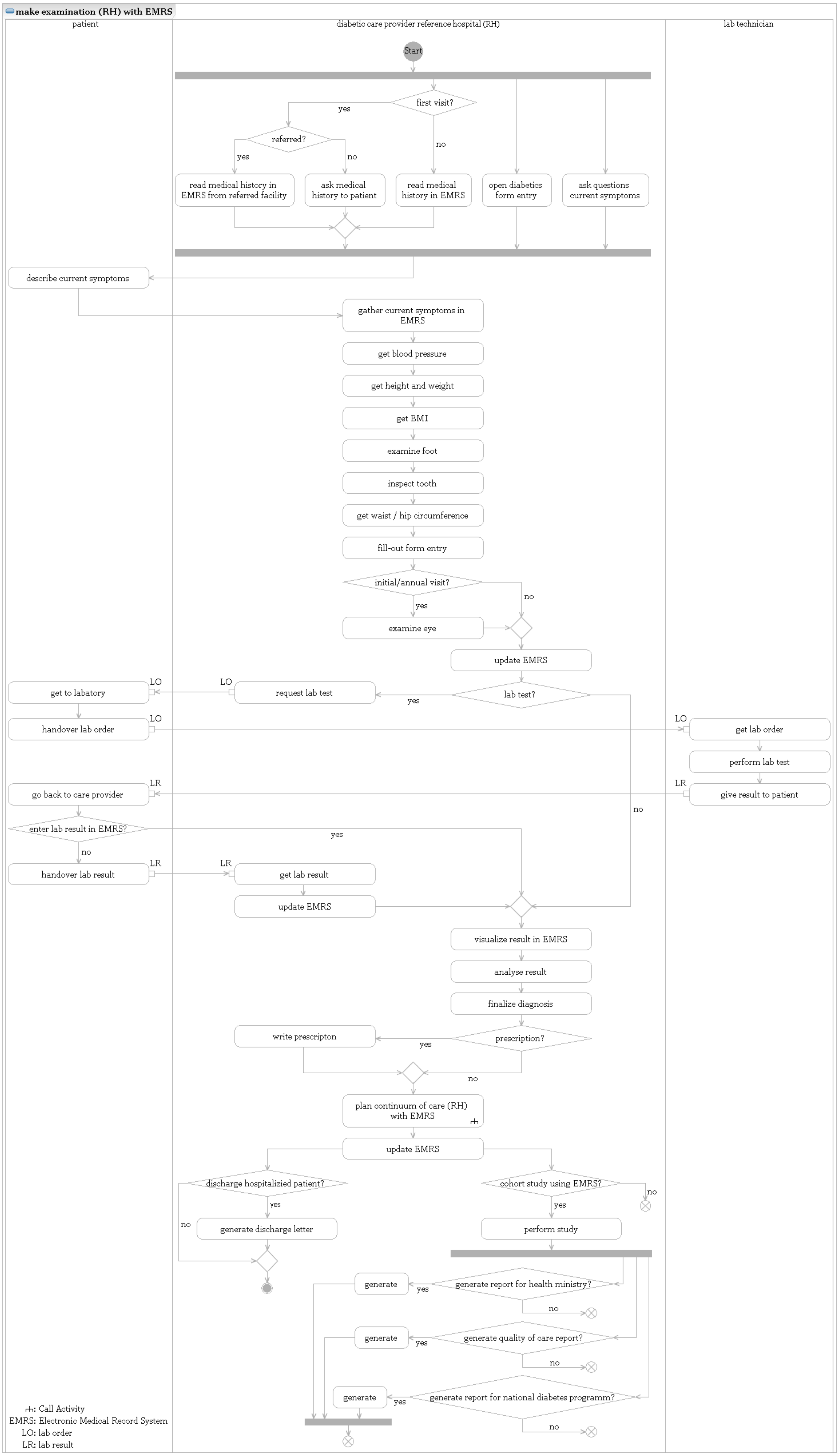
Appendix-Figure 3: Conceptual model for diabetes care and management at the secondary level of the care structure. Conceptual model for diabetes care and management at the secondary level of the care structure. The proposed solution is based on the case that patients start their care-process at the secondary level of the pyramidal healthcare structure



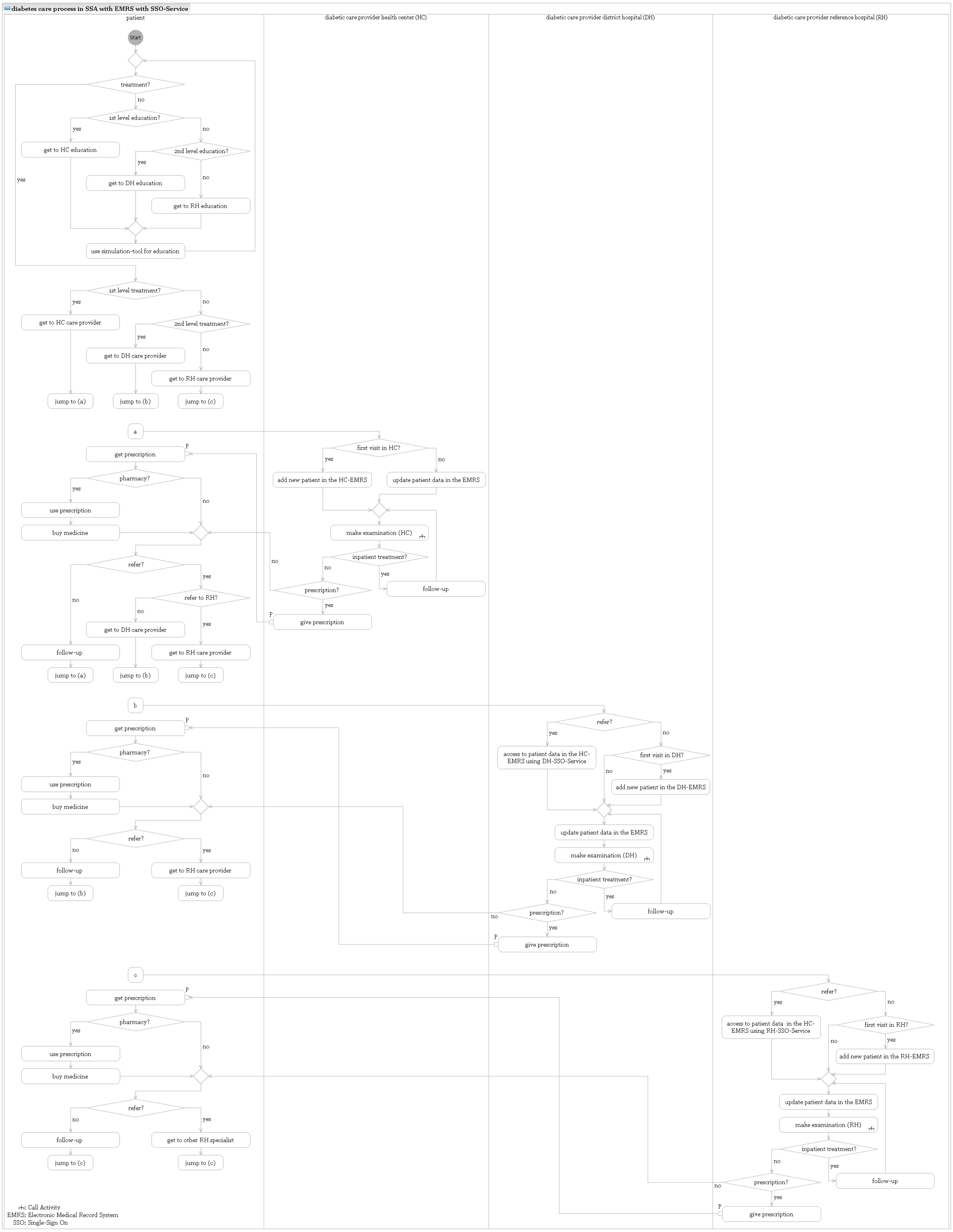
Appendix-Figure 4: Conceptual model for diabetes care and management at the tertiary level of the care structure



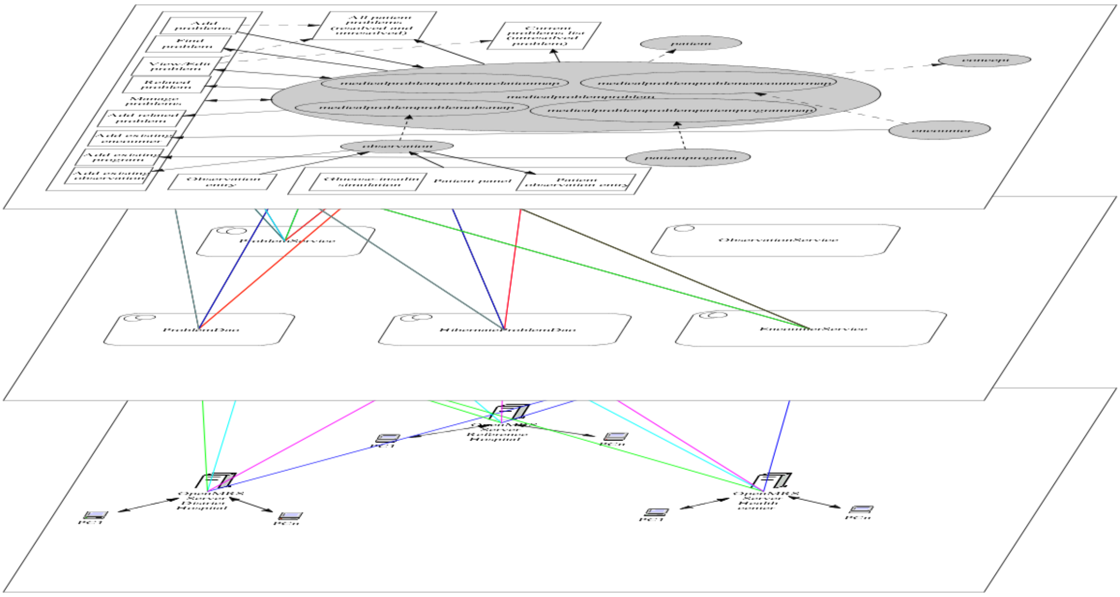
Appendix-Figure 5: The new examination process with EMRS at the DH



Appendix-Figure 6: The new examination process with EMRS at the RH



Appendix-Figure 7: Abstract view of the SSA diabetes care process with the use of SSO services



Appendix-Figure 8: The inter-layer relationship of the medical problem module. The link between functions define at the domain layer, application component of the logical layer and physical data processing components of the physical layer are highlighted

Appendix-Table I: Evaluation's questionnaire of the proposed conceptual model

1. **How much do you agree with the following statements with regard to the coordination of care in a multi- and interdisciplinary teamwork:**

The concept designed (Fig. 2) provides a framework for a coordinated care by offering access to patients' data for care-providers of other departments or settings.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

This framework is particularly important in sub-Saharan African countries for an efficient and effective uses of the limited well trained care-providers available.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

The problem-oriented data aggregation and presentation will support the multi- and interdisciplinary teamwork needed for co-morbid diabetes patients by facilitating the access to the patient problems list and their details (encounters, observations, treatment programs, and related problems).

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

Considering the fact that the majority of patients in sub-Saharan African countries has a low income and no insurance a closely teamwork of care-providers will help to avoid double test ordering and drug prescribing which increase the cost of treatment.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

2. How much do you agree with the following statements with regard to the support of diabetes research in Africa:

Population and medical data of a diabetes patient collected at the point of care using the EMRS will facilitate the work of local researchers.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

Since OpenMRS has been primarily developed to support care delivery and management of HIV patients, its current extension to diabetes provides the framework to support a research addressing the impact of HIV on diabetes development.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

Due to the privacy issue the development of a module for pseudonymizing research data is necessary.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

3. How much do you agree with the following statements with regard to the patient involvement:

The patient panel designed and developed here is a complementary component to the education session already organized by diabetes centers in sub-Saharan African countries

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

This solution by providing to patients a framework for simulating their daily insulin and glucose records could help to improve the communication processes between care-providers and patients and their family as well as the motivation for patient self-care and education.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

4. How much do you agree with the following statements with regard to strategic planning and diabetes surveillance:

In case of a roll out in all diabetes centers of a region, the report generated using the EMRS will facilitate the work of regional diabetes programs, decision and policy makers, and will support the work done by the WHO-Africa, the IDF, and other institutions active in this area in Africa.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

Using the EMRS for a regular diabetes data assessment will help to identify deficiencies which are important for the development of change strategies needed to improve the quality of healthcare delivery and its outcome.

Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree
☐	☐	☐	☐	☐	☐	☐

All considered, how would you rate your satisfaction with the concept?

Non-existent	Poor	Fair	Good	Very Good
☐	☐	☐	☐	☐

Do you know of any other aspects that are relevant to you and which are not mentioned here?

Comment

Appendix-Table II: Task-oriented evaluation's questionnaire of the significance of functions in the EMRS

In your opinion, how significant are the following EMRS tasks with regard to the improvement of diabetes care and management in sub-Saharan Africa

Review the patient's problems list, problem status	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Provide access to each problem detail	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Follow results of a test or investigation over time	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Diabetes data entry form (as recommended in the clinical guideline of IDF-Africa): result of lab tests and other diabetes important investigations are recorded	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Get encounters details, observations details, and regimens details	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Get patient history details	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Produce data reviews for specific patient groups	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Generate discharge letter after an inpatient hospitalization	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Display comparative graph of relevant clinical data of diabetes patient	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐

Track and manage patients and their diabetes-specific information	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Track patients requiring assessment (planned visit)	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Provide reliable data for diabetes surveillance and evaluation	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Generate report for the monitoring of quality of care as recommended in the clinical guideline of IDF-Africa	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Simulation tools for inexperienced health professionals: simulate a 24-hour profile of glucose-insulin interaction for diabetes patient	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Simulate responses to glucose equivalent of carbohydrate intake and different type of insulin injection	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Allows altering regimens and running another simulation, and displaying differences in glucose and insulin curves between current and previous runs	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
List existing location (location, department, specialty, room) and allow a location-restricted view of patient data	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
List inpatient care encounters	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Display a graphical timeline of the encounters for the last six months	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐

Provide a restricted access for patients to the EMRS	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Patients can simulate their daily data for education purpose	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐
Patients can use their portal to enter observation relevant to their diseases (eg. blood glucose)	Non significant ☐	Slightly significant ☐	Neutral ☐	Significant ☐	Strongly significant ☐

All considered, how would you rate your satisfaction with the function discussed?

Non-existent	Poor	Fair	Good	Very Good
☐	☐	☐	☐	☐

Do you know of any other functions that are relevant to you, which are not mentioned here?

Comment

Appendix-Table III: Diabetes Flow sheet for an initial or an annual patient visit

Diabetes Flow sheet based on the Clinical Practice Guideline for Sub-Saharan Africa developed by the International Diabetes Federation (IDF) Africa Region.

Flow sheet recommended for an initial or an annual patient visit

Name:

Date of Birth:

Gender:

History and Diagnosis

Physical Examination:

Height:

Weight:

BMI (Body Mass Index) = Weight (Kg)/Height $(m)^2$:

Waist circumference:

Hip circumference:

Exam	Date	Result	Target measure
Blood pressure			<=130/85 mm Hg

Exam	Date	Result	High Risk (Yes / No)
Detailed foot examination			

Exam	Date	Result	Expectation

Tooth inspection			

Eye Examination	Date	Result	Expectation
Fundoscopy			
Visual acuity			

Exam	Date	Result	Expectation
Electrocardiogram (ECG)			

Biochemistry

Exam	Date	Result	Target measure
Blood Glucose (HbA_{1c})			<= 7%

Exam	Date	Result	Target measure
Glycosylatted haemoglobin			

Lipids			
	Date	Result	Target measure
TC (Total Cholesterol):			
HDLC (High-Density Lipoprotein):			
LDLC (Low-Density Lipoprotein):			
TG (Triglycerides):			

Exam	Date	Result	Target measure
Creatinine			

Exam	Date	Result	Target measure
Sodium			

Exam	Date	Result	Target measure
Potassium			

Urine			
	Date	Result	Target measure
Glucose			
Ketones			
Protein			

Self-management

Date:

Goal:

☐ Education ☐ Nutrition advice

☐ Home Blood Glucose Monitoring ☐ Diabetics Organisation Membership

CAD (Coronary Artery Disease) Status:

☐ Past MI CABG PTCA Current Angina No History

Smoking Status:

☐ Non-smoker (since………) ☐ Smoker (PPD (Probing Pocket Depth) …)

ACE (Angiotensin-Converting Enzyme) Inhibitor:

☐ Yes ☐ No ☐ Microalbuminuria ☐ Hypertension

Aspirin Use:

☐ Yes ☐ No (If no, specify reason :…………………………………..)

Medication if needed or review therapy

Ps: Send automatic reminder when critical results

Appendix-Table IV: Diabetes Flow sheet for a three month patient visit

Diabetes Flow sheet based on the Clinical Practice Guideline for Sub-Saharan Africa developed by the International Diabetes Federation (IDF) Africa Region.

Flow sheet recommended for a three month (control) patient visit

Name:

Date of Birth:

Gender:

Relevant History

Physical Examination:

Height:

Weight:

BMI (Body Mass Index) = Weight (Kg)/Height $(m)^2$:

Waist circumference:

Hip circumference:

Exam	Date	Result	Target measure
Blood pressure			<=130/85 mm Hg

Exam	Date	Result	High Risk (Yes / No)
Foot inspection			

Biochemistry

Exam	Date	Result	Target measure
Blood Glucose (HbA_{1c})			<= 7%

Exam	Date	Result	Target measure
Glycosylatted haemoglobin			

Urine			
	Date	Result	Target measure
Protein			

Self-management

Date:

Goal:

☐ Education ☐ Nutritional advice

☐Home Blood Glucose Monitoring ☐ Diabetics Organisation Membership

CAD (Coronary Artery Disease) Status:

☐ Past MI CABG PTCA Current Angina No History

Smoking Status:

☐ Non-smoker (since………) ☐ Smoker (PPD (Probing Pocket Depth) …)

ACE (Angiotensin-Converting Enzyme) Inhibitor:

☐ Yes ☐ No ☐ Microalbuminuria ☐ Hypertension

Aspirin Use:

☐ Yes ☐ No (If no, specify reason :…………………………………..)

Review therapy

Ps: Send automatic reminder when critical results

Curriculum Vitae

Kouematchoua Tchuitcheu Ghislain Berenger

Born on 29 October 1976

EDUCATIONAL RECORD

Period	Institution	Qualification Obtained
September 2006 – to date	University of Goettingen	PhD Candidate in Computer Sciences
March 2004 – April 2006	University of Goettingen	Masters of Sciences in applied Computer Sciences Major: Medical Informatics - Health Information Officer (HIO)
Oct 2000 – Feb 2004	University of Goettingen	Bachelor of Sciences in applied Computer Sciences Majors: Core computer sciences

Award

March 2004 – April 2006: member of the scholarship-program of the Friedrich-Naumann Foundation for supporting highly-talented students

PROFESSIONAL EXPERIENCE

Period : January 2010 – to date

Position : eHealth consultant, Kassenärztliche Vereinigung Hamburg

Period : July 2009 – December 2009

Position : Research assistant, Department of Medical Informatics, University Medical Center, Georg-August University of Goettingen

Period	:	July 2008 to July 2009
Position	:	Research assistant, coordinator of the Medical Informatics Program, Department of Medical Informatics, University Medical Center, Georg-August University of Goettingen
Period	:	May 2006 to June 2008
Position	:	Research assistant, co-coordinator of the Medical Informatics Curriculum, Department of Medical Informatics, University Medical Center, Georg-August University of Goettingen
Period	:	October 2005 – April 2006
Position	:	graduate assistant, Department of Medical Informatics, University Medical Center, Georg-August University of Goettingen
Period	:	October 2004 – September 2005
Position	:	graduate assistant, Inverse Problems Group, Department of Numerical and applied Mathematics, Georg-August University of Goettingen
Period	:	April 2004 – September 2004
Position	:	graduate assistant, Software Engineering for distributed Systems Group, Centre for Informatics, Georg-August University of Goettingen

FURTHER TRAINING

ITIL Foundation Certificate in IT Service Management	08.-12.12.08
Integrating the Healthcare Enterprise (IHE)	October 29, 2008
Electronic Health Records and Health Level Seven (HL7)	October 31st 2008
Strategic planning	15-17.07.05
Political team management	17-19.06.05

PROFESSIONAL SOCIETY MEMBERSHIP

GMDS: Deutsche Gesellschaft für Medizinische Informatik Biometrie und Epidemiologie e.V.

SOCIM : Societé Camerounaise d'Informatique Médicale

SELECTED SCIENTIFIC PAPERS AND CONGRESS PRESENTATIONS

2010

- Koch S, Hasvold T, Kushniruk A, Marcelo A, Kouematchoua Tchuitcheu G.: eHealth – nurturing patient empowerment? State of the art and reflections from four continents. Panel discussion MEDINFO 2010, 12.09 – 15.09.10, Cape Town South Africa

2009

- Kouematchoua Tchuitcheu G: Diabetes management in Sub-Saharan Africa using an electronic medical record system; paper presented at the 6th Health Informatics in Africa Conference 16.04. – 17.04.2009, Abidjan, Côte d'Ivoire (conference paper)

- Kouematchoua Tchuitcheu G., Kozhushkov A., Rienhoff O.: Concept et développement de modules pour la gestion électronique du diabète en Afrique sub-saharienne, Poster presented at the 13ème Journée Francophone d'Informatique Médicale, 23.04. – 30.04.09, Nice, France

- Kouematchoua Tchuitcheu G, Rienhoff O.: Options for diabetes management in Sub-Saharan Africa with an electronic medical record system. Methods Inf Med 2011; 50(1): 11-22 Pre-published online: November 20, 2009

- Kouematchoua Tchuitcheu G, Kleinebreil L, Lokrou A, Rienhoff O.: eHealth and diabetes in Africa – results of and lessons learned from an international workshop. 2eme Journée Camerounaise d'Informatique Médicale 28 - 01.12.2009, Yaoundé, Cameroon (conference paper)

2008

- Kouematchoua Tchuitcheu G., Rienhoff O.: The future impact of the „third world“ on the health care system in Germany ; in Gesundheitswesen 2025 – Implikationen, Konzepte, Visionen, W. Niederlag, H. U. Lemke, E. Nagel, O: Dössel, Health Academy, Dresden 2008 12:70-77, ISBN 978-3-00-023876-5 (book contribution)

2007

- Kouematchoua Tchuitcheu G., Rienhoff O.: Sustainable development of medical informatics in Africa: need for a health informatics curriculum, paper presented at the 5th Health Informatics in Africa Conference 09.01. – 12.01.2007, Bamako, Mali (conference paper) Available at: http://www.sim.hcuge.ch/helina/1.pdf

- Kouematchoua Tchuitcheu G.: Developing Capacity through collaborative academic programs such as IAESTE, topic presented at the 2007 OpenMRS Implementers Group Meeting, 22.04. – 27.04.2007, Cape Town, South Africa

- Kouematchoua Tchuitcheu G.: The role of African graduates abroad in the development of Medical Informatics in Africa, topic presented at the 5th International VKII Symposium, 01.09.2007, Munich, Germany

- Kouematchoua Tchuitcheu G.: Improving the quality of health care delivery in African countries using health informatics facilities, topic presented at the 2007 CAMFOMEDICS Symposium, 20.10.2007, Cologne, Germany

- Kouematchoua Tchuitcheu G.: The OpenMRS Applications development in Africa, topic presented at the Medica-Media. Topic of the panel discussion: “Africa – telemedicine a factor for the development of healthcare?”, 16.11.2007, Düsseldorf, Germany

- Kouematchoua Tchuitcheu G., Rienhoff O.: Implémentation du dossier médical électronique OpenMRS en Afrique central et de l’ouest, paper presented at the 1ère Journée Camerounaise d’Informatique Médicale 21.11.2007, Yaoundé, Cameroun (conference paper)

- Kouematchoua Tchuitcheu G., Geissbuhler A., Kwankam Y., Rienhoff O.: Développement durable de l'informatique de la santé en Afrique : Formation des spécialistes locaux, paper presented at the 1ère Journée Camerounaise d'Informatique Médicale 21.11.2007, Yaoundé, Cameroun (conference paper)

- Kouematchoua Tchuitcheu G., Rienhoff, O. : Etat des lieux au Cameroun : analyse interactive des activités présentées, paper presented at the 1ère Journée Camerounaise d'Informatique Médicale 21.11.2007, Yaoundé, Cameroun (conference paper)