Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

REACTION (FP7 248590)

D4-3 Technical Requirements for Medical Data Management

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Table of Contents

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Abstract	This deliverable bridges the gap between the functional user requirements and technical system requirements for a REACTION data model. It presents business use-cases for the inpatient and the primary care prototypes identified in the initial user requirements of D2-5. Moreover, this deliverable summarizes technical requirements for the medical data management of the REACTION platform.
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1. Executive Summary

This document continues along the path set by D2-1 and D2-5, which began with the generation of scenarios for usage of the REACTION platform. D2-1 described the requirements, needs and priorities of the users. The short and medium-term expectations for primary care and inpatient care, derived from two workshops in Chorleywood and Graz, were outlined. D2-5 presented the methodology, process and results of the initial requirement analysis and engineering phase of WP2 related to the user centric requirements for engineering and validation. The main results of D2-5 was the generation of approximately 280 initial user requirements which forms the foundation for further work on the REACTION project.

This deliverable is based to a large extent on those initial user requirements and covers the task of analysing the technical requirements for a specific medical data management model for the REACTION platform.

D4-3 is an important initial working point for WP4. The objectives of WP4 are to research, develop and implement the complex Data Management structure of the REACTION platform. Based on the elicited requirements in this work, a suitable architecture for the data fusion/diffusion model in a device and network oriented environment and the technology to implement it in the REACTION platform will be specified. In consequence, this document bridges the gap between the functional user requirements and technical system requirements for a REACTION data model. Moreover, this deliverable presents business use-cases for the inpatient and the primary care prototypes. These use-cases enable technical partners to obtain a better understanding of the main tasks of the REACTION prototypes, including how system components interact with users. The work on this deliverable was carried out in six steps:

(Step 1) Typical business use-cases for inpatient insulin dosing and primary care disease management as well as a draft architecture for the REACTION were generated.

(Step 2) Based on the use-cases and on the draft architecture, an intensive discussion among involved partners was initiated. Suggestions for improvements arising from this discussion were incorporated and the draft architecture and use cases were distributed to involved partners.

(Step 3) Questions concerning system components, which may be interesting in eliciting technical requirements for the REACTION data management model, have been formulated and distributed to involved partners.

(Step 4) In order to define a data management model six different aspects of a data model have been defined: Data Interface, Data Source, Data Storage, Data Structure, Data Semantics, and Data Security.

(Step 5) JIRA has been set up for the elicitation of technical requirements. Each partner was responsible for eliciting technical requirements and resolving conflicting, overlapping, obsolete, or erroneous requirements.

(Step 6) Requirements were stratified by data management model subtypes and the outcome of the requirement elicitation phase was summarized and related to the needs of a REACTION data model as well as of the entire architecture, taking into account that the REACTION pilot applications need further steps of analysis.

There are over 130 technical requirements for a REACTION data management model which have been collected, revised, and analysed for this deliverable. Following conclusions can be drawn from the work:

- REACTION will implement a distributed system. From this it follows that the system architecture needs different interfaces for external and internal interfaces in order to exchange data.
- Several data interfaces will comply with various standards, primarily those intended for eHealth interoperability and communication with medical devices.
- In the REACTION platform patient data is collected from three different sources: (1) measurements from medical devices, (2) manually entered data by the patient or a member of the medical team, and (3) data imported from external source.
- Data storage is necessary in all distributed parts of the REACTION data management architecture: (1) Patient devices, (2) REACTION AHD/Hosting Client, (3) REACTION DEVICE Hosting Server, and (4) Data Mining / Risk Stratification.

- REACTION platform should be flexibly and support various types of disease management applications, i.e. REACTION should support model driven architecture with functions based on formal models and rules.
- REACTION platform needs flexibly data structures in order to consider the model driven architecture.
- REACTION will be based on a service oriented architecture and will be deployed in a distributed manner, i.e. data structures have to be exchanged between components.
- In order to support the semantic management of data and as a basis for knowledge management, REACTION will exploit semantic technologies.
- A medical knowledge base will be built.
- Confidentiality has to be guaranteed in order to allow medical devices to upload measurements.
- Authenticity of senders and recipients of medical data must be ensured.
- Data integrity must be verifiable and the verification must be carried out before the data is added to the EHR.
- Access to personal data will be given to authorised entities only.
- Patient's consent must be sought before any data processing can take place.

The early stage of the project combined with the ambitious overall aim of the REACTION project that covers wide areas of the treatment of diabetic patients, mean that current elicited user requirements are not as technical as needed to drive the platform design requirements. To alleviate this, D4-3 enables partners to gain a clear understanding of the main use-cases of the prototypes and to consider how technical solutions can help to implement a data management model that provides a sufficient technical basis for fulfilling the requirements of use-cases.

2. Abbreviations and Acronyms

For the purposes of this deliverable, the following abbreviations and acronyms apply.

3G	Third Generation (International Mobile Telecommunication-2000)
AHD	Application Hosting Device
API	Application Programming Interface
BAN	Body Area Network
BM	Bio Measurement
BMI	Body Mass Index
CA	Certification Authority
CGM	Continuous Glucose Monitoring
DB	Database
DoW	Description of Work
EAV	Entity-Attribute-Value
eDSS	Electronic Decision Support System
EHR	Electronic Health Record
EPR	Electronic Patient Record
GP	General Practitioner
GPRS	General Packet Radio Service
GSM	Global System for Mobile Communications
HbA1c	Glycated Haemoglobin
HIS	Health Information System
HL7 v2/v3	Health Level 7 Version2/Version3
IEEE	Institute of Electrical and Electronics Engineers
IEEE PHD	IEEE Personal Health Data
IHE-PCD01	Integrating the Healthcare Enterprise-Patient Care Devices Technical framework version1
IHE-XDS	Integrating the Healthcare Enterprise-Cross Enterprise Document Sharing
IP	Internet Protocol
ISO	International Organization for Standardisation
IT	Information Technology
IV	Intravenous
JIRA	Issue Tracker (Trunction of Gojira, Japanese for Godzilla)
LAN	Local Area Network
LIS	Laboratory Information System
MS	Microsoft
NLP	Natural Language Processing
OAD	Oral anti-diabetic Drug
OBS	Observations
OWL	Web Ontology Language
P2P	Peer to Peer

PAN	Personal Area Network
PDA	Personal Digital Assistant
PEG tube	Percutaneous Endoscopic Gastrostomy Tube
PHR	Personal Health Record
PID	Person Identifier
PII	Personally Identifiable Information
POCT	Point of Care Testing
QoS	Quality of Services
RDMM	REACTION Data Management Model Requirements
RPM	Remote Patient Monitoring
SC	Subcutane
SMS	Short Message Service
SNOMED	Systematized Nomenclature of Medicine -- Clinical Terms
SoA	Service oriented Architecture
SQL	Structured Query Language
SRS	Software Requirements Specification
TOC	Table of Contents
TP	Trusted Party
UI	User Interface
UML	Unified Meta Language
UMLS	Unified Medical Language System
WP	Work Package
XML	Extensible Markup Language

3. Introduction

3.1 Overview of the REACTION Project

The REACTION project aims to develop an integrated approach to improve long term management of diabetes through continuous blood glucose monitoring, monitoring of significant events, monitoring and predicting risks and/or related disease indicators, evidence-based decisions on therapy and treatments, education on life style factors such as obesity and exercise and, ultimately, automated closed-loop delivery of insulin.

The REACTION project seeks to use the significant potential of new technologies to cope with the increasing number of persons suffering from insulin-dependent diabetes. A user-centred approach will be used, focused on the involvement of all stakeholders (i.e. patients, relatives and professional carers as well as healthcare commissioners, business stakeholders, and regulatory authorities) in an iterative cycle aimed at maximizing the probabilities of success of the new technological platform of services.

Technically, the REACTION platform will be structured as an interoperable peer-to-peer communication platform based on service-oriented architecture (SoA), where all functionalities, including the measurement acquisition performed by sensors and/or devices, are represented as services and applications consist of a series of services properly orchestrated in order to perform a desired workflow. The REACTION platform will, in addition, make extensive use of dynamic ontologies and advanced data management capabilities offering algorithms for clinical assessment and evaluation.

A range of REACTION services will be developed targeted to the management of insulin-dependent diabetic patients in different clinical environments. The services aim to improve continuous blood glucose monitoring (CGM) and insulin therapy by contextualized glycaemic control based on patient activity, nutrition, interfering drugs, stress level, etc. to enable a proper evaluation and adjustments of basal and bolus doses. Decision support will assist healthcare professionals, patients and informal carers to make correct choices about blood glucose control, nutrition, exercise, and insulin dosage, thus ensuring better management of diabetes.

REACTION will further develop complementary services targeted at the long term management of all diabetic patients (Type I and Type II). Integrated monitoring, education, and risk evaluation will ensure all patients remain at healthy and safe blood glucose levels, with early detection of onset of complications.

Security and safety of the proposed services will be studied and necessary solutions to minimize risks and preserve privacy will be implemented. The legal framework for patient safety and liability as well as privacy and ethical concerns will be analyzed and an outline of a policy framework will be defined. Moreover, impacts on health care organizations and structures will be analyzed and health-economics and business models will be developed.

3.2 Purpose, Context and Scope of this Deliverable

This section discusses the main intention of the deliverable. It shows on the work on which this deliverable is based, i.e. D2-1 and D2-5, as well as future work which will be based upon it. Moreover, it outlines the target audience and the scope of the deliverable.

3.2.1 Background and Context

D4-3 “Technical Requirements for Medical Data Management” continues along the path set by D2-1, which began with the generation of scenarios for usage of the REACTION platform. D2-1 described the requirements, needs and priorities of the users. The short and medium-term expectations for primary care and inpatient care, derived from two workshops in Chorleywood and Graz, were outlined. In addition new care models to meet the requirements of possible future developments were described. Scenarios for the long-term requirement, and finally vision scenarios of future healthcare were presented. The main outcomes of D2-1, especially regarding user requirements, were summarized in a structured way in the Initial Requirements Report of D2-5. D2-5 presented the methodology, process and results of the initial requirement analysis and engineering phase of WP2 related to the user centric requirements for engineering and validation. The main results of D2-5 was the generation of approximately 280 initial user requirements which forms the foundation for further work on the REACTION project.

The purpose of T4-3 is the research and development of the software components required to perform the core data management task including data capture, support for contextualization, data fusion,

inferring of knowledge, and invoking of event handling. D4-3 is, to a large extent, based on the initial user requirements and serves as the basis for future work on T4-3 Data management. D4-3 should provide a good basis for the work in T4-3 as regards user requirements.

3.2.2 Target Audience

The target audience of the deliverable is primarily technically partners, but also ethical, legal and sociological aspects have to be incorporated into the data management model for REACTION. In particular questions concerning data privacy, data security or data availability must be addressed (see in particular section 5.6).

3.2.3 Purpose

D4-3 summarises the technical requirements for a medical data management model for the REACTION platform, based on the user requirements derived in WP2. It is an important foundation for the appropriate architecture of the data fusion/diffusion model in a device and network oriented environment of REACTION. In consequence, D4-3 bridges the gap between the functional user requirements and technical system requirements for a REACTION data model. Moreover, D4-3 presents use-cases for the inpatient and the primary care prototypes identified in the initial user requirements of D2-5. These use-cases enable technical partners to obtain a better understanding of the main tasks of the REACTION prototypes, including how system components interact with users.

3.2.4 Scope

The scope of D4-3 is not restricted to the gathering of requirements of a medical data model for the REACTION platform, but also includes how these requirements correlate with use-cases of the inpatient insulin dosing and the primary care disease management prototypes.

In accordance with D2-5, D4-3 similarly follows the iterative approach for the refinement of requirements in the context of a user-centred design approach. Thus, a change in user-requirements may influence technical requirements for the REACTION data management model. Requirements will be fully managed using appropriate requirement management tools.

D4-3 will cover neither the work on the detailed design of the medical data model nor the detailed architecture of the technical platform of REACTION or its prototypes.

4. Software Requirements Engineering

4.1 Definitions and Terminologies

4.1.1 Requirements

The user-centred approach of REACTION necessitates a structured and well documented strategy in order to perform software requirement engineering. D2-5 established a common understanding of what the requirements are and how the requirement engineering process should be performed. This document builds upon this common understanding. In this context, a *requirement* can be defined as a condition or capability that must be met or possessed by a system or system component to satisfy a contract, standard, specification, or other formally imposed documents. (PowerTest2010). According to D2-5 the following aspects are defined:

- *Functional requirements* identify what is required from different user perspectives. They are related to the use of the REACTION platform in the clinical settings and to the user expectations.
- *Non-functional requirements* are the properties that the platform must have such as performance, usability, security, legal, ethical, business and they are as important as the functional requirements.
- *Technical requirements* documents technical aspects that a system has to fulfil. This can performance related issues, reliability or availability. Often the term quality of service (QoS) requirements is used for these kinds of requirements. Many technical requirements can be thought of as quality attributes or constraints.
- *Constraints* are restrictions imposed to the platform due to the budget, the time or the way the platform is designed or will work or interact with third-party components.

4.1.2 Use cases

A *use case diagram* provides a visualization of user requirements. Instead of simply asking the users what the system should do, use cases help to examine what users need to accomplish. Use-cases therefore describe the main tasks users should be able to perform. (Wiegers2003) As use cases are a common practice for capturing functional requirements they have been used in D4-3 for the requirement elicitation process of the REACTION prototype applications.

The term *Business Use Case*[1]*,* defines the interaction of stakeholders with the business that achieves a business goal. Regarding REACTION a stakeholder is for example a physician. The business goal can be, for example, finding the right dose of insulin for the diabetic patient. In order to achieve this goal the business would in this case be an electronic decision support system. Thus, a *use case diagram* comprises the following elements, see Figure 1 (Podeswa2010):

- *Business actor:* Roles played by organizations, people, or external systems to the business (e.g. physician, nurse, diabetic patient, Hospital Information System)
- *Business use case:* Services and functions requested by the business (e.g. exchange clinical documents, measure blood glucose, electronic decision support)
- *Association:* An association between a business use case and an actor indicates that the actor interacts with the business over the course of the business use case (e.g. a physician uses the electronic decision support system for insulin dosing for his or her patients in the ward)

[1] In order to align with D2-1, instead of the term "*Business Use Case"*, which is a widely used notation in the technical domain, the term "workflow" analogically can be used for the healthcare domain.

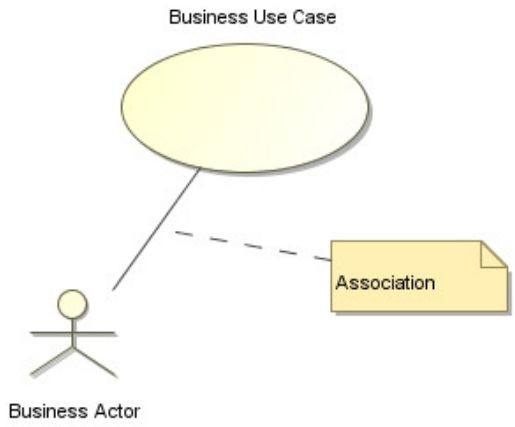

Figure 1: Use Case Diagram

D4-3 provides the starting point for the use-cases of the prototype inpatient and primary care applications and bridges the gap between initial user requirements and technical functional requirements for a REACTION data management model.

4.2 Bridging the Gap between User and Technical Requirements

Starting from the clinical partners, who desired a close alignment of the REACTION platform functionalities with prevailing clinical practice and medical reality, *short-term needs* were identified in two workshops which generated present clinical workflows in both in-hospital and primary care settings.

Additionally, a future scenario brainstorming session was carried out, which generated *long-term requirements* relating to key technological, security, socio-economic and business drivers for future end-user requirements. The results of the workflows analysing process and future scenarios were documented in D2-1.

As a next step, initial user requirements were derived from these workflows and scenarios. Each WP partner was responsible for extracting the detailed technical requirements and evaluating their architectural influence. Finally, conflicting, overlapping, obsolete or erroneous requirements were modified. D2-5 summarized the results of the initial user requirements phase.

All the steps have been carried out using a user-centred design approach according to ISO 9241-210 standards. In accordance with this evolutionary requirements engineering approach, D2-5 proposed the following iterative template:

- User requirements engineering and refinement
- Architecture design specification and refinement
- Clinical protocol and medical context planning
- Technologies research and development to implement architecture
- Integration and prototype development and field trial preparation
- Field trials in clinical domains
- Conformance testing, usability evaluation and user acceptance testing
- Lessons Learned and change analysis

D4-3 is an important initial working point for WP4. The objectives of WP4 are to research, develop and implement the complex Data Management structure of the REACTION platform. Therefore, the work package will design and implement a semantic data management server that will provide the necessary information management and service orchestration functionality to support the REACTION requirements.

The main objectives of WP4 can be summarized as follows:

- Analyse and define the overall architecture of the Data Management structure
- Define data structures, taxonomies and ontologies for the service components

- Research and develop a Data Management structure that provides a model-driven architecture for application development and deployment
- Research and develop a service oriented architecture with service ontology with high level concepts to be used in both development and run-time processes.
- Design and implement a context management framework and a context awareness mechanism capable of managing patient and user data across different contexts and situations in the REACTION architecture.
- Research and develop a rule-based service orchestration engine that allows for the static or dynamic assembly of services and their execution on the REACTION platform. This would be a basis for application-oriented workflows, including event handling and crisis management.
- Develop a resilient and intelligent event handling mechanism that can support crisis management and provide an interface to established emergency centres.

In the light of the enumeration mentioned above, D4-3 covers the initial task of analysing the technical requirements for a specific medical data management model for the REACTION platform. Based on the elicited requirements, a suitable architecture for the data fusion/diffusion model in a device and network oriented environment and the technology to implement it in the REACTION platform will be specified.

In preparation for the requirement elicitation phase, the draft version of a technological platform for REACTION, which was identified in the initial requirement phase of D2-5, was subdivided into the following six categories:

- Mobile Devices (PAN/BAN)
- Middleware, Internal communication
- Core server infrastructure
- External communication
- Security
- Overall platform

“Overall platform” contains technical requirements which are relevant to all categories. Each category was assigned to one or two partners in order to perform the requirement elicitation. The partners gathered technical requirements for the REACTION data model in JIRA. Furthermore, typical use-cases were identified and requirements regarding the data model for the two pilot applications - (1) inpatient glucose control and (2) Primary care diabetes management were gathered.

The following steps have been defined and carried out in D4-3:

Step 1:

In order to obtain a shared notion of what REACTION, from a technical point of view, will be, typical use-cases for inpatient insulin dosing and primary care disease management as well as a draft architecture for the REACTION were generated.

Step 2:

Based on the use-cases and on the draft architecture, an intensive discussion among involved partners was initiated. Suggestions for improvements arising from this discussion were incorporated and the draft architecture and use-cases were distributed to involved partners (see Appendix I)

Step 3:

Questions concerning system components, which may be interesting in eliciting technical requirements for the REACTION data management model, have been formulated and distributed to involved partners (see Appendix I).

Step 4:

In order to define a data management model we need to specify and define the following aspects:

1. Data Interface, including both internal interfaces between components and interfaces to external system.
2. Data Source, which are the sources of the data that need to processed and managed by the REACTION platform, ranging from measured raw sensor values to medical knowledge structures. Particular emphasis will be placed on PAN and BAN.
3. Data Storage, i.e., what are the needs for persistent as well as temporary storage of data.
4. Data Structure, which are the basic data structures we need to define.
5. Data Semantics, what are the requirements on the interpretation and understanding of the clinical data generated and maintained within the REACTION platform.
6. Data Security, i.e., issues including protection, privacy and informed consent.

Step 5:

JIRA has been set up for the elicitation of technical requirements (see Section 4.3.1). In the first iteration, each identified system component was assigned to one or two involved partners. The partners were responsible for eliciting technical requirements concerning the influence of the assigned component on the data management model. Each partner entered the identified technical requirements into JIRA. In the second iteration each partner went through all identified requirements and resolved conflicting, overlapping, obsolete, or erroneous requirements. The re-engineered list of requirements is documented in Appendix II: Complete set of Technical Requirements for a Medical Data Management Model.

In the next step improvements in the already derived business use-case models were incorporated into the inpatient and primary care prototypes from the initial requirements report. The use-cases will support the implementation of system use-cases in a subsequent step of the development phase (see chapter 6).

Step 6:

Finally the requirements were stratified by data management model aspects which are described in Step 4. For each aspect (corresponding to requirements subtype), the outcome of the requirement elicitation phase was summarized and related to the needs of a REACTION data model as well as of the entire architecture, taking into account that the REACTION pilot applications need further steps of analysis.

The early stage of the project combined with the ambitious overall aim of the REACTION project that covers wide areas of the treatment of diabetic patients, mean that current elicited requirements are not as technical as expected. Nevertheless, D4-3 enables partners to gain a clear understanding of the main use-cases of the prototypes and to consider how technical solutions can help to implement a data management model that provides a sufficient technical basis for fulfilling the requirements of use-cases.

4.3 Tools for Supporting the Requirement Management

4.3.1 JIRA Issue Tracker as RM tool and Structure of Requirements

Building on previous positive experiences with the JIRA Issue Tracker as a requirement management tool in D2-5, we decided to use the tool for requirement elicitation of D4-3. We added a new project named *REACTION data management model requirements* (RDMM). According to D2-5 a new issue type based on the Volere requirement template (Robertson2006) was created. The main reasons for the usage of the Volere template are: (a) the Volere Scheme is the atomic structure of the REACTION requirements; (b) there was a need to simplify the user interface and limit the possibility of errors from a generic user; (c) the Volere template has proven good usability and covers the main fields needed for the technical requirement elicitation.

In addition, we customized the existing Volere configuration for D2-5 in order to fit it to the special needs of D4-3. The following fields summarized in Fields marked * are compulsory.

Table 1 have been defined for the partners of T4-3 to enter their requirements into JIRA:

Field Name	Description	Type	Value/Values
Requirement #	A 3-digit number that is created by the system when a new issue is added	Auto incremented key	RDMM-XXX
***Requirement Type**	Type of requirement or constraint	Cascading Select (Consists of two Select Lists, where the values shown in the second depend on the value that has been selected in the first)	➢ **Functional** • Inpatient pilot application • Outpatient pilot application • REACTION platform ➢ **Non-functional** • Look and feel • Usability • Performance • Operational • Maintainability and portability • Security • Cultural and political • Legal • Ethical • Economical and business ➢ **Constraint** • Solution • Implementation Environment • Collaborative Applications • Off-the-Shelf Software • Off-the-Shelf Sensors & Devices • End-User Workplace Environment • Schedule • Budget
***Requirement subtype**	Subtype of requirement or constraint	Multi Select List	➢ None ➢ Data interface ➢ Data security ➢ Data source ➢ Data storage ➢ Data structure/data representation ➢ Other
***Component/s**	Component/s to which the requirement is related	Multi Select List	➢ Mobile Devices (PAN/BAN) ➢ Middleware, Internal communication (Hydra) ➢ Core server infrastructure (service, storage, …) ➢ External communication ➢ Security ➢ Inpatient glucose control ➢ Overall platform ➢ Primary care diabetes management ➢ Other
***Workpackage**	Workpackage/s to which the requirement is	Multi Select List	➢ WP1 ➢ WP2 ➢ WP3

	related		➢ WP4 ➢ WP5 ➢ WP6 ➢ WP7 ➢ WP8 ➢ WP9 ➢ WP10 ➢ WP11 ➢ WP12 ➢ WP13
***Priority**	Importance of the requirement	Select List	➢ Blocker ➢ Critical ➢ Major ➢ Minor ➢ Trivial
Asignee	Person in charge of resolving the requirement	Select List	Users Full Names that have access to the "REACTION Data Management Model Requirements" project
Reporter	Person who specified the requirement	Text Field (< 255 characters)	
*** Summary**	A one sentence statement of the intention of the requirement	Text Field (< 255 characters)	
***Rationale**	A justification of the requirement	Free Text	
***Source/Originator**	The source where this requirement was raised	Free Text	
***Fit Criterion**	A measurement of the requirement such that it is possible to test if the solution matches the original requirement	Free Text	
*** Customer Satisfaction**	Measures the desire to have the requirement implemented	Select List	➢ Uninterested ➢ Interested ➢ Pleased ➢ Very Pleased ➢ Extremely Pleased
***Customer Dissatisfaction**	Unhappiness if it is not implemented	Select List	➢ Very Low Unhappiness ➢ Low Unhappiness ➢ Neutral Unhappiness ➢ High Unhappiness ➢ Extreme Unhappiness
Conflicts	Other requirement that cannot be implemented if this one is	Text Field (< 255 characters)	
Dependencies	Other requirements with a change effect	Text Field (< 255 characters)	

Fields marked * are compulsory.

Table 1: Definition of JIRA issue to map data management model requirement

The significant linking of issues was used for the phase of requirement consolidation in D4-3. The linking of issues within D4-3 was necessary, as was the linking of issues between packages. Many requirements

of D4-3 are a specialization of already existing requirements of D2-5. Hence issue linking was very helpful to trace the path from initial user requirements to the detailed technical requirements and in turn to the final system specification. In addition the JIRA notification system was activated to improve communication and collaboration of project partners.

For the detailed user guide for JIRA issue tracking in REACTION we refer do chapter 5 of D2-5.

4.3.2 MagicDraw UML Design Tool

We designed use cases for the application prototypes using MagicDraw V16.8[2]. MagicDraw is a business process, architecture, software and system modelling tool with teamwork support and improved support code engineering mechanism for a wide range of programming languages. MagicDraw supports UML metamodel and notation, class diagrams, use-case diagram, sequence diagram and many more sophisticated IT-modeling modules.

For D4-3 we used the use-case functionality of MagicDraw. The main reason for using MagicDraw was its wide range of visualization and functional possibilities and its availability at MSG.

4.4 Towards a REACTION Data Model

D4-3 is one building block for the design of a REACTION data model. It delivers fundamental requirements concerning user and technician expectations of REACTION data management. Figure 2 shows a first draft of the data management part of the initial REACTION architecture. The focus in Figure 2 is on the data management to highlight the context of the requirements and not to the complete architecture. It is a first conceptual sketch. The following three parts correspond to the blocks in the figure (left to right).

- Patient vital signs captured with sensors
- Data management on the hosting client for individual patient measurements and observations
- Data management on the hosting server for individual patients treatment
- Data mining and analysis of historical data across patient populations

Another important component for the REACTION data model will be provided by D4-2 data structures, taxonomies and ontologies which manage contextualisation of data, based on semantic modelling and a knowledge representation framework. Communications standards within BAN and PAN prepared in D5-1 and finally the first internal version of D4-1 State of the Art – Concepts and technologies for a unified data fusion architecture will provide further input for T4-3 Data management.

[2] http://www.magicdraw.com/

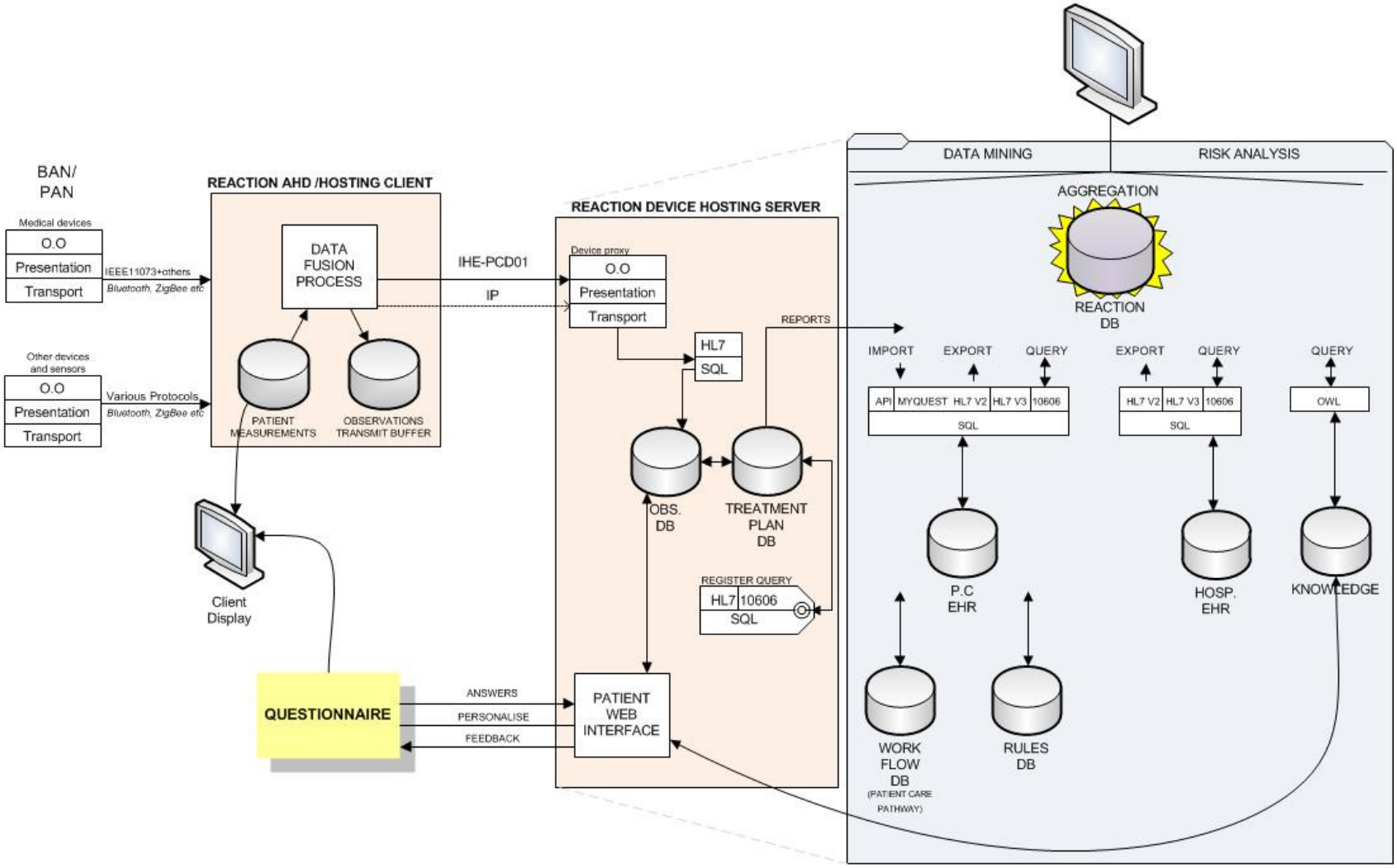

Figure 2: Data Management view of the REACTION architecture

5. REACTION Platform: Technical Requirements for a Data Management Model

When designing a healthcare data architecture that fits a particular need, there are many factors – some more important than others – that determine the optimal architecture.

At this initial stage, the REACTION project faced the well-known gap between clinical user partners' expectations and technological possibilities. The two initial workshops held in London and Graz aimed at bridging this gap helped in the specification of the clinical workflows in outpatient and inpatient settings. The two days workshop also provided information about clinical needs and enabled a common understanding between technical and medical points of view to be reached. In order to provide a semantic integration of a multitude of heterogeneous medical devices and media, information sources, services and communication, the Data Management requirements elicitation has been quite strict.

With the requirements phase, we have defined the restrictions and user needs (from a technological point of view) in order to define future steps for components of the REACTION architecture. The final goal is to decide upon (a) the interfaces and communications channels between the different parts of the system, (b) the information to be exchanged (clinical, daily life, demographic, etc), (c) the structures which we need in order to store data in a sufficient and efficient way, (d) the ensurance that the processed data will be presented in a satisfactory manner, and (e) the security mechanism to protect the data privacy.

Taking into account all of these issues, the REACTION system will improve the continuous glucose monitoring (CGM) and insulin therapy by means of contextualized glycaemic control based on patient activity, nutrition, interfering drugs, stress level, etc. for the proper evaluation and adjustments of basal and bolus doses.

Therefore, this chapter presents the technical requirements stratified by their main requirement subtypes. Considering that a single requirement can have more than a single sub-type, each requirement has been listed in this deliverable in the sub-type with most significant impact. Whilst the elicitation was conducted with a view to the main layered components of the REACTION platform, we choose a more abstract stratification by subtypes with focus on data management for the report. Following subtypes[3] have been defined for the REACTION data management requirements:

- Data Interface
- Data Source (with focus on PAN/BAN)
- Data Storage
- Data Structure
- Data Semantics (including data (re)presentation)
- Data Security

The sections that follow provide a short introduction to describe the main aim of the subtype related to the data management model. In addition the sections enumerate the gathered technical requirements ordered by requirement identifier. Finally the conclusion section examines the expected impact of the requirements on the further design process of the data model and architecture.

5.1 Data Interface

The REACTION platform will provide communication interfaces with numerous users, external systems, and internal components. This section describes what main interfaces are required.

5.1.1 Introduction

In order to yield the maximum value from current and future technological research, it is necessary to understand the importance of the Data Management architecture model. It is also necessary to ensure the robustness, accuracy, topicality (up-to-date-ness), and availability of clinical data assets as well as access to those assets. This section illustrates the communication requirements of the REACTION

[3] Requirements assigned to the subtype „Other" are not relevant for data management and therefore are not shown in section 5. They are listed in Appendix II.

system- representing different access to the information- and their respective needs regarding availability and accuracy (or suitability for use) of this data.

This section provides background information on how we should proceed to support our communication interface work in the REACTION project in order to define the requirements needed to connect the different components which play a role in the ”long term management of diabetes through continuous glucose monitoring, monitoring of significant events, monitoring and predicting risks and/or related disease indicators, decision on therapy and treatments, education on life style factors such as obesity and exercise and, ultimately, automated closed-loop delivery of insulin”. The communication within the REACTION project is the corner stone in exchanging clinical and daily life information between the sensor devices, the REACTION Hosting Client, the Device Hosting Server, the patient and carer sphere and the third parties (Microsoft HealthVault and Google Health) using several standards (IEEE 11073, IHE-PCD01, HL7, etc).

We will document where the standardized interfaces (e.g. HL7) have to be used, e.g. to retrieve demographic information of the patient and to exchange clinical data with the LIS / HIS / EPR / third parties and the inpatient pilot. The specific subset of IEEE 11073 medical devices to be supported, the communication methods (two way communication) and the recovery mechanisms in case of failure will be taken into account. The availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality in order to minimize risks and preserve privacy will be studied in section 5.6 Data security.

5.1.2 List of Requirements

Key	Summary	Rationale	Fit Criterion
RDMM-3	Interface to patient demographic register	In order to import demographic data from the patient demographic register has to be imported from the HIS. A standardized interface e.g. HL7 has to be used for data interchange. Required data fields are. - unique PID - name - age (data of birth) - sex - address	Standardized interface (HL7) to patient demographic register is available for the inpatient pilot application
RDMM-26	Interface to Lab Information System (LIS) for glucose data import	In order to perform decision support the blood glucose value has to be imported from the Lab Information System (LIS). A standardized interface from inpatient pilot application to the LIS has to be defined. HL7 would be a suitable standard.	Standardized Interface (e.g. based on HL7) to Lab Information System (LIS) for glucose data import.
RDMM-27	IEEE 11073 support	The support for a specific subset of IEEE 11073 medical devices has to be provided.	Once specified which medical devices have to be supported, show that data can be collected from at least two of them.
RDMM-28	Interface to Hospital Information System for clinical data import/export	In order to exchange clinical data between inpatient pilot application and Hospital information System (HIS) an interface based on HL7 has to be provided.	Standardized Interface (HL7) to HIS / EPR to exchange clinical data.
RDMM-33	Data exchange with third party systems	Ideally integrates information from outside the REACTION platform (e.g. Laboratory Information Systems in hospital or primary care with blood glucose and glycated haemoglobine).	Should be able to import and export data in an interoperable way (e.g. HL7) to third-party systems.

RDMM-34	Interface for user inputs from portable computer in order to store data in inpatient data storage.	For the inpatient prototype user input should be possible. The user data should be stored in the data storage.	User input can be stored in the inpatient prototype storage for further processing.
RDMM-35	(Web) Service to present decision support for glucose control to clinicians	After processing of data by the glucose prediction algorithm, the results should be presented by the system to the physician. The physician can use the result for decision support. The service uses data stored in the data storage and user additional user input as input for processing.	A service will be available to support physician with glucose control of patients.
RDMM-36	Interface for transmission of glucose values from POCT system to inpatient prototype	As decision support is a time critical process data from the POCT device should be transferred directly (without detour to LIS) to the inpatient prototype in order to speed up the transmission process. Therefore an interface has to be provided.	Interface to POCT device is available for the inpatient prototype.
RDMM-52	Patient enrolment (or recruitment)	When an interoperable HIS or EPR is present in the managing organization, then the patient data at the patient enrolment should be obtained from the HIS or EPR through interoperable user interfaces.	When an interoperable HIS/EPR is present a new diabetic patient cannot be created in the REACTION platform if not present in the HIS/EPR. When a diabetic patient is created his data have to be taken from the HIS/EPR.
RDMM-73	Data should be stored in proper way in order to be easily transmitted over mobile networks in case that broadband network is not available.	In the event that the hosting client is not connected through a broadband connection the patient will be able to upload data using GPRS / 3G data networks. In this case we need to examine possible limitations.	Functional test uploading data over slow mobile networks.

RDMM-108	Two-way communication between REACTION server and client	There is a need for two-way communication between server and client e.g. for remote configuration of the end-user application running in the AHD. The data fusion engine also needs to be configured based on which values the clinician wants to observe. There is also a need for 2-way communication from the point of view of error handling. If the observed values suddenly appear out-of-range it might be necessary to check with the client if this is an error state. Other devices/sensors, e.g. the Continua-devices, might also require different types of communication. It might be necessary to reverse a patient's consent that had to be given 'remotely', e.g. at the doctor's surgery, because the hosting client at the patient's home is simply a 'box' with no display or input capabilities. In this restricted 'boxed case', it would be hard to change the patient's privacy settings, once they are initially configured, if we were unable to push data back to the box.	Two way communications between Client and Server will be available for the REACTION platform in order to perform: e.g. data fusion configuration, error-handling, data security (consent management).
RDMM-109	Support of continua compliant devices	REACTION platform should provide Continua compliant devices.	The REACTION platform supports Continua compliant devices.
RDMM-113	Communication interface between REACTION Client and REACTION Server	A communication standard between REACTION client and server should be established (e.g. IHE-PCD01) in order to transport data from client to server side (and vice versa).	Communication interface between REACTION Client and REACTION Server will be available.
RDMM-117	IEEE 11073-20601 compatibility of Solianis device	Solianis would like to provide IEEE 11073-20601 compatibility (IEEE PHD protocols) for their blood glucose device.	REACTION middleware supports support IEEE PHD protocols.
RDMM-121	Connection with external services like MS HealthVault and Google Health	External interfaces to services of MS HealthVault and Google Health should be taken into account in the REACTION platform.	Interfaces to MS HealthVault and Google Health will be available.
RDMM-122	Maximum delay to transfer blood glucose value from POCT to inpatient prototype	Up-to-date Blood glucose values are absolutely necessary for electronic decision support. In order to improve usability for physicians the transfer delay from POCT device to inpatient server application should be max. 3 seconds. Therefore the interface has to be appropriate to fulfil this constraint.	Delay of blood glucose transfer is max. 3 seconds.

RDMM-123	Inpatient prototype communication with REACTION platform	The current design of the inpatient prototype and the primary care prototype does not consider the communication between these two prototypes (e.g. SoA). Thus, the data model should consider how the prototypes can be merged in future within the REACTION platform. A data/communication interface has to be defined.	Communication and transfer of data between inpatient and outpatient prototypes are possible.
RDMM-128	Connection with other external services	External interfaces to services of MS HealthVault and Google Health should be taken into account in the REACTION platform (RDMM 121). Other external services should be taken into account in the future.	Interfaces to other external services could be available (scalability).

5.1.3 Conclusion

The REACTION platform will implement a distributed system. This implies that the systems architecture will expose a number of different information exchange and data communications interfaces, internally as well as externally.

The requirements in this section address these interfaces with regards to their purposes and roles. We distinguish the following different types of data interfaces,

- External, i.e.,
  - Interfaces to other health-care sub systems, including EPRs, demographic databases
  - Interfaces to global services, like MS HealthVault and GoogleHealth
- Internal (inter component messaging and service invocation)
- Persistent storage media
- Medical devices
- Data entry/capture (for patients and carers)

Several of these interfaces will expose or be forced to comply with, various standards, primarily those intended for eHealth interoperability.

5.2 Data Source (with focus on PAN/BAN)

This section discusses data sources which are relevant for the REACTION platform. Particular emphasis is placed on BAN and PAN and data which are gathered by their devices.

5.2.1 Introduction

It is evident that the mobile devices and sensors comprise the forefront of the medical management model we design, whatever its architecture may be. The PAN sub-system is responsible for a series of operations and functionality, and must be able to ensure stability under all circumstances without compromising unquestionable requirements such as the safety of a patient or privacy and confidentiality of his medical data.

The BAN and PAN devices are responsible for collecting most of the medical measurements of a patient, along with any context information and environment factors which we want to gather and correlate, by using environment sensors or other ambient and background information. In addition, by using PAN devices we also collect medical data which is not collected automatically and have to be inserted manually or inferred by other pieces of information like external knowledge base systems, and questionnaires which complete our medical view of a patient or an episode. In addition to the data generated by PAN&BAN devices and sensors, other sources of data we need to process and managed through the REACTION platform, are EPRs, knowledge data bases, or historical data sets.

Apparently, the collected requirements are based on a first evaluation of the system architecture and as the project progresses, even more concerns and demands will arise from the end users, the technical restrictions or even from the overall system architecture. With an iterative and systematic approach we expect that gradually and progressively we will reach the convergence point between the limitations and the required functionality.

Based on these observations and facts, we collected the requirements which are summarized below. Due to the stratification of the requirements by data management related aspects not all requirements for PAN/BAN are summarized in this section. The complete set of PAN/BAN requirements for a REACTION data management model can be found in Appendix II: Complete set of Technical Requirements for a Medical Data Management Model.

5.2.2 List of Requirements

Key	Summary	Rationale	Fit Criterion
RDMM-31	All data entered must be checked for format, consistency and validity	Unintended user actions should not harm data integrity and the overall functioning of the platform. In case of doubt, the user must be warned and asked how to proceed. The user must be able to correct mistakes easily.	The functional test should include specific tests in order to verify such circumstances.
RDMM-80	Patient education	Continuous education of the patient adjusted to his/her needs.	Educational material is available.
RDMM-82	Manual data insertion	In case of no connectivity with the sensor or medical device or use of a non-interoperable medical device, the mobile device should offer the possibility of manual insertion of measurement data .	Check that measurements can be inserted manually using the mobile device.

RDMM-86	Device specialization	Based on the necessary information to be monitored from the patient, a complete list of IEEE 11073 device specialization has to be completed. Measurements which cannot be collected using IEEE 11073 device specialization are also to be mentioned in this list. The complexity of the IEEE 20601 manager also depends on the number of device specializations to be managed.	For each device the supported standard has to be specified (or the company documentation).
RDMM-87	Continuous blood glucose monitoring	Using the acquired values, the mobile device must be able to analyze the glycaemic variability and to generate alarms or alerts (hypo or hyper), based on configurable thresholds.	This functionality can be tested using the device simulator and simulated sequences of values-
RDMM-88	Patient questionnaires (lifestyle, physio-psychological condition, medication compliance, education, self management)	Questionnaire for patients in order to collect qualitative (or quantitative but not directly measurable) information related to the parameters to be monitored has to be available. They are part of the monitoring (using a frequency set) administered by the responsible clinician.	The mobile device shall have user interfaces allowing completion of these questionnaires.
RDMM-89	Collecting measured data ("many to one" traffic pattern)	Different sensors can have different acquisition rates and relay data at different frequencies. Specific policy for data aggregation/fusion has to be defined.	Check the measurements collected by different sensors (times & values) and evaluate if there are critical delays.
RDMM-90	Use of activity patterns for context annotations	Context has to be expressed synthetically in some way. A possible and common option is through activity patterns (to be specified for the two environments).	Collect measurements about physical activity, environmental data, additional information, and evaluate the activity patterns verifying their correctness.
RDMM-92	Insertion of baseline physiological measurements at the first visit	At the first visit baseline physiological measurements (the exact set has to be clearly defined) have to be inserted in the platform.	The data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrolment).
RDMM-94	Measurements of blood glucose and insulin injections in Inpatient environment	In inpatient environment, the blood glucose level measurements are, in most cases, performed by nurses with treatment performed by clinicians and/or nurses	Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.
RDMM-95	Basic workflow in Inpatient environment	The basic workflow is based on measurement of blood glucose and evaluation of the necessary insulin (bolus or basal), based also on additional parameters and insulin administration.	There should be the possibility of acquiring, storing and retrieving all the information generated during any basic workflow performed during any time of the day/night.

RDMM-101	Drug administration data (OAD and/or insulin)	Drug administration (time, insulin type, administration type -IV or SC-, dosage and other relevant information) has to be immediately registered in the data management by the administering nurse.	Data on drugs administered have to be stored in the data management where they can be also retrieved as part of the fever/sugar chart.
RDMM-102	Special examinations/treatments to be registered in fever chart	For some examinations/treatments in the hospital the patients have to be in a fasting and/or glycaemic condition. In such cases treatment must therefore be adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). However a problem may arise if the patient has to wait longer than expected due to unforeseen delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). The dose of insulin and/or OADs will therefore need to be adapted, the patient receives some food in the event of hypoglycaemia and receives insulin by injection in the event of hyperglycaemia.	These events (special examination/treatments) have to be registered in the data management where they can be retrieved for the composition of the fever/sugar chart.

5.2.3 Conclusion

A list of requirements is provided for the Data Management, based on the restrictions and facts imposed by the BAN and PAN components of the REACTION architecture. These requirements are drawn from the preliminary REACTION architecture (see section 10.1), in conjunction with the collected set of requirements for the overall REACTION project (see “D2-5 - Initial Requirements Report”) and the state of the art analysis regarding the BAN and PAN network structure and communication standards (see “D5-1 – Communication standards within BAN and PAN”). This list of requirements is expected to evolve together with the project architecture and will be refined as more input is collected both from the medical and the technical experts.

As we outlined above, the PAN and BAN devices comprise the fore interfacing sub-system of REACTION with the patient and his environment, thus must conform and take into account a number of factors, and harmonize or even trade-off between many legal requirements, technical restrictions, and functionality goals. The REACTION system has been foreseen to be used at different kinds of installations, both for remote monitoring of patients at home, or monitoring and applying the close-loop system on real patients in controlled environment.

The challenge in the PAN and BAN networks is to ensure interoperability, data consistency, privacy, low complexity, especially in the BAN network, and to decrease power consumed by the sensors. Moreover the data transmission from the devices and sensors must be secure and accurate. Faultless data transfer across the standards such as ZigBee, Bluetooth etc. must be retained. In addition to that plug and play device interaction must be endorsed and the systems must be scalable for further changes to facilitate well functioning.

The contextualization of measured values, such as blood glucose values, is an important factor to facilitate support for the REACTION applications, like decision support. The data management model has to provide context management due to different glucose levels that have different meanings for treatment which is essential.

Based on the above facts and observations, the system must be able to ensure smooth operation. In order to achieve this, the system’s fault tolerance, the operation under restricted power consumption, possible problems in communication, logging and caching of data acquisition must be taken into account.

Furthermore, in order to follow for example the Continua guidelines, the devices must conform to some specific standards and/or the middleware must be designed and implemented in a way to ensure this seamless integration. Requirements like the ability of the system to collect also manual measurements,

context information and environmental data are inevitable. Besides the automatic fetching of measurements, the system must support manual data insertion, for functional and technical reasons. All the data entered must be checked for format, consistency and validity in order to avoid unintended user actions that might harm data integrity and furthermore the overall functioning of the system itself.

Having mentioned all the above, the BAN and PAN devices are the first step on a series of actions which will ensure an open and flexible architecture. In order to satisfy the requirements for interoperable data formats and models, the devices and the middleware, should comply with the relevant standards, e.g., the IEEE 11073 set of medical device standards.

5.3 Data Storage

This section deals with requirements on the data content to be maintained within the REACTION platform.

5.3.1 Introduction

In all three parts of the REACTION platform (see Figure 2) there are needs to store data both temporarily and persistently. On the patient (client) side the measured values might not be possible to transfer to the hospital (server) side due to lack of connectivity and therefore data needs to be temporarily cached. The server side needs to manage a variety of information objects and data types, ranging from individual patient observations and treatment plans to aggregated population data. Thus, we need to store patient measurements and related context data, and in order to perform analysis and generate new knowledge related to diabetes treatments we also need to store large sets of historical and statistical data for current and historical patient populations. The following requirements have been elicited so far.

5.3.2 List of Requirements

Key	Summary	Rationale	Fit Criterion
RDMM-30	Integrity check for the stored data	To guarantee the integrity of the stored data in the case of an unwanted happening.	Use of adequate methods like e.g. Hash keys or redundancy codes for the data stored.
RDMM-32	Dynamic data structure for inpatient data storage	For the impatient pilot application (eDSS) a dynamic data structure for data storage has to be implemented. Data fields should be flexibly defined. A suitable model can be the Entity-attribute-value (EAV) model.	Dynamic data structure for data storage will be available for inpatient pilot application.
RDMM-42	Set of alerts and reminders	A set of possible alerts and reminders. These can be thought as “prototypes”. Action rules can define when and how they must be sent with which parameters.	Alerts and reminders can be defined and stored.
RDMM-53	Provide regular update of data model for Health Care profile	Most application depends on current clinical data (e.g. blood glucose). A mechanism for regular data updates should be provided.	The Data Model for REACTION should provide a regular update mechanism for personal health care profiles.
RDMM-54	Results of screening, symptoms and types of diabetes or hyperglycaemia	At the diabetic patient enrolment his/her symptoms or results of screening confirming presence of diabetes should be registered. Symptoms can be: polydipsia, polyuria, blurred vision, weight loss, tiredness, and recurrent skin infections. Results of screening can be: glucosuria or elevated BMs (both have to be confirmed with a diagnostic blood glucose measurement). Type of diabetes should be registered (if available data can be taken from the HIS/EPR).	Possible classifications should be present in the knowledge base & ontology and in the database fields for multiple selections from the classifications. Does the data need to be stored at each subsequent visit or evaluation?
RDMM-58	Different stages of patient management in outpatient environment	Different actions have to be performed at different stages (newly diagnosed / medication titration / investigative stage, ongoing management) of patient management in outpatient environment.	The data management has to allow the storage of the stage of management for each patient.

RDMM-60	Investigative stage	An investigative stage is required for all newly diagnosed diabetic patients. This stage (the duration of which is determined by clinicians) is used to: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, carry out patient education , and reassure patients concerned about their blood sugar levels.	Specific fields have to be present in ontologies and data management.
RDMM-61	Ongoing management	Ongoing management follows investigative stage. This stage is used to: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes	Specific fields have to be present in ontologies and data management
RDMM-63	Measurements of HbA1c	The risk of developing diabetic complications is strongly affected by HbA1c. This parameter has to be measured every 2-6 months until the blood glucose level is stable on unchanging therapy in outpatient environment and at the patient enrolment in the inpatient environment (updates are decided buy clinicians).	Specific fields have to be foreseen in data management.
RDMM-65	Storage of insulin administration	Insulin administrated to patient has to be stored with time, dosage (units), type of insulin and modality of administration (always subcutaneous for outpatient environment).	Specific fields have to be foreseen in ontologies and data management.
RDMM-66	Storage of events for context of measurements	Significant events (e.g. nutrition, drug administrations, and adverse events like hypoglycaemia or hyperglycaemia) have to be stored in order to provide a context (together with environmental measurements and physical activity) for the acquired measurements.	The data management should allow the storage of all events with impact on context.
RDMM-69	Reasons for end of process in primary care environment	There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from the practice catchment area or voluntarily stops to be monitored by the REACTION platform.	Patient discharge from the outpatient environment shall have the following options: a) death; b) patient removal outside from the practice catchment area; c) patient voluntarily stops to be monitored by the REACTION platform.

RDMM-71	Care space in primary care environment	The primary care processes only end in the event that the patient leaves the practice catchment area; voluntary withdraws from the REACTION monitoring system or dies.	Patient discharge from the outpatient environment shall have the following options: a) death; b) patient leaves the practice catchment area; c) patient voluntarily stops being monitored by the REACTION platform.
RDMM-72	Information related to informed consent stored in the platform	An ethical approved declaration of informed consent has to be signed (either digitally or in paper form) by patients before they can be enrolled in the REACTION platform.	The enrolment procedure shall allow the storage of the digitally signed informed consent or of a scanned copy of the signed paper This procedure shall be completed before any other operation can be performed.[4]
RDMM-74	Baseline and clinical history handled in the data management	Immediately after patient recruitment, his/her baseline and clinical history has to be entered in the platform. This can be done by extracting this information from the HIS/EPR (if available and interoperable) and completing the missing information.	The data management should allow the storage of baseline and clinical history and these data can be extracted from the HIS/EPR (if available and interoperable).
RDMM-75	Data should be automatically saved in temporary file when PDA's battery is running out.	In case of low battery the client application should be able to store temporary data. This will a) allow user to continue the process later and b) prevent corrupted / incomplete data to be uploaded to the main server.	The functional test should include specific tests in order to ensure that data are always stored correctly in case of a battery-forced shut down.
RDMM-76	Information should be cashed in local storage to prevent loss in case of a node or communication failure.	In case of network error the client application should be able to store temporary data. This will a) allow user to continue the process later and b) prevent corrupted / incomplete data to be uploaded to the main server.	The functional test should include specific tests in order to ensure that there is no data loss in case of network failure.
RDMM-77	Energy friendly data aggregation for mobile devices	Aggregation techniques should be used for reducing the overall data traffic to save energy. Depending on the need for a real-time response, the redundancy of the data, etc., specific data-propagation strategies should be defined.	The functional test should include specific tests on battery consumption using different communication methods with the sensors.

[4] Requirements concerning data security and data privacy can be found in section 5.6.

RDMM-78	Clinical data to be stored in the Inpatient environment	The data management shall be designed in order to allow the storage of the clinical data to be registered at the patient enrolment as well as other clinical parameters which have to be acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, co-morbidities, therapy scheme. Other parameters have to be measured more frequently: glucose level, injected insulin, food intake/nutrition, estimation of insulin sensitivity and resistance.	The data management shall allow the insertion and the update of all the listed clinical parameters.
RDMM-93	Clinical case conference	Any possible critical situation has to be accurately verified by the clinical care team with the support of virtual visits through e.g. the use of video-conference. The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed for. A clinical case conference report has to be stored.	Storage and retrieval of clinical case conference reports has to be possible.
RDMM-98	Clinical evaluation report	Supervision of glycaemia and associated treatment is performed once a day. The clinical evaluation report has to be produced daily. Adaptation of therapy or changes of medications has to be evaluated including by consultation with the duty-physician.	A daily clinical evaluation report has to be stored and available in the Inpatient application.
RDMM-99	Therapy scheme in Inpatient environment	Decision on therapy has to be performed immediately after performing any measurements based also on patient history and associated parameters. It might imply changes in the therapy scheme.	The pharmaceutical and non-pharmaceutical treatment (or therapy scheme) has to be stored in the data management and can be modified during any clinical evaluation of the patient. It has to be initialized immediately after the patient enrolment.

RDMM-100	Insulin sensitivity and insulin resistance	Insulin sensitivity and insulin resistance have to be used in the evaluation of the insulin dosage. However, these two parameters cannot be directly measured and have to be estimated by the clinicians. Their value can vary depending on the context (physio-psychological status of the patient, usage of specific drugs, etc.).	The data management has to allow for the insertion and subsequent modifications of these values by clinicians.
RDMM-103	Storage of hyperglycaemic or hypoglycaemic episodes	Reasons for any cases of hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered. Should the blood glucose level rise above a certain threshold, a hyperglycaemic episode has occurred. The reasons for such an episode have to be registered along with ensuing changes in treatment..	Specific procedures have to be present for the management of hyperglycaemic or hypoglycaemic episodes. These procedures shall also allow for the recording of the significant parameters and actions.
RDMM-104	Nutrition information has to be stored in the data management	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation (the use of glycaemic index and load tables for various types of food might be taken into account). Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	The data management shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.
RDMM-105	Registration of specific interfering drugs (including their dosage)	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference). Their administration should be registered.	The data management shall allow for the insertion of specific interfering drugs (including their dosage).
RDMM-106	Fever and infections shall be registered	Fever is very often associated with insulin resistance which means that the patient needs more insulin.	Fever and infections shall be registered in the data management where they can be retrieved for composing the fever/sugar chart. When estimating the insulin resistance, clinicians shall have access to this information.

RDMM-107	Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.
RDMM-119	REACTION data storage	The REACTION platform should provide a storage module (database). Data gathered within REACTION should be stored here, as well as relevant data from external sources. The REACTION data storage should also use security mechanisms to include/exclude patient data access.	The REACTION platform provides a persistence layer for data storage with emphasis on data security and data access.
RDMM-126	Communication failure recovery	In case of communication failure, the connection has to be restored as soon as possible and the information should not be duplicated or corrupted.	Ensure that there is no data loss in the event of communication failure.
RDMM-127	User transparency in case of communication failure	In case of network error the client application should be able to store temporary data (RDMM 76). The system should detect problems on the network and start the local storage. From the client's viewpoint, failures should be perfectly masked, and service should be completely fault-tolerant.	User transparency refers to a combination of user friendliness' and 'high efficiency'.
RDMM-134	Sensor quality parameters	The REACTION data management model should consider data storage for sensor quality parameters from devices reports like for example mis-calibration, or low battery. The parameters should be used for QoS.	Data fields for sensor quality parameters are available in the data management model.

5.3.3 Conclusion

Storage requirements pertain to both the client (patient) side and to the server side (carers sphere). We need to provide for caching of data on the patient device, primarily in order to ensure reliable data transfers and to handle intermittently connected devices

Measurements obtained from the patient devices connected to the REACTION platform, should be maintained in a separate REACTION observations database. The measurements can be stored as a series of observations, each aggregating a measured value with its possible context data. A plausible standard representation for such an observations data model should be researched. The observations database should be provided as part of the platform back-end/server side. Data from EPRs and other sources which are needed for the data mining process needs to be extracted, aggregated and stored in a separate analysis database.

5.4 Data Structure

This section figures out what data structures have to be provided to store, process and interchange data in the most satisfactory way.

5.4.1 Introduction

Since we envision REACTION platform to be very flexible and able to support many types of disease management applications, we will need to support a model driven architecture, meaning that the execution of many functions are based on formal models and rules and that REACTION applications to a large extent are generated from models. Consequently, we need to understand and define which the fundamental data structures we need in REACTION are. The following requirements have been elicited so far.

5.4.2 List of Requirements

Key	Summary	Rationale	Fit Criterion
RDMM-39	Data fields for the inpatient glucose control prototype (eDSS).	Following data fields should be provided: - administrative data (patient name, address, PID, ward, hospital bed, physician(s) in charge, nurse(s) in charge) - demographic data (age, sex, date of birth) - medical history (type of diabetes, medication, co-morbidities, former complications, pre-existing conditions) - anamnesis data (fever, infections, diarrhea, vomiting, hypo- hyperglycemia) - lab data (glucose level, HBA1c, ...) - external input (food intake, insulin sensitivity, ...) - context data (time of glucose measurement, what device, ...)	Required data fields will be provided by data structure.
RDMM-45	Personal Health Status Profiles	Personal Health Status Profile for each patient must be generated, stored and regularly updated. It serves as an input for risk assessment and disease management.	Personal Health Status Profiles can be generated.
RDMM-48	Case base	The case base contains a set of cases generated in the platform and/or imported from existing case bases. It can be used together with other knowledge elements (e.g. evidences) to discover new knowledge.	A case base is present.
RDMM-51	Mechanistic model and rules for insulin dose prediction (primary care)	A physiologic model and calculation rules/algorithm must be stored for insulin dosing support.	Necessary models and rules are defined and stored.

RDMM-55	Co-morbidities have to be registered	Co-morbidities are almost always present in diabetic patient and their presence can affect the overall management of the diabetic patient.	In the design of data management and ontologies the possibility of registering the co-morbidities with a basic set of attributes has to be guaranteed. Co-morbidities with their attributes have to be registered at the patient enrolment and at each subsequent visit or evaluation when new co-morbidities take place.
RDMM-56	Annual clinical checks	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies and data management.
RDMM-57	6-month clinical checks	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in ontologies and data management.
RDMM-62	Non-pharmacological and/or pharmacological treatment	Non-pharmacological (diet, lifestyle, education) and pharmacological (OAD, insulin and interfering drugs) treatments have to be assigned to each patient and can be modified at each check.	In the ontologies and data management there should be the possibility of registering the different types of treatment for each patient and of modifying them at each check.
RDMM-67	Management of complications	Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems).	Data management should include the necessary structures for assuring the storage of all necessary information for the management of complications.
RDMM-68	Outcomes of regular visits at primary health care centres	Outcomes of regular visits at the primary health care center shall be registered through the data management.	The outcomes of each visit have to be stored as much as possible in a structured way.

5.4.3 Conclusion

REACTION is based on a service oriented architecture and will be deployed in a distributed manner. Thus, there will be a need to exchange and synchronize the basic data structures. Therefore we recommend that they are expressed using an XML format and vocabulary.

5.5 Data Semantics

The section deals with the requirements on the interpretation and understanding of the clinical data generated and maintained within the REACTION platform.

5.5.1 Introduction

The complex management of data, information and knowledge is an essential part of the REACTION system. The connection of these three entities can be describes as following: information is transformed from raw data by interpretation or data processing. Knowledge can be derived from the information by learning and reasoning. The prior knowledge influences the whole process, for instance it contains the models for interpretation (see Figure 3). Moreover, inference methods can be used to generate new information from existing information by the use of available knowledge.

The proper definition of the required data, information and knowledge and the necessary transformations is an important step of the design of the system. An initial set was derived from the user requirements and inserted into the technical requirements. As a consequence of the evolutionary design method, the improvement of the requirements might affect these needs as well.

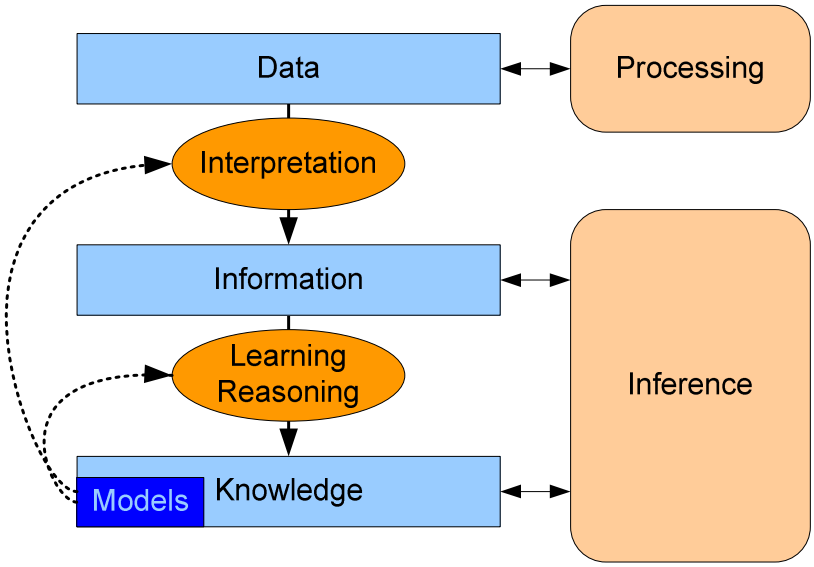

Figure 3: From data to knowledge

Terminology is the system of terms in a given domain. It can ensure that each actor understands the same concept on a certain term. The terminology management includes the maintenance of the taxonomy. If an external terminology is used, it must be regularly updated to the newest version. Suitable candidates for an external terminology can be the Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED) or the Unified Medical Language System (UMLS). If a custom terminology is used, its consistency must be checked and ambiguous elements must be corrected. Requirements concerning semantics needs of the REACTION data management model are summarized blow.

5.5.2 List of Requirements

Key	Summary	Rationale	Fit Criterion
RDMM-29	Definition of a common ontology to refer to data, metadata, interfaces and models	A common ontology facilitates components integration and maintain a common language among the technical people and stakeholders.	All logical entities in software components should correspond to terms from the ontology (or to a published source which justifies their introduction).
RDMM-37	Semantics based data management	The monitoring and other data need to be properly annotated with ontological descriptions.	Relevant entries in the REACTION's databases are annotated with semantic concepts.

RDMM-38	Monitoring scheme	Individual monitoring scheme for each patient must be defined and stored. This describes what parameters and how often they should be measured.	An individual monitoring scheme can be defined for each patient.
RDMM-40	Set of event rules	Event rules define the criterions of different events. Events are detected based on these rules. Personalization is possible through the use of individual thresholds and other parameters.	Event rules can be defined and stored.
RDMM-41	Set of action rules	Action rules define what should be done if an event occurs, e.g. who should be notified and how.	Action rules can be defined and stored.
RDMM-43	Models and rules for insulin dose prediction (inpatient)	A physiologic model and calculation rules/algorithm must be stored for insulin dosing support based on clinical protocols.	Necessary models and rules are defined and stored.
RDMM-44	Risk assessment models and rules	Models and rules must be defined to determine personal risks.	Models and rules for risk assessment are present.
RDMM-46	Health status model	The health status model serves as a generic prototype for Personal Health Status Profiles, i.e. defines its data content. This helps to define personal models (profiles), which permit the personalised disease management.	A health status model is present.
RDMM-47	Case generation	From the data of individual patients, a depersonalized case description is built which will be put in the case base.	Cases can be generated.
RDMM-49	Personalized care plan	A personalized care plan must be defined (and updated if necessary) for each patient. It includes disease management, risk management and lifestyle plan. Personalization methods must be defined.	Care plan can be personalized.
RDMM-50	Knowledge Discovery from unstructured clinical text information	EPRs often contain unstructured text information. In order to use this information for decision support or diabetes management the information has be pre-processed. NLP-technologies to find relevant information for REACTION applications from these data bases (annotation of text information: e.g. anamnesis information, co-morbidities, medical history) can be a useful tool.	REACTION provides a knowledge discovery module to process unstructured information and store this information in the data storage for further processing.
RDMM-59	Medical knowledge base	Contains the relevant medical knowledge or is able to connect to external sources, e.g. evidences, drug information etc.	A medical knowledge base is built.

RDMM-64	Context management for clinical (lab) values.	Contextualization of measured values (e.g. blood glucose values) is important in order to support REACTION applications like decision support. For example pre- or post-meal glucose values have very different meanings for treatment. Therefore the data management model has to provide context management.	The data management model support context management functionality for the inpatient prototype application.
RDMM-70	Alert / notification messages should be short enough in order to be delivered as SMS messages if necessary	User's terminal mobile device will be likely be used as a GSM mobile phone. Considering the advantages of Short Message Service (fast delivery, provides an alternative data path when an Internet connection is not available etc) the time critical messages for the patients should be able to be forwarded as SMS messages.	Functional tests when user is away from broadband connection.
RDMM-79	Computer interpretable guidelines	Evidence based guidelines as important constituents of the knowledge base must be encoded in a computer-interpretable way for decision support.	Guidelines are encoded.
RDMM-81	Self-management and lifestyle support	Support of the patients' self-management by lifestyle (diet, exercise etc.) advices, therapy advices, health status assessment.	Self-management is supported.
RDMM-83	Display of acquired measurements (values, time, context (if available))	Provide immediate and consistent (if possible also contextualized) information to the patient.	The user interface on the mobile device shall have this functionality.
RDMM-85	Content formatter	A formatter for converting the acquired data to useful information for the patient shall be available.	Use a standard format or a verification mechanism.
RDMM-96	Electronic fever/sugar chart	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.	In the design of the data management the electronic fever/sugar chart (or the possibility to compose it from the stored data) has to be present. Its access must be multi-user. The fever/sugar chart has to be initialized at the patient enrolment and updated at any data acquisition.
RDMM-97	Contextualization of measurements	The availability of all measurements (and mainly blood glucose levels) shall be accompanied also by the context of the measurements.	Measurements before any usage have to be contextualized.
RDMM-110	Context of observations	The middleware of the REACTION platform should support context management for observed values.	The REACTION platform supports context management on the client side.

RDMM-111	Low-level data fusion	The REACTION platform should support low-level data fusion in order to interpret measurements occurring in PAN. The Data Fusion needs to take place close to the patient/user.	Low-level data fusion will be available for the REACTION platform (middleware).
RDMM-112	High-level data fusion	Besides low-level data fusion on the client side a high-level data fusion should be available for the REACTION platform. The high-level data-fusion should provide the integration of external gathered information to the REACTION platform data structure and the fusion of REACTION-internal processed data.	High-level data fusion functionality will be available for the REACTION hosting server.
RDMM-124	RDMM-35 Visualization of current "insulin on board" and "carbohydrates on board"	As part of electronic decision support the current "insulin on board" and "carbohydrates on board" should be presented to the physicians and nurses. Methods/Functions: - trend information - active profile of insulin on board (using physiological models)	Inpatient prototype provides visualization of current "insulin on board" and "carbohydrates on board" for decision support.
RDMM-125	Context sensitive interface	"Best guesses" for input values and context-sensitive interface for data entry to keep efforts required for data entry as low as possible.	Users are satisfied with user input.
RDMM-131	Consider patient's preferences, wishes and decisions	The data set should allow documentation of patient's preferences, wishes and decisions. This information should also be considered in the evaluation of rules etc., so that no recommendations against the will of the patient are made.	Patient's preferences, wishes and decisions can be documented and rules consider this data.
RDMM-132	Management of referrals to and responses from other physicians (via EHR interface)	Referrals are part of clinical pathways and treatment plan. Referrals should be documented and the recommendation of referrals should be considered in decision support rules... Summary letters and other "responses" from other healthcare professionals should be managed. - Optimal solution would be an interface to a regional or national EHR infrastructure (e.g. IHE-XDS) from where documents can be received.	Referrals can be documented and are considered in decision support, summary letters can be received via an appropriate data interface.

RDMM-133	Telemonitoring data should be visualized to patients and professionals in a flexible and performant way	GPs and nurses as well as patients and their carers use the telemonitoring data to get an impression of the patient status. So telemonitoring data needs to be visualized in a flexible way (aggregation level, combination of parameters ...) Data has to be handled in a way that this visualization can be generated on-demand with good performance.	Data can be visualized flexibly and with good performance to professionals

5.5.3 Conclusion

To support the semantic management of data and as a basis for knowledge management, REACTION will exploit semantic technologies, specifically ontologies.

Ontology can be defined as “the formal specification of shared conceptualization”. This means that it describes the concepts and their relationships in a specific domain, facilitating interoperability both for machines and people. Within the REACTION data management it is only possible to define an ontology restricted to concepts related to diabetes and some general metadata, but not a full medical ontology. This limits the possible use of the ontology.

In the REACTION platform patient data is collected from three different sources:

- Measured by medical devices
- Manually entered by the patient or a member of the medical team (e.g. lifestyle data, visit outcomes (symptoms, new co-morbidities, etc.) or measurements which are not automatically transferred)
- Imported from external source. This mainly includes clinical information systems (EPR/HIS)

The data fusion service provides the integration of externally gathered data to the platform data structure. The data structures must be designed in such a way which takes security aspects into consideration and provides acceptable access speed and enables the joint management of associated data.

Methods must be provided to process data and generate calculated data. This process can be also considered as interpretation as it associates meaning to the data thus generates information. Another way of interpretation is the annotation (addition of metadata). These metadata should be terms from the terminology.

To facilitate the automated processing of text (e.g. the patient record), two possible solutions are available. If structured questionnaires are used to generate text, it can be easily interpreted. This solution is rather inflexible as the questionnaires must be altered when the demands change. The second option is the use of a semantic interpreter which is able to process natural language text. It is a more flexible although more complex technology. An ontology is an important component of a natural language processing system.

A diabetes knowledge base must be built to provide advanced disease management and decision support functions. It may contain the following elements:

- treatment algorithms and protocols
- guidelines represented in a computable way
- physiologic models (e.g. to calculate insulin dose)
- lifestyle models including the possible physiologic consequences
- risk models (take genetics, physiology, lifestyle, social environment into account)
- other schemes and algorithms (e.g. blood glucose patterns, if-then rules)

The knowledge elements must be expressed with terms from the terminology. To be consistent, every change and update must use the same terms. An ontology is an important technological component to perform searches in the knowledge base, e.g. to highlight the relevant parts of the guidelines.

The necessary inference methods apply the above described knowledge to the information known about the patient in order to draw conclusions and provide advices. Methods must be designed to evaluate the rules, apply the models and execute the guidelines.

Several representation formats exist which can be used to encode the necessary information and knowledge. The most appropriate ones will be selected and described together with other relevant details in the deliverable D4-2 Initial data structures, taxonomies and ontologies.

5.6 Data Security

This section analyses protection, privacy and security issues of the REACTION data management model.

5.6.1 Introduction

Privacy and security are especially important issues when it comes to sensitive personal information, such as a patient's medical record. Because of this, some patients may at first feel that having their medical records accessible in a computer network puts their health and privacy at a greater risk than having their paper file stored in a cabinet. In principle, the privacy and security threats for electronic health records are not new and are similar to those for paper records: files could be lost, stolen, disclosed, manipulated, etc. At first sight, it might look as if it is harder to acquire a medical file from a filing cabinet, as this requires physical access and medical personnel might be alerted by a stranger sifting through a cabinet full of medical files. However, privacy and security can be achieved in an electronic health record system – and with a higher level of protection. Under normal circumstances, access to an EHR system, like in the real-world example before, would never be given to strangers but only to authorised persons which are known to the system, e.g., medical personnel. In addition, electronic access control can be achieved on a much finer scale. First, anyone seeking access to the system can be asked to identify and authenticate themselves before any system resource would be made available. Second, persons which have been given access to the system can be grouped and assigned to specific roles which give them only specific access rights, or even none at all. For instance, there could be one group for administrative personnel and another for medical personnel, such that administrative personnel would not have access to the patient's health data but only to details such as name, address, and health insurance number. The medical group could also be further subdivided into, say, doctors and nurses, such that doctors would be allowed to fill out forms for diagnoses while nurses would only be allowed to read but not allowed to change them. Of course, all this is common behaviour in doctors' surgeries and clinics but it is largely 'enforced' by ethical and social norms. By introducing digital identities, role-based access control, and authentication mechanisms, it is possible to achieve a technical enforcement of these norms which can provide a higher level of protection. In addition, even in the event that someone manages to gain unauthorised access to an EHR, applying appropriate encryption mechanisms to such data can make it practically useless for the intruder as he/she would be unable to decrypt the data and hence could not learn anything from it.

The privacy aspect of (electronic) medical data is often overlooked, as it is commonly assumed that patients fully trust their doctors in almost every aspect. However, one thing that may change with an EHR is that it might not solely be managed by the doctor that the patient knows and trusts but it might be distributed over several management systems. In such a situation, it might be unclear to the patient who stores and processes which of her medical data and where. Legally speaking, the patient has the right to learn all this and often has to be asked for his/her consent before data is transmitted and processed. However, such requests could be equally confusing to the patients, if they are constantly informed about data transfers and asked for consents. Thus, patients must also be aided in the management of consents and other privacy preferences because otherwise they might be overwhelmed by notifications and requests for consents which ultimately may hinder them to exercise their privacy rights. On the data processor's side, the existence of a patient's consent for the processing at hand must be ensured before the data can be processed. Thus, data processors would also need help in managing consents, as they need to request them if they do not yet have one. If they have one, they must be able to decide whether the consent covers the intended processing. Also, it should not be overlooked that consents might be revoked by patients, which processors must take into account. In the case of a revoked consent, any future processing of the data covered by the former consent would not be permitted anymore. The following section lists several requirements which should help to ensure that the patients' privacy and security expectations are met.

5.6.2 List of Requirements

Key	Summary	Rationale	Fit Criterion
RDMM-4	Sensor devices (PAN/BAN devices) and receiving devices (AHDs) MUST be paired to ensure entity authentication.	Without any authentication, sensors may send data to unintended receivers, which might become a privacy problem, or AHDs may receive measurements from devices which are not the patient's, which might become a security problem and eventually a health problem if the patient receives the wrong treatment due to 'false' measurements.	Some kind of 'pairing mechanism' or entity authentication MUST be used before any sensor data is transmitted or received.
RDMM-5	Authentication and integrity of transmitted measurements MUST be ensured.	Without any data authentication, any measurement might be sent to the AHD without the AHD being able to distinguish between measurements from associated sensors and others. Also, if the measurements could be undetectably changed during transport, intentionally or unintentionally, this may have ill-effects on the patient's health because she may receive the wrong treatment due to 'false' measurements.	Mechanisms to ensure data integrity and entity authentication MUST be used for communication between sensors and AHDs.
RDMM-6	Confidentiality of transmitted measurements SHOULD be ensured.	Without any mechanism providing confidentiality, measurements sent from sensors might be overheard by third parties. This circumstance is alleviated a bit by the fact that sensors usually have a limited transmission range but active eavesdroppers may still use, say, antennas powerful enough to catch the signal.	A mechanism to ensure data confidentiality SHOULD be used whenever measurements are sent from the sensor to the AHD.
RDMM-7	Before transmitting any personal data, the patient's consent MUST be given. If no consent was given yet, the data MUST NOT be sent.	Privacy laws require that data subjects have to consent to the transmission and processing of their data. Without consent, transmission and processing of personal data is not permitted by law.	A 'watchdog' component must be in place that supervises the transmission of personal data and takes action if data to be transmitted is not covered by the subject's consent.

RDMM-8	If data was not transmitted for a lack of consent, the patient or her doctor (in case of a client without display and input capabilities) MUST be notified, e.g., through some pop-up or a notice in some message field.	Privacy laws require that data subjects have to consent to the transmission and processing of their data. If a new data item is to be transferred which was not foreseen in the initial consent, the subject has to give a 'new' consent before the new data item can be transferred and subsequently processed. If the subject's AHD has a display and input capabilities, the AHD may directly ask the subject for a new consent -- of course, the subject may also decline the request. If the AHD is an appliance without display, the transmission must include some kind of notice to inform the requesting party, usually the patient's doctor, that some data item was not transmitted and that the subject should be asked for an extended consent.	A notification mechanism for insufficient consents must be established for AHDs with and without display.
RDMM-9	A consent MUST NOT be considered valid if the patient was not involved in the decision.	If it cannot be verified that a consent was produced by or with the help of the affected data subject the 'expressed will' of the data subject is doubtful. Hence, no processing should be done as it is unclear that the data subject allowed it.	A mechanism is available that allows to verify (or infer) that a given consent was the data subject's own decision.
RDMM-10	If a consent was given, the patient's involvement in the decision MUST be verifiable by the REACTION Hosting Client, especially if the consent was given remotely, e.g., at the doctor's surgery.	Consents must be expressed by the data subject such that a third party, e.g., an AHD, can verify that the consent was actually given by the data subject herself -- this is especially relevant when the consent was given at the doctor's surgery and afterwards pushed back to the patient's AHD. Otherwise, anyone could produce a 'suitable' consent in the data subject's name.	Genuineness of a consent can be verified.
RDMM-11	Data MUST NOT processed at the REACTION Device Hosting Server if no consent is available and verifiable.	If patient data is to be processed at the REACTION Device Hosting Server, the server's provider must take the necessary steps to ensure that such a processing is permitted by the patient.	A 'watchdog' component must be in place that supervises the processing of patient data and takes action if data to be processed is not covered by the patient's consent.
RDMM-12	Communication between the REACTION Hosting Client and the REACTION Device Hosting Server MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the REACTION Hosting Client to the REACTION Device Hosting Server and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.

RDMM-13	It MUST be possible to revoke consent - data already stored MUST NOT be processed any further.	A patient must have the option to decide whether personal data is processed or not at any time. If the patient once gave her consent it must still be possible for the patient to revoke her consent, which means that any further processing of the affected data is forbidden. Also, if a patient revoked her consent the existing data may not necessarily be deleted, however, it MUST be excluded from any further processing.	Availability of mechanisms and procedures to enable consent revocation.
RDMM-14	Communication between the REACTION Device Hosting Server and the EPR/EHR System MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the REACTION Device Hosting Server to the EPR/EHR System and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
RDMM-15	Data/messages exchanged between the REACTION Host Client and the REACTION Device Hosting Server MUST be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the REACTION Host Client and the REACTION Device Hosting Server must be ensured even _after_ the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
RDMM-16	Data/messages exchanged between the REACTION Device Hosting Server and the EPR/EHR System SHOULD be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the REACTION Device Hosting Server and the EPR/EHR System must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	Availability of mechanisms to provide data authenticity, integrity, and confidentiality

RDMM-17	Data/messages exchanged between the REACTION Device Hosting Server and the GP EPR SHOULD be authentic (message authentication), with integrity, and confidential.	The security of messages transferred between the REACTION Device Hosting Server and the GP EPR must be ensured even after the message was received - this is true even if the message was received over a secure communication channel. To guarantee this, the messages themselves MUST be self-contained with respect to authenticity, integrity, and confidentiality.	Availability of mechanisms to provide data authenticity, integrity, and confidentiality
RDMM-18	Communication between the REACTION Device Hosting Server and the GP EPR MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the REACTION Device Hosting Server to the GP EPR and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
RDMM-19	Communication between the REACTION Device Hosting Server and the patient's/GP's web browser MUST be authentic (entity authentication), with integrity, and confidential.	It must be assumed that data transmission from the REACTION Device Hosting Server to the patient's/GP's web browser and vice versa takes place over an insecure channel, i.e., data might be overheard or tampered with. Since personal data is to be transmitted it MUST be ensured that the communication channel is authentic, with integrity, and confidential.	Availability of mechanisms to provide communication channels with authenticity, integrity, and confidentiality.
RDMM-20	Roles MUST be defined for stakeholders of the REACTION platform, e.g., doctor, nurse, patient, informal carer, administrative personnel etc.	Each person in the REACTION platform has the right to perform a certain set of actions. In order to simplify the administration of these rights, each person is assigned to a role and roles are assigned to permissible actions. The advantage of this approach is that it is easier to manage the rights of a role than managing individual rights for each person.	Roles are defined for every actor from the REACTION use cases.
RDMM-21	Every person represented in the REACTION platform MUST be assigned to one or more roles.	In order to interact with the REACTION platform, persons need certain rights. As rights are associated with roles, persons MUST have at least one role to interact with the REACTION platform.	Each person is assigned to at least one role.
RDMM-22	Each role MUST be assigned to a set of permissible actions.	Since some actions are reserved for specific roles it has to be decided which actions are permissible for which role.	According to the roles' needs, each role is assigned to a set of appropriate permissions.

RDMM-23	Each person MAY only perform actions permitted by her role.	Before a requested action is performed, a control mechanism has to check whether the requested action is part of the requester's set of permissible actions according to its role.	Availability of a control mechanism which decides whether a requested action may be granted or denied according to the requester's role.
RDMM-24	Each entity in the REACTION platform MUST be representable by a digital identity.	In the REACTION platform, entities must be uniquely identifiable and recognisable in order to allow repeated communication, referrals, accountability of actions, exclusion of ill-behaving entities, etc.	Availability of a digital identity mechanism.
RDMM-25	Digital identities for the REACTION platform MUST only be issued or revoked by trusted (third) parties, e.g., a certification authority (CA).	Without a trusted party (TP), anyone could produce its own digital identity and someone relying on such an identity would have to trust that the claimed identity is genuine. By incorporating a TP, relying parties trust that the TP ensures that its issued digital identities are genuine. This makes life easier for relying parties as they only have to establish a single trust relationship (with the TP) as opposed to having a multitude of trust relationships with others. The same goes for parties that had been excluded from the REACTION platform, as each relying party would have to determine by itself if another party is still part of the REACTION platform or not. In case of a trusted party, the relying part could simply query the TP if some identity is still valid or had been revoked, e.g., because its owner left the platform.	Availability of a party which is trusted to orderly issue and revoke digital identities.
RDMM-91	Privacy enhancing technology	Protect the privacy of users' personally identifiable information (PII) and further more personal data.	Each measurement in each transmission channel shall be separated from the patient data and association between measurements and patient shall not be possible for whoever can intercept the measurements.

RDMM-118	Privacy Enforcement Point	A component that could be added to the client side would be some kind of 'Privacy Enforcement Point'. Such a component could be examining outgoing data for information that the client did not authorize to be sent, yet. That is, the component would match the client's consents (with respect to the processing of her data) with the kind of information from the outgoing message and, possibly, delay the transmission of certain information which the client has not decided on. The component could stay hidden in other components for the time being, such as the Network Manager on the client side. The Privacy Enforcement Point should perform as a counterpart of the Consent Manager at the REACTION Device Hosting Server.	Privacy Enforcement Point is available for the REACTION client side.
RDMM-120	Telemonitoring profile/consent manager	This module should provide security mechanism for data stored in the REACTION platform. Patients have to acknowledge that personal data gathered from them can be stored and transmitted within the technical infrastructure of REACTION. Therefore the patient has to sign a consent form and the information about this should be stored within the system. It should be possible to exclude several personal information from storage/transmission. This manager could be queried, e.g. by the data fusion component (or any other component that processes personal patient data) before anything is processed in order to determine if the processing was permitted by the patient. Such permission would be expressed by way of consent.	Telemonitoring profile/consent manager will be technically implemented into the REACTION platform.

5.6.3 Conclusion

The REACTION platform is organised in a decentralised manner, such that personal, medical information is transmitted and shared by several parties. Therefore, it is necessary that such data is transmitted, managed, and processed in a secure, trusted, and privacy-preserving way. This means that confidentiality has to be guaranteed in order to allow medical devices to upload measurements (e.g. from patients' to their doctor's PC without anyone else being able to learn about these measurements. It also means that authenticity of senders and recipients of medical data must be ensured.

For instance, the patient's client device must be able to verify that the medical data is uploaded to the PC of the intended doctor or the doctor's device must be able to correctly identify the patient, thus enabling it to add the received data to the 'right' EHR. In addition, data may only be added to the EHR if it was not

tampered with during its transmission or subsequent processing, i.e., the data's integrity must be verifiable and the verification must be carried out before the data is added to the EHR. Access to such personal data may naturally be given to authorised entities only. If this is not the case, stored patient data could be easily manipulated which could have detrimental effects on the patient's health and would erode the trust in electronic health care.

Privacy laws also play a central role in the management of personal, medical data, as often the patient's consent must be sought before any data processing can take place. Consent, whether in paper or electronic form, must be given by the patient him/herself which, of course, should be verifiable. However, the lack of consent might constrain or even prohibit the treatment of a patient as it might not be possible to make a proper diagnosis due to missing or inaccessible data. Therefore technical means for detecting and informing patients and medical personnel about missing consents have to be considered as well.

The requirements can be assigned to functions and components of the data management model in the following way:

- (Sensor / mobile device) PAN/BAN security (RDMM-4, -5, -6)
- Data/message security (RDMM-15, -16, -17)
- Communication security (RDMM-18, -19, -12, -14)
- Access control (RDMM-20, -21, -22, -23)
- Digital identities (RDMM-24, -25)
- Privacy (RDMM-7, -8, -9, -10, -11, -13, -120)

6. REACTION Prototypes: Use-Cases for Applications

This section presents use-cases for the inpatient and the primary care prototypes identified in the initial user requirements of D2-5. These use-cases enable technical partners to obtain a better understanding of the main tasks of the REACTION prototypes, including how the system components interact with users. Moreover, this chapter relates technical requirements for the REACTION data management model to (1) the inpatient glucose control and (2) the primary care disease management application. Therefore, for each of the prototypes, typical use-cases have been designed and use-case diagrams have been created for visualization. Requirements related to each prototype have been assigned to the use-cases and finally the implications for the REACTION platform technology have been described.

6.1 Inpatient Glucose Control

6.1.1 Introduction

In-hospital hyperglycaemia has been found to be an important marker of poor clinical outcome and mortality among diabetic patients. The in-hospital care application domain of the REACTION platform will feature a range of services aiming at Safe Glycaemic Control of diabetic patients using an individual target level depending on the history and actual state of the patient. In order to understand the clinical needs in the inpatient ward, a workshop at the inpatient site in Graz was held. The outcome of this workshop has been documented in D2-1.

In the general ward, a REACTION application must monitor a range of parameters including blood glucose, nutritional intake as well as measures of insulin sensitivity. The data will be contextualised in the Data Management component and mathematical algorithms will be used to calculate the required insulin doses. Results will be delivered to dedicated diabetes experts specialised in glycaemic control (usually located in a specialist diabetes centre) for verification and evaluation. Their on-line appraisal will be fed back to the physicians and nurses at the point of care in the patients ward.For the implementation of the new REACTION application, hospital systems will need to be adapted and hospital protocols across wards for administration and monitoring of blood glucose levels and insulin infusions will be required.

Daily insulin treatment follows the natural workflows of humans based on three daily meals and a prolonged cycle of rest. The three meals are distributed over morning, mid day and evening. During and after meal intake the blood glucose level rises due to carbohydrates. In non-diabetic patients, this is compensated with the release of insulin from the pancreas resulting in a well controlled, steady glucose level. In diabetic patients, or patients with temporary insulin resistance, the flow of insulin is either reduced or non-existing and has to be compensated with manual injection of insulin.

The main outcomes of D2-1 indicated following mid-term improvements through the REACTION inpatient platform for managing in-hospital diabetes patients:

- Automated patient identification to avoid mistakes
- Performing measurements - Active alarm system, reminder to perform measurements
- Decision making – Electronic decision support system - standardised instructions and decisions
- Data handling - Automated transfer of data to patient record and hospital information system
- Documentation - Electronic paperless data records, centrally managed data repositories, different modes of visualisation with relevant parameters for decision support

Figure 4 shows the use-case diagram implementing the most important features for the inpatient insulin dosing prototype. Following main components can be identified:

Administer Glycaemic Management

In a first step the health status of the patient will be determined by the physician. The health status is based on data that will be extracted from existing medical data systems (e.g. the hospital information system, laboratory information system) or entered manually by the nurse. Data manually entered could include, for example, nutrition, glucose injection performed, or pre-existing conditions. If glucose data is needed immediately, glucose values can be entered manually from the POCT device by the nurse. The gathered data will be stored in a centrally managed system and relevant information will be presented to the main users (nurse, physician) via a paperless visualization system. For example the system can

support the nurse by presenting the most important information in the ward summary for all admitted diabetic patients. The nurse will be reminded to measure blood glucose or warnings of hyper- or hyperglycaemia will be signalled by the system. The administration of glycaemic management will be part of the electronic decision support system (eDSS) for inpatient insulin dosing.

Ward Round

The information gathered by glycaemic management will be displayed on a mobile device and, most importantly, the system will suggest the required insulin dose using an electronic decision support algorithm at the ward round, available to the physician. The suggested insulin dose has to be approved or declined (an alternative therapy has to be entered) by the responsible carer. In this way the physician is able to incorporate suggestions for insulin dose and information like glucose level into his or her overall decision-making process. All decisions, whether suggested by the system or the physician, will be stored in the electronic decision support system (eDSS).

Patient Data Handling

In addition to medical data handling for decision making, administrative non-clinical data must also be handled by the overall system. Therefore, interfaces to the hospital information system (incl. laboratory information systems) have to be implemented.

Retrospective Quality Analysis

The tight (glycaemic) control of the diabetic patient on the ward enables retrospective quality analysis for improvement of treatment quality to be performed. Information obtained from decision-making and the glycaemic management can be used to further enhance the algorithm of the electronic decision support system.

6.1.2 Use Case Diagram for Inpatient Glucose Control

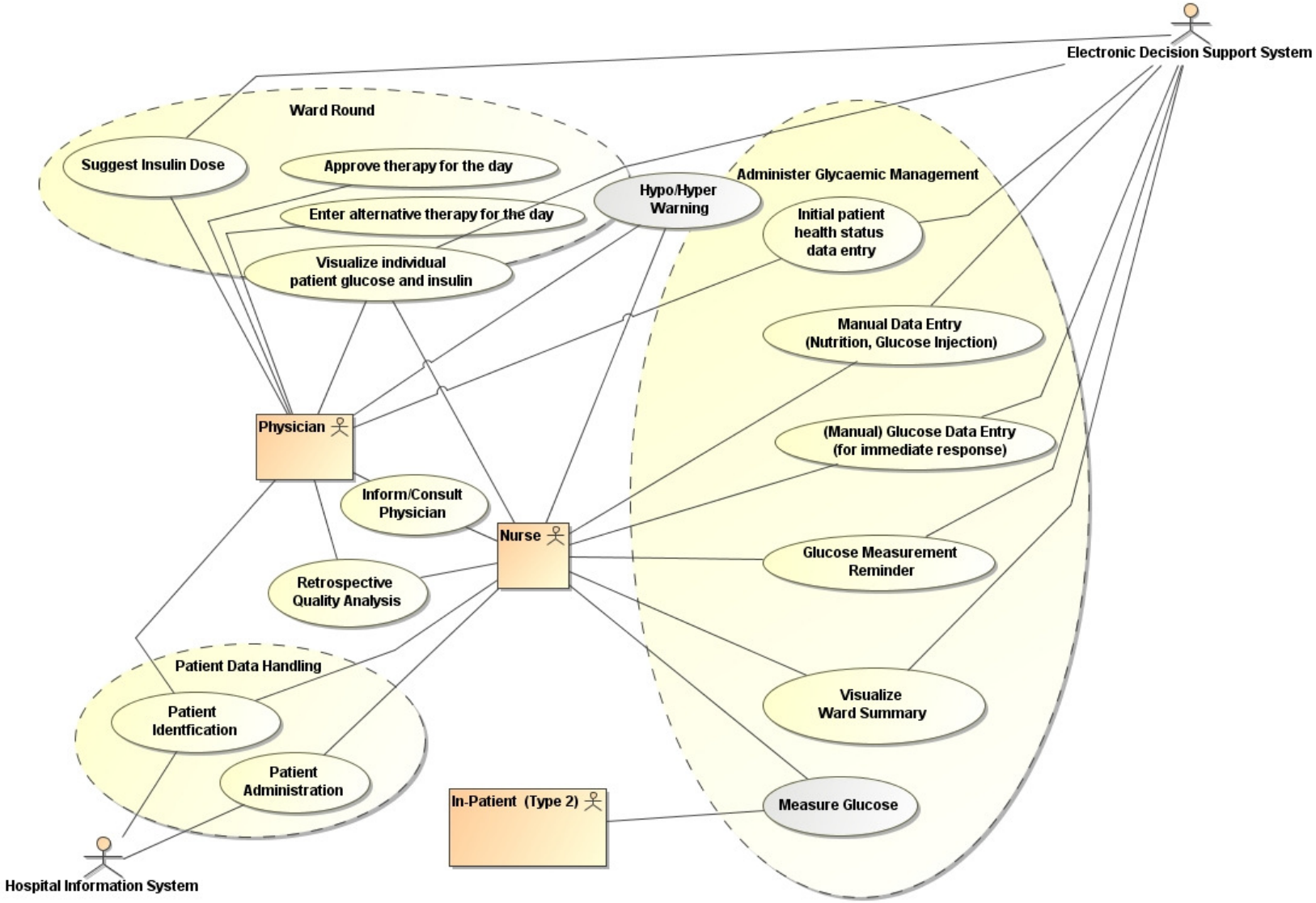

Figure 4: Use-Case Diagram for Inpatient Glucose Control

6.1.3 List of Requirements

Key	Requirement subtype	Summary	Rationale	Fit Criterion	Link to Use-Case
RDMM-3	Data interface	Interface to patient demographic register	In order to import demographic data from the patient demographic register has to be imported from the HIS. A standardized interface e.g. HL7 has to be used for data interchange. Required data fields are: - unique PID - name - age (data of birth) - sex - address	Standardized interface (HL7) to patient demographic register is available for the inpatient pilot application	Patient identification, Patient administration
RDMM-26	Data interface	Interface to Lab Information System (LIS) for glucose data import	In order to perform decision support the blood glucose value has to be imported from the Lab Information System (LIS). A standardized interface from inpatient pilot application to the LIS has to be defined. HL7 would be a suitable standard.	Standardized Interface (e.g. based on HL7) to Lab Information System (LIS) for glucose data import.	Glucose data entry
RDMM-28	Data interface	Interface to Hospital Information System for clinical data import/export	In order to exchange clinical data between inpatient pilot application and Hospital information System (HIS) an interface based on HL7 has to be provided.	Standardized Interface (HL7) to HIS / EPR to exchange clinical data.	Initial patient health status data entry
RDMM-34	Data interface	Interface for user inputs from portable computer in order to store data in inpatient data storage.	For the inpatient prototype user input should be possible. The user data should be stored in the data storage.	User input can be stored in the inpatient prototype storage for further processing.	Manual data entry

RDMM-35	Data interface	(Web) Service to present decision support for glucose control to clinicians	After processing of data by the glucose prediction algorithm, the results should be presented by the system to the physician. The physician can use the result for decision support. The service uses data stored in the data storage and user additional user input as input for processing.	A service will be available to support physician with glucose control of patients.	Suggest Insulin Dose
RDMM-36	Data interface	Interface for transmission of glucose values from POCT system to inpatient prototype	As decision support is a time critical process data from the POCT device should be transferred directly (without detour to LIS) to the inpatient prototype in order to speed up the transmission process. Therefore an interface has to be provided.	Interface to POCT device is available for the inpatient prototype.	Glucose Data Entry
RDMM-122	Data interface	Maximum delay to transfer blood glucose value from POCT to inpatient prototype	Up-to-date glucose values are absolutely necessary for electronic decision support. In order to improve usability for physicians the transfer delay from POCT device to inpatient server application should be max. 3 seconds. Therefore the interface has to be appropriate to fulfil this constraint.	Delay of blood glucose transfer is max. 3 seconds	Glucose Data Entry
RDMM-123	Data interface	Inpatient prototype communication with REACTION platform	The current design of the inpatient prototype and the primary care prototype does not consider the communication between these two prototypes (e.g. SOA). Thus, the data model should consider how the prototypes can be merged in future within the REACTION platform. A data/communication interface has to be defined.	Communication and transfer of data between inpatient and outpatient prototypes are possible.	--

RDMM-39	Data source	Data fields for the inpatient glucose control prototype (eDSS).	Following data fields should be provided: - administrative data (patient name, address, PID, ward, hospital bed, physician(s) in charge, nurse(s) in charge) - demographic data (age, sex, date of birth) - medical history (type of diabetes, medication, co-morbidities, former complications, pre-existing conditions) - anamnesis data (fever, infections, diarrhea, vomiting, hypo- hyperglycemia) - lab data (glucose level, HBA1c, ...) - external input (food intake, insulin sensitivity, ...) - context data (time of glucose measurement, what device, ...)	Required data fields will be provided by data structure.	Administer Glycaemic Management

RDMM-78	Data source	Clinical data to be stored in the Inpatient environment	The data management shall be designed in order to allow the storage of the clinical data to be registered at the patient enrolment as well as other clinical parameters which have to be acquired more frequently. The data to be registered at the patient enrolment are: type of diabetes (insulin requirement), newly diagnosed diabetes, weight/BMI/waist to hip ratio, HbA1c (updated), fever, infection, diarrhoea, vomiting, hypoglycaemia (last 3 days) and hyperglycaemia, limited renal/hepatic function, pancreas operation, co-morbidities, therapy scheme. Other parameters have to be measured more frequently: glucose level, injected insulin, food intake/nutrition, estimation of insulin	The data management shall allow the insertion and the update of all the listed clinical parameters.	Administer Glycaemic Management
RDMM-101	Data source	Drug administration data (OAD and/or insulin)	Drug administration (time, insulin type, administration type -IV or SC-, dosage and other relevant information) has to be immediately registered in the data management by the administering nurse.	Data on drugs administered have to be stored in the data management where they can be also retrieved as part of the fever/sugar chart.	Initial patient health status data entry; Manual data entry

RDMM-102	Data source	Special examinations/treatments to be registered in fever chart	For some examinations/treatments in the hospital the patients have to be in a fasting and/or glycaemic condition. In such cases treatment must therefore be adjusted to the particular needs (e.g. during fasting conditions the insulin dose is decreased). However a problem may arise if the patient has to wait longer than expected due to unforeseen delays. This may result in glycaemic excursions (hyper- or hypoglycaemia). The dose of insulin and/or OADs will therefore need to be adapted, the patient receives some food in the event of hypoglycaemia and receives insulin by injection in the event of hyperglycaemia.	These events (special examination/treatments) have to be registered in the data management where they can be retrieved for the composition of the fever/sugar chart.	Suggest Insulin Dose
RDMM-94	Data source	Measurements of blood glucose and insulin injections in Inpatient environment	In inpatient environment, the blood glucose level measurements are, in most cases, performed by nurses with treatment performed by clinicians and/or nurses.	Measurements of blood glucose and insulin injections are tasks performed by clinicians and/or nurses. They have to store the relevant data in the system or to start the procedure for the storage of the relevant data in the system.	Measure Glucose, (Manual) Glucose Data Entry
RDMM-95	Data source	Basic workflow in Inpatient environment	The basic workflow is based on measurement of blood glucose and evaluation of the necessary insulin (bolus or basal), based also on additional parameters and insulin administration.	There should be the possibility of acquiring, storing and retrieving all the information generated during any basic workflow performed during any time of the day/night.	Administer Glycaemic Control

RDMM-98	Data storage	Clinical evaluation report	Supervision of glycaemia and associated treatment is performed once a day. The clinical evaluation report has to be produced daily. Adaptation of therapy or changes of medications has to be evaluated including by consultation with the duty-physician.	A daily clinical evaluation report has to be stored and available in the Inpatient application.	Retrospective Quality Analysis
RDMM-99	Data storage	Therapy scheme in Inpatient environment	Decision on therapy has to be performed immediately after performing any measurements based also on patient history and associated parameters. It might imply changes in the therapy scheme.	The pharmaceutical and non-pharmaceutical treatment (or therapy scheme) has to be stored in the data management and can be modified during any clinical evaluation of the patient. It has to be initialized immediately after the patient enrolment.	Initial patient health status data entry; Manual Data Entry
RDMM-107	Data storage	Ontologies and data management designed for the storage and multi-user availability of all relevant information, actions, treatments, events	Centrally managed data repositories shall be designed and implemented able to store and display (multi-user) all the relevant information for the diabetic patient management in the Inpatient environment.	Data insertion and/or update and data retrieval for patients shall be possible in multi-user way.	Manual Data Entry

RDMM-103	Data storage	Storage of hyperglycaemic or hypoglycaemic episodes	Reasons for any cases of hypoglycaemia have to be registered (overdosing of insulin, change in nutrition, vomiting, changes in insulin sensitivity and/or resistance, etc.) and adequate treatment has to be provided and registered. Should the blood glucose level rise above a certain threshold, a hyperglycaemic episode has occurred. The reasons for such an episode have to be registered along with ensuing changes in treatment.	Specific procedures have to be present for the management of hyperglycaemic or hypoglycaemic episodes. These procedures shall also allow for the recording of the significant parameters and actions.	Hypo/Hyper Warning; Suggest Insulin Dose;
RDMM-106	Data storage	Fever and infections shall be registered	Fever is very often associated with insulin resistance which means that the patient needs more insulin.	Fever and infections shall be registered in the data management where they can be retrieved for composing the fever/sugar chart. When estimating the insulin resistance, clinicians shall have access to this information.	Visualize individual patient glucose and Insulin; Visualize Ward Summary
RDMM-105	Data storage	Registration of specific interfering drugs (including their dosage)	Some drugs interfere with glycaemia management: systemic interference (e.g. cortisone by increasing blood glucose), analytical interference with glucose monitoring devices (e.g. fructose, maltose- interference). Their administration should be registered.	The data management shall allow for the insertion of specific interfering drugs (including their dosage).	Manual Data Entry
RDMM-42	Data storage	Set of alerts and reminders	A set of possible alerts and reminders. These can be thought as "prototypes". Action rules can define when and how they must be sent with which parameters.	Alerts and reminders can be defined and stored.	Glucose Measurement Reminder; Hypo/Hyper Warning

RDMM-104	Data storage	Nutrition information has to be stored in the data management	Composition (proteins, fat and carbohydrates) of the meal has to be recorded and used for the insulin evaluation (the use of glycaemic index and load tables for various types of food might be taken into account). Also other parameters have to be taken into account (snacks in between, fasting, special diet, diarrhoea, vomiting, diminished/absence of appetite). Also special conditions related to nutrition have to be considered (PEG tube / parenteral feeding, fast adsorption of IV administered fluids).	The data management shall allow the insertion of time and composition of nutrition accompanied also by additional (context) parameters. The dosage of insulin shall vary with the variation of the nutrition.	Manual Data Entry
RDMM-32	Data structure	Dynamic data structure for inpatient data storage	For the impatient pilot application (eDSS) a dynamic data structure for data storage has to be implemented. Data fields should be flexibly defined. A suitable model can be the Entity-attribute-value (EAV) model.	Dynamic data structure for data storage will be available for inpatient pilot application.	Administer Glycaemic Management
RDMM-51	Data semantics	Mechanistic model and rules for insulin dose prediction (primary care)	A physiologic model and calculation rules/algorithm must be stored for insulin dosing support.	Necessary models and rules are defined and stored.	Suggest Insulin Dose

RDMM-96	Data semantics	Electronic fever/sugar chart	Currently medical history, general health status, actual status, nutrition and associated conditions, planned examinations & treatments, interaction with other medication, blood glucose measurements, dose type and timing of insulin or OAD are stored in a paper-based fever/sugar chart. The same information should be available in an electronic fever/sugar chart which can be accessed and shared by several users at the same time.	In the design of the data management the electronic fever/sugar chart (or the possibility to compose it from the stored data) has to be present. Its access must be multi-user. The fever/sugar chart has to be initialized at the patient enrolment and updated at any data acquisition.	Initial patient health status data entry; Visualize individual patient glucose and insulin
RDMM-43	Data semantics	Models and rules for insulin dose prediction (inpatient)	A physiologic model and calculation rules/algorithm must be stored for insulin dosing support based on clinical protocols.	Necessary models and rules are defined and stored.	Suggest Insulin Dose
RDMM-124	Data semantics	Visualization of current "insulin on board" and "carbohydrates on board"	As part of electronic decision support the current "insulin on board" and "carbohydrates on board" should be presented to the physicians and nurses. Methods/Functions: - trend information - active profile of insulin on board (using physiological models)	Inpatient prototype provides visualization of current "insulin on board" and "carbohydrates on board" for decision support.	Visualize individual patient glucose and insulin

RDMM-64	Data semantic	Context management for clinical (lab) values.	Contextualization of measured values (e.g. blood glucose values) is important in order to support REACTION applications like decision support. For example pre- or post-meal glucose values have very different meanings for treatment. Therefore the data management model has to provide context management.	The data management model support context management functionality for the inpatient prototype application.	Administer Glycaemic Management

6.1.4 Implications for REACTION Platform Technology

The following implications for the REACTION data management model/architecture can be derived from the gathered data model requirements:

Data Interface

The inpatient prototype requires various interfaces to internal and external systems. In order to enable the system to identify and manage patients on the ward, an interface to the patient demographic register of the hospital information system will be necessary. The Interface will be based on HL7. Moreover, lab data, especially glucose values, need to be transferred into the prototype system. An interface to the Lab Information System (LIS) is required for this task. If possible HL7 will be the preferred communication standard. If glucose values cannot be transferred from the Point-if-Care Testing (POCT) device via LIS to the prototype in time, an interface for the direct transmission of glucose values from POCT system to inpatient prototype has be provided.

Clinical data will be imported using an interface to the Hospital Information System. Again HL7 should be the preferred standard. Various values will be entered via the user-interface of the mobile device hosting the eDSS. Therefore an interface for user inputs has to be provided. Moreover, (Web) Service to present decision support for glucose control to clinicians has to be implemented.

In the first development phase, the inpatient prototype will be embedded into the technical environment of the hospital information system. In order to enable communication between inpatient prototypes, REACTION platform services and interfaces have to be provided.

Data Source

Different data will be required in order to perform decision support for insulin dosing in the general ward. Besides administrative data such as sex, age, or assigned hospital bed, clinical information such as type of diabetes, co-morbidities, drugs and symptoms such as fever, infection, diarrhea, vomiting or hypo-hyperglycemia are required. Moreover, laboratory data like HbA1c, glucose values, nutrition and also context data (e.g. time of glucose measurement, device type) will be needed. A detailed enumeration of required data can be found in the elicited requirements.

Data Storage

Data has to be stored within the inpatient environment in an adequate manner. Thus, the inpatient prototype should allow usual database operations like insertion, update or retrieval of data.

Data Structure

In order to hold the data for the impatient pilot application, a dynamic data structure for data storage has to be implemented. Data fields should be flexibly defined. A suitable model could be the Entity-attribute-value (EAV) model (Dinu2007).

Data Semantics

The complex management of data, information and knowledge is an important feature of the inpatient prototype. The data management model has to consider data semantics in order to gain information and knowledge from source data for following applications:

- Mechanistic model and rules for insulin dose prediction
- Adaptable electronic fever/sugar chart that meet requirements of physicians
- Visualization of current "insulin on board" and "carbohydrates on board"
- Context management for clinical (lab) values

Data Security

In the first development phase, the inpatient prototype will be fully embedded into the technical environment of the University Hospital of Graz. The hospital information system implements various mechanisms to ensure security and privacy of personal patient data. If the inpatient prototype is coupled with the REACTION platform, security mechanisms as summarised in Section 5.6.2 will be performed.

6.2 Primary Care Diabetes Management

6.2.1 Introduction

There are several measures and interventions known to improve the quality of diabetes care in general practice and specialised units outside the hospital. Many of them have previously been sufficiently evaluated and found beneficial – most of them have a higher impact on metabolic control than pharmaceutical agents in non-inferiority trials. There is therefore a solid basis of evidence for their recommendation, further implementation in the healthcare system and further research.

These measures and interventions are not purely medical but can also cover many organisational aspects which interact with the way healthcare generally is organised in a region. The following measures and interventions, which can often be facilitated or supported by information technology, have been taken into account[5].

Patient education

Patient education and self management are well established elements in the therapy of chronic diseases, as recommended by evidence-based guidelines. Self management education is not only about knowledge transfer, but more about developing and training problem-solving skills, so that the patient can participate and play an active role in the management of the chronic disease.

Telemonitoring - Self management support

Provision of equipment and resources for example for measuring blood glucose at home, electronically transmitting measurements and receiving feedback on insulin dose changes or other adaptations are considered to be measures to promote self-management.

Professional decision support / reminders

Several ways to support healthcare professionals by decision support can be identified. They mainly have the aim of supporting physicians in following clinical guidelines and clinical pathways.

- Repeat important procedures on a regular basis (for example check for risk factors such as eye and foot examination at least once in a year)
- Estimate risk for developing diabetes complications and take appropriate preventive action
- Visualization and intelligent annotation of blood glucose profile as a basis for decision-making
- Workflow (referrals – cooperation with other disciplines, treatment intervals)
- Prescription of medication or start of other medical interventions such as education
- Patient recall (actively contact patients to perform an action such as an examination or education)

Reminders can either be presented as computerised prompts, generated at the point of care for the professional. Alternatively another form of reminders is to analyse the data in the disease register/patient record to generate lists of patients for which a specific action should be taken (invite to practice = recall, send information leaflet etc.). Computerised prompts have the potential to cover several aspects at once and are therefore of special interest for quality improvement.

Patient decision support / reminders

These are all efforts to remind patients about upcoming appointments or important aspects of self-care. The content of these reminders is usually computer generated. Communication can either be performed via traditional channels like postcards or telephone calls or electronically.

Structured, electronic documentation

Electronic records or disease registers are commonly used and form the basis for structured documentation which can be taken a step further for use in measures like decision support and quality reporting.

[5] A closer examination of the scientific evidence will be taken in D6.1 “Assessment of existing disease management strategies including available risk assessment tools and their parameters”.

However, interoperability between systems, especially between different sectors and layers of the healthcare system, is still not sufficiently developed and requires some practical solutions.

Quality Reporting - Audit and Feedback

Feedback about quality of care is a summary of clinical performance of health care which was delivered by an individual clinician or a surgery/clinic over a specified period. Examples of feedback presented to the clinicians include the percentage of a clinician's patients who have achieved a target HbA1c level, or who have undergone a foot examination with a specified frequency etc.

Interdisciplinary care teams

In several studies, especially in the fields of diabetes and hypertension, changes to the structure or organization of the primary health care team have proven to be the most effective. This team change can take the form of either the revision of professional roles (e.g. nurse or pharmacist plays a more active role in patient monitoring or adjusting medication regimens), the use of multidisciplinary teams (e.g. cooperation of medicine, nursing, pharmacy, nutrition in the primary, ongoing management of patients) or adding a team member via "shared care" (e.g. routine visits with personnel other than the primary physician).

Of course these changes mainly require a paradigm shift and cannot be directly introduced via technology. But for the requirements analysis, we have to be aware of the fact that the developed technology has to support various ways of cooperation between healthcare professionals in different roles and different levels of institutional integration.

Interactive health communication applications

Interactive health communication applications are computer-based, usually web-based, applications for patients that combine health information with at least one type of support (social, decision or behaviour change support).

These applications have the potential to improve knowledge by providing information to patients. Furthermore these applications provide support to patients in several ways (social support, behaviour change support, decision support). The supportive inputs together with the provided information and patient's knowledge can combine to lead to improved motivation and self-efficacy (patient's belief in the own ability to carry out a specific action) and affective changes (e.g. reduced anxiety). These changes lead to a behaviour change which can result in improved clinical outcomes and quality of life.

6.2.2 Use-Case Diagram for Primary Care Diabetes Management

Diabetes mellitus is a chronic disease which starts slowly and progresses continuously. For this reason diabetes is diagnosed and treated mainly by primary care. In several healthcare systems in Europe, specialised units for diabetes care exist although their form and integration in health care varies (either hospital clinics mainly caring for complications as is the case in the U.K. or specialist practices outside the hospital that also take part in routine diabetes care as in Germany).

REACTION aims at building a platform to support routine care for diabetes patients.

Several aspects have been identified, which the REACTION platform aims to support:

- Continuous professional care: this comprises measures and actions to support disease management and patient care in the physician surgery.
- Self-management: this comprises measures and actions to support the patient in taking an active role in the management of the disease, supported by devices and an infrastructure to communicate measured values and receive support.
- Practice Organisation: Steps to improve quality of care to be taken at the level of the organisation (e.g. clinic, surgery).
- Administration: Required administrative steps

The Use-Cases envisioned for the REACTION project are given in Figure 5.

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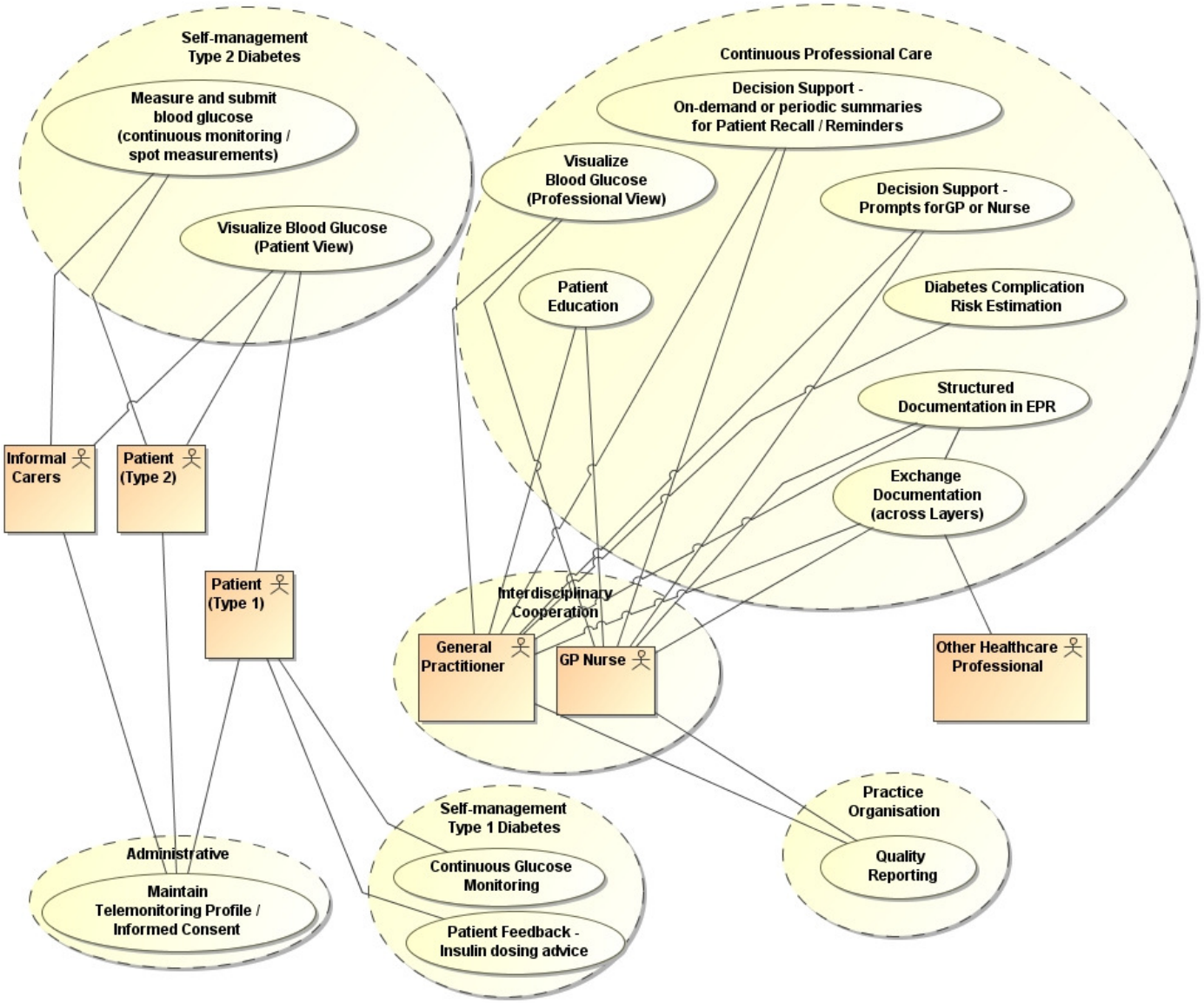

Figure 5: Use-Case Diagram for Primary Care Diabetes Management

6.2.3 List of Requirements

Key	Requirement subtype	Summary	Rationale	Fit Criterion	Link to Use-Case
RDMM-80	Data source	Patient education	Continuous education of the patient adjusted to his/her needs.	Educational material is available.	Patient Self-management support
RDMM-92	Data source	Insertion of baseline physiological measurements at the first visit	At the first visit baseline physiological measurements (The exact set has to be clearly defined) have to be inserted in the platform.	The data management shall foresee the possibility of introducing the baseline physiological measurements at the first visit (just after the patient enrolment).	Structured documentation
RDMM-58	Data storage	Different stages for the patient management in outpatient environment	Different actions have to be performed in different stages (newly diagnosed / medication titration / investigative stage, ongoing management) for the patient management in outpatient environment.	The data management has to allow the storage of the stage of management for each patient.	
RDMM-60	Data storage	Investigative stage	An investigative stage has to be used in all newly diagnosed diabetic patients. This stage (which duration has to be set-up by clinicians) has to be used for: confirm diagnosis, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, reassure patients concerned about their blood sugar levels.	Specific fields have to be present in ontologies and data management.	Continuous Professional care

RDMM-61	Data storage	Ongoing management	After the investigative stage there has to be the ongoing management. This stage has to be used for: support patients with difficulties in managing their diabetes, check effectiveness of lifestyle and medications, evaluate the optimal dosage of medications, perform patient education on diabetes, support changes in patient lifestyle, identify better diabetes management for patients.	Specific fields have to be present in ontologies and data management	Continuous professional care / Structured Documentation / Decision support
RDMM-69	Data storage	Reasons for end of process in outpatient environment	There is no end of process in primary care; the patient will only leave primary care if he dies or leaves the practice due to moving away from the practice catchment area or voluntarily stops to be monitored by the REACTION platform.	Patient discharge from the outpatient environment shall have the following options: a) death; b) patient removal outside from the practice catchment area; c) patient voluntarily stops to be monitored by the REACTION platform.	Structured documentation
RDMM-71	Data storage	Care space in outpatient environment	Patients and informal carers have to be included in the process of care. Care spaces (for each patient) have to be developed where the roles and tasks are distributed among the multidisciplinary health care team members.	The data management shall allow the storage of the care space for each patient with specific roles for each member of the care space.	Structured documentation / Maintain (telemonitoring) profile

RDMM-93	Data storage	Clinical case conference	Any possible critical situation has to be accurately verified by the care clinical team with the support of virtual visits through e.g. the use of video-conference. The completion of the accurate check shall be accompanied by changes in the patient treatment (if necessary) and also changes in the RPM schema have to be allowed. A clinical case conference report has to be stored.	Storage and retrieval of clinical case conference reports has to be possible.	
RDMM-57	Data structure	6-month clinical checks	Every 6 months the following tests have to be performed: blood tests as in the annual clinical checks (except for the thyroid function tests), BMI, blood pressure measurements, check smoking status, review of medications (including diet and lifestyle measures).	Specific fields (entries) have to be foreseen in ontologies and data management.	Continuous professional Care / Structured documentation / quality management
RDMM-56	Data structure	Annual clinical checks	The annual clinical checks for the outpatient environment includes (with the necessary attributes): foot check, retinal screening (photograph of patient's retinae), test for protein, height and weight, BMI, blood pressure measurement, check smoking status, blood test (glucose level, HbA1c, etc.), check/administer flu injections, depression screening, review of medication (including diet and lifestyle measures).	Specific fields have to be present in ontologies and data management.	Continuous professional Care / Structured documentation / complication and risk estimation / quality management

RDMM-67	Data structure	Management of complications	Apart from the diabetic management, the other managements for diabetic patients will be around the complications (cardiovascular, renal, ophthalmology, management of foot and neuropathy problems).	Data management should include the necessary structures for assuring the storage of all necessary information for the management of complications.	Structured Documentation / Continuous professional care / Exchange documentation (across layers) / Decision support
RDMM-42	Data structure	Set of alerts and reminders	A set of possible alerts and reminders. These can be thought as "prototypes". Action rules can define when and how they must be sent with which parameters.	Alerts and reminders can be defined and stored.	Decision Support Prompts for GP or nurse
RDMM-68	Data structure	Outcomes of regular visits at primary health care centres	Outcomes of regular visits at the primary health care center shall be registered through the data management.	The outcomes of each visit have to be stored as much as possible in a structured way.	Structured documentation
RDMM-131	Data structure	Consider patient's preferences, wishes and decisions	The data set should allow documentation of patient's preferences, wishes and decisions. This information should also be considered in the evaluation of rules etc., so that no recommendations against the will of the patient are made.	Patient's preferences, wishes and decisions can be documented and rules consider this data.	Structured Documentation / Decision Support

RDMM-45 RDMM-46	Data structure and data semantics	Health Status Model / Personal Health Status Profiles	The health status model serves as a generic prototype for Personal Health Status Profiles, i.e. defines its data content. This helps to define personal models (profiles), which permit the personalised disease management. Personal Health Status Profile for each patient must be generated, stored and regularly updated. It serves as an input for risk assessment and disease management.	Personal Health Status Profiles can be generated.	Structured documentation / Decision support / Risk estimation
RDMM-38	Data semantics	Monitoring scheme	Individual monitoring scheme for each patient must be defined and stored. This describes what parameters and how often should be measured.	An individual monitoring scheme can be defined for each patient.	Maintain telemonitoring profile / Self-management Type 1 and 2
RDMM-43	Data semantics	Models and rules for insulin dose prediction (inpatient)	A physiologic model and calculation rules/algorithm must be stored for insulin dosing support based on clinical protocols.	Necessary models and rules are defined and stored.	
RDMM-44	Data semantics	Risk assessment models and rules	Models and rules must be defined to determine personal risks.	Models and rules for risk assessment are present.	Diabetes complication Risk estimation
RDMM-51	Data semantics	Mechanistic model and rules for insulin dose prediction (primary care)	A physiologic model and calculation rules/algorithm must be stored for insulin dosing support.	Necessary models and rules are defined and stored.	Insulin dosing advice
RDMM-132	Data semantics	Management of referrals to and responses from other physicians (via EHR interface)	Referrals are part of clinical pathways and treatment plan. Referrals should be documented and the recommendation of referrals should be considered in decision support rules...	Referrals can be documented and are considered in decision support, summary letters can be received via an appropriate data interface.	Structured documentation / Exchange documents across layers / Decision Support

			Summary letters and other "responses" from other healthcare professionals should be managed. - Optimal solution would be an interface to a regional or national EHR infrastructure (e.g. IHE-XDS) from where documents can be received.		
RDMM-133	Data semantics	Telemonitoring data should be visualized to patients and professionals in a flexible and performant way	GPs and nurses as well as patients and their carers use the telemonitoring data to get an impression of the patient status. So telemonitoring data needs to be visualized in a flexible way (aggregation level, combination of parameters ...) Data has to be handled in a way that this visualization can be generated on-demand with good performance.	Data can be visualized flexibly and with good performance to professionals	Visualize Blood Glucose (Professional View / Patient View)
RDMM-49	Other	Personalized care plan	A personalized care plan must be defined (and updated if necessary) for each patient. It includes disease management, risk management and lifestyle plan. Personalization methods must be defined.	Care plan can be personalized.	Structured documentation / Risk management / Telemonitoring Profile
RDMM-81	Other	Self-management and lifestyle support	Support of the patients' self-management by lifestyle (diet, exercise etc.) advices, therapy advices, health status assessment.	Self-management is supported.	Self-management Type 2 diabetes / Patient feedback Type 1 diabetes
RDMM-129	Other	Scalable / easy to use solution for REACTION software in GP surgery	The REACTION software which is executed in the GP surgery has to be usable for practices in different setting with different EPR systems. It should provide a user interface for disease management as well as	REACTION software is easy to run beside an EHR application or EHR manufacturer is satisfied with ease of integration of REACTION	Continuous professional care

			Web Services which can be implemented by EPR manufacturers to easily integrate REACTION features into their products.		
RDMM-130	Other	A REACTION application needs to be executed in the patient surgery independent from the EPR	As it is not possible to influence / modify many EPR systems, REACTION features inside the GP surgery have to be provided by a dedicated and independent application. This application communicates with - the REACTION platform over the Internet. - other systems in the surgery (EPR, lab, etc.) This application can be server-based and always on, for a prototype also an application client could be used.	An easy to run possibility to run and access REACTION features inside the GP surgery is available.	Continuous professional care

6.2.4 Implications for REACTION Platform Technology

Summary

The following list summarizes the requirements for the reaction platform which are related to technical solutions:

- Structured documentation of all data assessed by nurses and physicians
  (RDMM-68, RDMM-56, RDMM-57, RDMM-92)
  - Management of clinical data collected during different types of patient encounters (visits, phone calls or other virtual visits):
    (data set should be specified according to clinical guidelines and European standardisation attempts[6])
    - Diagnoses, co-morbidities, complications
    - Current status: Objective and subjective
    - Current measurements: Blood pressure, Cholesterol, Creatinine, etc.
    - Eye exam, foot exam
    - Therapy (Insulin Therapy, other glucose lowering therapy, other medication)
    - Self management support / lifestyle modification: Structured diabetes education, dietary advice etc.
    - Management of complications
      (RDMM-67)
  - Reason for ending monitoring within REACTION
    (RDMM-69)
  - Data model for health status information (populated during patient visits and by analysis of remote monitoring data) (“Personal Health Status Model”)
    (RDMM-45)
  - Personalised care plan
  - Consider patient’s preferences, wishes and decisions
    (RDMM-131)
  - Management of referrals to and responses from other physicians (summary letters, if possible in a structured way) – via EHR interface
    (RDMM-132)
- Management of telemonitoring data
  (RDMM-133)
    - Visualisation of telemonitoring data for professionals
    - Visualisation of telemonitoring data for patients
- Allow configuration of workflows and documentation
  (e.g. which data fields should be documented how often / at which stage in the care process)
  (RDMM-56, RDMM-57, RDMM-92, RDMM-61, RDMM-58)
- Definition of “workflows” for patients which interact with physician workflows
  (e.g. different monitoring schemes for different patients)
  (RDMM-38)
- Definition of alerts and reminders for healthcare professionals (physician, nurse)
  (RDMM-42)
- Decision support for the insulin dose
  (RDMM-60, RDMM-51)

[6] www.eubirod.eu – EUBIROD – European Best Information Through Regional Outcomes in Diabetes

- Individually distribute roles and tasks among the multidisciplinary health care team (RDMM-93)
- Store and retrieve reports of clinical case conferences (RDMM-93)
- Models and rules for long term risk assessment (RDMM-44)

Excursion[7]: Level of integration and candidate user interfaces in primary care

There are several possible scenarios for making REACTION functions available to healthcare professionals.

- *Integration in EPR*: The integration of REACTION functionality into the EPR software would help to achieve acceptance of the system by the professionals because of the low entry barrier. However, as there is a multitude of EPR systems available, integration is not a very scalable solution. (RDMM-129)
- *Client access to central server*: This scenario executes no REACTION software in the GP surgery. The REACTION functionality is provided by a central server which is accessed by a remote client (e.g. Web interface). Access is easy to establish for any number of participants, but no access to any local resources such as EPR, laboratory and other devices is possible. (RDMM-3, RDMM-23, RDMM-26)

The following **solution** is a trade-off which can overcome the disadvantages of both above scenarios: (RDMM-130)

- REACTION application is executed in the surgery and independent from the EPR (recommendation server-based for multi-user environments)
- Communication with other components of the REACTION platform, mainly the central server, take place via Web Services
- Communication with EPR and other data sources inside the local network (via HL7 etc.)
- If an EPR manufacturer is interested in integration of REACTION features, this can be done via Web Service calls to the local REACTION application any time. (RDMM-129)

Candidate user interfaces are therefore both a web browser UI and an application client UI. Application clients used to be more user-friendly as they allowed development for higher interactivity- This has recently changed and various web toolkits allow almost the same level of interactivity in the browser. Therefore a decision has not yet been taken.

A user interface for a mobile device from the current point of view is an add-on which only makes sense after an interface on a stationary computer has been implemented.

Excursion: Candidate user interfaces for patients

Patients should be provided with a user interface that requires no installation (Web UI) or is very easy to install (mobile device App). Some reaction features are more suitable for a stationary PC, others of course are more useful or even exclusively useful if they are provided on a portable device. For this reason both interfaces will have to be provided for patients.

[7] Subsections marked with *Excursion* show an approach how the outpatient prototype application can be integrated into the REACTION overall architecture. They are partly out of scope of D4-3, but due to the dynamic process of finding a first architectural solution for REACTION initiated in D4.3, we decided to already present it in this deliverable.

7. Conclusions

This chapter summarizes the results of this deliverable. According to the overall structure of the report the conclusion is divided into the REACTION Platform and the Application Prototypes. For every aspect of the data management model the main impacts are figured out.

7.1 REACTION Platform

Data Interface

- REACTION will implement a distributed system. From this it follows that the system architecture needs different interfaces for external and internal interfaces in order to exchange data.
- Several data interfaces will comply with various standards, primarily those intended for eHealth interoperability ((e.g. HL7, IHE-PCD01) and communication with medical devices (e.g. IEEE 11073).
- Following data interfaces have to be considered:
    - External, i.e.,
        - Interfaces to other health-care sub systems, including EPRs, demographic databases, or hospital information systems incl. laboratory information systems
        - Interfaces to global services, like MS HealthVault and GoogleHealth
    - Internal (inter component messaging and service invocation)
    - Medical devices
    - Persistent storage media
    - Data entry/capture (for patients and carers)

Data Source (with focus on PAN/BAN)

In the REACTION platform patient data is collected from three different sources:

- Measurements from medical devices (e.g. glucose values, vital parameters)
- Manually entered data by the patient or a member of the medical team (e.g. insulin injections, patient questionnaires concerning physio- psychological conditions, medication, self management, lifestyle data, or measurements which are not automatically transferred)
- Data imported from external source (e.g. EPR/HIS, laboratory information system)

The BAN and PAN devices are responsible for collecting medical measurements of a patient, along with context information and environment factors. In order to use PAN/BAN for the REACTION data management following aspects have to be considered:

- Providing environment sensors or other ambient and background information for collecting of glucose, vital and context-related data.
- Contextualization of measured values, such as blood glucose values
- Collecting medical data which is not collected automatically and have to be inserted manually or inferred by other pieces of information like external knowledge base systems.
- Ensure interoperability, data consistency, privacy, low complexity, especially in the PAN/BAN network, and to decrease power consumed by the sensors
- Secure and accurate data transmission from the devices and sensors
- Faultless data transfer across the standards
- Endorsing plug and play device interaction
- Scalability for further changes to facilitate well functioning

- A middleware should be implemented in a way to ensure seamless integration

Data Storage

Data storage is necessary in all distributed parts of the REACTION data management architecture (see Figure 2):

- Patient devices and REACTION AHD/Hosting Client
  measured values might not be possible to transfer to the server due to lack of connectivity and therefore data needs to be temporarily cached;
- REACTION DEVICE Hosting Server
  storage of measurements as a series of observations, each aggregating a measured value with its possible context data; storage of individual treatment plan of patients
- Data Mining / Risk Stratification
  storage of large sets of historical data for all patients under treatment (e.g. from EPRs or other external data sources) in order to analysis and create new knowledge about diabetes treatments

In order to store and retrieve data securely following data management functions have to be considered:

- Dynamic data structure (see below) in order to provide flexibly data fields for changing needs of data storage
- Provide mechanism for consistent and regular insertion, update and deletion of data
- Emphasis on data security and data access (see section 5.6)

Data Structure

- REACTION platform should be flexibly and support many types of disease management applications, i.e. support model driven architecture with functions based on formal models and rules, applications are generated from models
- REACTION platform needs flexibly data structures in order to consider the model driven architecture
- REACTION will be based on a service oriented architecture and will be deployed in a distributed manner, i.e. data structures have to be exchanged between components
- XML format and vocabulary will be used for expressing the data structures

Following data should be considered in the data structure:

- Data for mechanistic model and inpatient glucose control
  (e.g. administrative data, demographic data, medical history, laboratory data, external input)
- Data for personal health status profile
- Data fields for storage of case base
- Data for Primary Care disease management
  (e.g. outcome of clinical checks, medication, complications)

Data Semantics (including data presentation)

In order to support the semantic management of data and as a basis for knowledge management, REACTION will exploit semantic technologies. Following main aspects have to be considered in the data management model:

- Definition of a common ontology to refer to data, metadata, interfaces and models
- Necessary models (e.g. for risk assessment), action and event rules are defined and stored
- Relevant entries in the REACTION's databases are annotated with semantic concepts
- A health status model is present; the care plan can be personalized
- An individual monitoring scheme can be defined for each patient

- REACTION provides a knowledge discovery module to process unstructured information and store this information in the data storage for further processing
- Data can be visualized flexibly (context based) and with good performance to professionals
- A medical knowledge base will be built. It may contain the following elements:
    - treatment algorithms and protocols
    - guidelines represented in a computable way
    - physiologic models (e.g. to calculate insulin dose)
    - lifestyle models including the possible physiologic consequences
    - risk models (take genetics, physiology, lifestyle, social environment into account)
    - other schemes and algorithms (e.g. blood glucose patterns, if-then rules)

A detailed work on data semantics will be provided in the deliverable D4-2 Initial data structures, taxonomies and ontologies.

Data Security

The REACTION platform is organised in a decentralised manner, such that personal, medical information is transmitted and shared by several parties. Therefore, it is necessary that such data is transmitted, managed, and processed in a secure, trusted, and privacy-preserving way. The following requirements can be identified for the REACTION data management model:

- Confidentiality has to be guaranteed in order to allow medical devices to upload measurements (e.g. from patients' to their doctor's PC without anyone else being able to learn about these measurements.
- Authenticity of senders and recipients of medical data must be ensured
- Data integrity must be verifiable and the verification must be carried out before the data is added to the EHR
- Access to personal data will be given to authorised entities only
- Patient's consent must be sought before any data processing can take place

7.2 Application Prototypes

Inpatient Glucose Control

Data Interface
The inpatient prototype requires various interfaces to internal and external systems:

- Interface (e.g. HL7) to the patient demographic register of the hospital information system in order to enable the system to identify and manage patients on the ward
- Interface to lab data, especially glucose values, preferably based on HL7
- Interface to POCT device if glucose values cannot be transferred from the LIS to the prototype in time
- Interface to the Hospital Information System in order to import clinical data like medical history based on HL7
- Interface for user inputs to allow manual user entries

Data Source
Different data will be required in order to perform decision support for insulin dosing in the general ward:

- Administrative data such as sex, age, or assigned hospital bed
- Clinical information such as type of diabetes, co-morbidities, drugs and symptoms such as fever, infection, diarrhea, vomiting, or hypo- hyperglycemia
- Laboratory data like HbA1c, glucose values, nutrition and also context data (e.g. time of glucose measurement, device type)

Data Storage
Data has to be stored within the inpatient environment in an adequate manner. Thus, the inpatient prototype should allow usual database operations like insertion, update or retrieval of data.

Data Structure
In order to hold the data for the impatient pilot application, a dynamic data structure for data storage has to be implemented. Data fields should be flexibly defined. A suitable model could be the Entity-attribute-value (EAV) model.

Data Semantics
The complex management of data, information and knowledge is an important feature of the inpatient prototype. The data management model has to consider data semantics in order to gain information and knowledge from source data for following applications:

- Mechanistic model and rules for insulin dose prediction
- Adaptable electronic fever/sugar chart that meet requirements of physicians
- Visualization of current "insulin on board" and "carbohydrates on board"
- Context management for clinical (lab) values

Data Security
In the first development phase, the inpatient prototype will be fully embedded into the technical environment of the University Hospital of Graz. The hospital information system implements various mechanisms to ensure security and privacy of personal patient data. If the inpatient prototype is coupled with the REACTION platform, security mechanisms as summarised in Section 5.6.2 will be performed.

Primary Care Diabetes Management

The following list summarizes the requirements for the reaction platform which are related to technical solutions:

- Structured documentation of all data assessed by nurses and physicians
  - Management of clinical data collected during different types of patient encounters (visits, phone calls or other virtual visits)
  - Reason for ending monitoring within REACTION
  - Data model for health status information (populated during patient visits and by analysis of remote monitoring data) (“Personal Health Status Model”)
  - Personalised care plan
  - Consider patient’s preferences, wishes and decisions
  - Management of referrals to and responses from other physicians (summary letters, if possible in a structured way) – via EHR interface
- Management of telemonitoring data
  - Visualisation of telemonitoring data for professionals
  - Visualisation of telemonitoring data for patients
- Allow configuration of workflows and documentation (e.g. which data fields should be documented how often / at which stage in the care process)

- Definition of “workflows” for patients which interact with physician workflows (e.g. different monitoring schemes for different patients)
- Definition of alerts and reminders for healthcare professionals (physician, nurse)
- Decision support for the insulin dose
- Individually distribute roles and tasks among the multidisciplinary health care team
- Store and retrieve reports of clinical case conferences
- Models and rules for long term risk assessment

8. Table of Figures and Tables

8.1 Figures

8.2 Tables

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10. Appendix I

10.1 Draft Architecture of REACTION Primary Care Diabetes Management Platform

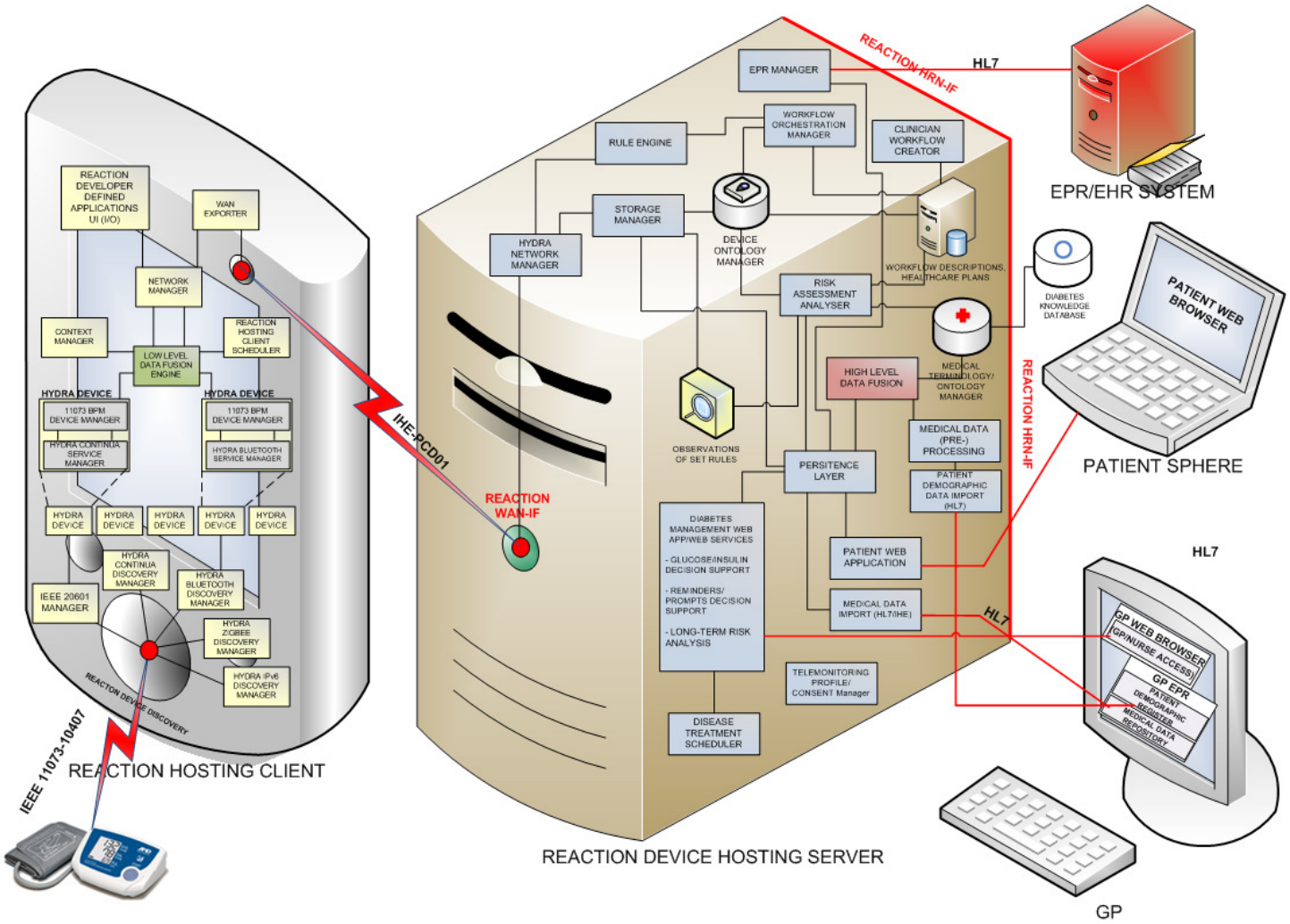

Figure 6: Draft architecture for REACTION (primary care) platform

10.2 Questions related to Requirement Elicitation Process

Mobile Devices (BAN/PAN)

- Which sensors (data) will be available for REACTION PAN/BAN?
- Which interfaces/standards do we need to communicate with PAN/BAN devices?
- Which additional PAN/BAN-related information do we need for context management?
- How can we secure/measure reliability of communication? Do we need data-buffer?
- Which security-mechanism we need for data/communication?
- Which feedback is generated on PAN, BAN or REACTION platform?

Middleware, internal communication (Hydra)

- How can devices be identified?
- Is user interaction required as part of the middleware (e.g. patient consent for transmission?)
- Does the middleware provide an API for applications on the mobile device?
- What do we need for a context management system?

Core server infrastructure

- Which data is stored in the core server?
- Which data (structures), thesaurus, ontology will be required?
- What data (structures) do we need for Information Extraction from existing medical data?
- How are activities triggered (e.g. data update, perform alarms, trigger events)?
- How is data synchronised?

External communication

- What external resources we take into account?
- What data do we need from external resources?
- Which standards/interfaces do we need for external communication?
- What data structure do we need for data transfer?
- How can we secure time-critical data transfer from external resources?

Security

- How data privacy can be ensured?
- How can REACTION securely transfer data?
- What access-roles do we need?

In-patient glucose control

- How does the inpatient glucose control prototype communicate with the REACTION platform? What interfaces/standards do we need?
- What data will be transferred to the REACTION platform?
- What services does the REACTION platform provide for inpatient glucose control (e.g. electronic decision support)?
- What data from inpatient prototype will be stored in the REACTION platform?
- How can we manage that physicians can work location-independently?
- How can we implement multi-user support?

Primary care diabetes management

- How can the REACTION platform perform Data Monitoring?
- Which interfaces do we need to GP-Systems?
- Alarm-Handling? Support Reminders? What data structures do we need?
- How can REACTION support glucose management for Type 1 diabetes?

11. Appendix II: Complete set of Technical Requirements for a Medical Data Management Model

The complete set of Technical Requirements for a Medical Data Management Model is listed in document "D4-3 Appendix II: Complete Set of Technical Requirements_V10.pdf".