Ontwerp en optimalisatie van medische-informatiediensten voor de ondersteuning van beslissingen

Design and Optimization of Medical Information Services for Decision Support

Kristof Steurbaut

Promotoren: prof. dr. ir. F. De Turck, prof. dr. J. Decruyenaere
Proefschrift ingediend tot het behalen van de graad van
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Eindelijk is het er dan, mijn doctoraatsboek over het ontwerp en de optimalisatie van medische-informatiediensten voor de ondersteuning van beslissingen. Dank dat je vandaag dit boek ter hand neemt, uit interesse in het gevoerde onderzoek, uit sympathie, uit steun of gewoon uit interesse om wie ik ben en wie ik geworden ben. Het nemen van een beslissing is niet steeds eenvoudig, zowel op medisch vlak als in het dagelijkse leven waar zich telkens weer keuzemomenten aandienen. Na de keuze voor de Universitaire opleiding Informatica, en na een thesis bij de onderzoeksgroep IBCN, begon in augustus 2005 het werk op de Zuiderpoort in Gent. Eerst als projectmedewerker en een jaar later als doctoraatsstudent kon ik werken in een domein dat me uitermate boeit, de elektronische gezondheidszorg. Daarnaast kon ik als assistent instaan voor de vakbegeleiding aan studenten. Het was steeds een boeiende mix, die voor afwisselend werk zorgde, en interessante ontmoetingen en boeiende leerrijke momenten teweeg bracht. Dit ongetwijfeld veel te korte dankwoord is een moment om hierop terug te blikken en een gelegenheid om een heel aantal mensen in het bijzonder te bedanken. Het doctoraatsonderzoek is immers een weg die je niet alleen bewandelt maar waarbij vele mensen onderweg een belangrijke rol spelen.

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Gent, 26 februari 2013
Kristof Steurbaut

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List of Acronyms

A

ADT	Admission Discharge and Transfer
AHLTA	Armed Forces Health Longitudinal Technology Application
AJAX	Asynchronous Java Script
AKI	Acute Kidney Injury
AM	Autonomic Manager
AMRS	AMPATH Medical Record System
AMUSE	Autonomic Management of Ubiquitous E-health Systems
API	Application Programming Interface
ARRA	American Recovery and Reinvestment Act

B

BFS	Billing Form Service
BICS	Brigham Integrated Computing System
BWH	Brigham and Women's Hospital

C

CASCADAS	Component-ware for Autonomic, Situation-aware Communications and Dynamically Adaptable Services
CASS	Computer-Assisted System Staff
CBIS	Computer-Based Information System
cCMV	congenial cytomegalovirus
CDC	Center of Disease Control and Prevention
CDS	Clinical Decision Support
CDSC	Clinical Decision Support Consortium

CHCS	Composite Health Care System
CIS	Clinical Information System
COSARA	Computer based Surveillance and Alerting of Nosocomial Infections
COSTAR	Computer Stored Ambulatory Record
CPIS	Coordinated Portfolio Investment Survey
CPOE	Computerized Physicians Order Entry
CT	Computerized Tomography

D

DAS	Doctors Assignment Service
DDD	Defined Daily Doses
DEC	Digital Equipment Corporation
DHCP	Decentralized Hospital Computer Program
DICOM	Digital Imaging and Communications in Medicine
DLS	Data Lookup service
DMS	Department of Medicine and Surgery
DOD	Department of Defense
DRS	Data Retrieval Service
DS	Doctors Service

E

EBM	Evidence Based Medicine
ECG	Electrocardiogram
EC UZG	Ethics Committee of Ghent University Hospital
EHRs	Electronic Health Records
eID	Electronic Identity Card
ESB	Entreprise Service Bus

F

FFS	Financial Format Service
FOCALE	Foundation Observe Compare Act Learn rEason
FTE	Full-Time Equivalent

G

GDP	Gross Domestic Product
GLIMS	Global Laboratory Information Management System

H

HCHP	Harvard Community Health Plan
HDI	Human Development Index
HELP	Health Evaluation through Logic Processing
HIMSS	Health Information Management System Society
HIS	Hospital Information System
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health Act
HL7	Health Level 7
HWCIR	Homer Warner Center for Informatics Research

I

IBM	International Business Machines
ICIS	Intensive Care Information System
ICU	Intensive Care Unit
IHC	Intermount Health Care
IMPROVE-IT	Indices Measuring Performance Relating Outcomes, Value and Expenditure through Information Technology
INFSO	Information Society and Media
IOM	Institute of Medicine
IT	Information Technology
IV	Intravenous

J

J2EE	Java Enterprise Edition
JMS	Java Message Service
JSF	Java Server Faces

L

LDS	Latter-Day Saints
LIS	Laboratory Information System
LOS	Length Of stay

M

MAPE	Monitor, Analyze, Plan and Execute
MAPE-K	Monitor, Analyze, Plan, Execute and Knowledge
MCS	Monitoring and Control Service
MISS	Meditech Interpretive Information System
MMRS	Mosoriot Medical Record System
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
MUMPS	Massachussetts General Hospital Utility Multi-Programming System

N

NEOREG	Neonatal Registry System
NICU	Neonatal Intensive Care Unit
NICHD	National Institute of Child Health and Human Development
NMR	Nuclear Magnetic Resonance

O

ODMT	Data Management and Telecommunications
OECD	Organisation for Economic Co-operation and Development
OS	Operating System
OSGi	Open Services Gateway initiative

P

PACS	Picture Archive and Communication System
PC	Personal Computer

PDF	Portable Document Format
PDMS	Patient Data Management System
PO	Per Os
PROMIS	Problem Oriented Medical Information System

Q

QMR	Quick Medical Reference

R

RFID	Radio-Frequency Identifiers
RIFLE	Risk, Injury, Failure, Loss and End- stage kidney disease
RIZIV	National Institute for Sickness and Invalidity Insurance
RMRS	Regenstrief Medical Record System
ROI	Return On Investment
RS	Rule Service

S

SAPS	Simplified Acute Physiology Score
SMC	Self-Managed Cells
SO	Service-Orientation
SOA	Service Oriented Architecture
SOFA	Sequential Organ Failure Assessment
SQL	Stored Query Language

T

TDS	Technicon Data Systems
TISS	Therapeutic Intervention Scoring System
TMIS	Technicon Medical Information System
TS	Timer Service

V

VISTA	Veterans Health Information System and Technology Architecture
VLAN	Virtual Local Area Network
VLBW	Very Low Birth Weight

W

W3C	World Wide Web Consortium
WBC	White Bloodcell Count
WHO	World Health Organisation
WS	Web Services
WSDL	Web Service Description Language

X

XHTML	EXtensible Hyper Text Markup Language
XML	EXtensible Markup Language

Samenvatting
– Summary in Dutch –

De jongste decennia onderging onze maatschappij ingrijpende veranderingen door de opkomst van internet en nieuwe informatie- en communicatietechnologieën. Deze technologieën bieden kansen om computergestuurde diensten te ontwikkelen die bijdragen aan de verdere uitbouw van een kwaliteitsvolle en efficiënte gezondheidszorg. Door de vergrijzing van de bevolking, een groeiende complexiteit van medische behandelingen, verhoogde kosten en een tekort aan artsen en paramedici komt onze gezondheidszorg onder extreme druk te staan. Het domein van de medische informatica overbrugt de kloof tussen computerwetenschappen en de medische sector. Het vormt een uitdaging om klinische applicaties te ontwikkelen om het besluitvormingsproces van medisch personeel te ondersteunen. Deze toepassingen verhogen de productiviteit, zorgen voor het maken van nauwkeurigere diagnoses en dragen bij tot het beheersbaar houden van de medische kosten. De applicaties of diensten krijgen te maken met enorme hoeveelheden gegevens versnipperd over de verschillende systemen aanwezig op diverse sites, dit terwijl de kwaliteit van de dienstverlening en geautomatiseerde ondersteuning in de gezondheidszorg moet worden gewaarborgd op alle momenten. In het ziekenhuis concentreert men zich vooral op de interpretatie van de beschikbare medische gegevens om een diagnose te stellen. Een medische diagnose wordt enerzijds gebaseerd op actuele patiënteninformatie afkomstig van geregistreerde metingen, klinische observaties, toegediende medicaties en labo-resultaten. Anderzijds worden beslissingen getoetst met relevante klinische richtlijnen en voorafgaande medische expertise. Momenteel voeren artsen echter nog steeds handmatige registraties en tijdrovende en arbeidsintensieve data-analyses uit zonder hierbij gebruik te maken van deze nieuwe computergebaseerde hulpmiddelen.

De belangrijkste doelstelling van dit onderzoek is het ontwerp en de optimalisatie van registratie en informatiediensten die de klinische besluitvorming in het ziekenhuis ondersteunen. Dit omvat de automatische registratie van de gegevens van patiënten, de visualisatie van elektronische dossiers, evenals het verlenen van advies en vereenvoudigen van diagnoses. Deze diensten kunnen de arts helpen door gemakkelijk toegang tot patiëntengegevens aan te bieden en zelfs therapieën voor te stellen rekening houdend met de individuele parameters van de patiënt. We dragen bij aan dit domein door computergestuurde oplossingen te ontwerpen en te implementeren. Eerst wordt het ontwerp van een *service platform* met alle essentiële bouwstenen onderzocht. Ten tweede wordt de medische dienst op zichzelf bestudeerd waaronder bijvoorbeeld medische protocollen die voor orgaanfalen of nierfalen waarschuwen en die infecties en gebruik van antibiotica beheren. Ten slotte worden optimalisaties bestudeerd om de robuustheid en de stabiliteit van dit platform te verzekeren. De betrokkenheid van artsen heeft geleid tot oplossingen die eenvoudig geïntegreerd kunnen worden in de dagelijkse werking in zowel administratieve als klinische scenario's op de afdelingen intensieve zorg en neonatologie.

De bijdragen van dit proefschrift omvatten (i) de transformatie van een op papier gebaseerd administratief proces naar een papierloos geautomatiseerd proces gebruik makend van een *service-georiënteerde* architectuur, (ii) de creatie van een *service platform* voor klinische registratie, infectie en antibiotica beheer op de afdeling Intensieve Zorg met (iii) integratie van klinische gegevens en ondersteunende diensten voor de besluitvorming, (iv) de ontwikkeling van een registratie platform op verscheidene sites voor geïnfecteerde pasgeborenen en (v) het optimaliseren van de data-prestaties door middel van autonome controlelussen.

Ten eerste dienen de huidige papiergebaseerde processen te worden omgevormd naar systemen die elektronische dossiers gebruiken, dit om gegevens elektronisch te kunnen verwerken. Hiertoe wordt in dit proefschrift de automatisering van het tarificatieproces bestudeerd op de afdeling intensieve zorg. Dit is een administratief proces waarbij alle medische uitgevoerde procedures per patiënt en per dag op papier worden geregistreerd door verpleegkundigen en nadien verwerkt worden om de medische kosten te kunnen berekenen. Omdat dit proces foutgevoelig en tijdrovend is, wordt een *service georiënteerde* architectuur voorgesteld om automatisch de registratietaken te behandelen en deze te integreren met de gegevens uit de databank van het ziekenhuis. Het blijkt dat deze *web services* ten opzichte van de traditionele gecentraliseerde aanpak voordelen hebben zoals herbruikbaarheid, eenvoudige integratie en flexibele verdeling over de beschikbare werkstations. De evaluatieresultaten tonen een direct terugverdieneffect aan na 4 maanden en een extra omzet van 5,1% als gevolg van een veel nauwkeuriger proces zonder gemiste of vergeten procedures en de tijdsbesparing.

Ten tweede bespreken we in dit proefschrift het toezicht op nosocomiale infecties en het beheer van antibiotica in de intensieve zorg. Artsen worden overstelpt met laboresultaten, metingen, klinische observaties en radiologiefoto's van elke patiënt waardoor nuttige informatie vaak moeilijk te vinden is. Bovendien werden de huidige informatiesystemen veelal gebouwd als alleenstaande applicaties, die toegang verlenen tot een bepaald type van gegevens en niet in staat zijn om gegevens te combineren. Het voorgestelde platform biedt artsen, aan de ene kant een waardevol instrument aan om medische elektronische dossiers te evalueren en te interpreteren. Aan de andere kant verzamelt het relevante informatie over infecties en antibiotica, die gebruikt kan worden in toekomstig klinisch onderzoek. Het is de bedoeling om prospectief gegevens te verzamelen tijdens de klinische activiteiten waardoor een inzicht in data voor later onderzoek en dagelijks klinisch gebruik gegeven wordt.

Ten derde zijn diensten vereist om overmatig gebruik van antibiotica en onaangepaste therapieën in te perken. Deze laten ook toe om infectiepatronen sneller op te sporen. Voorbeelden van deze diensten zijn automatische doseringsadviezen voor antibiotica, suggesties voor vroegere omschakeling van therapieën, en waarschuwingen van nierfalen of orgaanfalen. De ontwikkelde applicatie bestaat uit modules die de artsen een overzicht biedt van de infecties en antibiotica therapieën gecombineerd met actuele en historische patiëntparameters. Toegang tot de gestructureerde informatie van microbiologie en van bloedresultaten wordt aangeboden en scores worden automatisch berekend. Het laat artsen toe om de behandeling te koppelen aan hun diagnose. In de klinische scenario's worden grote problemen aangepakt met betrekking tot de registratie -en informatiesystemen in het ziekenhuis.

Terwijl de eerste hoofdstukken van dit proefschrift gericht zijn op registratie- en informatiediensten op één site, de intensieve zorg, behandelen we ook een registratiewebsite toegankelijk voor verscheidene sites, voor de afdelingen neonatologie en voor huisartsen. Een domeinanalyse voor de registratie van pasgeborenen met de cytomegalovirusinfectie werd uitgevoerd. Verwacht wordt dat aanvankelijk slechts 10 tot 50 gebruikers het systeem zullen gebruiken overeenkomend met een laadtijd tussen 28 en 48 milliseconden. De databankkenmerken en prestaties worden besproken.

Ten slotte worden optimalisaties voor de prestaties voorgesteld door het *service platform* uit te breiden met autonome mogelijkheden. Deze componenten zijn bedoeld om het systeem in zijn eigen beheer te laten voorzien en een minimale menselijke tussenkomst te vragen door zelf beslissingen te nemen. Meerdere controlelussen monitoren de prestaties van het systeem en redeneren over mogelijke aanpassingen en acties. De resultaten tonen aan dat de reactieve controlelus de gemiddelde query uitvoeringstijd van microbiologie queries reduceert met 8,61%. De combinatie van de reactieve en deliberatieve controlelus reduceert de gemiddelde uitvoeringstijd met 10,92% en de combinatie met de reflectieve controlelus resulteert in een reductie van 13,04%. Detectietechnieken worden bestudeerd om prestatieverminderingen van data queries op te sporen.

Toekomstig onderzoek kan zich uitstrekken op het gebied van standaardisatie van klinische richtlijnen, veiligheid en medische ontologieën. Een automatische vertaling van medische richtlijnen naar programmeercode zou de ontwikkeling van medische diensten kunnen versnellen. In dit proefschrift bestudeerden we het ontwerp en de optimalisatie van de medische registratie- en informatiediensten voor de intensieve zorg. De aangeboden diensten zijn ingezet op de afdeling Intensieve Zorg van het Universitair Ziekenhuis te Gent.

Summary

In the last few decades our society has undergone radical changes with the emergence of the Internet and new information and communication technologies. These technologies offer opportunities to develop computer-based services that contribute to the further development of a high-quality and efficient health care. Due to an aging population, a growing complexity of medical treatments, increased costs and a shortage of doctors and paramedics, our health care is under extreme pressure. The field of medical informatics bridges the gap between computer science and the medical sector. It is a challenge to design clinical applications to support the decision making processes of medical staff. These applications increase productivity, make more accurate diagnoses and contribute to the management of medical costs. The applications or services have to cope with enormous amounts of data fragmented across different systems and on multiple sites, while service quality and automated assistance in health care have to be guaranteed at all time. In the hospital, the focus is mainly on the interpretation of the available medical data for diagnosis. A medical diagnosis is based on information derived from current patients' registered measurements, clinical observations, administered medications and lab results. Furthermore, decisions are reviewed under relevant clinical guidelines and previous medical expertise. Nowadays physicians and nurses still put registrations in manually and conduct time-consuming and labor-intensive analyses of data without making use of the new computer-based devices.

The main objective of this research is the design and optimization of registration and information services for clinical decision support in the hospital. This includes the automatic recording of patient data, the visualization of electronic files, as well as providing advice and diagnostics. These services can help the physician to get easy access to patient data and suggest a therapy taking into account the parameters of the individual patient. We contribute to this domain by designing and implementing computer-based solutions. First, the design of a service platform with all the essential building blocks is investigated. Second, the medical services itself are investigated including for example medical protocols to alert organ failure or kidney dysfunction and to manage infections and the use of antibiotics. Finally optimizations are studied to insure the robustness and stability of this platform. The involvement of doctors has led to solutions that can be easily integrated into their daily operations in both the administrative and clinical scenarios of the intensive care and neonatology departments.

The contributions of this dissertation include (i) the transformation of a paper-based administrative process to a paperless automated process making use of a service-oriented architecture, (ii) the construction of a service platform for clinical registration, infection and antibiotic management in the intensive care with (iii) integration of clinical data and decision support services, (iv) the development of a registration system for multiple sites for infected newborns and (v) the optimization of data performance through autonomic control loops.

First, to be able to process information electronically, the current paper-based processes need to be transformed into systems using electronic files. To this end, this dissertation studies the automation of the tarification process in intensive care. This is an administrative process where all medical procedures are registered per patient per day on paper by nurses and subsequently processed to calculate medical costs. Because this process is error-prone and time-consuming, a service-oriented architecture is proposed to handle tasks automatically and integrate with the database of the hospital. It appears that these web services have advantages over a traditional centralized approach such as reusability, easier integration and a flexible allocation of available workstations. The evaluation results show a direct return on investment after 4 months and an additional revenue of 5.1% due to a more accurate process without missed or forgotten procedures, and time savings.

Second, in this dissertation we discuss the surveillance of nosocomial infections and management of antibiotics in intensive care. As physicians are overwhelmed by lab results, measurements, clinical observations and radiology images of each patient, useful information is often hard to find. Moreover, the current information systems were often built as a single application, providing access to a particular type of data without ability to combine. The proposed platform provides physicians, on the one hand, with a valuable tool to evaluate and interpret electronic medical records. On the other hand, it collects the information relevant to infections and antibiotics that can be used in future clinical studies. The intention to collect data prospectively during the clinical activities is to create an understanding of data for later research examination and routine clinical use.

Third, services to limit overuse of antibiotics, to track infections and to alert physicians have been designed. These services allow physicians to detect and follow up infection and disease patterns faster. Examples of these services are: automated antibiotic dosage recommendations, suggestions for conversion of former therapies, and warnings of renal failure or organ failure. The developed application consists of modules that offer physicians an overview of the infection and antibiotic therapies combined with current and historical patient parameters. Access to the structured information of microbiology and blood results is presented and scores are automatically calculated. It allows physicians to link therapies with their diagnoses. In the clinical scenarios major problems in registration and information systems in the hospital are addressed.

While the first chapters of this dissertation focus on registration and information services at one site, the intensive care, we also study a registration system spanning multiple sites, for the neonatology departments and for GPs. A domain analysis for the registration of newborns with a cytomegalovirus infection was therefore carried out. It is expected that initially only 10 to 50 users will access the system corresponding to a load time between 28 and 48 milliseconds. The database characteristics and performance are discussed.

Finally, performance optimizations are proposed by extending the service platform with autonomous capabilities. These components are designed in such a way that the system can control its own management and requires only minimal human intervention by taking its own decisions. Multiple control loops monitor the performance of the system and are able to reason about possible changes and actions. The results show that the reactive control loop reduces the average query execution time of the microbiology queries by 8.61%. The combination of the reactive and deliberative control loop reduce the average execution time by 10.92% and the combination with the reflective control loop results in a reduction of 13.04%. Detection techniques are studied to detect the performance degradation of data queries.

Future research may extend to the field of standardization of clinical guidelines, safety and medical ontologies. An automatic translation of medical guidelines into programming code could accelerate the development of medical services. In this dissertation we studied the design and optimization of medical registration and information services for the intensive care unit. The offered services are being used in the intensive care of the University Hospital in Ghent.

1
Introduction

"The complexity of modern medicine exceeds the inherent limitations of the unaided human mind" [1]
–David M. Eddy, MD, PhD

The focus of this research is on the design, development and optimization of hospital information systems and services. Information technology has been implemented in all aspects of our lives. Although computerized care is slowly adopted in hospitals, medical informatics has evolved to an important discipline that has the enormous potential to improve the process of care by delivering health services to improve the quality of care and to reduce medical costs. It creates new opportunities in the daily work of physicians and nurses. In this chapter, we set the context for the transitions in health care and discuss the potential of IT and also its associated challenges. Furthermore, this chapter summarizes the main contributions and outlines the structure of this dissertation. It also provides an overview of the publications that were authored during this research period.

1.1 The context of current health care

Being in good health is perceived as most valuable in life. Despite the difficulty to exactly measure the value of health [2], it is believed that health influences our individual behavior and development. The United Nations measure human development worldwide by combining indicators of life expectancy (health), access to knowledge (education), and standard of living (income) in a composite human development index (HDI) per country [3].

Today's health systems and services are under extreme pressure. Health expenditures are rising due to (i) an ageing population (Figure 1.1), (ii) more care for patients with chronic diseases, and (iii) medical innovations that lead to costly medical procedures. According to the expenditure data of the Organisation for Economic Co-operation and Development (OECD) [4] as shown in Figure 1.2, health care costs grew to $ 2.5 trillion in the US in 2009. It counts in the gross domestic product (GDP in 2009) for 17.4 % (in the US), 12.0 %(in the Netherlands), 10.9 % (in Belgium), 9.8 % (in the UK) of the expenditures. Figure 1.2 shows the evolution of health costs in the countries' GDP. US analysts predict it will reach 19.3 % of US GDP by 2019 or $ 4.48 trillion. The Australian Institute for Health and Welfare estimates the total health and residential aged care expenditure to increase 189 % over 30 years in the period 2003 to 2033 from $ 85 billion to $ 246 billion [5]. As a result, health providers are forced to control costs while still being obliged to offer high quality care to patients. Furthermore, there is an increasing demand for clinicians and a scarcity of medical workers on the labour market. Due to a rising nursing shortage, governments have already started marketing campaigns to promote vacancies in the health care sector. In 2006, the World Health Organisation (WHO) estimated a shortage of 4.3 million nurses, physicians and health human resources worldwide with a most severe shortage in the poorest African countries [6]. By 2025, the US alone will be short of 260,000 nurses and 124,000 physicians [7] and these estimates are already believed to be too low [8]. The challenge for health care is to create new ways of rapid, safe, effective and affordable service delivery.

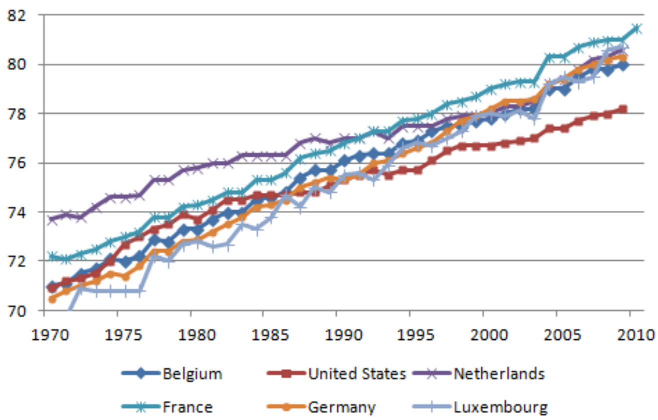

Figure 1.1: Life expectancy at birth in years of the total population based on OECD Health Data 2011 [4].

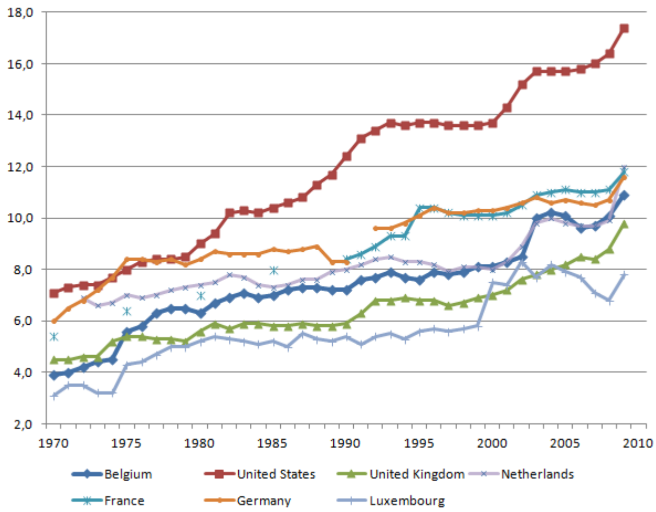

Figure 1.2: Total health expenditure, % Gross Domestic Product (1970-2009) based on OECD Health Data 2011 [4].

Estimations by RAND Corporation predict that costs can be reduced dramatically by the use of information technology. RAND calculated in 2005 that through adoption of health IT by most US hospitals and doctor's offices a potential efficiency saving for both inpatient and outpatient care could average over $ 77 billion per year [9]. The cost saving is attributed to reduced hospital stays, reduced nurses' administrative time, and more efficient drug utilization. RAND also estimates that elimination of 200,000 adverse drug events by IT alerting could yield an annual saving of about $ 1 billion [9].

Hospitals are responsible for the highest percentage of the health expenditures. In 2009, the 267 hospitals in Belgium took 31 % of the total expenditure of health, as shown in Figure 1.4. In the available OECD data [4], the same situation applies to the US (32.6%), the Netherlands (33.7%), France (35.3%) and Germany (29.5%). The Intensive Care Unit (ICU), a unit with critically ill patients with life-threatening diseases, is one of the most expensive departments in the hospital. We specifically focus on the ICUs of the hospital, with the aim to apply information technology solutions beneficial for physicians and nurses. In [10], a study of 253 geographically diverse US hospitals in 2005, the ICU cost was estimated between $ 31,574 and $ 42,570 (for mechanical ventilated patients) and the LOS on 14.4-15.8 days.

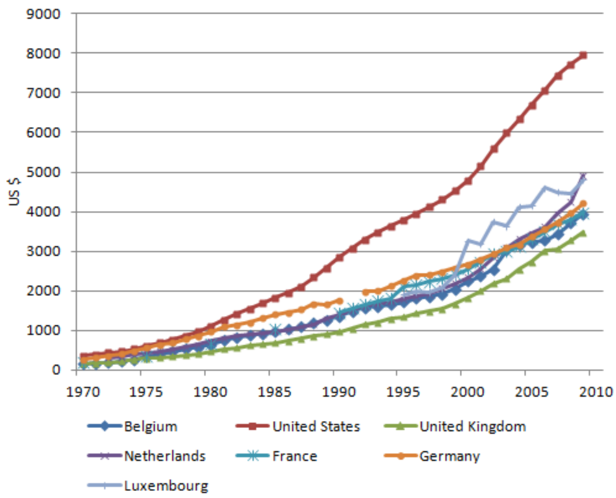

Figure 1.3: Total health expenditure, in US dollar per capita (1970-2009) [4]

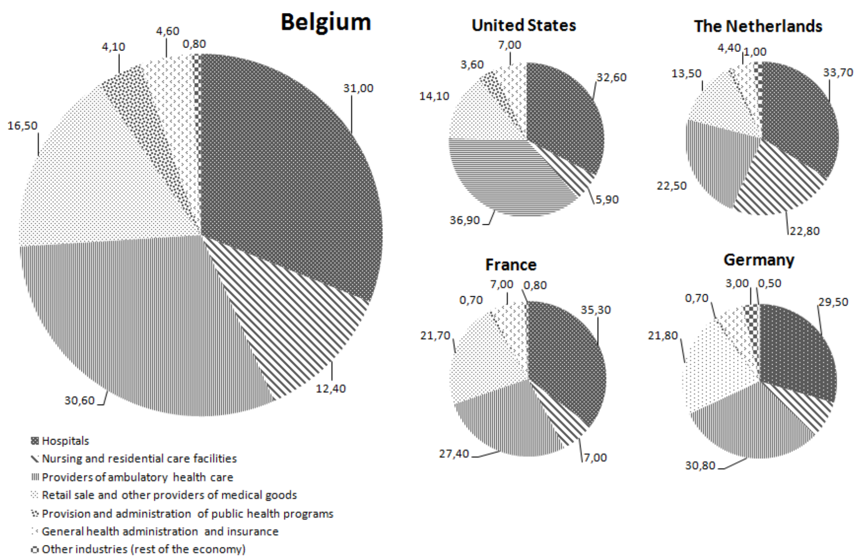

Figure 1.4: Division of health expenditures by provider type: the most significant parts of expenditures are the hospitals (32%) and providers and ambulatory care (30.6%).

1.2 The role for Information Technology

Information Technology has considerable potential to support the physician with patient data registration, information representation and advanced computerized decision support. Considering the growth in medical therapies and diagnoses in the physician's decision making process, understanding and interpreting all patients' conditions and results have become a huge challenge for the human brain. Making a clinical diagnose and deciding on treatment of a patient, include difficult choices with numerous involved parameters that exceed human manual analysis. Medical Informatics is an emerging discipline at the intersection of computer science and medical science. The terminology in this domain is often categorized under the name *electronic healthcare* or *eHealth*. The Information Society and Media (INFSO) department of the European Commission defines eHealth as:

eHealth means Information and Communication Technologies tools and services for health. Whether eHealth tools are used behind the scenes by healthcare professionals, or directly by patients, they play a significant role in improving the health of European citizens. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals. Examples include health information networks, electronic health records, telemedicine services, wearable and portable systems which communicate, health portals, and many other ICT-based tools assisting disease prevention, diagnosis, treatment, health monitoring and lifestyle management [11].

Initiatives to promote meaningful use of technology and financial incentives try to increase the adoption rate of health information technology (HIT). In 2004, the European Commission launched its first eHealth Action Plan [12] and stated that eHealth can act as a key enabling tool which could result in better access to care, quality of care, efficiency and productivity of care. It marked the start of a cooperation strategy between EU member states. It was followed by a renewed eHealth Governance Initiative [12] in 2008 with the aim to strengthen actively electronic healthcare in Europe, focusing on overall interoperability of electronic health record (EHR) systems by the end of 2015. One of the objectives of the Community health strategy (2008-2013) is to support dynamic health systems and new technologies, recognizing that new technologies can improve disease prevention, diagnosis and treatment, facilitate patient safety and improve health systems' coordination, use of resources and sustainability.

In the Health Information Technology for Economic and Clinical Health Act (HITECH), part of the American Recovery and Reinvestment Act (ARRA) of 2009, US president Obama included $ 19 billion dollar for investment in the expansion of Health Information Technology (HIT) in the US [13]. Adjustments in the current health systems are needed to maintain high quality while reducing health costs.

1.3 Problem Statement

> *"We have the most inefficient health care system imaginable. We're still using paper. Nurses can't read the prescriptions that doctors have written out. Why wouldn't we want to put that on an electronic medical record that will reduce error rates, reduce our long-term costs of health care, and create jobs right now?"* –US President Barack Obama, February 9, 2009 [14]

Integrating fragmented medical data registrations
Nowadays, physicians and nurses still perform time-consuming and complex data analyses on individual patient data for making medical decisions. The registration and collection of medical values is fragmented across numerous systems. The systems tend to follow a silo-based information approach which limits the exchange of data between applications. It provides the physician an incomplete view on the patient's state. As a consequence, physicians have to spend additional time to check different applications. Combining and interpreting data from different sources is complex, labor-intensive and time consuming. Therefore we focus on the design of medical information services, specifically designed to collect automatically data and to combine data in order to gain new insights for patient care. The linking process also requires additional data that is not registered up to now but is part of the physician's experience and knowledge. Furthermore, although commercial systems have been able to replace paper-based patient records, systems have not been integrated with each other and services that combine and process the data automatically for decision support are not available for specific ICU protocols such as renal failure, organ failure, infection surveillance or the sedation protocol.

Designing medical software services
The health care sector demands solutions to automate and improve processes in hospitals. However, it was not clear which appropriate software technology could be used to automate processes, integrate data and combine services and build a robust, sustainable platform. All these services would contribute to an increased efficiency of patient care. The role of information technology would not only be limited to automation but also to improve quality of care, safety and cost-effectiveness of critical care medicine. To this end, investigation of service platform design and implementation are needed. The services should be plugged in on a platform, offering generic functionality for data collection, event handling and service management.

Supporting clinical decisions
The management of decisions during the daily ICU activities is complex. Physicians and nurses would benefit from information management services and decision making tools. The increasing medical procedures in the Intensive Care Unit (ICU) requires time- and data driven software services. These procedures are often regulated by clinical guidelines. Services who constantly analyse parameters and track adherence to the guidelines should be developed. As the ICU deals with the treatment of critically ill patients decisions of antibiotic therapy to cure severe infections should be made quick and efficient. Services can offer earlier and more accurate detection of infections and antibiotic resistance. Furthermore, these services can reduce improper use of antibiotics and inappropriate therapies. The provisioning of a decision support system can enable the discovery of patterns in health data which might be important for the fight against nosocomial (hospital-acquired) infections and prevent incorrect diagnosis, unnecessary prescriptions, improper use of antibiotics and overuse of antibiotics. In this dissertation, we have chosen to focus specifically on application of software services in the ICU.

Optimizing configuration and maintenance
The management of services is still handled by manual operators. With the growing amount of medical services, the workload increases and management becomes extremely complex. Furthermore, the medical environment requires a 24/7 uptime of the services that consume and produce insights about the medical progress of the patient. When clinicians start to depend on data collector or integrators and clinical decision support offered by information services, solutions have to be offered immediately without harming the patient's safety. There is a need for autonomous configuration and maintenance. Because of the unpredictive nature of occurring service faults caused by for example increased workload, exceptions in originating systems or system failures, the system has to be able to adapt its configuration and take management decisions autonomously.

1.3.1 Medical Cases

In this dissertation the problem statement was investigated in the following medical cases:

- In an ICU administration, the billing process of medical technical procedures is still performed on paper, while this data can be retrieved automatically from the intensive care information system. The existing time-consuming and paper-based process should be transformed in an automated process. Analysis of the billing data flow and the participation of the different stakeholders (nurse, head nurse, secretary) is necessary. Financial policies and administrative decisions are enforced by the software.

- In the ICU wards, clinical decisions should be made quickly for the admitted patients. In contrast to the ICU administration, data is fragmented across different clinical applications such as laboratory system, intensive care system, radiology system. There is a lack of a uniform integrated view on the patients' infections. ICUs have the highest usage of antibiotics of the hospital and face antibiotic resistance, for example in case of nosocomial infections. Therefore services should be developed to integrate data, register additional infection-related data, automate medical guidelines, provide a graphical clinical overview and alert of changes in therapies automatically.

- While the problems of the administrative and medical processes in the ICU are found in one medical department, the newborns' cytomegalovirus infection should be registered and tracked by both in-hospital physicians and general practitioners. This adds additional requirements to the design of a registration platform. Furthermore, in the neonatology department there was a lack of an existing registration system.

1.4 Research Questions

The main objective of this research is the design and optimization of registration and information services for clinical decision support in the hospital. This includes the automatic recording of patient data, the visualization of electronic files, as well as providing advice and diagnostics. The services can help the physician to get easy access to patient data and suggest a therapy taking into account the individual patient's parameters. Therefore, computer-based solutions are designed, developed and evaluated. Patients data has to be combined and integrated by software services to allow an accurate and efficient data collection process. The service oriented platform consists of the essential building blocks to process the data. Services can be added to the platform to automate and ease tasks of physicians and nurses during their daily decision activities in the hospital. The platform can be used for both administrative and clinical purposes. For example, antibiotic consumption and therapy follow-up can be handled by the services. First, our focus is on the design of a service execution platform, with inclusion of support to alert physicians of infections or suggest therapy changes. Second, the medical service on itself encapsulates the logic that is a decisions plan or guideline that follows certain patient's conditions or alerts alarming values. Finally, it is also needed to model and optimize performance changes and adaptations in these services in order to ensure robustness and stability of the platform. This research is applied to the Intensive Care Unit, allowing a profound evaluation of services and a direct clinical benefit as result of the automation of the surveillance of infections and antibiotic consumption monitoring. This thesis provides an answer to the following research questions. These questions stem from the problems described in section 1.3.

1. *What is the best approach to design and develop medical and administrative services in the hospital? Which architectural components are required to construct an integrated health care platform in critical care?*
   Despite the rapid evolution of information technology, its adoption in health care is relatively low compared to other industries. There is a strong need for computer based health services to aid physicians and nurses, tailored to the needs at the point of care. Service orientation offers several benefits compared to traditional software development. These benefits include reusability, loose coupling of service functionality, design flexibility and ability to compositions. Although service orientation has been used in industry, the benefits have not been validated in specific administration and medical processes in the ICU. For example, the tarification is a manual administrative process to tick and count medical procedures to generate billing forms of the performed medical procedures, infection and antibiotics are manually searched by physicians in the documented data to form a diagnosis. In order to support the physician and nurse the use of existing clinical data sources and the creation of new data registrations should lead automatically to a complete electronic patient record. However, processes were also built as single applications, not sharing or integrating data. Therefore in this thesis we focus on the creation of reusable services and platform components to ease the registration of clinical data and stimulate the integration of data while not interfering with the clinical workflow in the hospital. This IT automation could replace current labor-intensive paper-based tasks with software services that automatically process and interprete clinical data in both medical and administrative cases.

2. *How can software services provide clinical decision support to physicians and nurses? How should patients' data be collected and integrated, analysed and interpreted, presented and reported efficiently?*
   The assistance by computer-based services in the daily clinical tasks, the potential reduction in time and workload offered, and the automation of routine tasks are stimuli to introduce IT in the health care sector. Although objective effects are difficult to measure, there is a need to develop and evaluate the effect of clinical services. Different clinical scenarios should be investigated ranging from usage on one single site to multiple sites. With the growing medical complexity initially services were developed as stand-alone applications that do not interact with each other. Current systems do not allow the integration of data through one single application. With the explosion of

data due to data gathered by monitoring devices, more registered observations, laboratory results and orders, there is a need to link all this data. The integration of data offers new insights in the patients' conditions. In this thesis we focus on the creation of services for the surveillance and alerting of nosocomial infections, the antimicrobial resistance and antibiotic consumption, and for alerting of kidney failure and organ failure of patients. These services act on real life data flows in the intensive care. We also focus on the on line registration of newborns infected with congenital Cytomegalovirus infection for the neonatology departments.

3. *How can the quality of service of the health care platform be optimized by introducing autonomic capabilities?*
   It is the aim of autonomic computing to create a self-managing system able to adapt dynamically when changes in the environment occur. Self-manageable components are introduced to overcome the systems complexity in maintenance and to reduce the human involvement in reconfiguration and maintenance. In order to increase robustness of the platform there is a need for autonomic control loops which manage the operation and state of the system. As such, the performance of data retrievals is monitored because of its direct influence on the client response times to present clinical data on the physicians' computers. In the thesis we focus on a detection mechanism to track data performance outliers and on automatic actions to reduce human maintenance of the service platform.

1.5 Main Research Contributions

This thesis contributes to the research domain of medical informatics. The focus of this research is to design and develop an optimal registration and information management system and services for the hospital. We present an elaborated list of the research contributions within this dissertation:

- The transformation of paper-based administration process to a paperless process through the use of a service oriented architecture.
  - Design of services based on analysis of the tarification process in the ICU. Tarification is the manual process to tick and count the medical procedures per patient and per day on paper. This billing process can be automated by using computer-based services.
  - Evaluation of the electronic tarification in terms of performance and cost benefits. Since investments in technology are costly, the return on investment of the software application is analysed.

- Construction of a service platform for clinical registration, infection and antibiotic management in one department, the Intensive Care Unit.
  - Registration, processing and presentation of decision support for infection surveillance and antibiotic management in the ICU.
  - Service design to advise and alert physicians at the point of care.
- The linking of clinical data sources and mapping of data to create an integrated electronic patient record.
  - Integration of data in the intensive care information system, laboratory database, and PACS system. Design of a database with linking information of the different sources.
  - Design and implementation of registration services for antibiotics and infection related data and decision support services for the evaluation of clinical guidelines.
- Development of a multiple site registration platform.
  - Registration of cytomegalovirus infection of newborns at multiple hospital sites through web based access to clinical data and the use of a document exchange format.
- Optimization of the quality of the service platform though autonomic components.
  - Design of a control loop architecture for performance optimization and fault management. The control loop continuously monitors the performance of the system. The performance of the platform is optimized by analyzing the data retrievals and taking actions in case of performance drops.
  - Design and implementation of analysis methods based on anomaly detection of performance measurements.

1.6 Outline of this dissertation

This dissertation is composed of a number of publications that were realized within the scope of this PhD. The selected publications provide an integral and consistent overview of the work performed. The different research contributions are detailed in Section 1.5 and the complete list of publications that resulted from this work is presented in Section 1.7. Within this section we give an overview of this dissertation and explain how the different chapters are linked together. Figure 1.5

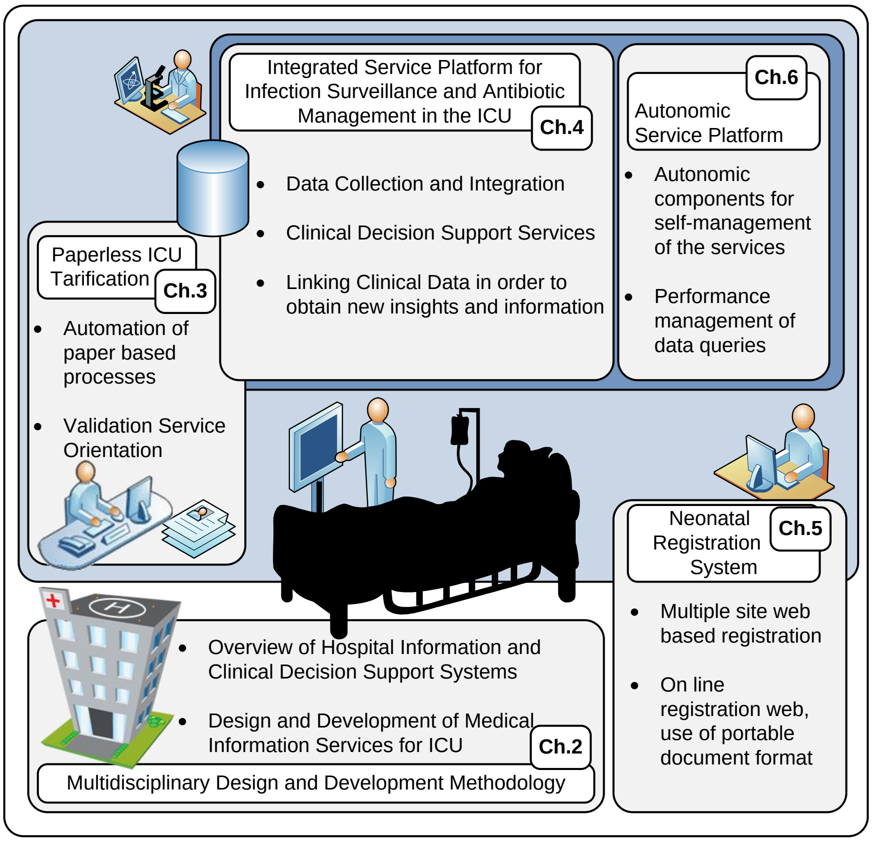

Figure 1.5: Schematic positioning of the chapters in this dissertation.

positions the different contributions that are presented in each chapter (Ch.).

Chapter 2 presents an overview of the design and development methodology applied in the hospital, specifically in the intensive care unit. The research is situated in real-life clinical scenarios. These scenarios cover utilization cases in the administration, in patient care and management. We study the developments of information platforms as examined from the literature. The choice for information technology in the ICU is motivated and challenges are found in the clinical scenarios. In chapter 3, we discuss the transition from paper-based methods towards a paperless digital process which involve electronic patient records. In the administration process of the ICU, a web services platform for the automation of tarification and billing process is studied and validated. We encapsulate the administrative processes as services in a service-oriented architecture. In addition, the proposed software prototype is evaluated for performance and the return on investment is analyzed. Chapter 4 provides the architecture for the COSARA platform, which facilitates the infection disease management and antibiotic management for patients in the ICU. This platform offers clinicians a unique registration, presentation and reporting facility. Several modules and applications are included which set steps towards next-generation platform for infection surveillance. In the evaluation, we focused on data quality and robustness of the platform. In chapter 5, we investigate the neonatology unit, which is not using an existing registration system. Compared to chapter 4 in which the design and development of an enterprise service platform is studied in one site, the ICU, in chapter 5 we study a web based registration platform accessible from multiple sites. We performed a domain analysis and proposed a platform for the registration of newborns with cytomegalovirus. This registration supports the physician in the hospital, but also the general practitioner with a web-based access. The medical platform is extended in chapter 6 with autonomic computing components. The application of autonomic control loops is proposed in order to optimize performance and fault management of the system. Finally, in chapter 7 the overall conclusions of this work are summarized. In addition, two appendices are added. In appendix A the results of the technology adoption survey conducted among the Belgian hospitals is described in detail. The central question in this survey is: 'Have ICU units adopted information technology?'. Appendix B gives a high-level functionality overview of the COSARA platform, which was elaborated in chapter 4.

1.7 Publications

The research results obtained during this PhD research have been published in scientific journals and presented at a series of international conferences. The following list provides an overview of the publications during my PhD research.

1.7.1 A1: Publications indexed by the ISI Web of Science "Science Citation Index Expanded" [1]

1. Kirsten Colpaert, Eric Hoste, Sofie Van Hoecke, Dominique Vandijck, Christian Danneels, **Kristof Steurbaut**, Filip De Turck, Johan Decruyenaere *Implementation of a real-time electronic alert based on the rifle criteria for acute kidney injury in ICU patients.* Published in Acta Clinica Belgica, 62:322-325, 2007.

2. Barbara Claus, Valerie Vanderstraeten, Kirsten Colpaert, **Kristof Steurbaut**, Johan Decruyenaere, Hugo Robays *Comparison between an antibiotic dose alert and clinical pharmacist for acute kidney injury.* Published in Pharmacy World and Science, 31(2):254-254, April, 2009.

3. **Kristof Steurbaut**, Sofie Van Hoecke, Kirsten Colpaert, Kristof Lamont, Kristof Taveirne, Pieter Depuydt, Dominique Benoit, Johan Decruyenaere, Filip De Turck *Use of web services for computerized medical decision support, including infection control and antibiotic management, in the intensive care unit.* Published in Journal of Telemedicine and Telecare, 16(1):25-29, 2010. http://dx.doi.org/10.1258/jtt.2009.001008

4. Sofie Van Hoecke, **Kristof Steurbaut**, Kristof Taveirne, Filip De Turck, Bart Dhoedt *Design and implementation of a secure and user-friendly broker platform supporting the end-to-end provisioning of e-homecare services.* Published in Journal of Telemedicine and Telecare, 16(1):42-47, 2010. http://dx.doi.org/10.1258/jtt.2009.001011

5. Femke Ongenae, Femke De Backere, **Kristof Steurbaut**, Kirsten Colpaert, Wannes Kerckhove, Johan Decruyenaere, Filip De Turck *Towards computerizing intensive care sedation guidelines: design of a rule-based architecture for automated execution of clinical guidelines.* Published in BMC Medical Informatics and Decision Making, 10:3, January, 18, 2010. http://dx.doi.org/10.1186/1472-6947-10-3

[1] The publications listed are recognized as 'A1 publications', according to the following definition used by Ghent University: A1 publications are articles listed in the Science Citation Index, the Social Science Citation Index or the Arts and Humanities Citation Index of the ISI Web of Science, restricted to contributions listed as article, review, letter, note or proceedings paper.

6. Thierry Verplancke, Stijn Van Looy, **Kristof Steurbaut**, Dominique Benoit, Filip De Turck, Georges De Moor, Johan Decruyenaere *A novel time series approach for prediction of dialysis in critically ill patients using echo-state networks.* Published in BMC Medical Informatics and Decision Making, 10:4, January, 21, 2010. http://dx.doi.org/10.1186/1472-6947-10-4

7. **Kristof Steurbaut**, Kirsten Colpaert, Sofie Van Hoecke, Sabrina Steurbaut Chris Danneels, Johan Decruyenaere, Filip De Turck *Design and evaluation of a service oriented architecture for paperless ICU tarification.* Published in Journal of Medical Systems 2012, 36(3):1403-1416, (Online first accepted September, 20, 2010), http://dx.doi.org/10.1007/s10916-010-9602-0

8. Kirsten Colpaert, Sem Vanbelleghem, Christian Danneels, Dominique Benoit, **Kristof Steurbaut**, Sofie Van Hoecke, Filip De Turck, Johan Decruyenaere *Has information technology finally been adopted in Flemish intensive care units?* Published in BMC Medical Informatics and Decision Making, 10:62, October, 19, 2010. http://dx.doi.org/10.1186/1472-6947-10-62

9. **Kristof Steurbaut**, Kirsten Colpaert, Bram Gadeyne, Pieter Depuydt, Peter Vosters, Christian Danneels, Dominique Benoit, Johan Decruyenaere, Filip De Turck *COSARA: Integrated service platform for infection surveillance and antibiotic management in the ICU.* Published in Journal of Medical Systems, 36(6):3765-3775, April 2012, http://dx.doi.org/10.1007/s10916-012-9849-8

10. Kirsten Colpaert, Eric Hoste, **Kristof Steurbaut**, Dominique Benoit, Sofie Van Hoecke, Filip De Turck, Johan Decruyenaere *Impact of real-time electronic alerting of acute kidney injury on therapeutic intervention and progression of RIFLE class* Published in Critical Care Medicine, 40(4):1164-1170, April 2012, http://dx.doi.org/10.1097/CCM.0b013e3182387a6b

11. Femke De Backere, Hendrik Moens, **Kristof Steurbaut**, Kirsten Colpaert, Johan Decruyenaere, Filip De Turck *Towards automated generation and execution of clinical guidelines: Engine design and evaluation through the ICU Modified Schofield use case* Published in Computers in Biology and Medicine, 42(8):793-805, August 2012, http://dx.doi.org/10.1016/j.compbiomed.2012.06.003

12. **Kristof Steurbaut**, Femke De Backere, Annelies Keymeulen, Marc De Leenheer, Koenraad Smets, Filip De Turck *NEOREG: Design and implementation of an online Neonatal Registration System to access, follow and analyse data of newborns with congenital cytomegalovirus infection.*

Accepted for Informatics for Health and Social Care, October, 5, 2012, http://dx.doi.org/10.3109/17538157.2012.741166

13. **Kristof Steurbaut**, Steven Latré, Johan Decruyenaere, Filip De Turck *Autonomic Care Platform for optimizing query performance* Submitted to BMC Medical Informatics and Decision Making, 2013.

14. **Kristof Steurbaut**, Johan Decruyenaere, Filip De Turck *A Multidisciplinary Design and Development Methodology for ICU Medical Information Services* Submitted to Computer Methods and Programs in Biomedicine, 2013.

15. Barbara Claus, Kirsten Colpaert, **Kristof Steurbaut**, Filip De Turck, Dirk Vogelaers, Hugo Robays, Johan Decruyenaere *The Impact of an electronic daily antimicrobial alert system on pharmacist utilization in ICU* Submitted to Journal of Managed Care Pharmacy, 2013.

1.7.2 P1: Proceedings included in the ISI Web of Science "Conference Proceedings Citation Index - Science" [2]

1. **Kristof Steurbaut**, Sofie Van Hoecke, Kirsten Colpaert, Chris Danneels, Johan Decruyenaere, Filip De Turck. *Granularity of medical software agents in ICU - Trade-off performance versus flexibility.* Published in Advances in Intelligent and Distributed Computing, Studies in Computational Intelligence, Vol. 78, 2008, pages 207-216, 1st International Symposium on Intelligent and Distributed Computing (IDC), 2007, Craiova, Romania, October 18-19, 2007

2. **Kristof Steurbaut**, Sofie Van Hoecke, Kristof Taveirne, Kristof Lamont, Filip De Turck, Kirsten Colpaert, Pieter Depuydt, Dominique Benoit, Chris Danneels, Johan Decruyenaere. *Design of software services for computer-based infection control and antibiotic management in the intensive care unit.* Published in proceedings of the International Conference on Ehealth, Telemedicine, and Social Medicine (ETelemed), 2009, pages 87-92, Best Paper Award, Cancun, Mexico, February 1-7, 2009

3. Sofie Van Hoecke, **Kristof Steurbaut**, Yannick Beheyt, Frederik Debruyne, Bart Dhoedt, Johan Decruyenaere, Filip De Turck. *Automatic WS-BPEL composition of medical support services in the ICU.* Published in proceedings of the International Conference on Ehealth, Telemedicine, and Social

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Medicine (ETelemed), 2009, pages 251-256, Cancun, Mexico, February 1-7, 2009

4. Kirsten Colpaert, Eric Hoste, **Kristof Steurbaut**, Dominique Benoit, Filip De Turck, Johan Decruyenaere. *Impact of knowledge of rifle status on therapy for AKI and AKI progression.* Published in proceedings of Intensive Care Medicine, September 2010, pages S171-S175, 23rd Annual Meeting of the European Society of Intensive Care Medicine (ESICM), Barcelona, Spain, October, 9-13, 2010

5. **Kristof Steurbaut**, Filip De Turck. *Autonomous platform for life-critical decision support in the ICU.* Published in Managing the dynamics of networks and services, Lecture Notes in Computer Science, pages 69-72, 5th International Conference on Autonomous Infrastructure, Management and Security (AIMS) 2011, Nancy, France, June 13-17, 2011

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2. Barbara Claus, Kirsten Colpaert, Valerie Vanderstraeten, **Kristof Steurbaut**, Johan Decruyenaere, Hugo Robays. *Comparison of the antibiotic dose prescription through an antibiotic dose alert system and by a clinical pharmacist in critically ill patients with renal dysfunction* Published in proceedings of the ACCP/ESCP International Congress on Clinical Pharmacy, 2009, Orlando, USA, April 24-28, 2009

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5. Kirsten Colpaert, Sem Van Belleghem, Dominique Benoit, **Kristof Steurbaut**, Sofie Van Hoecke, Filip De Turck, Johan Decruyenaere. *Has information technology finally been adopted in ICUs?* Published in proceeding of the 22nd European Society of Intensive Care Medicine (ESICM) annual congress, Vienna, Austria, October 11-14, 2009.

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2

A Multidisciplinary Design and Development Methodology for ICU Medical Information Services

The design and development of medical information services is increasing in complexity. There is an explosion of collected medical digital data while medical guidelines are becoming more personalized with analysis of the complete patient's state including numerous clinical results. It poses challenges for the software developer to create solutions that assist in the patient management but also fit in the daily workflow of physicians. We have involved clinicians in all stages of the design of clinical software solutions. By choosing a multidisciplinary design and development approach with participation of software researchers and medical experts, we believe adoption of health care information technology will be stimulated. In this article, we detail the methodology and our experiences of the healthcare projects in the Intensive Care Unit (ICU), in particular during the COSARA project. By describing our methodology we aim to encourage the further development of software solutions in the ICU.

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2.1 Introduction

The evolution of hospital information systems provides useful experiences and lessons for designing and developing future information systems [1]. Early clinical developments were restricted to major tertiary centers and large government projects [2]. In the 1960s, the main focus for introducing information systems was for financial needs and revenues, developed on large mainframe computers. On the mainframe system centralized systems were deployed rather than distributed systems. Using a client-server architecture, users entered and consulted data through terminals connected with the central mainframe. Later, components were distributed and shared across systems. The financial functionality was gradually extended with clinical functionality. In the 1970s, microchips and microprocessors became available. This was followed by the availability of the personal computer (PC) in the 1980s, that offered expanded memory capacity and an increased computation speed. The computing and calculation processes were soon included in most bedside devices including the monitoring of digital signals of cardiac output, respiratory display and pulse meters. Databases were created to store patient records allowing analysis for research. The introduction of the internet has enabled the provisioning of remote access to medical information since the 1990s. This has also influenced the ease of access to medical information. The focus was first on tools only for clinicians and health care workers. This focus has shifted to patient empowerment. Medical knowledge is now available via web portals to everyone. Based on patients' individual parameters, specific advice is given. Table 2.1 gives a chronological overview of the early hospital information systems, which reported upon in the appendix to this article.

Date	System	Hospital (H.)	Location
1965	TMIS	El Camino H.	Maintain View, CA, US
1967	HELP	LDS H. (Intermount)	Salt Lake City, UT, US
1968	COSTAR	Massachusetts General H.	Boston, MA, US
1972	RMRS	Wishard Memorial H.	Indianapolis, IN, US
1976	PROMIS	Vermont	Burlington, VT, US
1984	BICS	Brigham and Women's H.	Boston, MA, US
1988	CHCS	Military clinics	US
1996	VistA	Depart. of Veterans Affairs	US
2001	AMRS	Health centres in Kenya	Kenya

Table 2.1: Chronological overview of early hospital information systems.

Although medical informatics has evolved in a rapid pace, studies show that software solutions often suffer from poor compatibility with the clinical workflow. A national study [3] in Finland showed that physicians are very critical to ICT systems and the compatibility with their workflow was regarded poor.

Although by modeling the information and workflows, the relationship between healthcare work and technological change may be analysed [4]. The model should describe the work practice, evaluate the flows' adequacy and conjecture the impact of changes to it. Clinicians are more likely to use the technology if it is proven to be successful [4]. However, the impact of the use of information technology to health services in ICU is difficult to measure and few results of randomized trials were published [5]. In [6], Leonard and Sittig faced within the IMPROVE-IT (Indices Measuring Performance Relating Outcomes, Value and Expenditure through Information Technology) collaborative initiative the question whether better IT leads to better data and better information, hence to better decisions, and in the end to better health outcomes. The goal of the initiative is providing evidence that increased IT capabilities, availability and use lead directly to improved clinical quality, safety and effectiveness within the inpatient hospital setting. Medical systems have evolved but still seem not able to meet all expectations of the physicians in critical care departments. Unintended consequences and errors were attributed to the introduction of CPOE systems such as mismatches with the clinical workflow and paper persistance [7]. Physicians are also willing to participate in healthcare IT development [8], but they are often not involved in its design and development. The involvement of nurses in the design and implementation process can improve health information technology [9]. In 2009, an analysis of health information systems' implementation was conducted [10]. Slow adoption rates for information technology solutions are noticed in health care. Design and development support should clear the workflow mismatches and lead to successful health solutions.

In this paper, we describe the methodology of the development of the medical information services at the Intensive Care Unit of Ghent University Hospital, Belgium. We focus on the COSARA (Computer-based Surveillance and Alerting of Nosocomial Infections, Antimicrobial Resistance and Antibiotic Consumption in the Intensive Care Unit) research project and the decision support services deployed in the ICU. This paper described the requirements analysis, design considerations and multidisciplinary methodology that were applied in this software process. The technical details and features have been detailed in [11]. By describing our design and development approach, it is our aim to encourage the further development and adoption of IT solutions in this field. As such, the paper concludes with the lessons learned.

2.2 Background

In this section, we explain the terminology and detail the ICT setting in the ICU.

2.2.1 Terminology

Health Information Technology (HIT) is used to describe the application of computers and technology in health care settings [12]. *Medical Informatics* generally refers to informatics - the acquisition, storage and use of information - applied in health care [12].

- A *Computer-Based Information System (CBIS)* is a single set of hardware, software, databases, telecommunications, people and procedures that are configured to collect, manipulate, store and process data into information [13]. A *Hospital Information System (HIS)* combines financial and medical data about each patient in a common set of data files for computer processing [14]. A HIS has been defined with the following functions [15]: provisioning of computer-based patient records; facilitating information and communication to and from clinicians and between clinical services; providing clinical decision support and alerts or reminders; establishing a database; supporting education; and guarantee security, policy requirements and system reliability [15]. The system manages both administrative and medical data. This system is also known as *Patient Data Management System (PDMS)*.

- The *Electronic Health Record (EHR)* is defined in ISO/TR 20514:2005 as a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely and accessible by multiple authorized users [16]. The EHR offers a complete overview of the individual patient with retrospective, concurrent and prospective information. The EHR is the computer-based replacement of the paper charts. Where in the past paper-based approaches were used to keep track of patient records, data is now stored as electronic patient records. The EHR system is a system for recording, retrieving and manipulating information in EHRs [16]. The *Laboratory Information System (LIS)* processes and stores information generated by the medical laboratory.

- The *Computerized Provider Entry (CPOE)* allows physicians to enter medical orders for services or medication electronically and to maintain or change medication administrative records. The CPOE system is designed to replace the paper-based ordering in the hospital [17]. Most systems also offer alerting of duplicate orders or unsafe combinations and suggest alternative medications.

- The *Picture Archive and Communication System (PACS)* stores the X-rays images and related metadata electronically. PACS refers to the infrastructure for image archiving and the medical records in an integrated system [18].

The *Digital Imaging and Communications in Medicine (DICOM)* standard facilitates interoperability of medical images [19].

- *Clinical Decision Support (CDS)* refers to the computerized algorithms and guidelines to support the decision making process of the physician. Collected data in the EHR is used as basis for the decision making. The system is defined as an active knowledge system which uses two or more items of patient data to generate case specific advice [20]. The assistance is provided in the form of an interactive application, a reminder or alerting service.

- *Evidence Based Medicine (EBM)* and guidelines are intended to provide physicians with the best evidence on how to manage specific disease processes by integrating research evidence with clinical expertise and patient values. The guidelines are difficult to use and implement because they are often too complex or too general, and not patient specific [21].

2.2.2 Software development at Ghent University Hospital ICU

Ghent University Hospital is one of the largest hospitals in Flanders, Belgium. The ICU has an annual average of 4,000 admissions. In 2003, the computerization of the ICU unit started in order to shift from paper-based records to electronic patient records. Figure 2.1 shows the infrastructure of the medical ICU, located at 12K12, in Ghent University Hospital. The ward is equipped with bedside computers, desktops on nursing stations and computers in the physicians and assistants' offices. On the bedside computer, as shown in Figure 2.2, a commercial ICU platform, GE Clinisoft, is running. The GE Centricity Critical Care Clinisoft system is an information system with a built-in CPOE and connections to monitors, ventilators, syringe pumps and other hospital information systems [22]. It supports the prescription process of medication and infuses, shows vital information and is used for the registration of given medications. There is also a task list to manage the workflow of the nurses. Although functionalities for the registration of administrative data, diagnoses, medications exist and although the implementation is also evolving, at this moment the system does not incorporate an infection overview and linking module of antibiotics, infections and microbiology for infection disease management and antibiotic control.

2.3 Methodology

Our applied methodology consists of the following phases: (i) Requirements analysis and input of stakeholders, (ii) Design and creation of a prototype, (iii) design of medical services, (iv) Technical implementation, deployment, (v) Evaluation, (vi) Feedback and optimization, as shown in Figure 2.3. In every phase there was

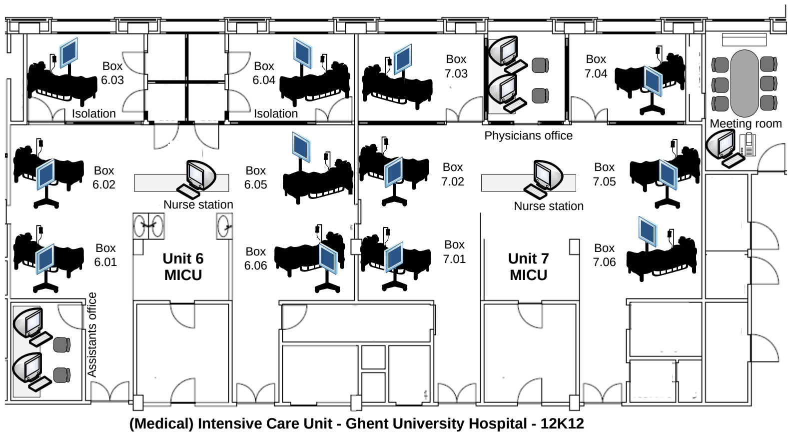

Figure 2.1: Overview of the medical ICU in Ghent University Hospital.

Figure 2.2: Bedside computer in the ICU.

a multidisciplinary cooperation between clinicians and software researchers. This methodology was used to create an infection surveillance and antibiotic management platform. Our objective was to create a platform which collects and integrates data automatically, allows the human registration of additional metadata, displays a complete view of the patient's state or history on the bedside screen, and offers direct decision support facilities. In this section we detail the experiences during the study at Ghent University Hospital.

The complete development cycle is not performed just once, but moreover it is an iterative cycle, which means that the design, develop, evaluate cycle is run during a short time frame and several times. This accelerates the development of the clinical services. A holistic development approach to improve the impact of eHealth technologies has been proposed in [23]. The approach provides thoughtful visions on the design and development of healthcare applications.

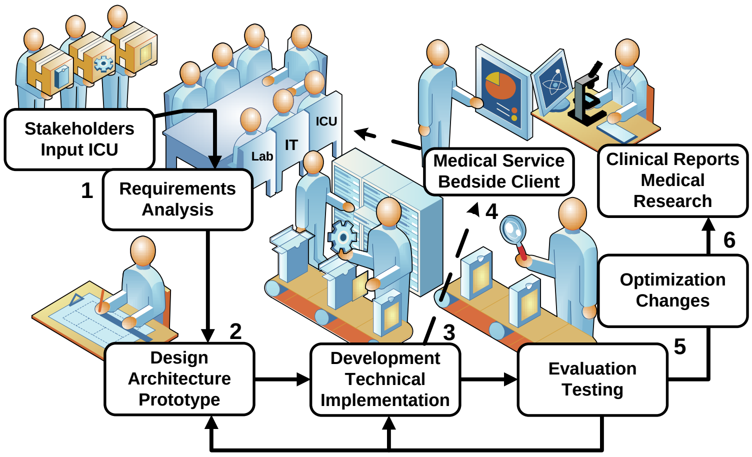

Figure 2.3: Multidisciplinary design, development and evaluation phases.

2.3.1 Phase 1: Requirements analysis and stakeholders' input

Meetings were organized with the stakeholders: the physicians, health IT administrator, software researchers and developers, to capture the requirements and needs. The physicians had different backgrounds and expertise including intensivists, pneumologist, responsible for burns unit, laboratory researcher, etc. but with a common aim to optimize antibiotics use and visualize infection occurrences in the software platform. When no final decision in a discussion could be reached, for example concerning the amount and selection of medical data on a computer dialog screen, the medical team or software team organized a small target group meeting, carrying out the specific needs in detail. After the submeetings the value of specific requested features was specified and communicated to and discussed with the software researchers. Use cases, scenarios and flowcharts supported these discussions.

The required functionality for the ICU systems, as proposed during these meetings, consists of (1) the data collection and automation of manual processes, (2) the integration of different data sources with (3) the creation of a complete electronic patient record, (4) the design and development of services platform with services for surveillance and alerting of nosocomial infections, antimicrobial resistance and antibiotic consumption and services to track kidney failure and organ failure. The information system also requires (5) optimization through performance monitoring and autonomic actions. The clinical data is presented on (6) the bedside application. Fig. 2.4 and this section illustrate the required functionality for clinical IT systems.

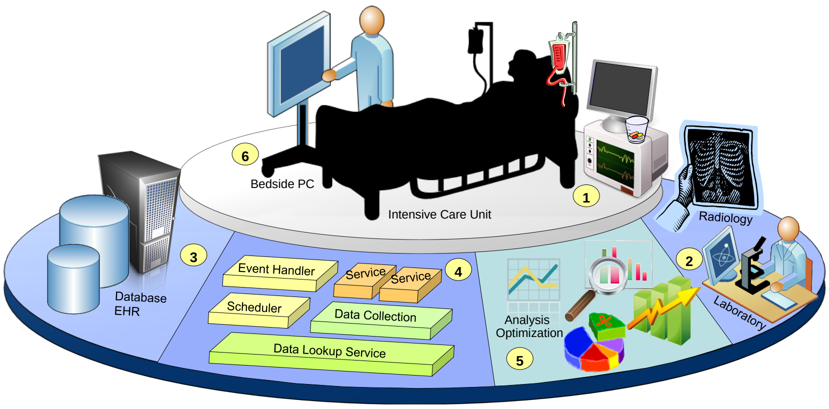

Figure 2.4: Overview of the Information System in the Intensive Care Unit.

1. **Data Collection and Process Automation**: The patients' vital signs, measurements and clinical observations are collected in electronic records. Despite the introduction of information systems, administrative processes and clinical guidelines are still being tracked on paper forms. For example, a transition to a paperless automated process can be established in the billing administration of medical procedures.

2. **Data Integration**: Besides collecting bedside monitoring and observations, the laboratory and radiology department also produce data results concerning the patients' blood results and X-rays. The availability of relevant information is crucial for physicians to make a diagnosis. Unfortunately, data is spread across applications and databases in the ICU. The data reports tend to be departmental and not integrated with each other [24]. The data is fragmented, not structured and not linked with information in other information systems. ICU physicians are specifically interested in infection related data and antibiotics consumption. In order to get insights in occurring disease patterns and physicians' motivation for prescribing antibiotics, data from several sources should be combined. IT can facilitate the integration of diverse data sources in one single system.

3. **Database with Electronic Patient Records**: The creation of a data repository with a complete infectiological record of each patient offers opportunities to apply computer-based clinical decision support services and also opens ways for longitudinal research.

4. **Design and Development of Services Platform**: Services should be designed and developed for data retrieval, synchronization, decision support

such as clinical guidelines with advice and generation of alerts on patients conditions or alarming values. A platform should support and integrate these services. Output is delivered on screen, to a mail client or a smartphone. Alerting can be applied in different scenarios: (i) offering feedback on physicians' interactions, (ii) issuing a critical alert, (iii) suggest another therapy or change in treatment, (iv) retrospectively analyse the patients evolution and physicians' decisions. In our research, we design services for (a) the computer-based surveillance and alerting of nosocomial infections, (b) antimicrobial resistance and antibiotic consumption and (c) services to alert in case of kidney failure and organ failure.

5. **Optimization**: Analysis of data for both clinical research and platform management is established. The platform is extended with autonomic components in order to automate maintenance and increase robustness.

6. **Bedside Application**: The bedside application assists physicians and nurses in their workflow.

2.3.2 Phase 2: Design and Prototype Creation

The platform combines and integrates collected patient data and adds interpretation to the values. The processing units or services together form a service oriented platform with services dedicated to data retrieval, handling of communication and alerting, and evaluation of a guideline. First, data is routinely checked for changes using a polling mechanism, secondly, the data is compared and checked against clinical rules. A substantial part of the platform is devoted to the identification, structuring and gathering of data over the large set of different clinical datasets, which all have their own database drivers, queries and configuration. The abstraction layer hides the complexity of the underlying database, the location of the database and the structure of the tables. If new data records are available in the database, these records are immediately retrieved. Then the state of the patient is reevaluated based on the changed data parameters. If this state changed to an alarming state, the physician gets informed with an alert via mail or text message. For example, services can track adherence to medical guidelines and alert or remind of changes in antibiotics therapy. However the potential of these services, commercial information systems do not offer a wide range of decision support services.

The results of the services are displayed in developed client applications on a bedside PC in the ICU. After the collection of initial requirements of the medical staff, first a prototype is made in code or visually on a slide screen. The physicians evaluate the prototype and add features or request changes before the actual implementation.

2.3.3 Phase 3: Technical Implementation

In this section we give a short overview of the used technologies in the ICU medical information services.

Service Orientation: Software design has evolved from monolithic applications to highly modular distributed services. Functional decomposition is a powerful technique for reducing the complexity of software into smaller partitions. Service-orientation is widely accepted as an important technology for enabling distributed computing. It provides an easy distribution of services and allows easy integration with both internal and external services using web service standards. Service-orientation (SO) expresses an architectural style that defines the use of loosely coupled services, which serve as building blocks for distributed software applications. It encourages a style where connectivity or interaction among software pieces is central and where the software design is broken down in interacting services. These services can be seen as facades that encapsulate the inner implementation and expose functionality to the outside through their service description. Web service technology is one way to implement a service-oriented architecture, providing platform interoperability, simplicity and platform neutral behavior. The web service (WS) has an interface description (Web Service Description Language or WSDL) and other systems interact using SOAP-messages, typically using eXtensible Markup Language (XML)-serialization in conjunction with standard Internet protocols. A service composition is a coordinated aggregate of services.

OSGi: OSGi is a module-based service platform designed for the Java programming language [25]. It implements a dynamic component model: OSGi components are called bundles and these bundles can be remotely installed, started, stopped updated and installed without requiring a reboot of the system. As such, the OSGi framework takes care of the application life cycle management of these bundles. OSGi bundles were initially intended to be grouped on one physical device, but the communication with remote OSGi bundles is also possible. Furthermore, OSGi incorporates some often required bundles such as the EventAdmin bundle, which features a publish/subscribe model that can be used to implement the bus functionality. The ICU bedside client is not an easy accessible environment, so there is a need to remotely manage these clients. The modifiability demands a simple and fast method to update the client instances using OSGi.

Rule based Systems: Rule-based systems [26] are used to represent and manipulate knowledge about a specific domain in a declarative and straightforward manner. The Knowledge Base models the domain-specific knowledge, described by a set of Rules. Rules are simple mathematical implications of the form A to C, where A is the set of conditions, or antecedent and C is the set of actions to be taken, or consequent. The Working Memory consists of the data on which the system will operate. This data is usually represented by a set of Facts that are known to be true in the current context. Finally the Rule Engine, or more specifically the Inference Engine, enables the Rule-based system to draw deductions from the Rules in the Knowledge Base. This is done by attempting to match the Facts in the Working Memory on the antecedents of the Rules. If a condition of a Rule is determined to be valid, it is fired and its predefined consequent will be executed. Adding expert systems to health care systems has the potential to enhance the quality and efficiency, for example in the computerization of guidelines [27].

Ontologies: An ontology is a complex data structure, which is oftentimes adopted to model real-life application domains. Such an ontology is made up of concepts (also called classes) describing the entities in the application domain. Properties (also called relationships) link those concepts together to describe the relationships between the concepts. Additionally, datatypes are supported and can be used to link a concept with a primitive datatype value.

2.3.4 Phase 4: Design of Medical Services

We designed and developed services for infection disease management, antibiotic management, kidney dysfunction and organ failure.

2.3.4.1 Infection Disease Management

Infection control is of great importance in the ICU [28]. Nosocomial infections concern 5 to 15% of hospitalized patients and can lead to complications in 25 % to 30 % of those patients admitted to ICUs. Nosocomial infections are infection that are not present at the time of admission but occur 48 hours after admission due to hospitalization. These infections are associated with unfavorable clinical and economic outcome. Current information systems do not offer functionality to analyse or integrate infection related information. This results in a labor-intensive analysis and limited integration of information regarding the match between nosocominal infection and the associated microbiology and given antibiotics.

2.3.4.2 Antibiotic Services

The Institute of Medicine (IOM) identified antibiotic resistance as one of the key threats to health in the US. Therefore it's one of the US Center of Disease Control and Prevention (CDC) top concerns. CDC has launched a 'Get Smart: Know when Antibiotics Work' campaign since 1995. In 2003, additional awareness about the use of antibiotics was created in a national media campaign. This campaign aims to reduce the antibiotic resistance by promoting adherence to appropriate prescribing guidelines, decreasing the demand for antibiotic for viral respiratory infections among healthy people, and increasing the adherence to prescribed antibiotics for upper respiratory infections. In Belgium, a national campaign 'Antibiotics: use them less often, but better' for more appropriate use of antibiotics was launched in 2001. On November 18th, an annual European public health initiative takes place, called: 'The European Antibiotic Awareness Day'. The European Health Protection Agency has also created an antibiotic and hygiene teaching resource kit 'e-Bug', an interactive website with games, puzzles, disease facts to create awareness among children. Intensive Care Units have the highest usage of antibiotics, with often double or triple the defined daily doses (DDD) of the rest of the hospital [29]. Moreover, ICUs face the problem of antibiotic resistance for nosocomial infections. Antimicrobial stewardships are very important and relevant in the ICU, as these programs strive to combat resistance, improve clinical outcomes and control costs by improving antimicrobial use [30].

Decisions in antibiotic therapies can be guided by computer-based services. In this section we propose the services:

- *Antibiotic IV-PO Switch Service*. The purpose of this service is to identify patients at the Intensive Care Unit (ICU) who are candidate for an early switch from intravenous (IV) antibiotic therapy to oral (per os, PO) antibiotic therapy.
- *Antibiotic Dose Service*. This service evaluates the creatinine clearance value of the patient and checks if the given antibiotic dose is compliant with the local hospital policy.
- *Antibiotic Duration Service*. This service reminds the physician of prolonged usage of antibiotics.

2.3.4.3 Kidney Dysfunction and Organ Failure

- *RIFLE Service*. This service detects kidney failure and gives an alert to the physician. RIFLE stands for RIFLE stands for 'Risk, Injury, Failure, Loss and End-stage kidney disease'. In the service, based on the urinary output and on serum creatinine levels, an alert for acute kidney injury (AKI) can be derived. A calculation is required based on baseline serum creatinine concentration and weight. The manual follow-up is labor-intensive. By creating a RIFLE service, changes in the patient's monitored values can be controlled immediately and alerts are raised if alarming values are detected [31, 32].
- *SOFA Service*. The SOFA (Sequential Organ Failure Assessment) score, as shown schematically in Figure 2.5, is used to determine organ dysfunction

and organ failure of critically ill patients. The score is calculated based on six parameters (respiratory, coagulation, liver, cardiovascular, central nervous system, renal). It is mainly used as an outcome prediction for the patient during the stay at the intensive care unit (ICU) and is associated with morbidity and mortality. Calculating a periodic SOFA score at ICU is a good indicator for the prognosis of the patient and also a predictor for mortality. The developed service calculates the score daily for all patients staying at ICU. For each of the parameters the worst score over a 24-hour period is used in the total score.

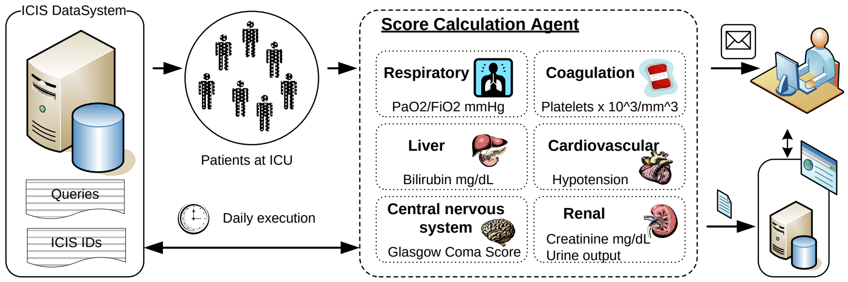

Figure 2.5: Illustration of the developed SOFA Service for the intensive care unit.

2.3.5 Phase 5: Evaluation

We investigate how the current platform and services can be optimized. The evaluation consists of a technical and clinical evaluation. The technical evaluation includes performance tests. In the clinical evaluation, we check data consistency. A dedicated study nurse was appointed with an evaluation task of the platform. At the start of the development, mail messages were send to the developers and evaluation meetings were planned to exchange the user experiences. With the introduction of a feedback website, the noticed faults or request for changes could be registered immediately in a web site, directly connected with the software developers.

2.3.6 Phase 6: Optimization

Although the offered services might be complex and advanced, the management of the computing systems that support them is often still very static: a computing system is manually configured by an operator and any type of changes (e.g., triggered by changes in the environment) again requires a manual intervention by the same operator. Autonomic systems offer a solution to the shortcomings of current static management approaches. The term **autonomic computing** was originally coined by IBM [33] in its aim to develop a new generation of intelligent computer systems. The term autonomic refers in IT to the ability of a component to manage itself based on high-level administration objectives. With an autonomic system, human operators are freed from the burden of performing low-level management and can concentrate on the higher level management process. An autonomic system is thus able to govern itself (self-governance).

2.4 Status report

Several studies evaluate the effects of computer-based support on improvements in health service delivery. Schiff and Bates (2010) believe the key selling point for EHRs is the potential for preventing, minimizing, or mitigating diagnostic errors [34]. In [35] (2009), it is shown that a patient data management system with nutritional advice and automatically generated feedback improves the delivery of perioperative nutrition. Other studies examine the impact on mortality and patient safety by the investments in electronic medical records. Computerized clinical decision support offers a method to decrease variability, test interventions, and validate the improved quality of care [21] [36].

In this section we enumerate the open challenges of ICU information systems. These challenges originate from the registration of medical data on one site and on multiple sites, the development of medical services with clinical decision support functionality, and the optimization of the proposed IT solutions.

- **Data overload**: The critical care unit has to cope with a large amount of data. This causes an information overload among the clinicians. Methods to filter and display selective data were needed.

- **Reducing hand entry data**: Problems of data quality are created by manually input of data [37]. Input of hand written data is error-prone. Therefore there is a need to interface with clinical systems in order to automate and validate data transfer automatically. **Quality control of data** is an issue that still remains today.

- **Integration of hospital systems and data**: The ICU requires the integration of data from several clinical sources (laboratory, radiology, pharmacy) to make appropriate diagnostic and therapy decisions. Many systems were build as stand-alone systems, not interfacing with each other.

- **Knowledge based systems** are needed to assist and suggest therapies. Decisions are based on expert knowledge and policy rules.

- **Stimulating user acceptance and system adoption**: First of all, computer system have to be robust, offer adequate performance and be reliable. If a screen takes more than 2 seconds to load, it is unacceptable for the clinician [37]. Also, if they have to page through 2 or 3 screens, the system is turned away. The system has to be user friendly, have an intuitive interface which is easy to use without large training time. Second, routine work can be replaced by computerized actions. For example, time-consuming checks on medications, routine tasks and manual investigations of recurrent patterns could be performed by computer actions and alerting facilities. Third, systems should create benefits in the decision support for the physician and for large research studies. For example, if retrieval tasks and linking of data can be automated in a software tool, an enormous potential for clinical studies is created.

- **Access from multiple sites**: Access to medical data should not be constrained to one single point of access, but medical data should be available at the point of care, for physicians and nurses, and also remotely. For example, data registration of newborns are also performed by general practitioners. Today, these registrations are only written on paper, as there is a lack of an on line registration site. By building an on line platform, patient data can be reused and analysed more easily.

- **Quality of service**: The performance and robustness of the proposed IT solution should be guaranteed. Therefore, there is a need for monitoring and logging of flows between services and in the platform.

The challenges have been addressed in the authors' publications. In [38], the manual administrative process for tarification and billing is automated, thereby reducing hand entry of data. In [11, 39], which present the COSARA platform, the data services handle the data overload from several medical sources. An integrated services platform is proposed and clinical knowledge is incorporated in medical decision support services [27, 31]. The NEOREG platform offers secure access to multiple general practitioners in order to follow-up data of newborns. Furthermore, we investigated extensions of the services platform [40] to guarantee adequate quality of service. Adoption of information technology has also been surveyed in Flemish ICUs [41].

2.5 Lessons Learned

The purpose of this section is to share the lessons from our design and development of medical information services. We involved the clinicians, the end-users, actively in all design and development phases. Besides active user participation, the application was constructed in a generic, modular way, paving the path for reuse in future services. The development cycle was iterative and incremental, including many evaluation points. Further a good understanding of the infrastructure and of the capabilities and training level of the user were important. The main lessons learned are described next:

1. The **commitment and participation of the physician is essential** for the medical services. First, time must be taken to work out a domain analysis including the objectives, detailed requirements and needs. The active involvement of the end-users, the clinicians, is crucial. It sets the expectations clear from the start. In contrast to other projects, in which the end-user only participates at the start and end of the project, the active collaboration with periodic user-driven evaluations of the medical software was essential for the success of the projects.

2. To ensure reuse of the software components, the **design must be modular and generic**. Being able to reuse a component, for example the data component, reduces development time. Therefore in the design phase the components must be well-defined to stimulate future use in other medical services.

3. **Data quality is extremely important** in the clinical information service. The developments should be **evaluated periodically** by the medical end-users, the physicians and nurses. The evaluation criteria should already be defined in the requirements phase, to match the expectations. For example, a wizard asking physicians motivation for making a prescription should not hamper the clinical workflow and should be completed in less than a minute. Validation points should be set, even for data originating from external clinical sources. We also propose to build-in monitoring and logging, for the analysis of the application, the data flow and the underlying server.

4. The end-user is usually not aware of the system infrastructure on which the software application is deployed. However, it is necessary to gain a **clear understanding in the integration points, the available database structures and the current data flow** in the systems for the software developer.

5. Physicians are often not familiar with all the functionalities of the software system. **Training should create awareness of the functionalities**. In addition to the participation of clinicians in the design and development, it is important to make them aware of the reporting functionality in the developed registration and information system. For example, selecting patients who conform to specific medical conditions or therapies become much easier in the developed application. If the data collected by the application can

be used in clinical studies and statistical analysis, the application also offers benefits for research and administration.

2.6 Future Plans

Future plans include conducting research for the automatic generation and deployment of clinical guidelines in the hospital and performing clinical studies using the data gathered by the COSARA platform. In the first plan, the in-house development of decision support services that incorporate medical protocols is targeted. By offering an editor and composition tool, the physicians should be able to edit and reconfigure the guidelines. The guidelines are presented flowcharts and implemented as rules in the application. This would decrease the service development time. Future research about medical guidelines construction will be conducted. Second, clinical studies evaluating the impact of the COSARA application on the medical data quality are being performed. The maintenance of a comprehensive clinical database not only affects the decision process at the point of care. By building a large historical database, data mining for clinical research can be applied.

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Conflict of Interest

The authors declare that they have no conflict of interest.

2.7 Appendix: History of Hospital Information and Clinical Decision Support (CDS) Systems

2.7.1 Technicon Medical Information System (TMIS)

The development of one of the first hospital information systems, the *Technicon Medical Information System (TMIS)*, started in the El Camino Hospital, Mountain View, California, US in 1965 [42]. The hospital information system is well known, because of its pioneering role with the CPOE system and later as one of the first customers of the commercial information system Eclipsys. The system includes physicians' order entry, result reporting, medication tracking and scheduling, vital signs, flow sheets, active patient care and daily management tasks. It was build as a spin off of the space program, in conjunction with Lockheed Missiles and Space Company in Sunnyvale, California, US. The technology advancements developed for in space, could have applications on earth. In 1971, it was sold to Technicon Data Systems (TDS) and used in the patient care unit. Later, the medical system was acquired and renamed by Eclipsys. Its original database M1 was influenced by MUMPS. The *Massachusetts General Hospital Utility Multi-Programming System (MUMPS)* [15] was a programming language created in 1960s, for use in the healthcare sector. The TMIS product disappeared in the late 1990s.

2.7.2 Health Evaluation through Logic Processing (HELP)

The *Health Evaluation through Logic Processing (HELP) System* is one of the best known pioneering hospital information systems. The system is operational since 1967 in the Latter-day Saints (LDS) Hospital at Salt Lake City, Utah, USA, which is now part of the Intermount Health Care (IHC) group. LDS is a 520 bed private acute care hospital. Initially developed to support the heart catheterization laboratory and open heart ICU with techniques for diagnosis, and evaluation of patients to investigate cardiovascular abnormalities through mathematical modeling, the system evolved for wider use in the ICU [43]. The founder of HELP, Dr. Homer R. Warner, is seen as one of the fathers of Medical Informatics because of its groundbreaking work in this field. Already in mid-1950s, he began with computer-based decision support in cardiology. The idea of HELP was to create a system offering automated clinical decision support, in which the computer can recognize patterns of events in the patients' conditions based on gained knowledge from historical patient cases. The hospital information system was later extended with the use of computer-based antibiotic and infection assistant services [44]. The foundations of HELP can be found in several commercial systems. Three basic functions were supported: (i) data acquisition, (ii) data interpretation and (iii) data review [45]. 3M Health Information Systems acquired the rights to HELP [46]. Their aim was to evolve the system towards distributed processing of protocol and alert logic and establish better performance while including administrative facilities such as scheduling, billing and referral services [47]. In [24] the transition towards the construction of HELP II is described. Technological advances in software tools and database standards and inclusion of features such as longitudinal records for both inpatient and outpatient, Health Level 7 (HL7)-integration with departmental subsystems, and wide application of decision support, stimulated this transition. Examples of medical reports that assist decision-making include a diabetic report that combines glucose values with insulin therapy records, infectious disease reports correlated with antibiotic therapy and White Bloodcell Count (WBC), temperature, renal function [24]. In 2005, Intermount partnered with GE Healthcare to start developing the next-generation clinical information system [48]. In February 2011, the new Homer Warner Center for Informatics Research (HWCIR) opened in Salt Lake City in order to accelerate the developments in information system tools to help doctors and nurses better care for patients. In [45], experiences with the HELP system are discussed. It is shown that computer systems can contribute to improvements in the quality of medical care and in the efficiency of care delivery. It advocates an active aid of clinical computer systems in health care.

2.7.3 Computer Stored Ambulatory Record (COSTAR)

The *Computer Stored Ambulatory Record (COSTAR)* was developed between the Massachusetts General Hospital, National Center for Health Services Research, Digital Equipment Corporation (DEC) [49] and the Harvard Community Health Plan (HCHP) by Barnett and Grossman in 1968. It was programmed in MUMPS. Support for patient registration, scheduling, retrieval and storage of medical data, billing functionality was included in COSTAR. Two system characteristics enabled usage at multiple sites: (i) modular design allowing reuse of separate modules, and (ii) the extensible data dictionary of medical terms. COSTAR was included in the Navy Occupational Health Information System (NOHIMS) as medical information component, to collect current and historical demographics and patient data [50]. In 1988, MUMPS became an IBM supported programming language.

2.7.4 Regenstrief Medical Record System (RMRS)

The *Regenstrief Medical Record System (RMRS)* has its origin in 1972, when Dr. Clark and Dr. McDonald started with the creation of computer-stored medical records for their diabetes patients. The RMRS captures laboratory results, narrative reports, orders, medications, radiology reports, registration information, nursing assessments, vital signs, EKGs, and other clinical data [51]. The aim of RMRS was to eliminate the paper based records, reduce work of clinical book keeping, make data available for clinical, epidemiological, outcome and management research [51]. It evolved to a system with more than 1.5 million patients. The system was used in Wishard Memorial Hospital in Indianapolis. It also provided rule-based reminders in the clinicians' workflow.

2.7.5 Problem Oriented Medical Information System (PROMIS)

The *Problem Oriented Medical Information System (PROMIS)* was a hypertext reference system for the maintenance of electronic health records. Dr. Lawrence Weed launched the project in 1976 [52]. The system, developed by the University of Vermont, included a touch sensitive screen terminal [53] for access and input of medical records.

2.7.6 Brigham Integrated Computing System (BICS)

The *Brigham Integrated Computing System (BICS)* provides clinical, administrative and financial computing services to the Brigham and Women's Hospital (BWH), an academic tertiary-care hospital in Boston, US [54]. The computing in BWH began as a port of the Beth Israel Hospital mini-computer-based Meditech Interpretive Information System (MIIS) in 1984. Initial BICS developments in 1988 had two purposes: (i) create a new client-server platform and (ii) shift from the passive role of the computer as a reporter, to an active role for the computer in reducing adverse events, reducing cost, and promoting optimal quality of care [54].

2.7.7 Composite Health Care System (CHCS)

In the 1988, the implementation of the *Composite Health Care System (CHCS)* was started by the US Department of Defense (DoD) as follow up of the earlier TRIMIS system. The system was developed with functions supporting the laboratory, radiology, pharmacy, and patient appointment scheduling [2]. The core components of 3M's Health Information System, Care Innovation are adopted in the CHCS II. Its successor, the *Armed Forces Health Longitudinal Technology Application (AHLTA)*, has stored the health records of 9.2 million military personnel, family members and retirees since 2004.

2.7.8 Veterans Health Information Systems and Technology Architecture (VistA)

In the late 1970s, the US Office of Data Management and Telecommunications (ODM&T) was asked to computerize the Veterans Affairs in the US [55]. The Department of Medicine and Surgery (DM&S) supported the computerization outside the purview of ODM&T by creating the DM&S Computer-Assisted System Staff (CASS) Office in 1977. In the Decentralized Hospital Computer Program (DHCP) [55] architectural principles and blocks became central such as interactive programs, use of mini-computers, MUMPS as programming language, reusable modules, and rapid prototype development. The DHCP system was deployed first in 1983 and has evolved since then, for example by the visual layer implementation in Delphi programming language and the shift to a three-tiered architecture. In 1996, it was renamed into VistA. An alternative open source implementation based on VistA EHR is WorldVistA EHR [56].

2.7.9 AMPATH Medical Record System (AMRS)

The *AMPATH Medical Record System (AMRS)* was designed for the management of patients with HIV in sub-Saharan Africa. AMPATH stands for Academic Model for the Prevention of and Treatment of HIV/AIDS. The Mosoriot Medical Record System (MMRS) was developed and installed in Kenya, adopted since 2001 by AMPATH and renamed AMRS. The electronic records provide care documentation, monitoring of drug adherence and response, and data for research. It is used in six rural health centers in Western Kenya. However, a combination of paper-based encounter forms and electronic records in a relational database is used. Diagnostic test results, demographic and clinical data and treatment information are registered on paper. Then these records are entered in a database. There are plans for further development and migration to a web-based platform.

2.7.10 MYCIN

The *MYCIN System* was developed at Stanford University in the 1970s. Dr. Edward H. Shortliffe created this expert system [57]. The aim of the system was to identify infectious diseases and to suggest a therapy. The knowledge base contains knowledge from disease specialists. The inference mechanism selects the rules that are applicable and relates them. Although the system was not used in practice, it showed valuable theoretical results.

2.7.11 INTERNIST-I

INTERNIST-I was a rule-based support system, which used a heuristic reasoning method with a quasi-probabilistic scoring scheme to suggest disease candidates and to guide the physician [58]. The system was developed at the University of Pittsburgh as an experimental decision support tool in general internal medicine [58]. The medical knowledge base was later used in the *Quick Medical Reference*.

2.7.12 DXplain

DXplain is a computer-based diagnostic decision support system which accepts a list of clinical signs and laboratory results and produces a list of diagnostic hypotheses [59]. It also provides an explanation and justification of the proposed hypotheses.

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3

Design and Evaluation of a Service Oriented Architecture for Paperless ICU Tarification

This chapter focuses on the transition from paper-based towards a paperless digital processing of data from electronic patient records. In the administration process of the ICU, a web services platform for the automation of the tarification process is studied and validated. We encapsulate the administrative processes as services in a service-oriented architecture. In addition, the proposed software prototype is evaluated for performance and the return on investment is analyzed.

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Abstract The computerization of Intensive Care Units provides an overwhelming amount of electronic data for both medical and financial analysis. However, the current tarification, which is the process to tick and count patients' procedures, is still a repetitive, time-consuming process on paper. Nurses and secretaries keep

track manually of the patients' medical procedures. This paper describes the design methodology and implementation of automated tarification services. In this study we investigate if the tarification can be modeled in service oriented architecture as a composition of interacting services. Services are responsible for data collection, automatic assignment of records to physicians and application of rules. Performance is evaluated in terms of execution time, cost evaluation and return on investment based on tracking of real procedures. The services provide high flexibility in terms of maintenance, integration and rules support. It is shown that services offer a more accurate, less time-consuming and cost-effective tarification.

3.1 Introduction

Despite potential benefits of Information Technology (IT), its adoption in healthcare organizations is still slow. In a study [1] that examined the use of Electronic Health Records (EHRs) in hospitals of six industrialized countries, it is estimated that less than 5-10% of the hospitals have been using EHRs. In 2009, it was estimated that only 7.6% of hospitals in the US is using a basic EHR and only 1.5 % is using comprehensive electronic records across all hospital units [2, 3]. The implementation of a Computerized Physician Order Entry (CPOE) for medication prescriptions was estimated to be 17% in the US hospitals [3]. Critical care medicine and ICU provide medical advanced but expensive treatment. The ICU consumes up to 20% of the total hospital's cost [4, 5]. There are indications that the computerization in Intensive Care Units (ICUs) is increasing [6]. For instance in 2008, 19% of all ICUs in Flanders, a region in Belgium, had already implemented an Intensive Care Information System (ICIS) [6].

IT can be used as a tool for tracking the patient's health conditions and in supporting physicians' daily workflow. The Electronic Health Record (EHR) is defined as a collection of electronic patients' data. The records may include demographics, medications, medical progress and history, vital signs and test results. The Clinical Information System (CIS), also called a Patient Data Management System (PDMS), provides access to the EHRs and assists the physician's workflow with charting of vital signs, displays with monitored values and work lists for the nurses. CISs often come with a Computerized Physician Order Entry (CPOE) for electronic medication prescriptions. When paper-based records are replaced by electronic medical records, repetitive data tasks can be automated.

As an early adopter, the Intensive Care Unit of the Ghent University Hospital in Belgium is equipped with an Intensive Care Information System (ICIS). The system interfaces with monitors, ventilators and syringe pumps, has an incorporated CPOE, and captures all patient data in a central database. The availability of CPOE has already resulted in a significant decrease in the occurrence and severity of medication errors [7]. Furthermore, as the ICU is a data intensive environment, an overwhelming amount of electronic data becomes available for both medical and financial computerized analysis.

Although the ICIS offers automated monitoring, the collected data can be exploited in advanced decision support services [8–10]. Using electronic records could result in cost and quality improvements in clinical studies [11]. Examples of decision support services already in use in ICU include services detecting kidney dysfunction [12], services calculating performance scores [13] and services suggesting antibiotic dose adaptation based on automated creatinine clearance calculation [14]. By combining and mapping different clinical data sources (such as the ICIS data, microbiology results in the laboratory database and photos of the radiology department), computer-based surveillance and alerting of nosocomial infections, antibiotic resistance and antibiotic consumption is performed in the ICU [10].

IT systems also have the potential of improving the patient's tarification administration. The tarification process in a hospital is one of the non-medical routines that can be extremely labour-intensive. The tasks still have to be performed manually by the nursing staff through the use of pen and paper. Although electronic records of the medical procedures exist, the data is not exploited for financial purposes. Tracking medical procedures manually, makes the current process susceptible for human errors. In this paper, a flexible alternative service oriented approach to calculate ICU costs and integrate the tarification process with the existing information system is presented in detail.

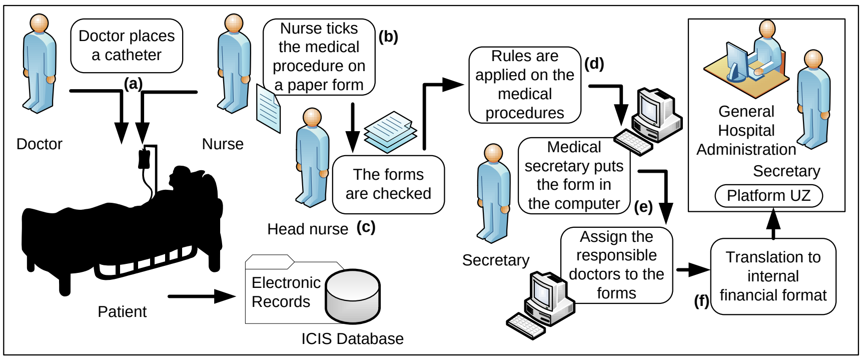


Figure 3.1: The current labour-intensive manual billing process at the ICU

The current required human effort, interactions and paperwork in an administration process are illustrated in Fig. 3.1. Each of the labour-intensive and time-consuming 8-steps process depends on the human effort of a nurse, head nurse and secretary. As an initial point, (a) the physician or nurse performs a medical procedure (e.g. the placement of a catheter). A nurse ticks this patient's procedure on a specific designed paper form (b). The head nurse controls if each form contains all the daily procedures (c). At the administration the medical secretaries check if all procedures are compliant with the billing rules of the hospital (d). The registered procedures on the form are put in a computer application and assigned to a responsible physician (e). The application transforms the form into an internal financial format (f). Later, this format is delivered to the general hospital administration, where other rules are applied and patients' invoices are printed.

In this paper the transition is discussed from a paper-based billing process of medical procedures to an automated electronic process that requires the integration with the intensive care information system (ICIS). ICIS offers a collection of monitored and laboratory data and has a list of observations and medication treatments.

Tarification is the process to tick and count all the patients' medical procedures. With the presence of medical records, the individual tarification tasks are encapsulated in services. The main functionalities of these tarification services are investigated: (1) Automatic extraction of the patient's medical procedures from the ICIS system. Data is extracted with a periodic frequency. (2) Mapping this data to a specific list of refundable procedures. (3) Generating the complete electronic version of the tarification form by applying policy rules. Therefore, specific financial rules have to be applied to the dataset. (4) Offering a management module to view, review and change tarification forms for the secretary. An electronic version of the tarification form is shown in Fig. 3.2. The application is used to monitor the entire process.

Software services are able to collect all patients' executed medical procedures from the database that continuously gets data from medical monitors and devices. By automated querying of the database, the nurse no longer has to tick the procedures on a paper form. Completely relieved from the manual billing process, more time can be given to patient care. The tarification services are tailored to the ICU but are extendible to other health departments. The services are designed as independent software components, following the principles of a service oriented architecture. This offers a higher flexibility in terms of maintenance, coupling with other departments, support for tarification rules. The architecture consists of interacting services, each responsible for an independent task. The services are designed following the principles of a service oriented architecture.

In this paper, we discuss the methodology and results of the transition to computer-based tarification services in the ICU. We investigate if the tarification process can be automated and evaluate the impact of the services. The goal is to evaluate the tarification services in terms of execution time, cost evaluation and return on investment. The services were evaluated by the department of Intensive Care of Ghent University Hospital on real data of the information system during a 32-days period.

Figure 3.2: The generated electronic tarification form

3.2 Materials and Methods

3.2.1 Architecture

The tarification application has been designed as a service oriented architecture (SOA). The SOA describes the usage of loosely coupled services, which serve as independent units of functionality. The use of SOAs has also been favored in the design of healthcare applications [14, 15] because of its simpler design, decomposition, improved service reusability, adaptability and flexibility, interoperability and cost savings. The services, implemented as web services (WSs), act as building blocks for the complete application [16, 17]. The web service is defined by the World Wide Web Consortium (W3C) [18] as a software system designed to support interoperable machine-to-machine interaction over a network. Communication with other services happens through data exchange of messages in extendible markup language (XML) [19]. Services can be distributed across different machines, to provide scalability and increased performance.

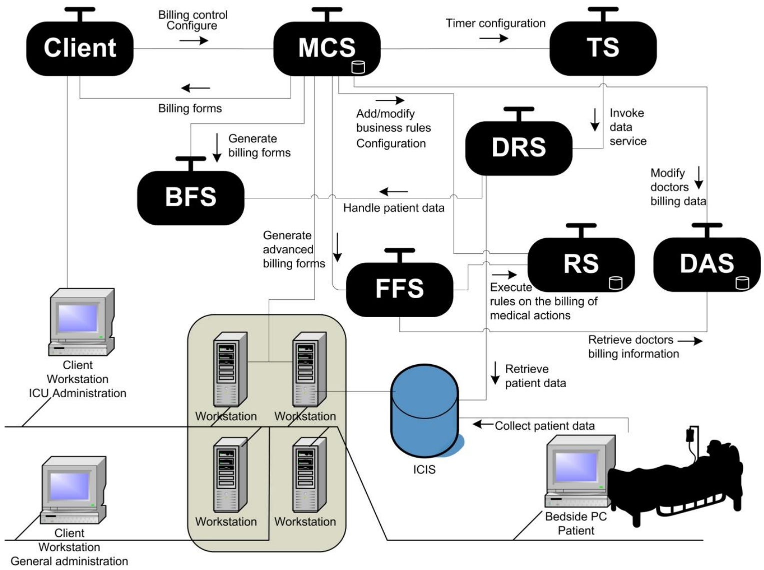


Figure 3.3: General concept of the service oriented billing platform with the timer service (TS), the data retrieval service (DRS), the billing form service (BFS), the rule service (RS), the doctors assignment service (DAS), the financial format service (FFS) and the monitoring and control service (MCS)

The services for data retrieval, processing and generation of tarification forms, modification to the forms, and translation into an internal financial format are listed and described in detail. Fig. 3.3 shows the flow between the tarification web services. A graphical representation of the platform architecture is shown in Fig. 3.4. The architecture consists of:

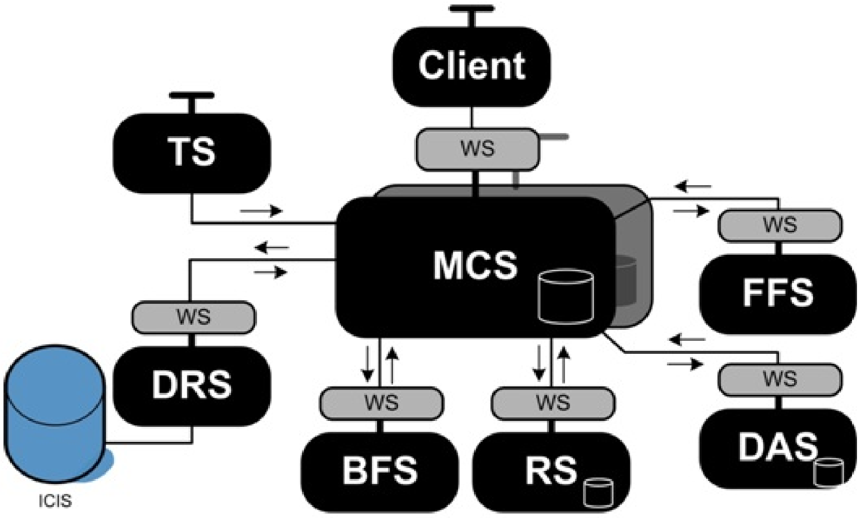


Figure 3.4: Design of the automated tarification process with the interactions of the timer service (TS), the data retrieval service (DRS), the billing form service (BFS), the rule service (RS), the doctor assignment service (DAS), the financial format service (FFS) and the monitoring and control service (MCS)

(a) The Timer Service (TS) runs as a background process. It indicates the moment when the Data Retrieval Service (DRS) should be invoked. The DRS is invoked daily to get the latest patients' medical procedures from the database.

(b) The Data Retrieval Service (DRS) stores all queries and handles the communication with the ICIS database. No details of the Stored Query Language (SQL) statements and about the structure of the database should be known before using this service. As a result, it limits the impact of database changes because changes in the data structure only imply changes in this service. The service offers a method to retrieve the number of all medical procedures for each patient by extracting the data from the ICIS database.

(c) The Billing Form Service (BFS) generates the electronic tarification form. The data from the patient's medical procedures is filtered and used to build up an XML record. Later, this record can be modified by other services that perform a specific task (e.g. assigning responsible physicians, applying billing rules). The electronic version of the tarification form is the common format during the complete billing process. It lists all medical procedures and the patient's actions.

(d) Rule Service (RS) applies a number of rules on the data of the tarification form. The hospital can be subordinate to the legislation concerning medical revenues and repayment of the social security institute, typically different for each country. The number of the charged items, for example, should be adjusted if it exceeds the amount of legal medical revenue. In Belgium, some medical procedures are refunded by the National Institute for Sickness and Invalidity Insurance (RIZIV). For example, a RIZIV rule for ventilation: the reimbursement of invasive ventilation is limited to the first 21 days of ICU admission. So these ventilation procedures should only appear in the tarification on the first 21 days. The original amount of data can be large because this data is coming from health monitoring devices and stored accordingly with large amounts in the database. Then these amounts should be changed to an upper limit, according to the RIZIV rule. Other medical procedures should be decomposed in other medical actions to generate a detailed billing form.

(e) The Doctor Assignment Service (DAS) assigns a physician to the medical procedures listed on the form. The assignment is based on a duty list which is added into the service. For example, a measurement can be performed by a nurse under the authority of a physician, while the ICIS database does not mention the responsible physician for this procedure. Then, the duty list is consulted and the physician on duty is assigned to the procedure.

(f) The Financial Format Service (FFS) deals with the translation of the XML tarification form into an internal textual financial format, as input for the general administration system.

(g) The Monitoring and Control Service (MCS) controls the interaction between services and handles the external communication with vendor-specific services. If a new service is needed, only the MCS should be aware of this change. It acts as an interface for the graphical user interface and configuration options.

3.2.2 Service Interactions

The platform can be designed in two different ways which form a trade-off between the creation of highly intensive XML data-exchange between all the services and the creation of a central storage location of data with minimal exchanges. These two configuration approaches are detailed below.

The first approach is the exchange of XML data forms through the services, where the services are actors on a specific tarification form. Each service obtains a form to act on. This is similar to passing the paper forms to other human actors. The disadvantage is how to coordinate form updates. In this situation, one update in the form can force all services to change their internal behavior and actions upon the form. (A complete match between the administrative process in the real world and the architecture is therefore not advisable when change management is a requirement.) In fact it breaks the whole concept of independent services and service orientation as each service has to agree upon the standard data format. The other approach is a central data management with demand-driven data exchange. Here the monitoring and control service acts as a central manager for all patient data and forms that are retrieved from the other services. This means that requests for information are sent to the services but only the monitoring and control service is building the tarification forms during the interactions. This coordinating service knows which services should be invoked in the correct sequence. This second configuration approach is advisable because it shows a better extendibility of the administrative services. A third party service or service can be added more quickly as it can be requested without knowing the internal data format. In Fig. 3.5 the sequence diagram of the data exchange is shown.

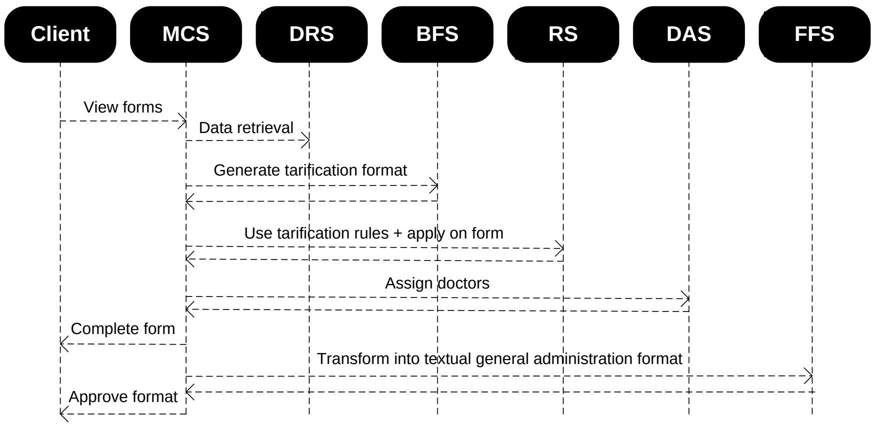


Figure 3.5: Demand driven data exchange

3.2.3 Implementation Details

3.2.3.1 XML Web Services

All tarification services were implemented as web services (WSs) in the Microsoft .NET environment, using Visual Studio as a development tool. The Timer Service (TS) invokes the Data Retrieval Service (DRS) each night at 0h30 AM. This time was chosen because at that time there was a minimum activity on the database (both production and replica) and no other hospital database audit procedures are active at that moment. Figure 3.6 illustrates the response from the Data Retrieval Service (DRS). First, it retrieves a list of all the patients residing at ICU or discharged in the previous day. Then, for each patient the service retrieves a list of medical treatments during the specified period (one day). The service extracts the data even while the patient is still at ICU to make periodic bills by the central administration possible, for example, when critically ill patients are admitted to ICU for weeks or months. The SQL queries are executed on a real-time replicated ICIS database which collects the monitoring data from the patient's devices and contains the data of laboratory, medical treatment and manual clinical registrations. Each ICIS data record has a patientID, parameterID, timestamp, and the parameter can be linked through a specific tarification-RZ-code in a system table with the medical procedure for the tarification form. It makes a separate manual registration redundant. In the DRS a preconfigured list contains all the mappings and the names similar as on the paper form. For example, when the procedure is: "Daily supervision of Swan-Ganz monitor" the database has been queried and the results contain cardiac output values. In this case, the data mapping "SWAMET" with RZ-Code "RZ-26" or parameterID "214126" exists. In another case, the procedure "Supervision of blood pressure measurements" is mapped to the systolic arterial blood pressure values (code "ARTMET", RZ-code "RZ-23" or parameterID "214023"). The DRS service returns both continuous monitoring procedures and non-continuous procedures as shown in Fig. 3.6. There is no difference between continuous and non-continuous activities for the tarification process. Continuous activities (for example, from monitoring devices) will create a large number of data records in the database. This will be reflected in the large number of counted medical procedures, which can be modified in the Rule Service (RS). For non-continuous activities the same process applies. Then, only one medical procedure is counted, is shown on the tarification form and probably not affected by any rule. However, only if the procedure has a tarification code in the ICIS database (the initial integration and thus mapping), the procedure will be billed.

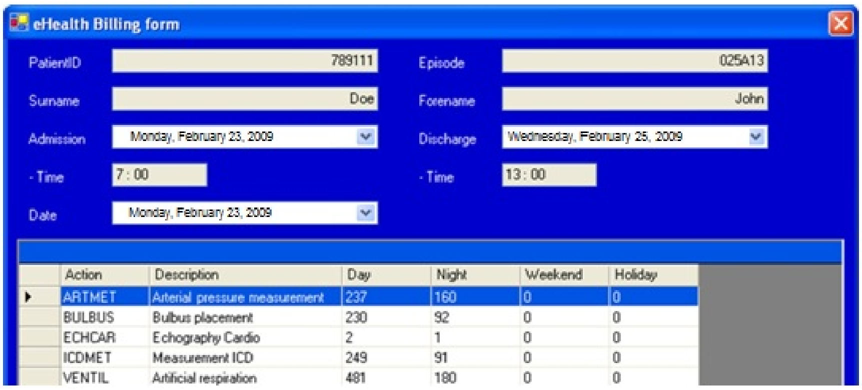

```
<actions>
<code>RZ_011</code>
<time>2009-02-23T15:23:35.3928475+01:00</time>
</actions>
<actions>
<code>RZ_005</code>
<time>2009-02-23T15:24:45.0983745+01:00</time>
</actions>
<actions>
<code>RZ_045</code>
<time>2009-02-23T15:24:53.9847201+01:00</time>
</actions>
<actions>
<code>RZ_011</code>
<time>2009-02-23T15:31:56.0739659+01:00</time>
</actions>
```


Figure 3.6: A part of the SOAP-response from the data retrieval service

In the Billing Forms Service (BFS) the procedures are grouped and a tarification form is generated. A part of this form is shown in Fig. 3.7. It contains the counted number of a medical procedure, which is divided in 'morning' (0 AM to 8 AM), 'day' (8 AM to 8 PM), 'night' (8 PM to 0 AM) and an indication for weekend duty and holidays, based on the timestamps of the records. All procedures are counted and no minimum or maximum interval limitations were set. For continuous monitoring procedures the counted number can be large (as illustrated by procedure "ARTMET" and "VENTIL" in Fig. 3.8) but these numbers are changed in the Rule Service (RS) in accordance with the billing rules (as shown in Fig. 3.9).

```
<action>
   <code>ARTMET</code>
   <text>ARTMET pressure measurement</text>
   <time>
    <morning>233</morning>
    <day>337</day>
    <night>104</night>
    <weekend>0</weekend>
    <holiday>0</holiday>
   </time>
</action>
```

Figure 3.7: A part of the tarification form, which shows the counted procedures 'ARTMET' of a patient



eHealth Billing form

PatientID: 789111 | Episode: 025A13

Surname: Doe | Forename: John

Admission: Monday, February 23, 2009 | Discharge: Wednesday, February 25, 2009

- Time: 7 : 00 | - Time: 13 : 00

Date: Monday, February 23, 2009

Action	Description	Day	Night	Weekend	Holiday
ARTMET	Arterial pressure measurement	237	160	0	0
BULBUS	Bulbus placement	230	92	0	0
ECHCAR	Echography Cardio	2	1	0	0
ICDMET	Measurement ICD	249	91	0	0
VENTIL	Artificial respiration	481	180	0	0

Figure 3.8: The billing form before the rules are executed by the rule service (RS). The medical procedures were retrieved automatically from the ICIS database

The services are implemented as web services (WSs) in the Microsoft .NET environment, using Visual Studio as a development tool. This choice does not limit the integration with Java EE and Java-based systems because web services are platform neutral. The functionality of the Data Retrieval Service (DRS) is illustrated. The web service offers a method to retrieve for a particular patient, with given patientId, a list of medical treatments of the patient during the specified period (between start and end-date): public DataSet GetActions(int patientId, DateTime start, DateTime end). This request is sent as a SOAP-request with an XML-structured form. The result of this request yields a list of medical actions, as shown in Figure 3.6.

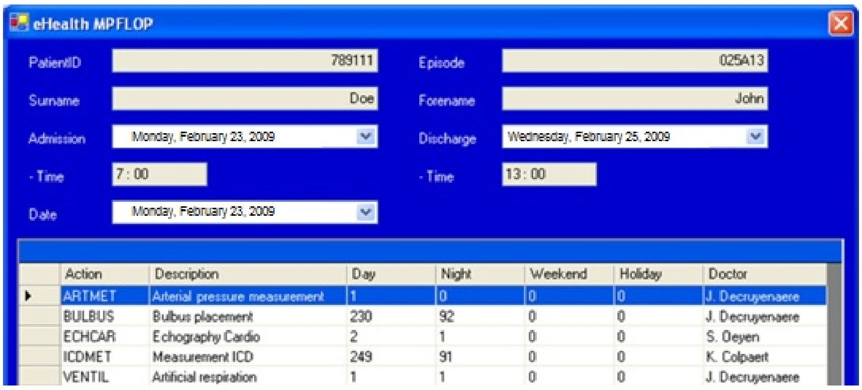


Figure 3.9: The billing form after the execution of the rule service (RS) and the doctors service (DS). The number of procedures has changed after the rules were applied (e.g. ARTMET, a monitored procedure (with 237 monitored values), can occur only on the final billing form)

3.2.3.2 Rule Engine

The rule engine in the Rule Service (RS) contains all the tarification rules. The tarification data form is checked against these rules and for example the amounts are modified if they exceed the upper boundary values for the billing of the medical actions. Rules can be added to the system through the graphical application. Internal in the service the rule is added in the XML-format. All these rules are working on the patient data forms that can be easily opened in the application as shown in Fig. 3.8 and Fig. 3.9. Notice that the amounts are adjusted according to the settings (for example: charge only one ARTMET medical action per day). Initially the rules were enforced through variable comparisons with the billing form numbers. In the current version a rule based engine is used for the application of tarification rules.

An automated billing decision support system, called the Clinical Event Monitor [20], was based on the Arden Syntax for medical logic modules. It was a system that consults a central patient database and based on events and patient data was able to generate alerts, interpretations, screening messages and administration (through billing rules) [20]. The Arden syntax is a language for encoding health knowledge [21]. Another system, closer to the proposed web services architecture is SEBASTIAN, a decision support web service [22]. It is also implemented as a web service. The XML description of the policy which contains a condition and possible actions can be used. In this context an example condition could be ’the occurrence of some related surgery actions’ and then the administrative action must be executed ’mark as surgery set instead of charging each surgery action independent of the other actions’. Defining policies can be done in XML but it is more user friendly to create an editor. With an editor the user does not need to know the exact syntax and semantics of the created policy. Instead of programmatically comparing variables as in the first prototype, the condition is structured as a boolean expression which is then evaluated against the specific amount of medical actions from the tarification data. Examples of existing rule engines which can be used are JESS [23] or ILOG JRules [24]. JESS is a scripting environment and rule engine written in Java and ILOG JRules is a complete business rule management system for Java.

3.2.3.3 Client Design

One of the reasons why e-health adaptation is not widespread is the difficulty of use and a lack of integration [25]. As such one of the requirements for the billing system was a user-friendly and easy to use graphical user interface. All configuration settings and billing tasks are available through several windows. Usability may increase the overall productivity and efficiency. Figure 3.10 shows the screenshots of the application. The bottom window shows the general menu: opening tarification forms or configuring settings. The window in the middle gives an overview of all the possible settings. We opened, for example, the general settings. In the general settings window the time server settings and the storage location for the tarification forms can be adjusted.

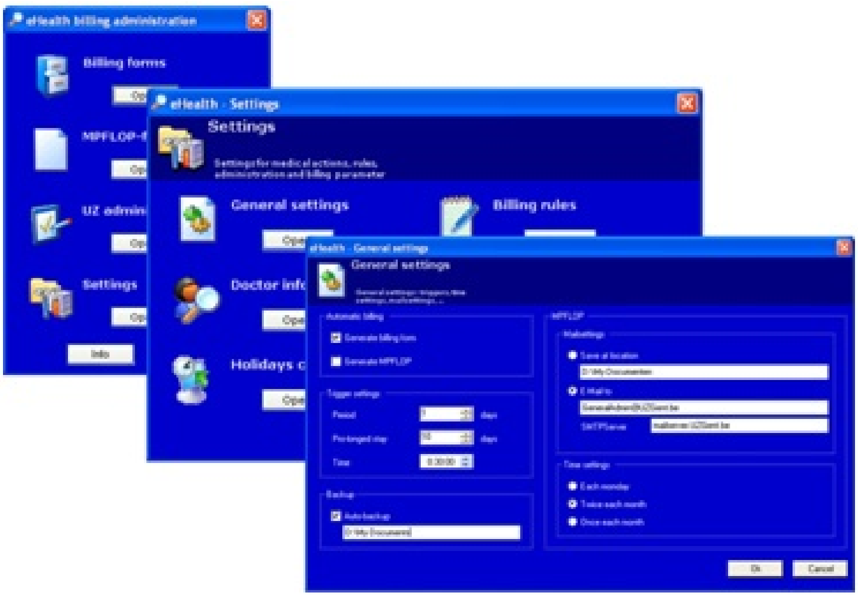


Figure 3.10: Screenshots of the graphical user interface of the designed application

3.2.4 Platform Deployment and Maintenance

In our proposed design of the health administration the monitoring service forms a vital link. Failure of this service can obstruct the whole process dramatically. Therefore the availability of the tarification forms and the monitoring service must be guaranteed. A system failure should not result in the loss of forms. Through data replication the billing forms are made available also on another server. When a failure of the initial active server is detected, the other server (with a duplicate standby monitoring service) takes over the process. This server contains all duplicate forms of the initial server. Data replication is managed through a synchronized copy of all data forms. When the monitoring service stores the form, the form is also copied to the other server, which acts as a backup and remains always synchronized during the tarification process. Fig. 3.11 illustrates the replication and the distribution of the work load across different machines.

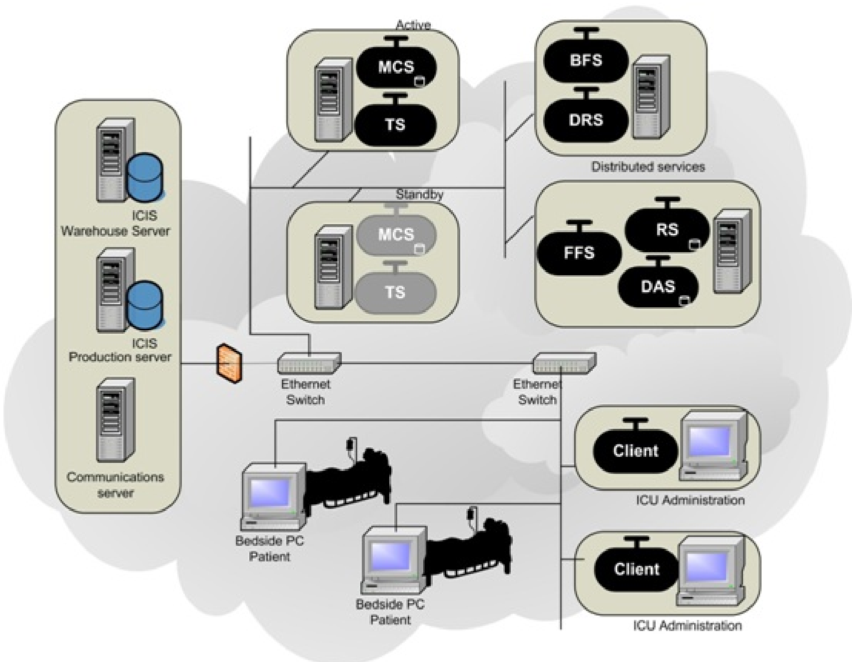


Figure 3.11: Platform deployment

Updates of the services can be easily performed because there are no direct dependencies between the services. The internals of the service can change without having to worry about the other services. The monitoring service maintains all service interactions. Moreover, new services can be plugged in easily.

In order to ensure no impact on the production database, the Sybase ASE 15 database of the hospital was replicated in real-time to the ICIS replication server. All database statements (insert, update, delete of records) were replicated in real-time to the replication database by the Sybase replication software.

Fault detection is performed through logging in each service. When a fault occurs in a service, a fault description is added to a log-file and the system administrator gets notified of this error. Each detected fault contains a timestamp and exact location where the application failed. For example, if a communication link is not functional the extraction of data will fail (no patients detected) and the administrator will be notified through the logging of an abnormal event. This helps the administrator in maintaining and configuring the service-based platform.

3.2.5 Evaluation Setup

The tarification services were evaluated by the department of Intensive Care of Ghent University Hospital, a tertiary care facility in Belgium. The ICU has a total of 56 beds and consists of a surgical ICU (22 beds), a medical ICU (14 beds), a cardiosurgical ICU (8 beds), a pediatric ICU (6 beds) and a burns unit (6 beds). There are about 3,800 admissions each year with an average length of 3.6 days. The ICU of Ghent University Hospital is already using an Intensive Care Information System (ICIS) to monitor the patients' data. Although the shift from paper-based diagnosis records to electronic records stored in ICIS, the system has no features to replace the existing paper-based tarification process. The described tarification services were integrated with the ICIS database to automate the process. The ICU administration counted a total of 108,018 medical procedures in 2009.

In section 3.2.6 the evaluation methodology is presented. The real data of medical procedures from February, 1, 2009 to March, 4, 2009 was used. First, a validation of the medical procedures was done. After the automated tarification process was validated, a technical and cost evaluation was conducted. The results of this evaluation are presented in section 3.

3.2.6 Evaluation Methodology

Before conducting the evaluation of the tarification services, validation tests were executed after the initial deployment of the system. The evaluations, in which a clinician compared each medical procedure on the tarification paper forms with the electronic forms, guaranteed that every medical procedure was captured correctly from the Intensive Care Information System (ICIS). In a pre-test period of 2 weeks the extracted patients' procedures were systematically compared and the configuration (mapping of ids and tarification codes, queries) was adjusted to capture every procedure. All procedures are included in Appendix 1. At first, these tests showed numerous missing electrocardiogram (ECG) procedures. Physicians had the attitude to give orders to nurses without registering them in ICIS. Moreover, the ECG measurements were also not registered in ICIS. This issue was solved after physicians started registering all ECGs in ICIS as part of their clinical workflow. The physicians are reminded, by additional task items in the ICIS system, to make the manual registrations in ICIS. Other minor configuration issues were also detected and solved in the pre-test period.

The tarification services make the assumption that all procedures are correct in ICIS. In order to allow validation, we added a view on the patients' tarification forms, which can be modified by a secretary, system administrator or authorized physician (e.g. head of department) while the process is still active. The number of the procedures can be changed or procedures can be removed or added on the form, even after extraction. This functionality can also be used as backup mechanism if ICIS should be under maintenance or if procedures were added after discharge of the patient in ICIS.

The evaluation study included both a technical evaluation and a cost evaluation. In the technical evaluation the performance of the interacting services was measured. The cost evaluation included a comparison between the revenues generated by the paper-based approach on the one side, and the automated tarification software services on the other side. During the evaluation period all medical procedures on paper were compared with the electronically extracted procedures.

3.3 Results

3.3.1 Service Performance Details

The response times were measured for the services that are involved in the billing form generation process. Fig. 3.12 shows the average response times, taken for extraction periods of one day and one to three weeks. On the graph the data retrieval service (DRS), billing form service (BFS), rule service (RS), doctor assignment service (DAS) and financial format service (FFS) are shown. The evaluation was done on an AMD Athlon 64 Processor 3200+, 2.00 GHz and a Realtek RTL8139 Family PCI Fast Ethernet card (100 Mbps) with a version of the tarification services. This server is connected with the database server through a LAN network. This database server is running Windows Server 2003 with Sybase Adaptive Enterprise Server edition.

All measurements were done from the monitoring and control service (MCS), which calls the different functional operations of the other services. The data retrieval service is used to obtain the medical procedures from the clinical database. The response time shows a linear behaviour. For a patient with a form generation after one day the average time is 1.4 seconds for this data retrieval of medical procedures. The billing form service (BFS) generates the XML forms with the number of medical procedures as monitored in the database. The average data size

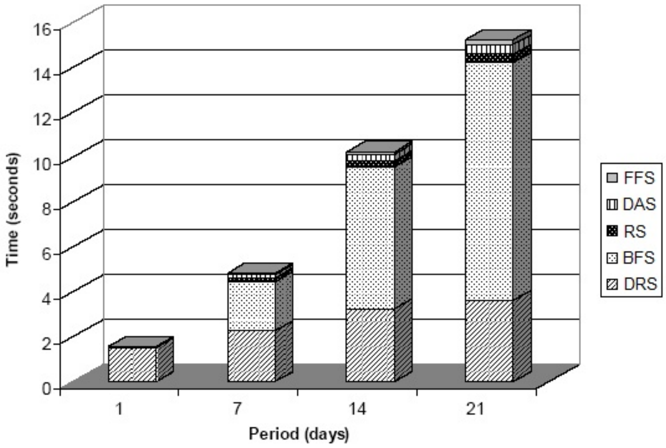


Figure 3.12: Average time for the billing form generation for patients with an ICU stay ranging from 1 day to one to three weeks. The graph shows response times of the data retrieval service (DRS), billing form service (BFS), rule service (RS), doctor assignment service (DAS), financial format service (FFS)

(49.8 kilobytes) of the data forms is shown Fig. 3.13. Most of the time is spent in this billing form service, when compared to the other services in a longer period. The rules service (RS) and the doctor assignment service (DAS) are executed fast because these services do only small manipulations (such as adding a doctor or changing the amount of medical procedures in the rule service).

3.3.2 Clinical Cost Evaluation

The evaluation study compared the cost benefit of implementing the automated tarification system at ICU with the current paper-based process. This study included both direct costs (medical procedures, implementation software) and indirect costs (human resources) of the tarification services.

The cost evaluation was performed from February, 1, 2009 to March, 4, 2009. During the 32-days period all medical procedures registered on paper were compared with the electronically extracted medical procedures. There were no missing medical procedures reported in the comparison. Moreover, the comparison showed that medical procedures were extracted more accurately from ICIS than the counted procedures that were written on paper. Frequent medical procedures that did not appear in the paper files were atrial pacemaker stimulation, ECG, mechanical ventilation, and supervision during administration of blood products. The tarification services offer a better tracking of all procedures compared to the manual approach. For some rare procedures such as use of an intra-aortic bal-

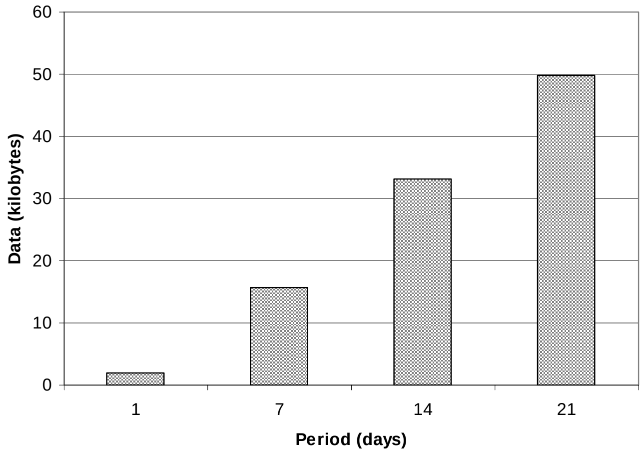


Figure 3.13: The average data size of the XML data output for a patient staying one day up to three weeks. The XML files contain a complete description of a billing form for a patient with the medical procedures. For example: for one patient, over a period of 21 days, the average file size is 49,8 kilobytes

loon pump, defibrillation and percutaneous tracheostomy, there was an incomplete registration in ICIS and thus no occurrence of these procedures on the electronic tarification form. A pop-up screen is displayed to enter information about these medical procedures. The pop-up screen is used in two cases: in case of missing data or when additional procedures should be registered by the physician. Using the service oriented approach, services are plugged in easily to request feedback or a registration by the physician, which makes a complete tracking of all procedures possible. This service oriented approach takes advantage over report generation tools because it offers the ability to extend the application with new services.

As a consequence of the complete extraction of all procedures by the tarification services, extra revenues could be generated. The ICU had a total revenue of 3,000,050 in 2009. In the 32-days period 9,300 medical procedures were registered on paper, compared to 10,057 procedures that were extracted by the tarification services. This means an increase of 6.2 % and an associated extra revenue of 13,420. After extrapolation of the evaluation period to one year, the annual extra income is 153,072 or an increase in revenue by 5.1 %.

The return on investment (ROI) was estimated, with inclusion of the costs of implementing the software. A local commercial software vendor would ask 58,000 for the implementation of this automated tarification software. With an annual additional revenue of 153,072, this means a total ROI after 4.56 months. The short ROI period is exceptional for software applications.

Besides the direct financial benefits, there are also indirect financial benefits related to human resources. Nurses do not have to register each medical procedure on paper anymore. Ticking the procedure on a specific paper form takes about 10 minutes in a shift of 8 hours. The head nurse does not have to check the completeness and a secretary is relieved from entering all procedures in a computer application. All routine-based human tasks in the tarification can now be avoided. The tasks of one full-time equivalent (FTE) secretary, earning 49,918 per year, are all executed by the computerized system. When the total ROI is recalculated, taking the indirect revenues into account, a total ROI is already established after 3.96 months. Table 3.1 summarizes the cost savings by using the tarification services compared to the usage of paper forms. It is proven that the services' deployment results in time gain for nurses and medical secretaries and cost savings for the hospital.

Yearly benefit estimation of the tarification services			
	Paper	*Tarification Services*	*Benefits*
Medical Procedures	9,300	10,057	+ 6,2 %
Medical Revenues (Euro)	+ 3,000,050	+ 3,153,122	+ 153,072
Time of one nurse	- 182 hours	0	+ 7,5 days
Secretary cost (Euro)	- 49.918	0	+ 49,918

Table 3.1: Clinical evaluation of the tarification services: yearly benefit estimation.

3.4 Discussion

The results show that an Intensive Care Unit can benefit from the design of a service oriented architecture for paperless ICU Tarification. The most important findings of the study are the reduction in workload through the automation, the extra income generated by a complete extraction by the tarification services, and a total return on investment of less than 4 months. First, the labour-intensive administrative tasks that had to be done by nurses and secretaries are now performed by the software services. The nurse is completely removed from the tarification process and has more time for healthcare tasks. By integrating with the existing Intensive Care Information System (ICIS), the number of medical procedures is automatically retrieved and processed in the tarification services. Moreover, the automatic extraction process was more accurate than the tarification on paper. Second, the automatic tarification is a cost-effective process. In the clinical cost evaluation it was shown that on a total revenue of 3,000,500 euro in 2009, an extra income of 153,072 euro could be generated by using the tarification services, compared with the tarification on paper. Third, the estimation of the total return on investment (ROI), with inclusion of the costs of implementing the software and the indirect cost of human secretary, showed a total ROI after only 3.96 months.

From a technical perspective, implementing the tarification services in a service oriented architecture was considered the best choice for the tarification solution. This approach was favored because it allows the decomposition into reusable services, better adaptability and flexibility, interoperability and additional cost savings. Interoperability was an important motivation for choosing web service technology. The software service is an independent component, which gets data input and processes this data and subsequently triggers the appropriate actions. Examples of these actions include the invocation of another service, generating graphs or retrieving data from a remote database. Due to the complexity of ICU medicine, it is expected that several tens of software services will be active simultaneously in order to optimize the care and the administrative management of critical ill patients.

Therefore, an architecture for easy distribution of the services along multiple workstations was developed. A middleware platform, based on web service technology, has been developed for the intelligent subscription of the medical decision support data, offering advanced features such as transparent data migration, user-friendly patient/service subscription and profile based filtering of support messages [8]. Examples of medical decision support services already in use in ICU include services detecting kidney dysfunction, services calculating daily several performance scores and services suggesting antibiotic dose adaptation based on daily automated creatinine clearance calculation. In a computerized ICU it should be possible to deploy a software system for the automatic generation of tarification forms. In this paper, it is illustrated that a service based software system is efficient for automating the ICU tarification process.

The automation of the tarification process has some limitations. First, the assumption is made that the data in the Intensive Care Information System (ICIS) always contains the correct information with the registrations of all medical procedures. Although the registrations are imposed in the workflow through reminders and tasks for physicians and nurses, the data quality of ICIS and thus the quality of the tarification is dependent on their registrations (for example: ECG registrations). Second, the system administrator should be aware that the configured list of procedures mappings (in the Data Retrieval Service) and the RIZIV rules (in the Rule Service) should strictly correspond to the ICIS and to the hospital RIZIV policy respectively.

The designed system can be extended for the administration in the entire hospital. The services have been evaluated by the department of Intensive Care of the Ghent University Hospital. It is already observed that the services' deployment results in significant time gains for nurses and medical secretaries and hence cost saving for the hospital. Moreover, it is shown that it results in a reduction of forgotten procedures and hence contributes to a more accurate tarification process.

3.5 Conclusion

In this paper, we described the design of a service oriented architecture for paperless ICU tarification and we evaluated this automated solution in terms of execution time, revenue and return on investment. The tarification process on paper was compared with the automatic solution which is integrated with the existing information system. The evaluation was performed on real data of the medical procedures in the Intensive Care Unit of Ghent University Hospital. It was shown that the service-based approach offers a more accurate, less time-consuming and cost-effective tarification process.

3.6 Appendix: List of all ICU activities included in the tarification

- Arterial blood sample, without arterial line
- Arterial catheter: placement or exchange
- Arterial measurement: surveillance
- Ascites puncture: diagnostic
- Ascites puncture: evacuating
- Arterial catheter: surveillance
- Ventilation: invasive
- Marrow puncture: sternum
- Marrow puncture: crista
- Marrow puncture: bone needle for a child < 7 y.
- Bladder probe: placement
- Bronchoscopy by an ICU physician
- Bulbus catheter: placement
- Cardioversion
- Central catheter: placement or exchange

- CO_2 measurement
- Defibrillation with reanimation
- Defibrillation without reanimation
- Dermatologically related: Burn wounds
- Dermatologically related: Decubitus 2nd and 3rd grade
- Dermatologically related: Skin disease, Lyell, necrotizing fasciitis
- Dermatologically related: Extensive wounds
- Dialysis catheter: placement or exchange
- Transthoracic echocardiography by an ICU physician
- Transoesophageal echocardiography
- Echocardiographic monitoring for punctures: tax
- Electrocardiography (ECG)
- Epidural catheter placement
- Cardiopulmonary Resuscitation (CPR)
- Hypothermia: surveillance to 34 degrees Celcius
- Intra Aortic Balloon Pump (IABP) - surveillance
- Intracranial pressure measurement - surveillance
- Liver biopsy
- Linton probe: placement
- Lumbar puncture by an ICU physician
- Lumbar puncture by a pediatrician
- Gastric tube: placement or replacement
- Medical surveillance blood, plasma, PPSB, Human Albumin, globulines, thrombocytes (if no post-traumatic or post-surgical or post-hemorrhagic indication)
- MUG-emergency (internal): defibrillation
- MUG-emergency (internal): intubation

- MUG-emergency (internal): monitoring
- MUG-emergency (internal): reanimation
- Monitoring: surveillance
- Narcose or additional sedation: Examination
- Narcose or additional sedation: Transport of the patient
- Narcose or additional sedation: Therapeutic purpose (Penthotal coma, curarisation)
- Narcose or additional sedation: Defebrillation
- Narcose or additional sedation: Intubation, reintubation
- Narcose or additional sedation: Tracheotomy
- Pericardiocentesis
- Peripheral infusion for a child < 7 y.
- Peritoneal dialysis for children
- PICCO: placement, the PICCO system monitor
- PICCO: measurement-surveillance
- PICCO: Cardiac output
- Phi-probe placement
- Phi-measurement: surveillance
- Pleural puncture: diagnostic
- Pleural puncture: evacuating
- Oxygen saturation measurement
- Supra-pubic puncture
- Swan Ganz: catheter placement
- Swan Ganz: cardiac output
- Swan Ganz: measurement, surveillance
- Thermometry: electrode or scanner

- Thoracic drain placement: pigtail, bullow
- Tracheotomie: percutaneous by ICU-physician
- Interhospital transport of ventilated patient, with monitoring by ICU physician
- Atrial stimulation
- Temporary pacemaker by an ICU physician: pacingball
- External pacing: Zoll
- Massive transfusion for a child < 7 y.
- Massive transfusion for a malaria patient

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4

COSARA: Integrated Service Platform for Infection Surveillance and Antibiotic Management in the ICU

The COSARA research project has the aim is to register and integrate infection-related data of the individual patient. COSARA targets the extraction and integration of clinical data and provides a visually attractive presentation of infections, antibiotics and clinical results of the ICU patient in real time. Moreover, it offers data analysis for clinical studies. In this chapter, we describe, analyze and evaluate the service platform for the Intensive Care.

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Abstract The Intensive Care Unit is a data intensive environment where large volumes of patient monitoring and observational data are daily generated. Today, there is a lack of an integrated clinical platform for automated decision support and analysis. Despite the potential of electronic records for infection surveillance

and antibiotic management, different parts of the clinical data are stored across databases in their own formats with specific parameters, making access to all data a complex and time-consuming challenge. Moreover, the motivation behind physicians' therapy decisions is currently not captured in existing information systems. The COSARA research project offers automated data integration and services for infection control and antibiotic management for Ghent University Hospital. The platform not only gathers and integrates all relevant data, it also presents the information visually at the point of care. In this paper, we describe the design and value of COSARA for clinical treatment and infectious diseases monitoring. On the one hand, this platform can facilitate daily bedside follow-up of infections, antibiotic therapies and clinical decisions for the individual patient, while on the other hand, the platform serves as management view for infection surveillance and care quality improvement within the complete ICU ward. It is shown that COSARA is valuable for registration, real-time presentation and management of infection-related and antibiotics data.

4.1 Introduction

The Intensive Care Unit (ICU) of a hospital is an extremely data intensive environment. With the emerge of information technology the monitoring data from medical devices, laboratory results, electronic prescriptions and therapeutic decisions, clinical observed values by physicians and nurses are captured in electronic medical records in clinical information systems. In Flanders, Belgium 65% of all ICUs used an electronic patient record, 41.3% a computerized physician order entry system, and 27% a computerized medication administration record in 2008 [1]. Initially electronic records were only used to store the registrations and for financial and administrative purposes. According to Lin et al. physicians' resistance to adopt health information systems was driven by low involvement in the design of user interfaces and the documentation of the systems [2]. A study to benchmark electronic medical records initiatives in the US, showed an increased adoption of medical records between 2005 to 2007 [3]. With the presence of high data volumes of clinical data, automated decision support, infection surveillance and antibiotic management have become important challenges.

Automated clinical decision support, based on the individual patient's conditions in the electronic records, can support the physicians in their medical actions. Examples of existing services include a service to alert for kidney dysfunction [4] based on laboratory parameters, a service calculating the Sequential Organ Failure Assessment Score (SOFA) as outcome score [5] and a service giving antibiotic advice [6]. Infection surveillance comprises on-going, systematic collection, analysis and interpretation of health data [7]. Especially in ICUs, infections are an important concern. The ICU is clearly the epicenter of the nosocomial infection

(NI). In Belgium the prevalence of NIs in the ICU is estimated on 25% based on the number of infections [8]. A nosocomial infection is an infection for which there is no evidence that the infection was present or incubating at the time of hospital admission [7]. Symptoms usually appear after 48 hours of admission. These infections are highly associated with antimicrobial resistance. Antibiotic resistance is the resistance of micro-organisms against several antibiotic medications. Policy regulations were introduced to reduce the improper use of antibiotics in several hospitals. An example is the adjustment of the antibiotic dosage.

The existence of electronic records facilitates the automation of clinical decision support by replacing the manual time-consuming analysis. However, current information systems do not offer an integrated view and analysis of all data present in the ICU, as data exists in stand-alone vendor-specific applications. As such, the physician has to consult all applications before being able to make a decision. There is a lack of an integrated patient record, and still the metadata and therapy intentions of the physician are missing in the electronic record, making clinical handover difficult. During clinical handover, the conditions and therapies of the patients are discussed between physicians. This diagnosis for infection and initiated therapy is not captured by the information systems.

The COSARA research project (Computer-based Surveillance and Alerting of nosocomial infections, Antimicrobial Resistance and Antibiotic consumption in the ICU) aims at the registration and integration of infection-related data of the individual patient. COSARA targets the extraction and integration of clinical data and provides a visually attractive presentation of infections, antibiotics and clinical results of the ICU patient in real time. Moreover, it offers data analysis for clinical studies. The client application consists of modules with infection overview, chest X-ray, antibiotics overview, microbiology results, linking and registration, catheters overview. A management view is created for statistics and quality improvement. This secondary use of data was previously not possible because existing electronic medical records typically do not track ICU-specific syndromes, care processes or outcomes [9].

The related work is summarized in Table 4.1. It includes recent research in which the focus is on infection control. Most of these research prototypes also prefer a service-oriented architecture in their design, in which independent functionality is designed as a service. Few ICUs have developed an integrated data warehouse [10, 11]. The COSARA service platform integrates the clinical sources, provides decision support and presents all relevant processed data on bedside client or nurse workstation.

This paper presents the COSARA research project at the ICU of Ghent University Hospital, an ICU with 56 beds and around 4,000 annual admissions. The objective of this paper is to address the integration of heterogeneous patient data sources in ICU in one system, create an overview for infection control and daily

Characteristics of related infection surveillance platforms
MERCURIO System (Lamma (2000)(2006) [12]) Research system at University of Bologna, Italy - Validation of microbiological data and real-time monitoring of infections - Creation of real-time epidemiological information system - Validation of microbiological data and alerting - AI techniques (expert system and data mining) - Database, Knowledge base and statistical module
GermWatcher electronic microbiology surveillance application, redesigned to enterprise infection control application (Kahn (1993), Doherty (2006) [13]) BJC Barnes Jewish Hospital, St. Louis, US - Parsing + organisms classification (1993:C++, 2004:Java) - Extraction of microbiology data from laboratory systems - Web-UI (JSF, Apache Tomcat), expert system - XML messages, XML-based rule set, Java Rule Engine
HAI surveillance information system (HASIS) (Lo (2010) [14]) Tapei Medical University Wanfang Hospital, Taiwan - Detection algorithms for infection control (guidelines) - Data collection, filtering processing and analysis - Service-oriented architecture - Web-based display with infection information
Multidisciplinary Epidemiology and Translational Research in Intensive Care (METRIC) Data Mart (Herasevich (2010) [9]) Mayo Clinic, Rochester, MN, US - MS SQL relational data warehouse - Data feeds imported from Electronic Medical Records - Web-based tabular reports, as report tool; Control charts
Monitoring of Nosocomial Infections in the ICU (MONI-ICU) (Chizzali-Binfadin (1995), Koller (2010) [15]) Vienna General Hospital, Austria - Automated real-time system for recognition, monitoring - Data import interfaces to existing clinical systems - Web-based + Java, Service-oriented architecture - Fuzzy logic, Medical knowledge in Arden Syntax
Computer-based Surveillance of nosocomial infections, Antibiotic Resistance and Antibiotic consumption in the ICU (COSARA) (new ICSP platform) (Steurbaut (2010) [5]) Ghent University Hospital, Belgium - Multidisciplinary design and development - Automatic data extraction from existing clinical systems - OSGi-clients + Java, Service-oriented architecture - Clinical guidelines as service logic, data reporting - Real-life application running at bedside clients in ICU

Table 4.1: Related work of recent infection surveillance platforms

follow-up and a complete data warehouse for clinical research. This paper addresses the following research questions: *What are the functional requirements of the integrated service platform? What platform components are necessary in its design? What are the evaluation results of the deployment at the hospital?* The multidisciplinary involvement of physicians and software engineers in the development process, with the use of web services and client modules led to a successful implementation with promising initial results [5].

This paper is structured as follows. In section 4.2 a functional overview of the platform is given, section 4.3 describes the platform components and implementation details are described in section 4.4. Platform scenarios are presented in section 4.5. Evaluation results of data performance and validation are shown in section 4.6.

4.2 COSARA Functional Overview

This section provides an overview of the main functional requirements of COSARA in order to deliver monitoring, follow-up and decision support at the patient level and extended management and reporting facilities at the unit or management level. Figure 4.1 shows the ICU setting of COSARA.

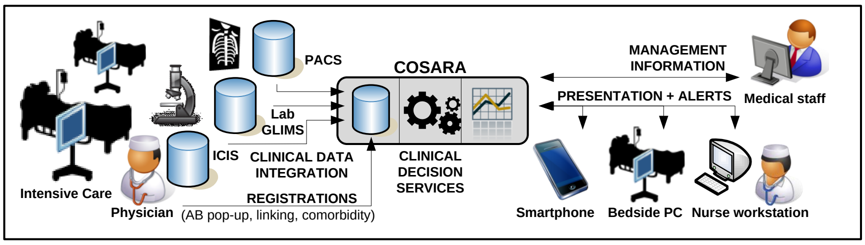

Figure 4.1: Overview of the COSARA ICU setting with data flow from clinical sources and physician's registrations, processing in the services platform and output to smartphone, bedside PC and nurse workstations.

- *Automatic Integration of Clinical Data*: Data from a range of different data sources is continuously automatically extracted and integrated in a clinical data warehouse COSARA, including the Intensive Care Information System (ICIS), the LabView-interface with access to the GLIMS Laboratory System, the X-ray photos in the Picture Archiving and Communications System (PACS). ICIS stores all data from monitors (ex. heart frequency, blood pressure), ventilators, observations (ex. placement of dialysis catheter, temperature measurement, urine output). Laboratory results (such as results of blood samples, detected bacteria, antibiogram) can only be accessed in the

LabView application. Every patient's X-ray chest photos are requested from PACS. Previously, multiple existing vendor-specific applications had to be accessed before the physician was enabled to make a complete diagnosis and decisions. With COSARA, additional metadata of the antibiotic prescriptions is also collected. Each time an antibiotic prescription is made, the physician's motivation for starting a therapy is registered in real-time by using a pop-up screen. COSARA permits the physician to review the microbiology history of the patient. Laboratory results from the patient's ICU admission as well as results from outside the ICU are collected (for example, results from up to 10 days before admission are also available in COSARA).

- *Presentation and Clinical Interpretation*: Infections and antibiotics data are presented in an up-to-date client as charts, visual bars on time lines and graphs. It gives the physicians an attractive real-time overview of all infections, the chosen antibiotic therapy and associated microbiology with cultures and antibiograms. Physicians can link the data and reconstruct their decision making process in the application. Links between all data that influenced the therapy decisions are made.

- *Clinical Decision Support Services*: The decision support logic is available as services and rules in a service-oriented architecture. Guidelines form the basis of the service logic [16]. The decision support services include a service to identify patients who receive prolonged antibiotic therapy (AB Prolonged), who receive inappropriate drug doses (AB Dose), who can switch from intravenous to per os antibiotics (AB IV/PO). These services assist the physician with suggestions on mail or in text message to optimize antibiotic management in the ICU.

- *Autonomous System Detection and Recovery*: Data gaps and unusual parameter values are detected in the extracted data. Data gaps can be caused by a link outage, communication failure, or failure in the services or originating system. A monitoring interface (of for example antibiotic prescriptions) shows if platform support is needed. Data and service recovery mechanisms have to be taken into account to limit possible downtime and to recover all data.

- *Alerting of Alarming Trends*: Timely interventions are crucial in the ICU. Therefore physicians should be alerted if patient conditions show an alarming trend.

- *Management and Reporting*: With the presence of a new integrated database, data can be used for reporting, research and data mining. This may lead to the discovery of new infectious patterns or new insights in therapy decisions.

4.3 Platform Design

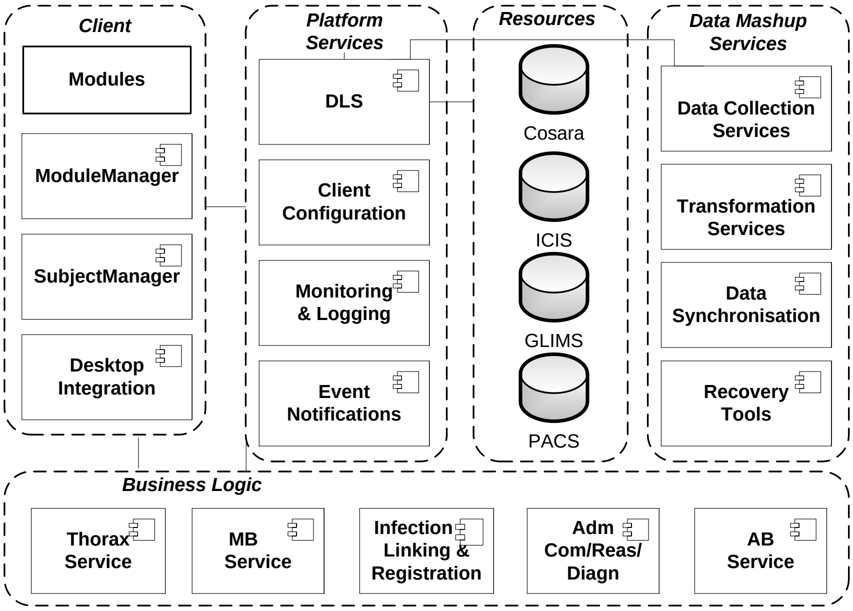

Figure 4.2: Design of the COSARA platform with client, platform services, data sources, data mashup services and business logic.

The COSARA platform components are shown on Figure 4.2, structured in components for the COSARA client, the platform services, data mashup services, the data resources and the business logic. COSARA integrates different data sources in one single application. First, data is continuously collected and transferred to the COSARA platform by the *Data Collection Services*. These services invoke the *Data Lookup Service (DLS)*. The DLS web service allows transparent access to the data sources (ICIS, GLIMS). It uses logic names for all data retrievals and hides the specific queries from the end user. The different database structures require a preprocessing step in the *Transformation Services* before storing the values in the relational database COSARA. The process differs from direct replication because only a selection of relevant values related to infections and antibiotic therapy are included. Other results such as microbiology reports and antibiograms need a parsing transformation step from text-based report to structured format of the susceptibility tests. The synchronization between the originating sources and the newly created database is a continuous real-time process. To ensure data quality in the client application, the database has to match the originating sources at all time. The *Data Synchronization* component periodically invokes the data collection services to gather the data. Synchronization is performed through a polling mechanism in which the databases are checked for new data in a recent time window. Polling was chosen because the vendor-specific external systems did not provide an interface for triggers as push-based mechanism. The chest X-rays are also retrieved with a polling mechanism which retrieves metadata and thorax photo. The synchronization service also checks if the data remains constantly in sync. If not, *Recovery Tools* provide a recovery mechanism of the data services or platform services and in case of detected failures it recollects all missed data.

The COSARA client provides access to a complete patient overview. This client is composed of *Modules*, such as infection overview, which is discussed in detail in section 4.5 in the platform scenarios. When the client is started from bedside PC or nursing workstation, the modules are loaded from the *Module Manager* on the client. In the *Client Configuration* the availability of modules can differ depending on the workstation or physician's specialization. For example, the management module is only shown to the medical staff while this module is hidden from nurses and physicians.

The client modules interact with the server-side *Business Logic Services*, which include thorax service, microbiology service, infection linking and registration, admission comorbidity, admission reason and admission diagnosis and antibiotic service. The *Thorax Service* calculates the CPIS score and handles the integration with the PACS database by requesting and filtering all ICU patients studies. The service queries for X-ray chest photos using the Digital Imaging and Communications in Medicine (DICOM) standard and caches the photos with its meta-data, after transforming them into JPEG-format. The *Microbiology Service* stores the sample orders, specimen, detected culture and antibiograms. The *Infection Linking and Registration Service* handles the linking of all related data in the system. The *Comorbidity and Admission Reason and Diagnosis Service* allows the registration of admission information, data that is not available today. The *Antibiotic Service* handles the processing of the prescriber's intentions in the antibiotic pop-up.

The *Desktop Integration* component integrates the COSARA client with the bedside ICIS client. When these two applications (COSARA and ICIS-client) are running, a switch in the patient selection in ICIS, automatically changes the selected patient in COSARA. This minimizes the client interactions. The patient selections are handled in the *Subject Manager*.

The platform services also include *Monitoring and Logging* and *Event Notifications*. These services can both be used for medical actions and for maintenance of the platform. Interruptions of the antibiotic pop-up service or interruptions in data from external sources can be monitored on a web-based display that shows the rate of complete antibiotic prescription pop-ups and data gaps in the system.

4.4 Implementation Details

For the platform design the service-oriented architecture (SOA) was chosen due to the advantages of reuse, rapid integration and flexibility. The services are deployed on a JavaEE Application server Glassfish. The application container contains Enterprise Java Beans (EJBs), Web Services and Business Process Execution Language (BPEL) interaction flows. EJBs are modular components that encapsulate business logic of the application at the server-side. The application server, on which these components are deployed, provides a persistence mechanism that stores entities (data objects) directly in the database through a persistence mapping. As such the data instances of objects are mapped on records in a database table. The application server also offers a security service, timer service and transaction processing. The server has already been widely used in eCommerce applications. A detailed description of the Enterprise Service Bus (ESB), that defines the communication infrastructure between services for routing medical data is given in [17].

The COSARA client is composed of modular components. OSGi (Open Service Gateway Initiative) offers a programming model in which the modules are loaded at runtime, without restart of the application and platform. Benefits of OSGi are the hot-swappable plug-in architecture, high reusability and efficiency [18]. The OSGi Base is Apache Felix, which implements the OSGi R4 Service Platform. OSGi is the framework for Java in which units of resources (referred to as bundles) can be installed. Bundles export services or run processes, and have their dependencies managed. A bundle can be expected to have its requirements managed by the container. Each bundle can serve as an independent unit. This modular update mechanism minimizes the maintenance effort on the 56 bedside PCs and nurse workstations. Using OSGi, updates of the programmed modules can be installed across all bedside PCs with minimal or no human interaction.

The clinical data is stored in a MySQL database. The amount of data of one year is shown in Table 4.2, which presents the data categories in COSARA, number of records and originating source. The Intensive Care Information System (ICIS) stores data in a Sybase database, the Laboratory system stores data in an Oracle database, and the Picture Archiving and Communication System (PACS) stores the thorax images in files that include also meta-data of the patient and the image.

4.5 Platform Scenarios

This section details scenarios of the application of COSARA in the ICU of Ghent University Hospital.

Data Category	Number records	Original source
Patient admissions	5,223	ICIS
Monitored values summary	131,464	ICIS
Lab orders analyse	217,321	Lab
Lab values (morning lab)	566,943	Lab/ICIS
Thorax metadata registr.	24,445	Thorax/COSARA
Catheters data	7,087	ICIS
Antibiotic orders	7,236	ICIS/COSARA
Infections	2,664	COSARA
Linked data	4,572	COSARA
Linked infections	1,819	COSARA
Scores	169,171	COSARA/ICIS

Table 4.2: Yearly number of data records in COSARA (April 2010-2011).

4.5.1 Daily patient-specific follow-up of infections and therapy

Figure 4.3 shows the patient-specific overview, as consulted on the bedside screen or central nursing workstation. It has graphs (with thrombocytes and temperature (A), CRP and WBC count (B), SOFA scores (C)), time line (D) with antibiotics, infections and microbiology access icons, and a details view (E) which displays extra information when the cursor if moved over the timeline. The physician has access to the complete history and current parameters of the patient. When a new antibiotic is prescribed in the intensive care information system, a pop-up appears on the screen to register the prescriber's motivation for starting or changing the antibiotic therapy. In the pop-up the diagnosis is associated with laboratory results such as new detected bacteria or the antibiogram with antimicrobial susceptibility tests of antibiotic resistance. Immediately after prescription, a time bar with the antibiotic prescription is visually shown on the screen. Both antibiotic therapies and infections can be seen in one view. With a few clicks all other related data (microbiology, antibiogram and responsible culture) can be linked with the current therapy. During handover between physicians, all previous decisions can be reconstructed easily.

4.5.2 Daily patient-specific follow-up of patient's chest X-rays

The thorax module shows the patient's chest X-rays (Figure 4.4 (A)). It has a timeline (C) which includes all photos transcoded from the PACS system. During weekly photo staff meetings all photos are discussed. Based on the input (B) from the physician, such as if a new or grown infiltrate and if the acute respiratory distress syndrome (ARDS) is observed, the thorax service automatically calculates

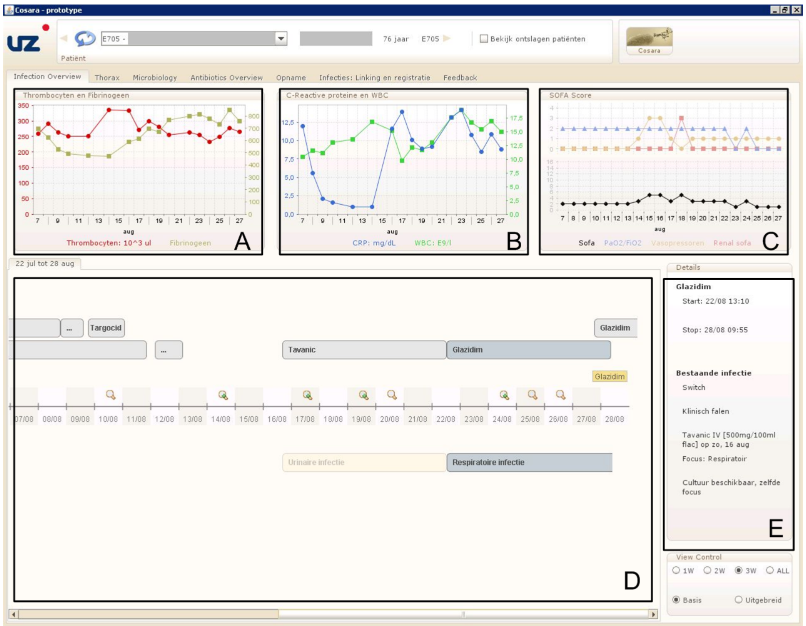

Figure 4.3: Screenshot of the infections and antibiotics overview in the COSARA client on the ICU bedside PC with graphs (thrombocytes, temperature (A), CRP, WBC count (B), SOFA scores (C)), a time line (D) and details (E).

the Clinical Pulmonary Infection Score (CPIS) and presents it in the client (B). Besides visual symptoms of pneumonia, part of this score is calculated based on clinical signs [19]. The following parameters are taken into account: temperature, leukocytes, presence and aspect of tracheal secretion (sputum), oxygenation, culture of tracheal aspirate (microbiology) [19, 20]. These parameters are automatically collected from the clinical information database by the COSARA platform. By interpreting the X-rays during the photo staff meeting clinicians enter the visual observation of infiltrates on the application. The Clinical Pulmonary Infection Score (CPIS) has been used in ICU as a decision research tool for initiation of antibiotics in suspected ventilator-associated pneumonia (VAP) and also for discontinuing antibiotics if the CPIS is lower than 6 on day three of the therapy, relying on the available clinical, radiographic observation and microbiology criteria, but is not common in clinical use [20].

There are also modules for microbiology, antibiotic therapy, admission cause with comorbidity and admission diagnosis, infection linking and registration, feedback and catheters overview. The microbiology module shows the antibiotic susceptibility reports (antibiograms) and a list of lab sample results. The antibiotic therapy module provides a historical overview of all given antibiotics to the pa-

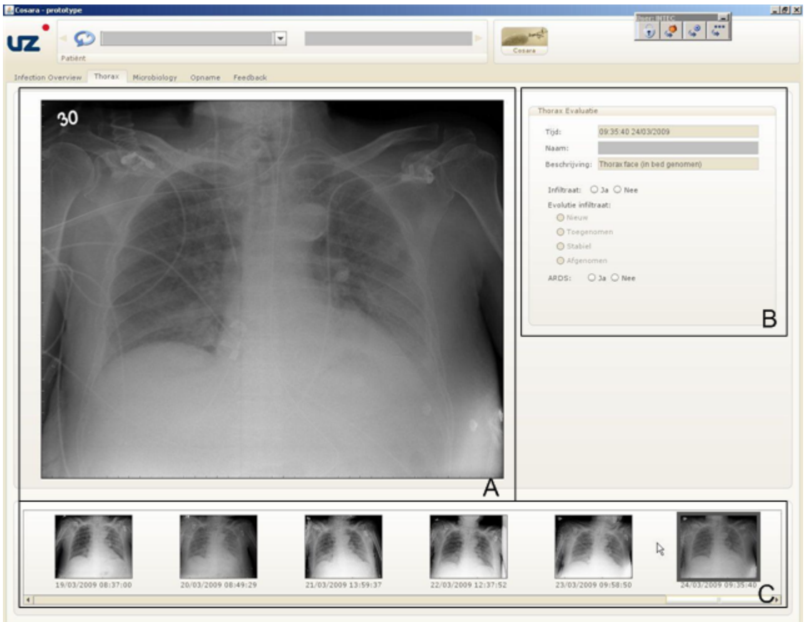

Figure 4.4: Screenshot of the chest X-rays (A,C) with feedback form (B), retrieved from the PACS system, in the COSARA client.

tient. In the linking module, the physician can link the patient's infections with the found micro-organisms and the given antibiotics. Feedback about the application can be collected in the feedback module. The catheters module provides an overview of all catheters.

4.5.3 Infection management on ICU unit

The management client (Fig. 4.5) offers statistics on the incidence of infections. Besides the graphical view, advanced queries of antibiotic consumption and microbiology results are executed on the COSARA database for clinical academic research. An example of an advanced query is: 'give the patients which were admitted to the medical ICU in 2010 and had a pneumonia infection for which the bacteria pseudomonas was identified, and where an antibiotic therapy with Glazidim was started'. The queries can be refined through the SQL viewer or with Crystal reports. By using data mining techniques patterns of infections and antibiotic therapies can be discovered, leading to new insights for the ICU. For example, if infection transmission across patients should be detected in a ward, new policy restrictions concerning hygiene can be applied very fast.

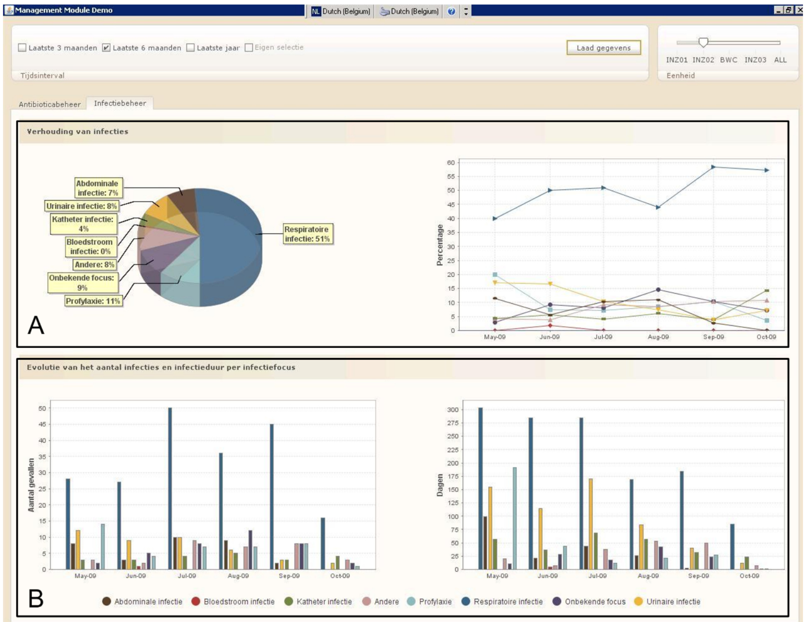

Figure 4.5: Screenshot of the COSARA management module with graphs displaying the division (A) and statistics of infections in the ICU wards in the last 6 months (B).

4.6 Evaluation Results

4.6.1 Performance Evaluation

The COSARA platform is running on AMD Dual-core Opteron Processor 2216 2.00 GHz, with 8 GB RAM and an installation of Windows Server 2003 R2 Enterprise Edition SP2. Fig. 4.6 shows the the daily total execution time of the queries in the DLS for the display of the graphs in the infection overview module (Fig. 4.3 A-C) across all running clients (invoked by refresh or patient switch in the client). The graph includes the execution times of the data retrievals of thrombocytes, temperature, CRP, WBC and SOFA score. Fluctuations in these values can be an indication of an infection. Each individual query has an average execution time of 3 ms.

Fig. 4.7 shows the number of invocations in the DLS to ICIS, GLIMS Lab and COSARA database spread over one day. The daily morning retrieval of grouped values such as maximum and minimum of monitored values and retrieval and checks of all data is noticed in the ICIS line. At 3 AM the number of COSARA queries is lower because a maintenance procedure runs. Both graphs display the average daily measurements. Continuous synchronization of clinical data between the systems ensures that COSARA is near real-time in sync with the originating system. Data is retrieved within a few seconds, dependent on the periodicity of configured data retrievals.

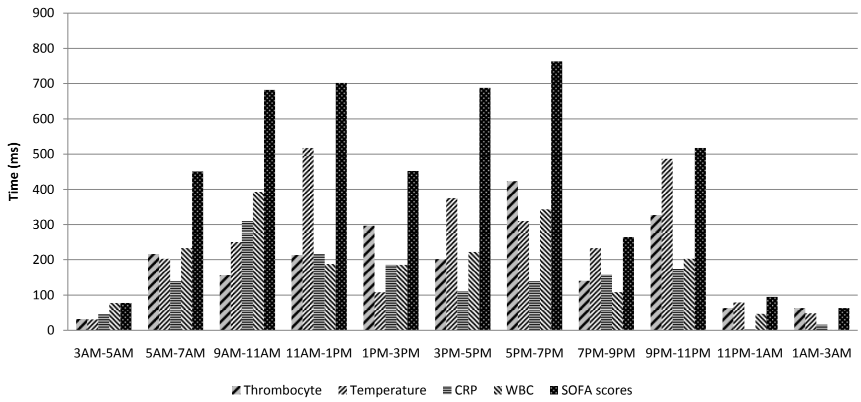

Figure 4.6: Total execution time in the Data Lookup Service (DLS) for the Infection overview graphs over one day, measured in time frames of 2 hours.

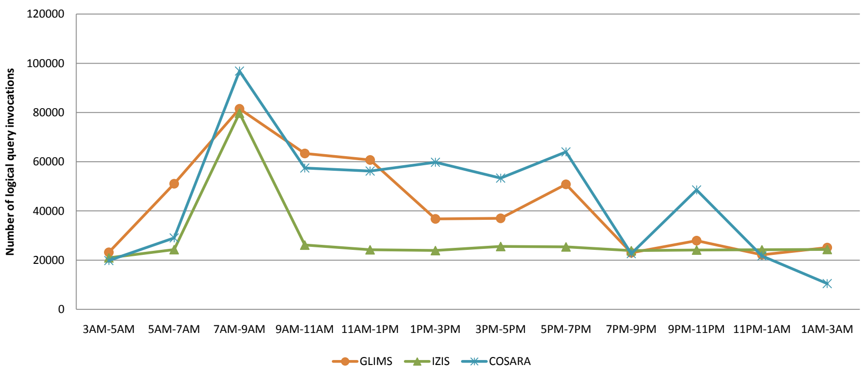

Figure 4.7: Number of logical query invocations in the Data Lookup Service, grouped by retrievals from ICIS, Laboratory Database GLIMS and COSARA

4.6.2 Study Nurse Validation

Since April 2010, the COSARA application has been evaluated. The study nurse compared the electronic records, stored in COSARA, with the records in the originating databases. To ensure data quality, manually, a selection of patient records were compared. Feedback of usage of the application was collected from the ICU staff, and the application was used as part of the clinical workflow, and during weekly staff meetings when patients' conditions are discussed.

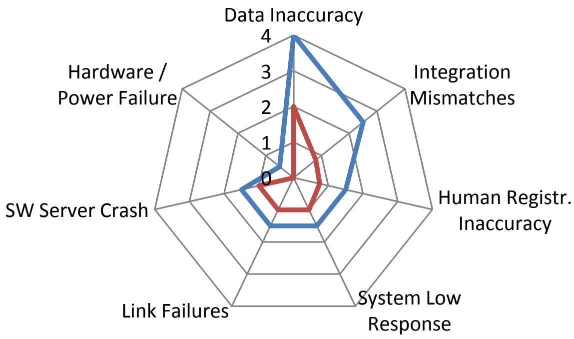

Figure 4.8: The relative number of issue reports by the study nurse split up in categories for data inaccuracy, integration mismatch, human registrations, low system response, link failures, server crash, hardware or power failure.

Fig. 4.8 shows the impact of reported issues by the study nurse to the developers. The issues included data inaccuracy, integration mismatches, human registration inaccuracy, slow system response, link failures, software server crash, hardware and power failures. Most issues were recorded on data inaccuracy as a result of external configuration changes. This has already resulted in changes in the synchronization service (changes in the frequency of retrievals, additional retrieval of parameters). Fig. 4.8 shows the issues importance in 3 months from April-July 2010 (outer line) and from January-April 2011 (inner line). It is shown that less issues are now recorded. Data inaccuracy could only be tackled for 50% due to configuration changes in the external systems which were still affecting the COSARA client. These issues include for example the intention of antibiotics which could not be registered due to a pop-up that did not appear as result of user rights which were not given to the application. Also sudden changes in structure of data strings led to parsing issues. COSARA hasn't led to erroneous decisions, because the inaccuracies were immediately noticed by the physician when the antibiogram did not appear entirely or as intention details were missing. Communication with the IT administrators of the external system minimized these issues. It is important to validate data where possible and to be informed of changes in data or external configuration. The COSARA development has been a continuous iterative process.

During the study nurse evaluation it was noticed that a thorough domain study of the ICU with all available infrastructure and dependencies for systems and data is essential. In order to replicate the platform to other ICUs, integration points with existing computer systems should be clearly identified. The queries in the Data Lookup Service can be replaced if databases have other structures, and the synchronization configuration such as timing and data variables and names should be changed. However, logic in automated decision support should be replicated with care, as the guidelines in the antibiotic services might be an implementation of local or regional guidelines.

4.6.3 Benefits

Although the availability of information systems, in which clinical parameters of laboratory and clinical condition are stored, before the introduction of COSARA a complete infectiological record of the patient could not be provided without consultation of all clinical software applications by the clinician. Unfortunately, not even in an ICU that utilizes advanced computerization, when the physician returned to work, all infectiological details had to be investigated in a way a detective does. The physician faced questions such as 'What was the chosen antibiotic therapy? Why was a therapy changed? What was the infection focus? Was it a firm diagnosis or suspicion? Are there cultures? What is the resistance? What is the radiological evolution?' With COSARA all data regarding infections, antibiotics and microbiology are brought together so that the physician can link these together in order to create new infectiological information. This reduces time for clinical handover between physicians. In addition, it also provides a high-quality database that supports infection surveillance and control policies and acts as a source to test research hypotheses. By linking the data to the intention of the physician is immediately registered in the system. Moreover, describing the clinical practice of prescribing antibiotics in ICU will be helpful in two ways: (1) to identify antibiotics overuse, (2) to contrast clinical perception of infection or non- or poorly resolving infection with a set of objective clinical or laboratory parameters and scores, including outcome. The multidisciplinary development of COSARA with cooperation of the department of Information Technology (IT) and the department of Intensive Care, makes the platform tailored to the specific detailed needs of clinicians and recent IT techniques are incorporated in the iterative design and development of the system.

4.7 Conclusion

In this paper we presented the COSARA research project, deployed in ICU of the Ghent University Hospital. The Computer-based Surveillance and Alerting of nosocomial infections, Antimicrobial Resistance and Antibiotic Consumption enables physicians to make clinical decisions provided with a complete view on infection parameters, antibiotic usage, microbiology results, the physicians therapy decisions and thorax photos.

In a multidisciplinary team of software engineers and physicians, the functional requirements were captured and agreed upon. These requirements include (i) automatic integration of clinical data, (ii) presentation and clinical interpretation of infections, antibiotics and pathology-related data on a bedside screen, (iii) provisioning of clinical decision support services that automate clinical practice guidelines, (iv) autonomous system detection and recovery mechanisms to maintain the platform, (v) alerting of alarming trends and (vi) management and reporting facilities for clinical research. In the design of the COSARA platform a layered service-oriented architecture was preferred. The design has platform services to access the different clinical data sources of laboratory (GLIMS), Intensive Care Information System (ICIS) and the Picture Archiving and Communication System (PACS). Due to the different data formats preprocessing services are necessary. The data processing has a Data Lookup Services, Data Collection Services, Transformation Services. Services such as Monitoring and Logging, and Recovery Tools support the maintenance. In the business logic clinical services that support the data flow in the modules on the client are included.

Three clinical scenarios were described in detail. At patient level COSARA is used for the daily patient-specific follow-up of (a) infections and therapy, and (b) the follow-up of chest X-rays. At the ICU level the management module offers statistics in the incidence if infections in the ward. The service platform offers daily value in the clinical workflow of physicians in the ICU. The clinical data integration of different databases and electronic registrations of physicians' intentions and decisions creates a unique source for daily bedside follow-up and infection surveillance with antibiotic management for the complete ICU.

In the evaluation, a performance evaluation and study nurse validation were included. Individual queries have an average execution time of 3 ms, and the execution time for the display of an infection related graph varies from 16 to 763 ms, depending on retrieval time. It is shown that most logical query invocation occurred during 6 and 9 AM, for data synchronization. In two validation periods of 3 months, a study nurse reported issues of the application. The platform had a continuous iterative development which resulted in less reported issues during the second period in 2011.

Future research of this COSARA platform will be devoted to the extension of the autonomic system monitoring and detection of changes in system performance through anomaly detection which signals abnormal behavior and data pattern changes of platform services. The platform is currently being extended with autonomic components in such a way that the system can self-maintain and self-govern the services. The study nurse validation process shows that data quality was perceived as the most important driver to adopt the full platform in the ICU setting. In future extensions, the role of the human operator should be reduced from taking recovery actions to changing policy rules or configuration settings.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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5

NEOREG: Design and implementation of an online Neonatal Registration System to access, follow and analyse data of newborns with congenital Cytomegalovirus infection

In this chapter, we design and implement a web-based registration system for the departments of neonatology. There is a strong focus on the web-based access in order to create a registry for multiple sites. The Java Enterprise layered architecture is discussed in detail. The NEOREG system differs from COSARA, as it provides remote access to the electronic patient records for physicians and general practitioners. The application consists of web-based interfaces and a document exchange template for the registration forms.

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Abstract Today's registration of newborns with congenital cytomegalovirus infection (cCMV) is still performed on paper-based forms in Flanders, Belgium. This process has a large administrative impact. It is important that all screening tests are registered to have a complete idea of the impact of cCMV. Although these registrations are usable in computerized data analysis, this data is not available in a format to perform electronic processing. An online Neonatal Registry (NEO-REG) System was designed and developed to access, follow and analyse data of newborns remotely, replacing existing paper-based cCMV forms. It allows remote access and monitoring by the physician. The Java Enterprise layered application provides patients' diagnostic registration and treatment follow-up through a web interface and using document forms in Portable Document Format (PDF) which incorporate all elements from existing forms. Forms are automatically processed to structured EHRs. Modules are included to perform statistical analysis. The design was driven by extendibility, security and usability requirements. The website load time, throughput and execution time of data analysis were evaluated in detail.

5.1 Introduction

The Flemish Society of Paediatrics' Neonatology and Perinatal Epidemiology Working Group aims to provide guidelines concerning diagnosis and therapy of newborns infected with congenital cytomegalovirus (cCMV) and to manage the follow-up of those children with the aim of studying the outcome prediction of the disease [1]. The guidelines provide physicians with evidence-based information and recommendations to treat patients with cCMV. The working group consists of neonatologists, otorhinolaryngologists and general paediatricians in Flanders. In eight Flemish hospitals, equipped with a neonatal intensive care unit (NICU), paper-based registration forms for cCMV infection have already been used since January 2007, with the purpose to register as much new-borns as possible with cCMV and track their progress.

Cytomegalovirus is the most common cause of congenital infection [2]. The incidence varies worldwide with an incidence of 0.5 to 1.3% of all live born infants in Flanders. With an annual birth number of 65,000-70,000 new-borns in Flanders [3] this means that about 400-600 newborns are affected per year. cCMV is the leading cause of sensor neural hearing loss, an important cause of neurologic developmental delay and causes a great disease burden on child, parent and community. The infection is transmitted prenatally. 10% of the infected newborns are symptomatic at birth, with symptoms being various, including hepatitis, low platelet count, microcephaly, intra-uterine growth restriction, hepatosplenomegaly or convulsions. Most of the infected new-borns (85-90%) have no clinical symptoms at birth. It is important that all of the infected children undergo screening tests (blood analysis, MRI and ultrasound of the brain, ophthalmologic and hearing evolution) to evaluate the impact of cCMV. Only the children, who are symptomatic at birth or have aberrant screening tests, may benefit from treatment with Ganciclovir (Cymevene) [4]. When an infant fails the hearing test, the baby is retested with at least one week interval. When failing is confirmed, the baby is referred to the audiology department for further assessment with brainstem evoked response audiometry. When hearing loss is confirmed, therapy with (val)ganciclovir is discussed with the parents [5]. However, the asymptomatic children are still at risk to develop long term sequel over the next years. These sequelae include hearing problems, neurodevelopmental delay and visual impairment. For that reason, it is suggested that all children with cCMV are followed during several years, so pending neurological, hearing, and visual problems can be detected in time.

The Neonatology departments of the academic hospitals of Ghent, Antwerp, Louvain and regional hospitals in Bruges, Antwerp, Wilrijk, Ghent perform a detailed registration of cCMV. For example, the NICU of the Ghent University Hospital consists of 32 beds, and acts as the coordinating study centre. Collecting patients' data has the potential to reveal correlations between diagnostic variables, offer new insights in the data and hence lead to better treatment and improved quality of care. However, today, this data is still collected manually in paper forms, making it very difficult to perform data mining or apply computing techniques to discover trends.

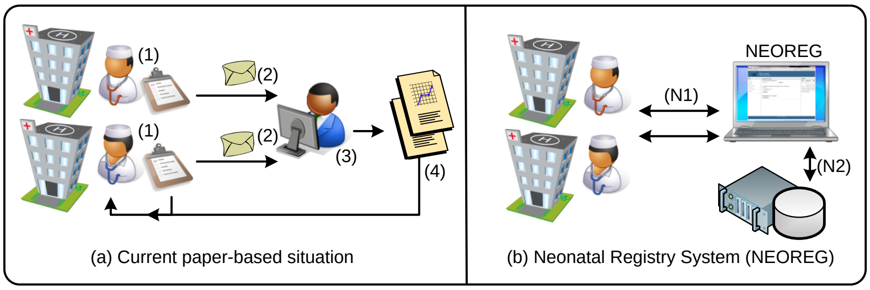


Figure 5.1: Transition from (a) the current paper-based workflow to (b) electronic records using NEOREG.

When cCMV is detected in the laboratory results of the new-borns' urine, the physician fills out a paper-based form, after informed consent of the parents. The parents permission is asked to record the data in an electronic register and data is anonymized for data research. Figure 5.1 shows schematically the current workflow. The diagnosis forms (1) include the results of central radiology (based on echography, CT scan or NMR scan), eye fundus, audio logical results and blood analysis. A follow-up process has to be completed with audio logic evaluation each 3 months till the age of 3 years and later each year till the age of 6 years. The neurological development is evaluated at 4 months, 1 year, 1.5 years, 4.5 years and

6 years. The ophthalmologic follow up is repeated every year. All paper forms are delivered to the coordinating centre (2). Current analysis of the paper-based records is time-consuming, labour-intensive and difficult. At the coordinating hospital, the content of the forms is entered in a computerized spread sheet (3) to enable minimal data analysis (4). For long-term statistical and pattern analysis, a database is needed. It is important that the system supports flexible updates when new data types or decision support facilities are needed.

The potential of electronic records to conduct data analysis and support clinical decisions has already been widely recognized [6–8]. However, data is often not available in a format for analysis and research [9]. Computerized decision support systems can be developed that estimate prognosis, detect patterns and as such support ethical decision making in complex medical issues for parents and physicians in NICU [10]. Yang et al. [10] address the challenging question if there are data indicators with respect to the childs' health status that can guide the best decisions regarding when to initiate, withhold or terminate treatment. Skouroliakou et al. [11] studied the benefits of an electronic registry in a NICU in Greece and found that electronic collection and analysis led to significant findings at epidemiological, medical resource utilization and hospital cost levels. According to Cordero et al. [12], the implementation of computerized physician order entry (CPOE) resulted in reduction in medication times, medication errors and decreases in service response times.

Electronic Health Records (EHR) facilitate better follow-up of physician's diagnosis and the patient's condition. Urschitz et al. [13] reported about the experience with a Patient Data Management System (PDMS) at a NICU in Vienna, Austria. The database gets manual input and inputs from the monitoring system, by collecting data from external data sources, and from the lab information system. Knowledge based systems are available for calculating the parenteral nutrition of newborn infants, for advising medication, for managing mechanical ventilation. More than 2/3 of the users preferred computer assisted documentation to charting by hand. PDMS have to be constantly adapted to the user's needs and to the changing clinical environment. However the benefits of electronic registration, not all departments have already adopted an electronic register. Moreover, the cCMV registration is not included in existing clinical information systems.

In this paper we propose the web-based Neonatology Registration System (NEOREG) which supports data registration of CMV and automates the follow-up process. The system has the following objectives for registration of newborns: registration of (i) the physician's diagnosis, (ii) abnormalities at birth, (iii) evolution of treatment and (iv) the periodic follow-ups of psych motoric function, hearing and visas at long term (till the age of 6 years). NEOREG aims to provide a patient registration and remote follow-up system for all children infected with cytomegalovirus in Flanders, Belgium. Using NEOREG, human processing tasks are eliminated, as shown in Figure 5.1. The website offers statistical components to visualize patient's prognosis at long term. If a follow-up is necessary, an e-mail alert is generated to arrange an appointment with the patient. All records can be accessed remotely on the secure website. In previous work [14, 15] we have already demonstrated the benefits of computerized support for the Intensive Care Unit (ICU) for the follow-up of infections and management of antibiotic therapies. In contrast to the latter research project, where integration with already existing electronic records from diverse sources was performed, the NEOREG System replaces the existing paper-based registrations of cCMV.

Paper Organization

This article is structured as follows. The Methods section details the registration scenario. Design objectives for the architecture are described, together with a detailed explanation of the architecture. Next, implementation details are provided. Furthermore, a description is provided of the usage of the Java Enterprise framework, the PDF form generation process, persistence of data and data analysis. The Results section contains the dataset characteristics and the performance evaluation. The discussion section deals with the impact of electronic records versus paper-based records. Finally, in the conclusion the contributions to the registration of cCMV are summarized.

5.2 Methods

In this section the development methodology is described. First, the registration scenario with several questionnaires is described in detail. Second, the design objectives are formulated. In the architecture details, the layered application is shown. Finally, implementation details are presented.

5.2.1 Registration scenario

After secure login, a newborn infected with CMV can be registered by uploading a filled-out questionnaire. The system starts a follow-up mechanism, in which a timely follow-up of the patient is requested, as an electronic alert to the responsible physician or paediatrician. Each data entry form is a Portable Document Format (PDF) file, as required by the infection working group in order to guarantee a higher adoption by physicians after a switch from the paper-based files. PDFs can be stored and filled-out on off line systems too. Only for the upload and access to historical patient records an Internet connection is required. The system converts the information in the PDF file to electronic records in a database. Figure 5.2 shows a screenshot of the registration form. There are six available CMV questionnaires in the system:

1. Registration form: this form consists of general information about the newborn. It includes detailed information about the birth and the mother.

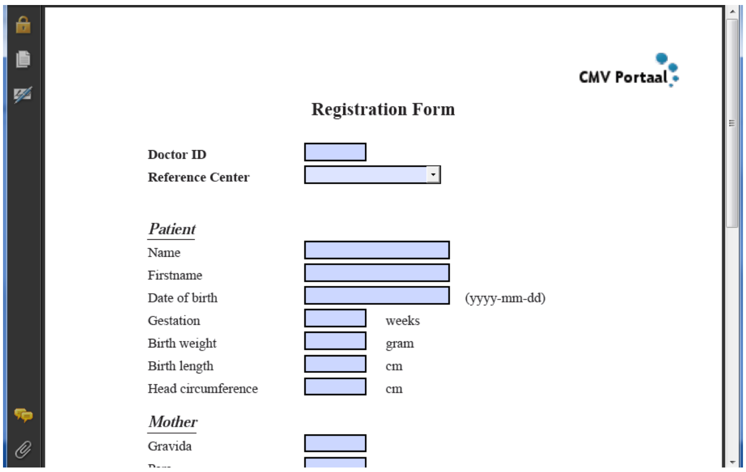
2. Diagnosis form: the form contains the results of the examinations, which forms the basis for the physician's diagnosis. It has the results of examinations in prenatal and postnatal phase.

3. Treatment form: this form enables the physician to start or stop a therapy.

4. Follow-up Development form: periodic follow-up concerning the patient's condition, the mental state, IQ, psych motoric functioning, is registered.

5. Audio logical Diagnostics Intake form: the form includes several clinical evaluation results of the hearing of the patient.

6. Audio logical Diagnostics Follow-up form: the audio logical aspect is continuously followed. The form is filled out at the age of 3, 6, 12, 18, 24, 30 months and at least once per year till the age of 6 years.



CMV Portaal

Registration Form

Doctor ID

Reference Center

Patient

Name

Firstname

Date of birth (yyyy-mm-dd)

Gestation weeks

Birth weight gram

Birth length cm

Head circumference cm

Mother

Gravida

Figure 5.2: The CMV Registration form gives an example of our CMV questionnaire including the text fields to register a newborn with cCMV.

5.2.1.1 Design objectives

The focus was on the security, usability and extendibility requirements. We applied the layered approach of enterprise applications. The three-layered architecture consists of a Presentation layer, Processing or Business layer and Data layer. The Presentation layer offers a registration website. Through a security component, access is given to the medical records according to the user's role and the hospital policy. The website enables the upload and download of forms. The Processing layer collects the information in the forms and instantiates the information in data objects. The Data layer provides the persistence of the objects in the database.

Security is enforced by a role-based authentication mechanism. This means that at login only access is given to functionality according to the role access privileges. NEOREG has three user roles: system administrator, physician or paediatrician, clinical researcher. The last role has only access to anonymous data analysis for clinical studies, while the physician can see all data. The system administrator has access to configuration of the system. Additionally, the registration and login of a user can be done with an electronic identity card or by user-password credentials. The Belgian identity card can be used for authentication and authorization. The PDF forms are also protected with the user's password.

The second objective is usability for registration, display and analysis of patients' data to stimulate adoption. The system must be integrated in the existing physician's workflow. Therefore, this electronic registration is almost identical as paper-based registration. Instead of the paper forms, data is entered in a PDF, which can be processed by a computer. If the physician still wants to keep a paper-based print-out, an identical paper will be produced, while the system stores the data entries for long term analysis. The system should offer a display with a summary of all entered data. In addition to simply storing the data, the system should provide data analysis functions (allowing for instance estimation of hearing prognosis of the patient or statistics of the population of newborns with cCMV).

A third architectural driver is extendibility of the registration. As the medical therapies are evolving, the registration forms should be extendable with new data entries. The existing template form contains a list of possible diagnostic options, treatment or measurement categories. This list can be adapted at runtime by changing the configuration. In fact, these configured options are added in the database, which enables the PDF template form to dynamically rebuild itself. The new empty template can be downloaded by the physician. Existing filled-out templates are still supported.

5.2.1.2 Architecture Details

The layered architecture is shown in Figure 5.3. The *Web-Presentation layer* with the web pages (Figure 5.4) has a Security component that ensures authorized access to the records. The *Processing layer* has specific components for the follow-up and analysis. The PDF processing component creates automatically new survey forms and processes the filled out forms. Initial questionnaire templates are configured and can automatically be updated in the web interface, if new questions should be added. E-mails and alerts of data changes, new registered users or platform maintenance are delivered by the Alerting component. A Timer component keeps track of the follow-up moments and sends automatically an e-mail to the

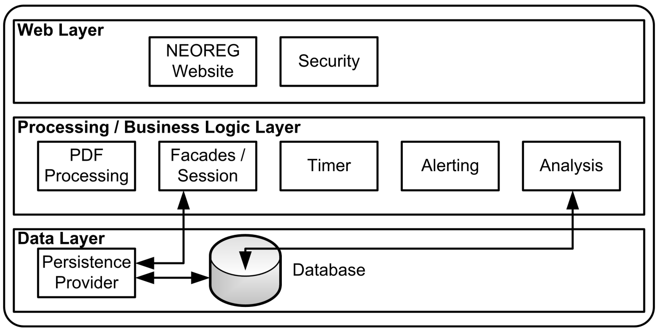


Figure 5.3: High level overview of the NEOREG Layered Architecture.

physician to remind that a new consultation is needed. The periodic follow-up periods are preconfigured. The Analysis component includes 17 predefined analysis cases. For each case specific data queries are available. It can be used in statistical clinical research. The main purpose of the *Data layer* is to provide a complete storage of CMV records. The database consists of general information of the newborn and the mother. Diagnosis, follow-up, audio logical diagnose and audio logical follow-up data are linked to the patient data when a form is uploaded.

5.2.2 Implementation of the web-based registration system

5.2.2.1 Java Enterprise Application

Java Enterprise Application The NEOREG system was developed using Java Enterprise Edition (Java EE) platform and deployed on the Glassfish Application Server. Java EE technology has already been applied in cases from e-commerce [16], e-learning [17], as well as in e-health with real life clinical cases at intensive care [18], dental care [19], and laboratory [20]. Its layered approach has several advantages [19]: (a) changes in database do not affect the user's application, (b) scalability or extendibility is provided by using a separate business layer, and (c) security mechanisms are provided by the platform.

Java Server Faces (JSF) technology is embedded in XHTML. Additional JSF component are used from the Primefaces library, for example to support AJAX calls. The role-based security is enforced by the Java Authentication and Authorization Service. The web layer has managed beans to call session beans. Language independence is enabled through property files. In the business layer session beans act as facade to the data layer or provide logic. Facade session beans have operations to create new entities, persist, remove, find and merge with existing data objects. The timer is implemented as an EJB Timer session bean and checks daily if new alerts for consultations are needed.

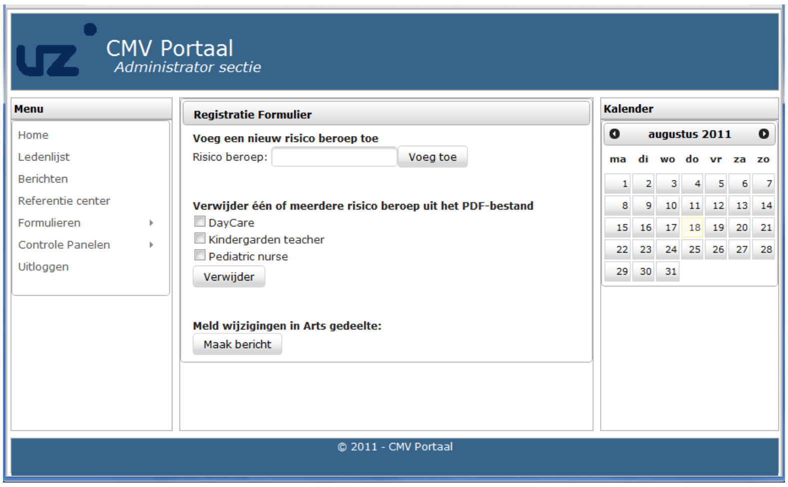


Figure 5.4: Overview of the cCMV portal website. On the left hand side of the website, the physician can access the pages to register new forms, access previous data and check registered patients. On the right hand side a calendar pane is shown which is connected with the alerting component, to track follow-up of patients. The central pane contains a list of registration options for diagnostics or treatments. By adding options, the form is automatically changed and a new questionnaire template is produced.

5.2.2.2 Portable Questionnaire Forms

The paper-based forms are replaced with Adobe Portable Document Format (PDF) forms. It has the advantage of being independent from the applications, hardware and operating system. The PDF files contain interactive elements such as form fields. In the NEOREG system we used the iText open source Java Library [21] to create and read the PDF forms. PDF Encryption is enabled at creation time. The PDF template form is built up from code and the input values for checkboxes and text fields are selected from the database. Since the PDF 1.2 specification, AcroForms or Acrobat Forms have been supported for integrating data and PDF forms. The AcroForms provide standard form components (such as text fields, radio buttons and checkboxes) and support limited Javascript usage for validation of input fields. The data elements are kept in key-value pairs. The PDF component uses iText to read data form entries and insert data in the database.

5.2.2.3 Data Persistence

The database (Figure 5.5) is built up through the Java EE Persistence API, a Java programming framework for the management of relational data. An entity maps to a table in the database, while instances of the entity correspond to individual rows in a table. Relationships between entities can be expressed in objects with metadata and annotations. Considering the hospital's experience, we used the Oracle 9 database.

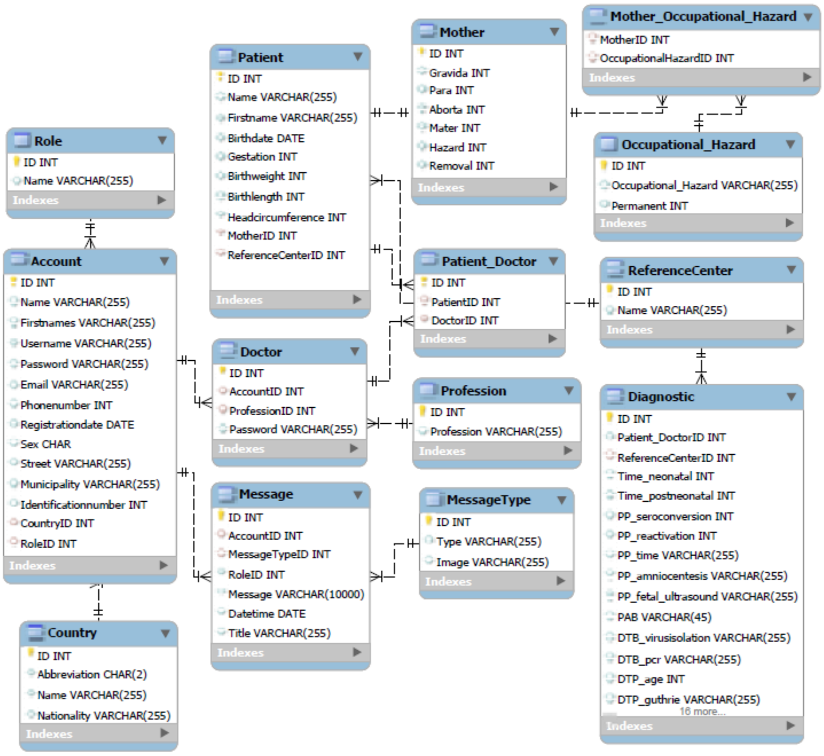


Figure 5.5: Overview of the NEOREG database structure.

One of the main objectives was the possibility to change and extend existing functionality and persisted data. During the development we investigated two persistence approaches to cope with changes in the data forms. One approach is to rebuild and automatically change data columns and tables when major changes are applied to the form templates. Each object (entity) contains annotations which guide the persistence process. For example the annotation Entity means that the object will be transformed into a data table. As such, relationships between objects and the actual objects are modelled at design time. When new templates are created, Java reflection is used to create the necessary Java programming code, which is later deployed on the server. The second approach is to maintain the current data structure, but change the configuration of data values. In this approach, additional data values are stored in the configuration table that builds up the form. By creating many-to-many relationships between data variables and form template, the form is automatically built up with the necessary data variables that should be included in the questionnaire. We chose the second approach for the system to minimize redeployment of the system.

5.2.3 Results

5.2.3.1 Dataset Characteristics

The current dataset of the NICU of Ghent University contains 149 patients. The working group consists of 20 members from the participating hospitals. The 149 patients comprise 74 (49.7%) male newborns, 70 (47.0%) female newborns and 5 (3.4%) missing documented cases. The set spans the period from January 1, 2007 to December 31, 2010. The register of patients with congenital cytomegalovirus infection in Flanders and the informed consents are approved by the Ethics Committee of Ghent University Hospital (EC UZG 2008/247, Belgian Registration number: B67020084124). The patients' parents approved the registration by signing the informed consent (in Dutch, French or English) giving permission to include the newborns' data in the electronic database and to use the data for scientific purposes on the condition that confidentiality is ensured. The registration is also included in the public register of data operations maintained by the Commission for the Protection of Privacy of the Belgian Federal Government [22].

5.2.3.2 Performance Results

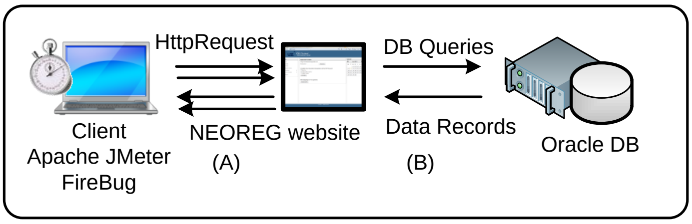


Figure 5.6: Evaluation setup simulating (a) user requests and (b) data queries.

The performance was evaluated by emulating 500 simultaneous users interacting with the web application. We evaluated the performance by measuring the load times of the web frontend (as shown in Figure 5.6). Each user calls the website through an http request. The evaluation was performed on a client that has an Intel Core 2 Duo CPU with 2.4 GHz and 4 GB RAM, running the 64-bit Windows 7 Operating System (OS), Java Runtime 1.6.21 and Apache JMeter. The web application was deployed on a Windows XP Pro OS server on an AMD Athlon 64 X2 Dual Core Processor 5200+ with 2.7 GHz and 3 GB RAM. The server has the Glassfish 3.0 Application Server. It is expected that initially only 10 to 50 users will access the application. This corresponds to a load time between 28 and 48 milliseconds, which results in an excellent quality of experience of the users.

Webpage	*Size (KB)*	*Time (s)*	*Std dev (s)*
Login page	613.7	4.036	0.957
Physician overview	623.4	3.319	1.031
Download page	624.9	3.998	1.277
PDF selection page (register)	291.2	12.950	1.321
PDF selection page (follow)	283.2	11.924	1.421
Patient list page	670.8	5.534	1.853
Data analysis page	807.7	6.564	1.515

Table 5.1: Website performance measurements (Load time for most consulted webpages of NEOREG).

Figure 5.7 shows the throughput and number of kilobytes per second for 10 to 500 users. Table 5.1 shows the detailed results of a typical user scenario, measured by FireBug, a plug-in for web browser Firefox. The user logs in on the website with his/her user credentials, downloads an empty PDF questionnaire, fills in this template and uploads the form. Later the user reviews and analyses this data on the website. The display and download times are within acceptable range but the PDF takes more time due to the generation process. In addition, the execution times for the retrieval of data analysis cases were also measured. Figure 5.8 shows the execution times for the audio logic data and neurologic data for several data analysis cases. One case had a longer execution time and took 61.12 s. All other cases' execution time ranges from 0.23 to 2.54 seconds and are shown on Figure 5.8. The queries for audio logical data take more time due to a higher number of variables in the queries.

5.3 Discussion

Today, most hospitals are equipped with an information system that monitors vital parameters and collects records from laboratory and observations. Unfortunately, the coordinating NICU was not using a complete system for registration of newborns' diagnosis. The NEOREG system fulfils the need for the registration of congenital cytomegalovirus infection and could even be extended to registration of other parameters by adding forms or integrating the outputs of medical devices directly in the system. The NEOREG system follows a centralized approach in which cCMV patient records of the hospitals are stored in a central database. In the paper-based registration it was noticed that there were a large number of missing registrations. Afterwards, it was not clear if the values were left intentionally blank on the paper forms or if part of the follow-up process was missing. Using

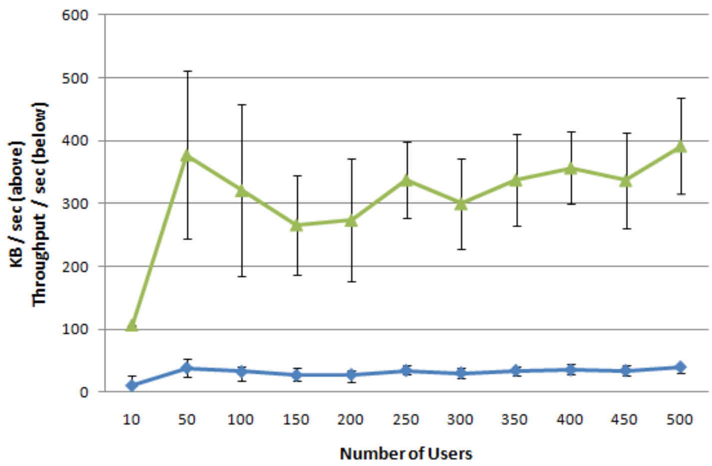


Figure 5.7: Throughput and KB/sec with standard deviation.

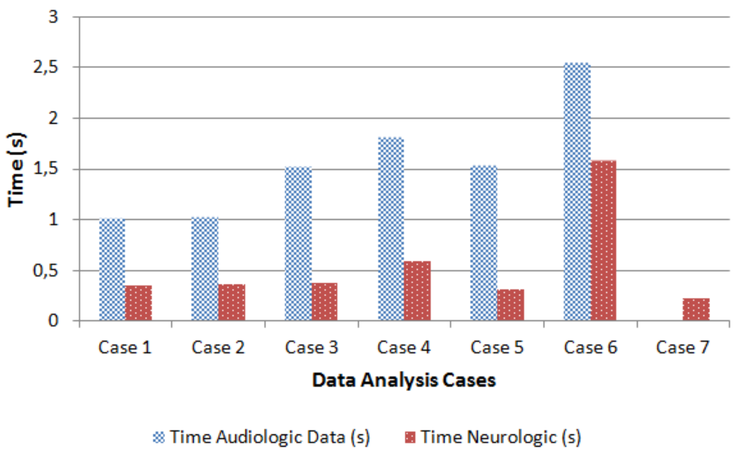


Figure 5.8: Execution time of the data analysis cases.

a computerized registration, the completeness of the forms and the timely follow-ups can be validated automatically and users can automatically be reminded at regular times.

Christensen and Grimsmo [23] conducted a study of GPs' use of electronic patient records in terms of the use of different functionality, time spent and the effects of EHRs in Norway. The overall availability of individual patient records had improved compared to the handwritten paper-based records, but the information within the EHR was not satisfactory. Time studies on physician use of EHR didn't show a time reduction but the potential benefits were: simultaneous access by multiple users, improved readability compared to handwriting, automated generation of reports in different formats to do analysis. The proposed system also offers these benefits. Raptis et al. [24] suggested for the management of cancer target referral patients that web based software is effective in facilitating and improving the quality of information between users.

The Erasmus Medical Centre of Rotterdam developed an open structured data entry application to support structured recording of patient data in any medical domain. Roukema et al. [25] found that the electronic records of physical examination in paediatric outpatient care were more complete and contained additional information whereas in the patient history, which has mostly a narrative information nature, information was missing. Similar to NEOREG free text data entries are allowed to register findings which were not present as structured checkbox values. Some free text entry boxes could not be replaced by a structured entry. Configuration in NEOREG turns frequently occurring text entries into permanent checkbox values by adapting the variables and dynamically rebuilding the PDF questionnaire templates. Despite the increasing availability of electronic systems, clinicians often continue to use paper to complete their work. Saleem et al. [26] explored the factors that cause users to use papers instead of EHR. The technology should offer the same convenience in the clinical workflow as the usage of pen and paper to guarantee full adoption.

To guarantee system adoption, specific training of physicians will be required. Although the user interface is easy to use, previous implementations have already indicated that training is essential. Alberdi et al. [27] investigated the role of computerization in neonatal intensive care and found that a lack of system training affected the staff usage of the computerized information system for NICU. During the consultation of NEOREG on a client PC, we detected that users should be made aware of all functionality, their browser requirements and how to effectively fill out the PDF forms by demonstrating the usage. Additionally, documentation and a manual with the functionality are provided.

NEOREG Data may contribute to investigations of neonatal research networks. Fanaroff et al. [28] describe the changes in therapy practice and outcome amongst network centres during 15 years. The paper details the collected information of the Enice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Neonatal Research Network in the US. A very low birth weight (VLBW) registry has been maintained. VLBW incorporates perinatal and neonatal data of all infants with a birth weight lower than 1500g cared for at the participating centres. Similar to NEOREG, maternal and infant data are collected and stored.

5.4 Conclusion

The NEOREG system supports the registration of newborns infected with congenital cytomegalovirus. The web-based system replaces the existing paper-based forms with a similar electronic portable document forms. It allows remote access and telemonitoring of the patient's records. This paper describes the architecture and evaluation of the electronic registration system NEOREG. The database characteristics and performance of the NEOREG website have been thoroughly evaluated in this paper. When NEOREG electronic data records are used, data can be queried more easily to conduct clinical studies. It is expected that NEOREG electronic registration will contribute to higher data quality and detailed follow-up of patient registrations.

Conflict of Interest

The authors declare that they have no conflict of interest.

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6

Autonomic care platform for optimizing query performance

In this chapter, we focus on autonomic extensions to the COSARA architecture, as presented in chapter 4. Control loops are presented to optimize the query performance. The detection of performance drops by anomaly detection is studied in detail. It is shown that autonomic management components significantly improve the quality of service of the studied COSARA health care platform.

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Abstract

Background: As the amount of information in electronic health care systems increases, data operations get more complicated and time-consuming. Intensive Care platforms require a timely processing of data retrievals to guarantee the continuous display of recent data of patients. Physicians and nurses rely on this data for their decision making. Manual optimization of query executions has become difficult to handle due to the increased amount of queries across multiple sources. Hence, a more automated management is necessary to increase the performance of database queries. The autonomic computing paradigm promises an approach in which the

system adapts itself and acts as self-managing entity, thereby limiting human interventions and taking actions. Despite the usage of autonomic control loops in network and software systems, this approach has not been applied so far for health information systems.
Methods: We extend the COSARA architecture, an infection surveillance and antibiotic management service platform for the Intensive Care Unit (ICU), with self-managed components to increase the performance of data retrievals. We used real-life ICU COSARA queries to analyse slow performance and measure the impact of optimizations. Each day more than 2 million COSARA queries are executed. Three control loops, which monitor the executions and take action, have been proposed: reactive, deliberative and reflective control loops. We focus on improvements of the execution time of microbiology queries directly related to the visual displays of patients' data on the bedside screens.
Results: The results show that autonomic control loops are beneficial for the optimizations in the data executions in the ICU. The application of reactive control loop results in a reduction of 8.61% of the average execution time of microbiology results. The combined application of the reactive and deliberative control loop results in an average query time reduction of 10.92% and the combination of reactive, deliberative and reflective control loops provides a reduction of 13.04%.
Conclusions: We found that by controlled reduction of queries' executions the performance for the end-user can be improved. The implementation of autonomic control loops in an existing health platform, COSARA, has a positive effect on the timely data visualization for the physician and nurse.

6.1 Background

With an increased growth of clinical support services and data sources, clinical information service platforms are becoming more and more complex. The emergence of medical devices, which monitor and collect data at high frequency, the availability of data in numerous databases and the increased utilization of the electronic patient data to support physicians' clinical decisions, demand a high speed of data processing. Physicians and nurses put trust in electronic medical records to evaluate the patients' conditions and to treat patients by taking therapeutic decisions. Slow data retrievals force the physician to wait longer for results of the current state of the patient. Due to the large amount of data variables and hence a high number of database queries, manual maintenance operations are no longer possible. For example, manually disabling time-consuming non-priority data retrievals in case of high load on the system is difficult. Moreover, in the medical environment the contents of the database is constantly changing with inserts of medical data or updates of existing values from medical devices which monitor the patient at high frequency or analyse the patients' laboratory samples. Despite system administrators' efforts to maintain critical health systems, symptoms of data slowdown cannot be detected in time and actions cannot be taken quickly enough to prevent performance decrease or system failure. This leads to a degradation of service quality and availability. Therefore, the manual reaction to such slow processes undermines the robustness and performance of the complete system.

The autonomic computing paradigm aims to develop systems capable of self-management, which make decisions on their own and respond with appropriate actions on system failures or optimizations. This concept is in analogy with the autonomic nervous system, which manages our vital functions in the body without conscious directions [1]. In autonomic computing, an autonomic manager implements control loops in which the managed element and the environment is monitored, data is analyzed, and actions are taken if components are in an undesirable state. It envisions a self-aware software system.

In this article, we extend the existing COSARA health care platform with autonomic components. COSARA is an infection surveillance and antibiotic management service platform for the Intensive Care Unit (ICU) [2]. We propose extensions to COSARA by introducing multiple autonomic control loops. The reactive control loop takes an immediate action when slow data query executions are detected. In the deliberative control loop the decision to act is evaluated in an anomaly detection algorithm with detection of anomalies in the execution times of data retrievals. Anomalies are also predicted in the reflective control loop by detecting temporal periods with slow performance. A detailed analysis has been performed based on real-life data logs from the COSARA platform in the ICU of Ghent University Hospital.

This article is structured as follows. In Section 6.1.1, an overview of autonomic computing architectures is presented and specific models from the health care domain are explored. The problem of managing COSARA data queries is thoroughly explained in Section 6.2.1. The extended architecture of the COSARA service platform is presented in Section 6.2.2. Section 6.2.3 describes the multiple control loops, which enhance performance of data queries. This includes a reactive loop, a deliberative loop that takes a decision by executing an anomaly detection algorithm and a reflective control loop that takes a proactive approach by detecting temporal patterns. Subsequently, the optimizations are evaluated in detail in Section 6.3. Finally, Section 6.4 presents the conclusions of this paper.

6.1.1 Related work

Although autonomic management has received attention in enterprise wide network platforms, only a limited number of studies apply autonomic management to health care platforms. In this section we examine related work in both domains.

Autonomic Management in Health Care

Autonomic computing has already been applied in body area networks in health care. On-body sensors monitor the patient's vital functions such as heartbeat, body temperature or electrocardiogram (ECG) in a body area network and transmit the signals to a processing unit. Since this equipment is hard to maintain by its developers, the system should adapt automatically to changes. The telemonitoring applications that use continuous monitoring of patients' health conditions require the self-management ability that autonomic systems propose [3]. In [4], an event service for autonomic management support for e-health systems is proposed using Self-managed cells (SMCs). SMCs are autonomic systems that are able to add or remove components, detect failures of sensors automatically and adapt the system.

In [5], it is described as an architectural pattern to provide Autonomic Management of Ubiquitous e-health Systems (AMUSE). The system needs to be self-configuring and self-managing with limited user interaction and autonomously adapts to changes in user activity, device failure and service addition. The SMC consists of an event bus, for communication between devices and management services, a discovery service and policy service [4]. The policy service specifies the adaptation strategy (adaptation, authorization policies and event-condition-action rules) whereas the discovery service implements the protocol to search and integrate new devices in the SMC and maintains the connections. Changes in the environment are indicated by events, which trigger policies in the policy service and hence perform the action [6]. In the used publish-subscribe mechanism, messages are published on the event bus and delivered to its subscribers, instead of directly delivering the message. In the VESTA system, the AMUSE system is extended with security support and policy management for authentication and access control [6].

In [7], an autonomic model for the management of health care applications has been presented, adopting the MAPE control loop. This control loop consists of monitor, analyse, plan and execute phases and interacts with a knowledge layer. The model has been used to assure process quality of the medical information system and as supervisor of the compliance of medical decisions with the protocols [7]. It has been applied for the treatment planning of diabetes. The prediction service in this system, which predicts the patient's diagnosis using multiple regression, is implemented as a web service.

Autonomic computing has also been applied in the hospital's emergency department to maintain optimal quality of service and optimize performance of operations [8]. These departments suffer from a high workload due to an increased demand on health resources and a limited clinicians staff. Sensors monitor the state of the environment (for example by using optical sensors, radio-frequency identifiers (RFIDs) and counters for people and workload).

However, related work in papers covering autonomic health care mainly concentrates on the architectural models. To the authors best knowledge, no previous studies have been conducted which design, implement and evaluate autonomic control loops in the intensive care, with the aim to increase performance of data retrievals.

Autonomic Architectures

Autonomic architectures have been applied in industry systems to find early indications of failures and to investigate fault causes. The MAGNETO project [9](2010) focuses on probabilistic fault diagnosis to find the cause of service problems, such as service degradation and service breakdowns, in home area networks. The causes of network failures and observed network variables are modeled in a bayesian network which can infer the probability of the cause of a service failure.

Several initiatives for building autonomic network architectures have been investigated in [10], consisting of hierarchical architectures, flat autonomic architectures and self-organizing networks. One of the hierarchical architectures is the Autonomic Internet project (AutoI) which deals with the autonomic management for the future internet in which autonomic management is applied to the management of virtual resources. The Component-ware for Autonomic, Situation-aware Communications, and Dynamically Adaptable Services (CASCADAS) deals with the development of an autonomic framework for creating, executing, and provisioning situation-aware and dynamically adaptable communication services [11].

In [12], an anomaly detection framework was proposed to provide techniques to analyze and detect anomalies in runtime data of cloud systems by applying (i) data transformation, (ii) feature selection, (iii) outlier detection. Anomalies or outliers are patterns in data that do not conform to a well defined notion of normal behavior [13]. Detection techniques have been developed to find these patterns which often represent exceptions, indications of system failure or interesting data which should lead to actions. Anomaly detection has been used in a variety of domains such as fraud detection of credit cards, fault detection in safety critical systems, insurance or health care, military surveillance using a diversity of techniques such as statistical methods, data mining, machine learning [13]. Rabatel et al. [14] addressed the problem of maintaining complex systems through preventive maintenance which detects abnormal behavior though collecting sensor data and analysis and found that these anomalies may lead to failure. In our case, we want to detect low data query performance.

Control loops

The core of an autonomic system is the Autonomic Manager (AM) which includes one or more control loops that monitor the resources, analyze the data to determine if the status is normal or if adaptations are needed. If actions are needed, these are planned and executed. This type of control loop maps the sequence: Monitor, Analyze, Plan and Execute (MAPE), as introduced by IBM [1]. Since the original proposal of autonomic computing by IBM several new control loops have been proposed extending the MAPE control loop. One of the most widely used set of control loops is those of the FOCALE architecture. The FOCALE autonomic architecture (Foundation - Observe - Compare - Act - Learn - rEason) consists of advanced control loops with extended capabilities for knowledge use and learning [15]. The FOCALE control loops have served as basis for the CASCADAS architecture and have been successfully applied to, amongst others, fault management [16] and management of the home network [17]. Because of its popularity, we use the FOCAL control loops as the basis of our autonomic manager and discuss its details in the remainder of this section. The FOCALE control loops are shown in Figure 6.1. The components in FOCALE are connected by an enterprise service bus (ESB), an event-driven message broker that supports different types of knowledge and performs processing before delivery. FOCALE uses a combination of information/data models and ontologies [15].

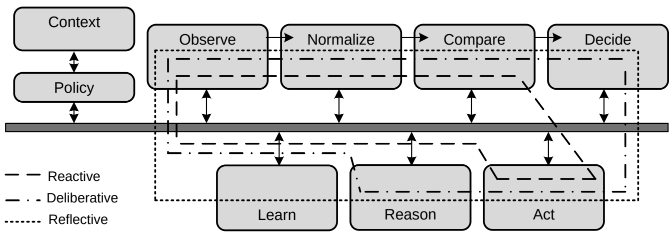

Figure 6.1: The FOCALE Control Loops

The FOCALE control loops are formed by running through a number of steps. In the Observe step, monitored observations are retrieved and fed to a model-based translation process of the Normalize step. The process facilitates the translation of device specific information into a normalized form. This normalized data is then analyzed to determine the current state of the system. Subsequently the current state is compared to the desired state of the system in the Compare step. In the Reason step, a reasoning algorithm evaluates the decisions and in the Learn step future predictions are made.

FOCALE features several dynamic control loops, which can be classified into three categories that also resemble actions identified in mental concepts of the human brain [18]. More specifically, FOCALE allows to define three different types of control loops that each have an increasing level of cognitive capabilities. Reactive control loops take immediate responses based on external stimuli. They react in order to carry out one or multiple goals. Additionally, shortcuts can be taken in order to perform high-priority and urgent tasks. The reactive control loops run at the highest frequency and circumvent the decide, reason and learn components. Deliberative control loops receive data from and can send commands to the reactive processes. They use long and short term memory to create more elaborate plans of action. The deliberative loops run at a lower frequency and circumvent the learning component. Finally, the reflective control loops supervise the deliberative processes. They study decisions made in the past, and analyse them. The conclusions are then used to prevent sub-optimal actions from being taken again in the future. The reflective loops run at the lowest frequency.

6.2 Methods

6.2.1 Problem Statement

The COSARA platform is a platform for infection surveillance and antibiotic management in the intensive care [2]. It is being used by physicians and nurses at the ICU of Ghent University Hospital, as part of the clinical workflow. COSARA is designed as a service oriented architecture and manages the antibiotic consumption and infection related information in the ICU [2]. The COSARA system collects data from the laboratory, the clinical information system, and its own historical COSARA-database, processes these data, and presents the information or medical advice on a bedside computer, desktop at the physician's office or at a mobile device.

The most frequently consulted data on the bedside computers consists of the patient's clinical values and the microbiology results in this ICU. COSARA has a module offering a clinical overview with the values of temperature, white blood-cell count (WBC), thrombocytes, organ failure score, and prescribed antibiotics, and a module giving all microbiology results (samples with cultures, antibiogram and blood analyses). Besides these queries who feed the displayed modules, other COSARA queries update data in the background. On an average day, approximately 2 million COSARA queries are executed, with an average of approximately 85,000 queries per hour.

The growing popularity of the COSARA application affects the data response times in the client. With more queries being executed simultaneously, the execution time of data retrievals increases and delays are noticed. This is illustrated in Figure 6.2, which shows the average execution time and 98th percentile required to retrieve the microbiology samples, cultures, antibiogram and analyses on the microbiology module. It shows the page load of the microbiology module in the COSARA application. As shown, the highest peaks of the 98th percentile show execution times of 182 s, 162 s and 59 s in a 60 minutes time frame, whereas average execution times are observed around 27 s execution time.

As physicians depend on the application to support their clinical decision, high

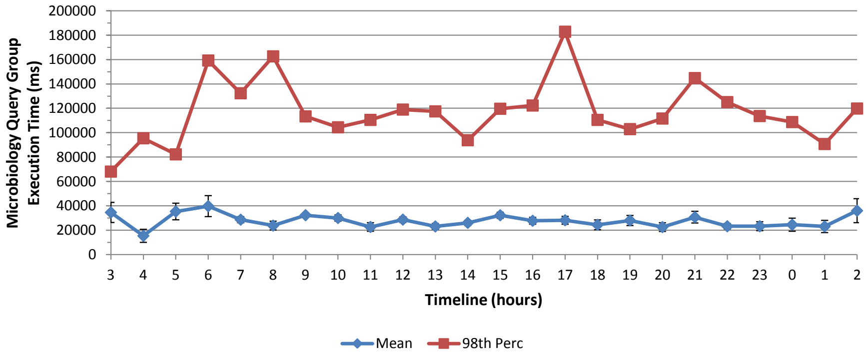

Figure 6.2: Delay of the COSARA microbiology query group, consisting of microbiology samples, cultures, antibiograms and analyses, over a 24h time window: the average execution time and 98th percentile

delays have to be prevented. The human operator is unable to guard the execution of the 150 different query types in the COSARA database. Therefore, potential delays in the data retrieval should be prevented autonomously by system components.

6.2.2 Architecture

The system should identify, manage and thus prevent the performance issues autonomously by reacting quickly on behavior changes in the system components. These changes can result, for example, from high utilization or an increased frequency of data retrievals. To make appropriate and reliable decisions, the concern is to possess data that is accurate enough, timely enough and consistent enough [19]. Figure 6.3 illustrates the domain where autonomic management is applied in health care: (i) the data management of timely bedside procedures and (ii) the management of data retrieval and processing. The COSARA service-oriented architecture consists of layers for presentation, business processing and data persistence [2]. We extended the architecture with components, as shown in Figure 6.4.

The client is designed in a modular way (Modules and Module Manager) using the OSGi technology as basis. Modules can be added, removed or updated on all bedside clients by changing the configuration on the server. Both in client and platform services, *monitoring and logging* components are added in order to be able to track the state of bedside client and server-side components. The Data Lookup Service (DLS), which forms the interface towards the data sources, is extended with a statistics component. The DLS logs every data access and includes the invocation time, the logical query name and the query's execution time (in mil-

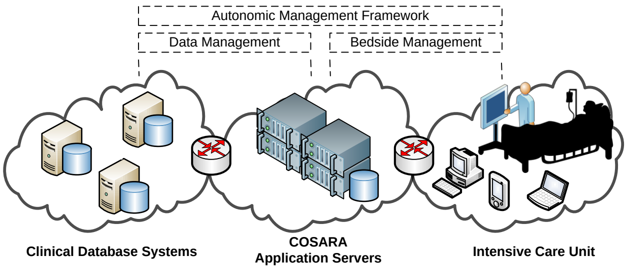

Figure 6.3: Overview of the COSARA setting in ICU.

liseconds). The DLS executes all queries (antibiotics, laboratory, microbiology, infection-related queries) on the different data sources (the laboratory database GLIMS, the intensive care information system (ICIS) or the COSARA database). The *autonomic analyzer* ensures that the monitored data and logs are examined dynamically (as detailed in the control loops). In the iterative design and evaluation of COSARA, we already started with the addition of recovery tools and limited detection mechanisms, but the loop was not closed and the human administrator had to take action. The analyzer now detects performance decreases in the execution of queries and instructs the *Controller-Anticipator* to respond and adapt the query executions autonomously to optimize the quality of service.

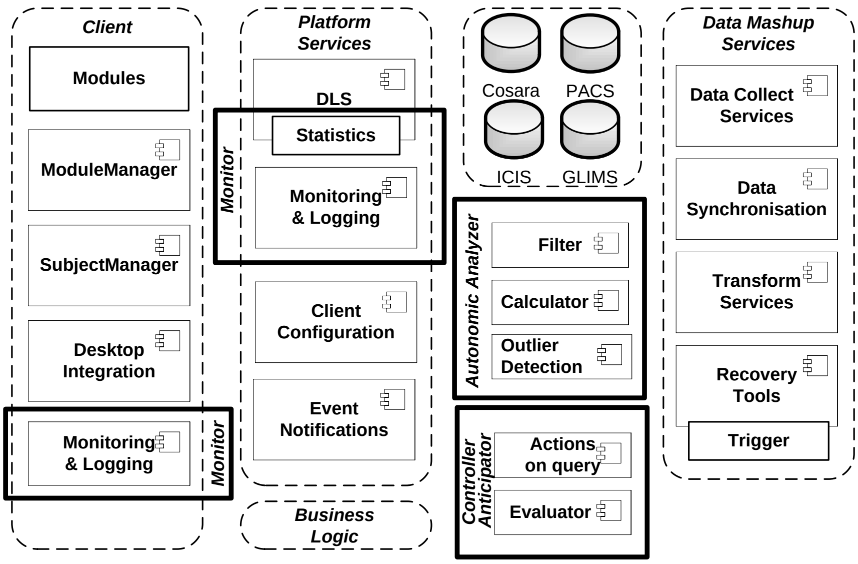

Figure 6.4: The extended COSARA Architecture

6.2.3 Design of FOCALE-based Control Loops in the COSARA Architecture

Following the FOCALE cognition model, we define three dynamic control loops with the aim of optimizing the performance of query execution. Performance is monitored via a statistics component in the data lookup service (DLS) which stores the execution time for each query. By analyzing the execution time and deciding when a serious performance delay occurs, other queries can be disabled temporarily to ensure faster retrieval of patient's data in the displayed client module. The method to decide and take action differs in the three presented control loops. Figure 6.5 depicts the activities of each control loop as explained below. Reactive control loops take immediate actions based on immediately perceived external stimuli, while the deliberative and reflective loops feature an increased level of learning: the first based on anomaly detection, while the later focuses on the clustering and detection of temporal patterns. We describe the details of all three loops in the remainder of this section.

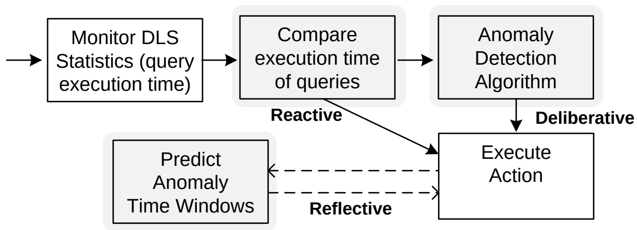

Figure 6.5: Activities in the control flows for performance optimization

6.2.3.1 Reactive Control Loop

The goal of the reactive control loop is to detect the occurrence of a large disruption of the system. Only if the performance of the system is severely affected, an immediate action is taken corresponding with the disablement of less important queries. As such, the reactive control loop continuously monitors the delay of page loads, as observed by the physician, in the COSARA application (cfr. Figure 6.2). To do this, the execution times of all all queries in the DLS component are monitored (FOCALE's monitor step) and summed to a total delay as several queries will be responsible for a single page load (observe step).

When this total delay is unacceptably high, denoted by the threshold $t_{reactive}$, an alarm is raised in the control loop (Compare step). The effect of this alarm is the following: on one hand the administrator gets notified of the data problem to allow him to have a closer look of the root cause of the anomaly. On the other hand, an automatic action is also taken to ensure a graceful degradation of the system. Therefore, the automatic execution of a subset of queries, corresponding to less important data retrievals (e.g., cron jobs, side information) is disabled for a time window $W_{reactive}$. As the total number of queries will decrease, the goal of the reactive control loop is to considerably reduce the overall perceived delay. For example, to improve the execution of microbiology samples, redundant queries of urine sediment are disabled because these queries are not shown in the module. If the physician wants to consult this urine value, a warning informs him that the query is disabled temporarily. The physician can retrieve the value by clicking a request button, in which case the value is retrieved using a duplicate urine sediment query (which can only be executed on request and is not filtered). As these urine sediment queries will only be executed when the data is actually required by the physician, the number of queries will be considerably reduced.

6.2.3.2 Deliberative Control Loop

In the deliberative control loop, decisions and actions are made using an anomaly detection algorithm. In this loop there is an explicit evaluation of the decision before acting. This control loop continuously monitors the query execution time of each individual query and groups them according to the query type. Note that, in contrast to the reactive control loop, the monitoring occurs based on each individual query and not on the grouped perceived page load. By monitoring each query type, a specific model is built that represents the typical expected query execution time of each query type. Based on this model, an anomaly detection algorithm can detect out of profile behaviour, i.e., outliers. If the share of recently detected outliers becomes abnormally high, a similar query disablement action as carried out in the reactive control loop is executed. Queries are proactively disabled when a disruption of the system is likely to occur (i.e., signalled by an increased share of abnormal individual query executions). This is in contrast to the reactive control loop where queries are disabled after a system disruption is detected. Additionally the deliberative control loop incorporated knowledge from a domain expert to detect the outliers. As such, the control loop consists of a training phase, where the system is trained to build the model and detect outliers, and a deployment phase, where the outliers are detected on-line and appropriate actions are taken. We discuss the algorithmic details of both phases in the remainder of this section.

Training phase During the training phase, a model is built for each query type based on knowledge from a domain expert. This is shown in Figure 6.6. In a first step, a historical data set D containing the query execution times and query types over the course of a day is labeled by the domain expert (e.g., the system operator). The goal of the labelling is to select a subset D_{normal} corresponding with normal query execution times for each query type. Consequently, the subset $D_{outlier} \equiv D \setminus D_{normal}$ corresponds with abnormal or out of profile query executions.

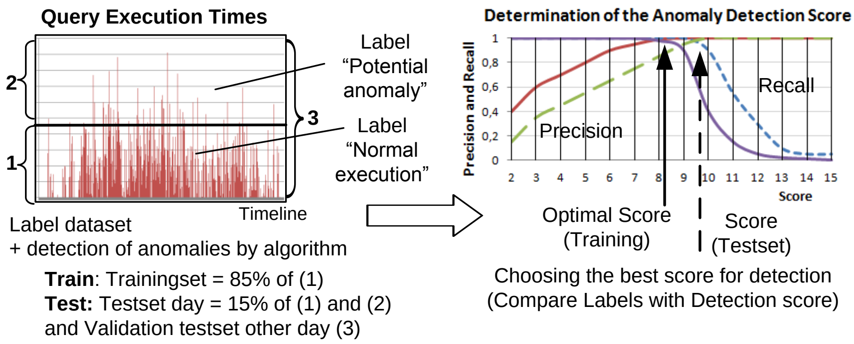

Figure 6.6: Schematic illustration of the anomaly detection algorithm and determination of the detection score

In a second step, a random subset $D_{train} \subset D_{normal}$ is taken as training set. In our case, we take 85% of random samples out of D_{normal}. Based on D_{train}, a model can be built of normal query execution times by calculating the mean and standard deviation of the population in D_{train}. These values are then used to determine whether a random sample x of query execution times belongs to the calculated model or not. To do this, a z-score is calculated, which is a well known anomaly detection algorithm, as follows:

$$z(x) = \frac{|x - \mu(D_{train})|}{\sigma(D_{train})} \tag{6.1}$$

Here, $\mu(D_{train})$ denotes the mean of D_{train}, while $\sigma(D_{train})$ corresponds with the standard deviation of D_{train}. The larger the calculated z-score is, the more likely the sample x is to be an outlier. However, it is difficult to define a threshold for this as this depends on the distribution of the dataset, which is unknown.

To address this, in a third and final step, the remaining dataset $D_{test} \equiv D \setminus D_{train}$ is used for determining a threshold z_t. Based on this threshold, a random sample x can be classified as an outlier (if $z(x) > z_t$) or not. Note that $D_{outlier} \subset D_{test}$: hence, D_{test} will contain both normal and out of profile query execution times. For each $x \in D_{test}$, the z-score as defined in Equation (6.1) is calculated. Furthermore, for several possible values of z_t, the samples x are classified and the classification is compared with the labelling of $D_{outlier}$ and D_{normal} by the domain expert. By comparing the classification for a given z_t parameter configuration and the classification by the domain expert, the best zt parameter configuration can be chosen. More specifically, we select the z_t parameter that maximises the precision and recall values, two metrics that are used to assess the accuracy of a classification system. Precision is calculated as the number of true positives (i.e. the number of true outliers) divided by the total number of elements belonging to the positive/outliers class (i.e. the number of detected outliers by the algorithm, and also including those that were listed as outlier but are not observed outlier). Recall is defined as the number of true positives divided by the total number of elements observed as outlier (i.e. the number of outliers that were detected, and also including those that were missed by the outlier detection).

The result of the training phase is (i) a model for each query type, defined through the mean and standard deviation of a population of that type, that defines the normal behaviour of query execution times for that query type and (ii) a threshold z_t for each query type that can be used to perform an on-line outlier detection in the deployment phase.

Deployment phase Once trained, the calculated model and threshold can be used to detect the occurrence of outliers on-line for each query type and act accordingly. Therefore, the deliberative control loop will continuously monitor the query execution times for each individual query and will classify each execution time as being normal or out profile according to the trained configuration. Next, the share of outliers compared to the total set of queries in the last time window W_{delib} is continuously calculated. If the calculated share exceeds a predefined threshold $s_{outlier}$, the deliberative control loop assumes that there is a high risk of system degradation. As a reaction, it decides to execute actions that can reduce the typical query execution times (e.g., disabling other queries as discussed in Section 6.2.3.1).

6.2.3.3 Reflective Control Loop

In the reflective control loop, the long term memory is taken into account to take proactive actions (i.e, before the execution of the actual queries). The reflective loop detects temporal patterns in the occurrence of outliers and proactively disables low priority queries. In practice, the COSARA system often experiences quality degradations during peak periods (e.g., at the beginning and end of the work day of physicians). The goal of the reflective control loop is to autonomically detect these peak periods and disable the queries accordingly.

In order to detect these peak periods, clusters of outliers have to be detected over a longer period of time. Therefore we take the frequency of outliers into account over 24 hours and select the highest frequency of outliers over a time frame of 30 minutes. By applying the z-score test on the frequency set, it gives the peak periods. For each detected period, the action is taken (disable queries). This process is illustrated in Figure 6.7.

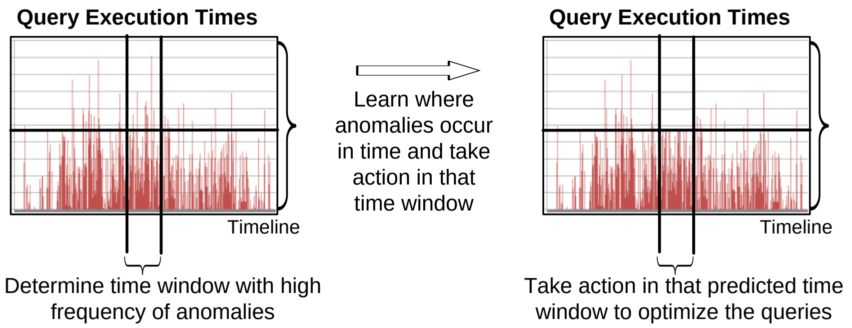

Figure 6.7: Schematic illustration of the choice of a time window with a high frequency of anomalies to optimize

6.3 Results and Discussion

In this section we study the influence of the actions of the FOCALE based reactive and deliberative control loops on the query execution time. The executed queries of a random day in January 2012 were taken and executed again in a test environment, as described in the evaluation setup. The duration of each COSARA query was measured. In these experiments we evaluated the impact of an immediate action in reactive control loop, the decision to take action by the described anomaly detection algorithm in the deliberative loop and its impact.

6.3.1 Evaluation Setup

The COSARA platform is set up in the real life production environment of the Ghent University Hospital. By logging the performed queries in the production environment, we were able to emulate the query executions on the COSARA database in a test environment and evaluate the impact of optimization without interfering in the clinical workflow of the production environment. Due to the sensitivity of the patients' electronic health records and the medical decisions based on this data, we have replicated the COSARA database queries on test servers. In this section, we detail the used experimental setup to replicate COSARA's behavior.

In the experiments we measure the query execution times by replicating the COSARA queries in a multi-threaded application. By replaying the queries again with a specific action, we are able to evaluate the impact of action by the control loops on the query execution time. In the action we disable the queries COSARA UrineSediment and Identification. The UrineSediment queries retrieve the urine sediment value. The Identification queries retrieve changes made to the identification. Both queries are not important when the physician is actually displaying the

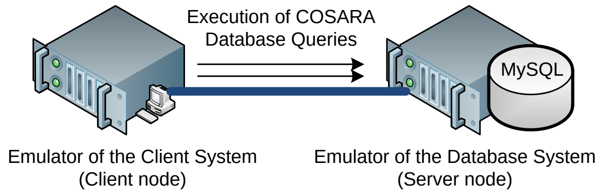

Figure 6.8: Setup of COSARA client and server on nodes of the generic test environment.

patients' microbiology.

The results include the average query execution time of the query executions. These percentiles show the worst execution times. These executions cause delay on the physicians screen while displaying microbiology samples. The experiments were carried out on one core Intel Xeon E5620 processor with 2.40 GHz and 3.0 GB RAM. We emulated the client and server interaction by replicating the COSARA queries of the trace log. As such, we replayed the trace log of January, 19, 2012. It shows behavior identical to the query executions in production environment. Figure 6.8 shows the test setup. On the server node a MySQL database server 5.0.51 is running and on the client node we rerun the real executed queries and measure its execution time and the improvements by the actions in the presented control loops.

6.3.2 Performance Evaluation of the Control Loops

6.3.2.1 Performance Evaluation of the Reactive Control Loop

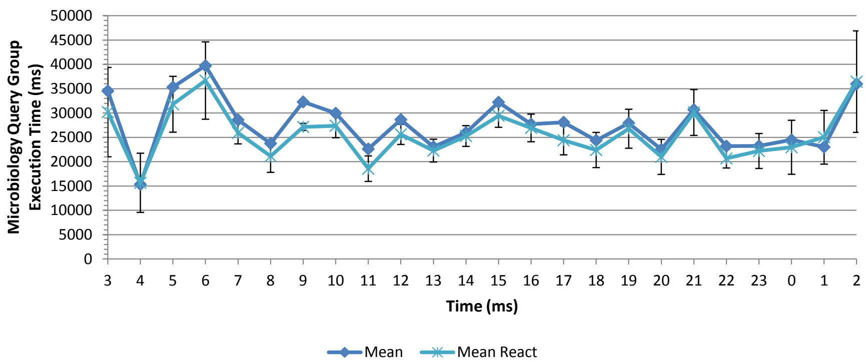

Figure 6.9: Average execution time of the microbiology query group over 24 hours without autonomic management and with actions taken by the reactive control loop.

In the reactive control loop an action is immediately taken if the performance is severely affected. We set parameter $t_{reactive}$ to 90,000 ms and parameter $W_{reactive}$ to 2 minutes. The value $t_{reactive}$ corresponds to the execution time which is considered very obstructive by the COSARA user. It is expected that similar high execution times are prevented by setting a time window of 2 minutes for the action.

Figure 6.9 depicts the average execution time of a COSARA microbiology group without autonomic management actions and with the action taken in the reactive control loop. The average execution time is 27,308 ms without autonomic action and 24,956 ms with the reactive action. The reactive control loop provides a gain of 8.61% or 2,352 ms on the average query execution time of the microbiology query group. The impact of the control loops on the query execution times of microbiology queries group is analysed per hour, as shown in Figure 6.9. The highest gain is observed in the period from 9 to 10 am with a reduction of 15.92% on the average execution time.

6.3.2.2 Performance Evaluation of the Deliberative Control Loop

The reactive control loop already offers an important gain but optimizations are still possible. In the deliberative control loop the decision and action are made using an anomaly detection algorithm. In this section we evaluate the effect of the deliberative control loop on the query execution times. First we determine the detection score z_t, as discussed in Section 6.2.3.2. We varied the score from 2 to 8. Figure 6.10 shows an example of the determination of the anomaly detection score with precision and recall (based on training set, data log of January, 19, 2012). Based on this we set the anomaly detection score z_t to 2 because of its highest precision and recall. The figure also shows the precision and recall of D_{test} (log results of January, 20, 2012, the test set). We analysed the queries which retrieve microbiology samples, cultures, antibiogram and analyses and determined the scores.

Then, we set W_{delib} to a time period of 1000 ms in which queries were executed. The parameter $s_{outlier}$ was set to 20% to obtain the best share of outliers. The action, identical to the disabling of queries in the reactive loop, was performed when $s_{outlier}$ was exceeded.

Figure 6.11 shows the average query execution time without autonomic management and with actions taken in the reactive and deliberative control loop. We compared each observation with its original execution time.

The combination of the reactive and deliberative control loop performs better than only the reactive one. The combination gives a reduction of 2,980 ms or 10.92% to the original average execution time without management. The combined actions give an average execution time of 24,327 ms. The highest reduction of the average execution time is observed in the period from 9 to 10 am with a reduction of 19.69%.

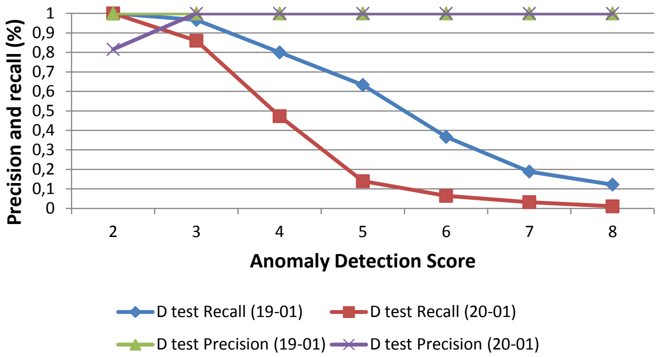

Figure 6.10: Example of the determination of anomaly detection score z for query COSARA Microbiology Samples based on highest precision and recall

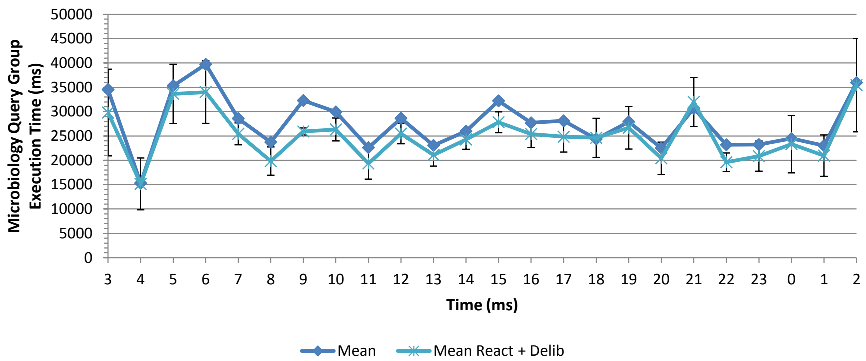

Figure 6.11: Average execution time of the microbiology query group over 24 hours without autonomic management and with actions taken by the reactive and deliberative control loops.

6.3.2.3 Performance Evaluation of the Reflective Control Loop

In the reflective control loop, queries are disabled proactively during peak periods of high query execution times. In the detected time intervals (7h to 7h30), (9h to 10h), (12h to 12h30) and (16h to 17h), we disable the UrineSediment and Identification query proactively. The combination of the reactive, deliberative and reflective actions affects the query group execution times additionally during the selected time intervals. Figure 6.12 shows the average query group execution time per hour. The microbiology group query execution time without autonomic management is 27,308 ms, where the execution time with the combination of reactive, deliberative and reflective actions is 23,747 ms or a reduction with 13.04%. In the selected time interval from 9 to 10 am, a reduction of 36.11% is observed on the average exeution time by applying the three control loops where the reactive gave only a reduction of 15.92% and the reactive and deliberative gave a reduction of 19.69%. The reflective control loop acts proactively during predicted peak periods and hence prevents high query execution times.

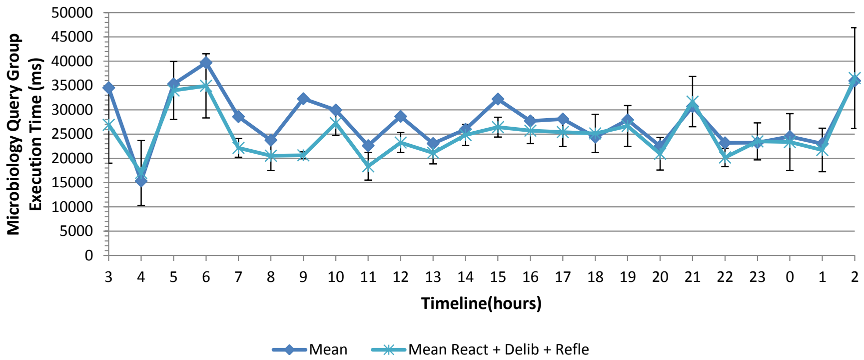

Figure 6.12: Average execution time of the microbiology query group over 24 hours without autonomic management and with actions taken by the reactive, deliberative and reflective control loops.

6.3.3 Discussion

Figure 6.13 and figure 6.14 summarize all the evaluation results. Figure 6.13 compares the average query group execution times. The reactive control loop reduces the average execution time by 8.61%. The combination of the actions of the reactive and deliberative control loop reduce the average execution time by 10.92%. The combination with the reflective control loop affects the average execution time with 13.04%. By disabling the queries during the whole day the baseline is set. Although the baseline shows the highest possible gain, the queries COSARA UrineSediment and Identification are disabled completely. Compared to the baseline, the control loops provide a reduction of more than one third of the possible improvement. The baseline showed a difference of 32.09% compared to the average execution time without actions. We also compared the effect on the 95th and 98th percentile, as shown in Figure 6.14. The reactive control loop, reactive and deliberative control loop, and reactive, deliberative and reflective show reductions of 8.79%, 11.04% and 13.57% respectively in the 95th percentile. In the 98th percentile the execution time is reduced by 6.27%, 8.07% and 8.50% respectively.

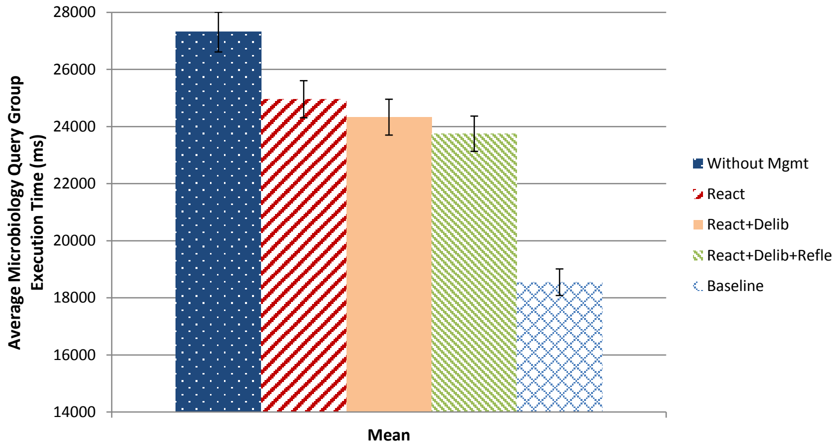

Figure 6.13: Comparison of the average microbiology query execution time without and with autonomic management of the reactive, deliberative and reflective control loops. The figure shows the affected average query execution times with the combined control loops and the baseline over 24 hours.

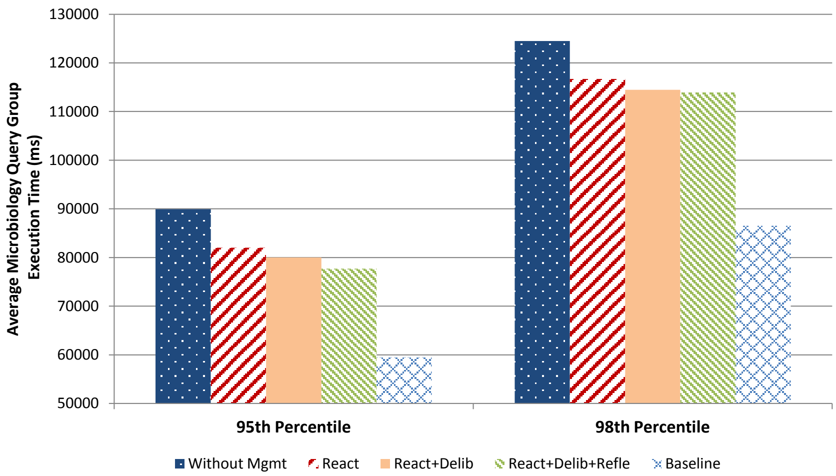

Figure 6.14: Comparison of the 95th and 98th percentile of the microbiology query execution time without and with autonomic management of the reactive, deliberative and reflective control loops. The figure shows the affected 95th and 98th percentile query execution times with the combined control loops and the baseline over 24 hours.

6.4 Conclusions

This paper presents the extension of the existing health care platform COSARA in the ICU with autonomic control loops. The introduced control loops provide an automated mechanism to detect low performance and to take action, thereby limiting human technical interventions. The monitoring of the execution times of the data queries of this real life intensive care platform allow the investigation of low performance. A reactive, deliberative and reflective control loop have been proposed to optimize the data query performance and thus the page load of the microbiology module. In the reactive control loop the action is immediately taken when the performance of the system is affected. The action disables less important queries not relevant for the display of microbiology data. In the deliberative control loop we use an anomaly detection algorithm with an explicit evaluation of the decision before the action is taken. In the reflective control loop, proactive actions are taken after temporal patterns of outliers are detected. We evaluated the impact of the reactive, deliberative and reflective control loop on the query execution of the microbiology data. The results show a time reduction of 8.61% by the reactive control loop on the average query execution times. The addition of the deliberative control loop reduced the average query execution time by 10.9% and by combining the three control loops the average execution time was reduced by 13.04%.

Authors' Contributions

The work presented was carried out in collaboration between all authors. KS and SL carried out the study of the control loops on the COSARA platform, participated in the design and development of the control loops as described in this paper and drafted the manuscript. FDT and JD supervised the study, participated in the design and coordination and helped to draft the final manuscript. All authors read and approved the final manuscript.

Conflict of Interest

The authors declare that they have no conflict of interest.

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7 Conclusions and Perspectives

In this dissertation we presented contributions in the domain of medical informatics. Medical services were designed and developed to support both administrative and clinical processes in the hospital. The services have been evaluated in real life prototypes, running in the production setting and collecting, interpreting and integrating patients' data at the hospital. We specifically focused on the application of information technology in the intensive care and neonatology, units with critically ill patients in the hospital. This chapter highlights the contributions of this work and summarizes future perspectives for this research domain.

7.1 Review of the research questions

The previous chapters provide an answer to the research questions in chapter 1 as follows:

1. *What is the best approach to design and develop medical and administrative services in the hospital? Which architectural components are required to construct an integrated health care platform in critical care?*
   We have proposed service oriented architectures in the design of the hospital's services. The architectures proposed in chapter 3-5 include reusable service components that offer on the one hand data collection functionality and data processing, and other other hand business logic with medical guidelines for decision logic. The services are running server-side, accessible through bedside clients in the hospital. It is shown that using services is

beneficial for the reusability of components, design flexibility and composition, integration in the platform and access. In chapter 3 the automation of the tarification process, which is an administrative process to tick and count medical procedures, has been studied in detail. We have validated a service oriented architecture taking into account the functional requirements and user expectations. The labor-intensive and time consuming administrative tasks could be replaced by these computer-based services. To support medical advice and diagnosis, a platform for antibiotic management and infection surveillance, called COSARA, was designed, implemented and evaluated. A detailed description of the platform is given in chapter 4. The COSARA platform consists of data collection and handling services, access to the diverse data resources, platform processing services, business logic with medical modules and a client interface. The client is composed of modules such as infection overview and microbiology view. The platform was implemented using the JavaEE application server and using the OSGi framework as programming model for the pluggable modules. We have shown that it is possible to integrate patients' data from different sources to provide optimal access to the patients' records in several scenarios. As physicians not only want access to the patients' records inside the hospital, but also from multiple sites, outside one hospital, we created the ability to review patient files remotely. Therefore in chapter 5, we studied a web based portal for the registration and analysis of the cytomegalovirus infection for newborns, called NEOREG. The multidisciplanary approach to discuss, design, implement and evaluate clinical services has been found to be promising to construct tools tailored to the needs of physicians and nurses at the point of care.

2. *How can software services provide clinical decision support to physicians and nurses? How should patients' data be collected and integrated, analysed and interpreted, presented and reported efficiently?*
   We have studied the usage of computer based services for infection and antibiotics management. In chapter 4 we studied the application during the daily patient follow-up of infections and therapy, during the daily follow-up of patient's chest X-rays, and in the infection management of the unit. The requirements of the COSARA platform included the automatic integration of data, presentation and clinical interpretation of infections and antibiotics on the bedside screen, provisioning of clinical decision support, maintenance procedures, and alerting and reporting services. Data collection processes and automatic integration from clinical data sources was established. In chapter 4 we studied the architecture and clinical scenarios in detail. Examples of the clinical decision support services were also given in chapter

2, in which the clinical domain was explored. In chapter 5, we studied the registration on multiple sites, for the neonatology departments. In this web based registration platform precautions for role-based secure access had to be taken. Paper-based forms were in this case replaced by document exchange formats. In chapter 3, we investigated the application of information technology in the tarification process. The process was supported by shifting from paper-based flow to paperless computer-based services. The evaluation results show that the total return on investment (ROI) estimation of this transition from paper-based tarification to paperless tarification (with the use of the clinical database and services) showed a total ROI after 3.96 months. Further, the use of services was considered the best choice because it allows decomposition of functionality in reusable units, adaptability, flexibility, interoperability and cost savings. It was shown that due to a more accurate computer-based tarification, an annual extra income of 153,072 euro or an increase by 5.1 %. Besides financial benefits a time reduction of the work of the secreatary was noticed. In chapter 4, a performance evaluation and study nurse validation of COSARA is included. The detected issues in data quality led to the extension of the platform with synchronisation and maintenance procedures and later with autonomous components. The performance of the NEOREG system has also been evaluated. The software prototypes for the tarification (Chapter 3) and the COSARA platform (Chapter 4) have been evaluated in the ICU. Meanwhile these prototypes have evolved and are now running in the medical unit at the hospital. COSARA provides a daily unique overview of all relevant infection related information for patients in the ICU of Ghent University Hospital. The NEOREG platform (Chapter 5) is in test phase on the department of neonatogy.

3. *How can the quality of service of the health care platform be optimized by introducing autonomic capabilities?*
   In chapter 6 we turned our focus to the extension of the medical service platform with autonomic components offering optimizations in the platform's performance. This maintenance process was handled entirely by human operators. The query execution times of the platform have been analysed based on performance data of the real data queries and log files. Using autonomic control loops, performance drops were noticed and the platform was able to react upon high query execution times. The results showed that the reactive control loop reduces the average query execution time of the microbiology queries by 8.61%. The combination of the reactive and deliberative control loop reduced the average execution time by 10.92% and the combination with the reflective control loop resulted in a reduction of 13.04%. These results show that control loops can be used in the platform management.

7.2 Future perspectives

The evolution in information technology applied to health care is still ongoing: applications have not only been introduced in the hospital, but have also become available in our everyday life, at home and on our mobile devices.

Patient empowerment through homecare and social media: Instead of hospitalization of elderly people with chronic diseases, care can also be provided at home using smart devices. A more patient centered approach of care information is gaining attention. It envisions a situation in which the patient is an active participant in treatment decisions and communication about medical examinations. The patient interacts with the applications or services, taking control of his/her medical history and progress. With the evolution of social media, internet users share their health related information on line, share their own experiences and become members of social online communities to discuss their health and therapies. In the near future, lots of services will be provided on hand-held mobile devices, allowing the patient to interact immediately with the physician and nurse. This evolution requires further research about the relationship of social media and health care, in order to provide valued, trusted interactions and qualitative and secure information exchange.

Security refinements: Protection through log-in and electronic identity card identification was used in the web based registration platform. The other services were developed in the intensive care network, separated from the outside world. As applications get used in wider environment, also outside the hospital, ensuring privacy and applying security policies, procedures and techniques is very important. Future research of clinical services should be devoted to the application of security mechanisms that enforce strict policies on the exchange of data between services.

Formal modeling and reasoning strategies: The use of medical devices, resources or access by physicians, nurses, patients can be modeled using an ontology. It is a formal representation of the relationships in the medical domain. Furthermore, in the autonomic components and reasoning, as introduced in chapter 6, semantic meaning can be added to the data. Ongoing PhD research concentrates on the use of ontology based reasoning in health care. This consists of the modeling of the medical domain and usage in algorithms to optimize the reasoning process.

Standards and automation of clinical guidelines development: As the potential of clinical decision support in health care becomes more and more recognized, more computer-based complex guidelines and tracking of clinical pathways will be demanded from the developer. For this reason, PhD research is ongoing towards the automatic translation of a guideline template into a running guideline, working on medical patients' data and freeing the developer from specific implementation tasks. Future service platforms need to be able to automatically translate a guideline based on a description of the guideline. As the physician will be involved in this interaction with the computer, ongoing research will also focus on the human-computer interface research.

We hope that this dissertation, together with the eagerness to adopt information technology in the medical environment, will contribute to the design, development and optimization of next generation registration and information services in health care. On the other hand, we also hope that IT will still be proposed as a means to assist the physician in the decision making process and that physicians will always get involved in the development of future solutions in this domain. In our proposed services, it was never the purpose to replace the physician, on the contrary, we want to support the physician by offering the needed information at the point of care. The complexity of the medical decisions and the handling of medical data require thoroughly evaluated solutions in order to provide safety critical tools. Although we studied mainly services inside the intensive care and evaluated the services in terms of performance, return on investment or valued benefits by clinicians, we are convinced that the identified services with their support in the registration and decision making process can also help physicians and nurses in other departments. We contributed to an efficient management of patient information by introducing new information technology solutions in health care.

A
Has information technology finally been adopted in Flemish intensive care units?

In this appendix, the adoption of information technology is investigated in Flemish intensive care units. The survey is conducted in 2005 as a written questionnaire and was followed by a telephone survey in 2008.

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Abstract
Background
Information technology (IT) may improve the quality, safety and efficiency of medicine, and is especially useful in Intensive Care Units (ICUs) as these are extremely data-rich environments with round-the-clock changing parameters. However, data regarding the implementation rates of IT in ICUs are scarce, and restricted to non-European countries. The current paper aims to provide relevant information regarding implementation of IT in Flemish ICU's (Flanders, Belgium).

Methods
The current study is based on two separate but complementary surveys conducted in the region of Flanders (Belgium): a written questionnaire in 2005 followed by a telephone survey in October 2008. We have evaluated the actual health IT adoption rate, as well as its evolution over a 3-year time frame. In addition, we documented the main benefits and obstacles for taking the decision to implement an Intensive Care Information System (ICIS).
Results
Currently, the computerized display of laboratory and radiology results is almost omnipresent in Flemish ICUs, (100% and 93.5%, respectively), but the computerized physician order entry (CPOE) of these examinations is rarely used. Sixty-five % of Flemish ICUs use an electronic patient record, 41.3% use CPOE for medication prescriptions, and 27% use computerized medication administration recording. The implementation rate of a dedicated ICIS has doubled over the last 3 years from 9.3% to 19%, and another 31.7% have plans to implement an ICIS within the next 3 years. Half of the tertiary non-academic hospitals and all university hospitals have implemented an ICIS, general hospitals are lagging behind with 8% implementation, however. The main reasons for postponing ICIS implementation are: (i) the substantial initial investment costs, (ii) integration problems with the hospital information system, (iii) concerns about user-friendly interfaces, (iv) the need for dedicated personnel and (v) the questionable cost-benefit ratio.
Conclusions
Most ICUs in Flanders use hospital IT systems such as computerized laboratory and radiology displays. The adoption rate of ICISs has doubled over the last 3 years but is still surprisingly low, especially in general hospitals. The major reason for not implementing an ICIS is the substantial financial cost, together with the lack of arguments to ensure the cost/benefit.

A.1 Background

Over the past decades there have been substantial changes in medicine, with more effective but also increasingly complex therapies. This results in an increased life expectancy on the one hand, but also in an increased number of medical errors on the other hand. In 2003, the Institute of Medicine published the groundbreaking report ”To err is human, building a safer health system”. This report estimated that at least 44,000 people die in US hospitals each year as a result of medical errors that could have been prevented [1]. Furthermore, the progress in medicine is at least partially responsible for the increasing health care cost, which has risen exponentially over the last two decades. At present it even comprises between 10 to 16% of the gross domestic product in developed countries. Several organisations claim that Information Technology (IT) could contribute in a significant way to improving the quality of health care while at the same time controlling costs [2]. However, until now, no strong evidence has been provided.

The intensive care unit (ICU) has several typical characteristics which make it favorable for computerization, because caring for the critically ill is even more complex, resulting in substantially higher numbers of medical errors and costs [3, 4]. Donchin et al. reports an incidence rate of 1.7 errors per patient per Intensive Care Unit (ICU) day and several other authors have confirmed that the ICU is a very unsafe environment [5–9]. In addition, the cost of intensive care medicine is exorbitant and can be as high as 0.5 to 1% of the gross domestic product [10]. Various US critical care organizations made some recommendations to the government in 2004 in answer to what they called ”the critical care medicine crisis”. Their second recommendation was that ”information technology should be leveraged in critical care to promote standardization and improve efficiency” and that ”information technology is a key factor in the future of intensive care medicine delivery” [10–12].

For the above reasons it is advisable to study the current level of intensive care computerization, both for general and dedicated specialized IT applications used in the ICU. General IT applications are the electronic patient record, the computer laboratory system (also known as the Global Laboratory Information Management System (GLIMS)), the computer radiology system (i.e. Picture Archiving and Communication System (PACS)), and the Computerized Physician Order Entry (CPOE) applications. The term CPOE can be confusing however, because some authors restrict its use to prescribing medication, and add the term ”order communication system” for laboratory and radiology requests. In this paper, we will use CPOE in the broader sense, and we will specify reference to medication CPOE, laboratory CPOE or radiology CPOE. The dedicated IT solution for the ICU is often described as an ICU Patient Data Management System (PDMS), but we prefer the term ”Intensive Care Information System” (ICIS), which describes the broader functionalities of more advanced IT programs better, i.e. doing more than mere data storage and representation. These systems are developed in order to meet the specific requirements to optimize data processing and workflow support in critical care medicine. In our survey, an ICIS has to fulfill all of the following conditions: (i) automated collection of physiological and monitoring variables from monitors and ventilators, (ii) incorporation of CPOE for medication prescription and (iii) one bedside personal computer for every ICU bed.

In this paper, the present IT adoption rate in ICUs in Flanders (Belgium) is evaluated, as well as its evolution within a 3-year time frame. This includes both the use of general hospital information system components such as the electronic patient record, CPOE for medication, radiology and laboratory requests and the computerized display of these results, as well as ICU-specific IT software such as ICIS. Furthermore, we have explored the main benefits and obstacles for taking the decision to implement an ICIS as perceived by ICU directors.

A.2 Methods

This study is based on two separate but complementary surveys conducted in the region of Flanders.

A.2.1 Survey development

The first survey was performed in January 2005 and consists of a written questionnaire which was sent to the medical directors of all Flemish ICUs. Six weeks later the non-respondents were sent a reminder. After another month the remaining non-respondent ICU directors were contacted by phone, and a second reminder was sent when necessary.

The second survey was carried out in October 2008 (i.e. 3.5 years after the first survey). This telephone survey was carried out by Kirsten Colpaert, who interviewed each ICU director, or the ICU head nurse if the medical director suggested that the head nurse was the more competent person regarding IT use in the ICU.

The Local Ethical Committee of Ghent University Hospital approved the study, and informed consent was waived. All answers were kept confidential.

A.2.2 Region of interest

Flanders has 6,117,440 inhabitants and represents the largest region of the federal state of Belgium. The federal state contains 10,580,000 inhabitants. The Region of Flanders had a total of 54 ICUs in 2005, and a total of 63 ICUs in 2008. Differences between these two numbers are mainly due to changing alliances between hospitals, or new approved ICUs (all part of general hospitals) which have been approved by the government. All these ICUs provide mechanical ventilation and are approved by the national government (as listed on http://www.health.fgov.be webcite). They are located in three different types of hospitals: general hospitals (52/63 or 82.6%), tertiary non-academic referral hospitals (8/63 or 12.7%), and university hospitals (3/63 or 4.7%). General hospitals have approximately 250 to 700 beds, tertiary non-academic referral hospitals 500 to 1,100 beds and university hospitals 700 to 1,600 beds. The number of ICU beds consists of 5 to 7% of the total number of hospital beds (excluding post-anaesthesia care beds, specific coronary care unit beds and neonatology beds). Especially the larger hospitals have 24/7 junior or senior critical care physicians available, whereas smaller ICUs usually have anesthesiologist-intensivists (with board certificate in critical care) who combine their anesthesia care with intensive care.

A.2.3 Domains of interest

For the construction of the surveys, five domains of interest were selected:

1. **Use of general IT programs within the ICU**, such as the use of the electronic patient record, computerized display of laboratory and radiology results, CPOE for laboratory and radiology requests, CPOE for medication prescription and computerized recording of medication administration;
2. **Use of an ICIS in the ICU**, or the intention to implement an ICIS in the near future;
3. **The level of integration between the available ICIS and the Hospital Information System** such as administrative data exchange, connection to the pharmacy information system for automatic medication ordering and dispensing, and automatic billing;
4. The effective use of highly detailed **data extraction from implemented ICISs**;
5. **The decision-making process** in implementing an ICIS, including recording of the perceived benefits and obstacles by the ICU management decision makers.

A.2.4 Statistics

Statistical analysis was performed using the SPSS 15 software package. The chi-square test was used to compare proportions. A P-value less than 0.05 was considered statistically significant.

A.3 Results

For the 2005 survey, we obtained 31 responses from the 54 hospitals which had been selected for the study, representing a response rate of 57.4%. Twenty-six of these hospitals (83.9%) were general hospitals, 3 (9.7%) were tertiary non-academic referral hospitals and 2 (6.4%) were university hospitals. The number of ICU beds per ICU varied between 6 and 56.

For the 2008 telephone survey, a 100% response rate was obtained (63/63). It must be stressed that both the 2008 telephone survey and the 2005 questionnaire probed into the use of hospital information system components and the availability of ICIS. For this reason, the results concerning the IT adoption rate, and its evolution over time, are highly accurate. The results regarding the benefits of and obstacles for implementing an ICIS have mainly been derived from the 2005 written questionnaire.

A.3.1 Use of general IT programs within the ICU (Figure A.1)

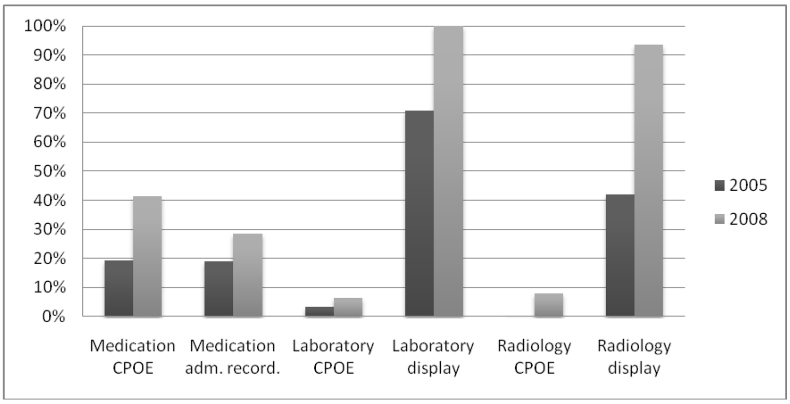

Figure A.1: Implementation and usage rate of general IT components within the ICU. (Medication CPOE = medication prescription by computerized physician order entry; Medication administr. recording = computerized recording of medication administration; Laboratory CPOE = computerized physician order entry of laboratory tests; Laboratory display = computerized display of laboratory results; Radiology CPOE = computerized physician order entry of radiology requests; Radiology display = computerized display of radiology images and/or protocol.)

- *Electronic patient record*

  In 2008, 41 out of 63 ICUs (63.1%) use the hospital electronic patient record within the ICU. This is a limited increase compared to 2005 (16/31 ICUs or 51.6%). Of these 31 hospitals, an additional 7 ICUs shifted to an electronic patient record during the 3-year time frame.

- *Medication CPOE and the computerized recording of medication administration*

  A larger proportion of ICUs report using medication CPOE in 2008 compared to 2005: 41.3% vs. 19.3%. Currently, 11 of these CPOE programs are part of an ICIS, 7 have been bought commercially for use in the entire hospital and another 8 CPOE programs are hospital-specific and have been developed in-house. Many of the latter less sophisticated programs needed extensive adaptations, however, especially for continuous infusion pump recording. Another 5 ICUs are using Microsoft Office documenting (i.e. Excel), but as this software has not been developed specifically for medication CPOE we did not include it as such. One ICU that implemented an ICIS more than a decade ago still uses paper-based medication prescriptions, and chose to discard the available CPOE functionality due to integration problems with the pharmacy department. It is important to note that only 6 of the CPOE programs that are not part of a dedicated ICIS also provide facilities for computerized medication administration recording by the nursing staff. In the other ICUs, print-outs of the medication CPOE are taken and used as part of the paper charts.

- *The computer laboratory system.*

  At present, every Flemish ICU uses the computerized display of laboratory results, whereas this was only 70.9% in 2005 (see Figure A.1). However, the number of ICUs that use CPOE for laboratory requests is still extremely low (6.3% in 2008 vs. 3.2% in 2005), and half of them does this by using the built-in functionalities of their ICIS.

- *The computer radiology system (i.e. The Picture Archiving and Communication System (PACS)).*

  A larger proportion of ICUs report using the computerized display of radiology results and the CPOE module for radiology requests in 2008 compared to 2005 (93.5% vs. 41.9%; 7.9% vs. 0%) (as presented in Figure A.1).

A.3.2 Use of an ICIS in the ICU, or the intention to implement an ICIS in the near future

In 2008, 12 out of 63 ICUs (19%) had implemented an ICIS and another 20 (31.7%) ICUs were planning to implement a system within the next 3 years (i.e. before 2012), of which 5 were scheduled to go live in 2009.

In 2005, 5 out of 31 (16.1%) of responding hospitals had an ICIS in place. Another 7 hospitals (22.5%) had the intention of implementing an ICIS within the next 3 years (i.e. before 2009), while the remaining 19 hospitals (61.3%) had no explicit intention to implement an ICIS. None of the seven ICUs from the 2005 survey which intended to adopt an ICIS within the following 3 years, actually did so. Finding adequate financing, together with anticipated integration problems with the hospital information system, were the main reasons for postponing the implementation. However, 3 hospitals which showed no interest in adopting an ICIS in 2005, did implement an ICIS before the end of 2008 (cf. Table A.1).

	2005 (n=54)	2008 (n=63)
ICIS, n (%)	5 (9.3%)	12 (19.0%)
ICIS uptake $<$ 3 years, n (%)	7 (13.0%)	20 (31.7%)
No ICIS, n (%)	42 (77.7%)	31 (49.2%)

Table A.1: Number of ICIS Implementations in 2005-2008. (ICIS: ICIS already implemented; ICIS uptake $<$ 3 yrs: intention of implementing ICIS within the next 3 years; no OCOS: no ICIS available within the first 3 years.

There is a significant correlation between the type of hospital and the availability of an ICIS ($P < 0.001$) (Figure A.2). ICUs with ICISs also have a significantly higher number of ICU beds (average 23.9 vs. 11.5 beds).

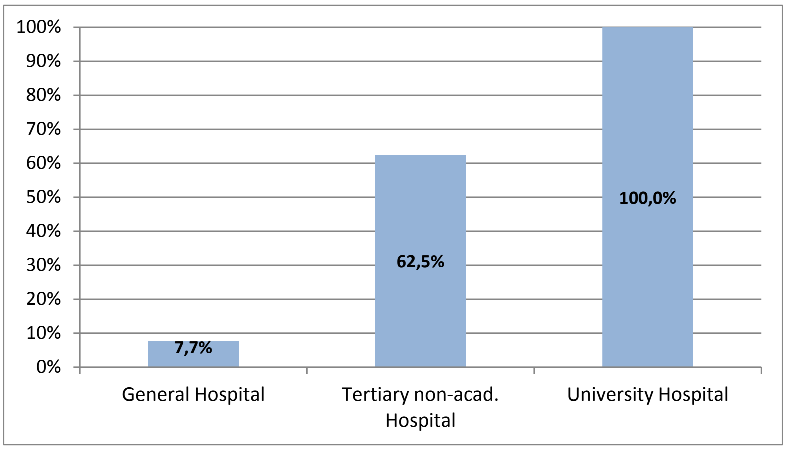

Figure A.2: Implementation rate of ICIS as a function of the type of hospital. (Tertiary non-acad.Hospital: Tertiary non-academic Hospital)

All ICISs are commercial systems, and the market is shared between a variety of software vendors (as represented in Table A.2).

Product	Vendor	n
Centricity Critical Care	GE Healthcare IT	3
ICM	Drager	3
ICIP Critical Care / Care Vue Chart	Philips	3
MetaVision Clinical Information System	iMDsoft	3
Picis Critical Care Manager	Picis	1
QCare ICU	Critical Care Company (C3)	1

Table A.2: Implementation rate of different commercial ICISs in Flemish ICUs.

A.3.3 The level of integration between the available ICIS and the hospital information system

Integration with the hospital information system for administrative data exchange, the so-called admission, discharge and transfer (ADT) coupling, has been carried out in 83% of ICISs, and most systems are integrated with the electronic patient record and laboratory system as well. Direct integration with the radiology system and the pharmacy department on the one hand, and ICIS on the other hand is technically more demanding, resulting in an integration rate of only 25%.

A.3.4 The effective use of highly detailed data extraction

The regular use of data extraction tools for management or scientific purposes is still limited (4 out of 12), and is only accomplished in university or tertiary non-academic referral hospitals.

A.3.5 The decision-making process in implementing an ICIS, including the benefits and obstacles perceived by the ICU decision makers

Data are obtained from the written 2005 questionnaire. The main anticipated benefits of an ICIS according to ICU directors are listed in order of importance in Table A.3. The main concerns of buying an ICIS are listed in order of importance in Table A.4. These major drawbacks are the cost, the need for dedicated personnel, and problems of integration with other hospital information systems.

Almost 40% of ICU directors are convinced that investing in an ICIS should be a top priority for their ICU. However, around 80% of ICU directors doubt whether there is enough evidence to ensure the cost/benefit of an ICIS.

The major reason for not implementing an ICIS is the substantial financial cost. One hospital even invested in a new paper medical record recently. The extra cost per ICU bed for installing an ICIS ranged between 20,000 and 25,000 Euros, which is a substantial investment. Twenty-nine out of 31 respondents hold the

Main anticipated benefits of switching from paper charting to an ICIS
1. Automatic compact archiving;
2. Improved exchange of information between the different caregivers;
3. More complete and automatic data acquisition;
4. Higher quality of care with prevention of errors, in the first place medication errors;
5. Automatic calculation of scores and support for coding (e.g. APACHE II (Acute Physiology and Chronic Health Evaluation II), SOFA (Sequential Organ Failure Assessment), SAPS (Simplified Acute Physiology Score), TISS (Therapeutic Intervention Scoring System));
6. Automatic reporting and automatic generation of discharge documents;
7. Data extraction possibilities.

Table A.3: Main anticipated benefits of switching from paper charting to an ICIS.

opinion that the government should finance at least 40% of total costs, and 1 out of 3 hospitals even feel that governmental financial assistance should cover over 70% of the implementation cost. Some ICU directors in our study even suggest full reimbursement by the government.

A.4 Discussion

To our knowledge, this is the first study evaluating the actual use of IT applications in the critical care environment in a European country, together with its evolution over time. We have evaluated both the adoption rate of hospital-wide IT-applications, which are part of the hospital information system, as well as the use of dedicated ICU IT applications (i.e. ICIS).

In our study, we found that laboratory results and radiology images are digitally available and are used in respectively 100% and 93.5% of the Flemish ICUs. But the use of IT for computerized requests of laboratory analyses and radiology investigations is still rare. Although few surveys have been conducted in this respect, we have noted substantial national variability regarding this issue [13–18]. In line with our results, Jha et al. also found a low adoption rate of 12% of U.S. ICUs using computerized requests for laboratory orders [17]. However, Lapinsky has found that 52% of Canadian ICUs use computerized laboratory and radiology requests [13]. The reason for this substantial difference is unknown. Regarding the computerized prescription of medication, we note that Flemish ICUs make more use of it (i.e. 41.3%) than Canadian (22%) or American ICUs (5 to 15%) [13–16]. The higher adoption rates of medication CPOE in contrast with the low adoption rates for laboratory and radiology CPOE may perhaps partly be attributed to the increasing number of publications showing that medication CPOE can improve care by reducing medication errors [19–26].

In Flanders, the ICIS adoption rate is currently 19% and this low rate correlates well with the rate mentioned in the Canadian report by Lapinsky et al. [13]. However, in the latter survey, only 7 out of 50 ICUs (14%) capture data directly from patient monitors, and merely 6% are connected to infusion pumps or ventilators [13]. Our second survey in 2008 showed that by the end of 2009 the ICIS adoption rate would have increased to 26.9%. However, these adoption rates can be an overestimation, as many ICUs intend to implement an ICIS, but fail to do so. Therefore, in August 2010, we contacted the 5 Flemish ICUs of our study once more. In the 2008 survey these ICUs had expressed their plans to implement an ICIS in the near future (i.e. before 2010). Only one out of these 5 ICUs delayed the project due to financial reasons, which gives an actual ICIS implementation rate in Flanders of 25.3% (16/63).

In line with the survey by Jha et al. the Flemish larger and teaching hospitals are the leading ICUs investing in an ICIS (see Figure A.2) [17]. Possibly the innovative role of teaching centres, the more powerful financial possibilities and the interest in scientific research facilitated by data extraction, have influenced the ultimate decision to surmount the barriers to implementation. However, there is a remarkable gap between the initial enthusiasm in data extraction and the actual use of it, as only 4 out of 12 ICUs query and use refined data for management or research purposes. The specific expertise needed to perform complex database queries remains an important obstacle, despite the availability of commercial data extraction software packages which reduce the need for extensive knowledge of the Structured Query Language (SQL) and the exact relational database structure.

In contrast to the USA or the UK, there are no Flemish governmental financial incentives for the computerization of ICUs [11, 27]. Yet this survey shows that especially the high cost associated with the purchase and implementation of an ICIS is the most important obstacle (see Table A.4). This finding is supported by the general literature on this issue [13, 17]. It is, nevertheless, clear that governments are highly interested in optimising the cost-efficiency of intensive care medicine and are hence interested in detailed data on resource use and outcome. This would allow them to shift to a form of performance-based financing in the future. Therefore, financial incentives for a complete computerization of ICUs could result in a win-win situation both for the ICUs and for the government.

In our survey, it became clear that ICISs are not always used to their full capacity. In fact, two Flemish centres which implemented an ICIS experienced major difficulties in linking their systems to the hospital information system. These problems created failure for automated charting in one hospital, and failure of the pharmacy linking in the other. Furthermore, at least 5 other hospitals admit that the implementation schedule of an ICIS has been significantly delayed due to integration problems with the hospital information system and/or pharmacy department.

Main drawbacks to buying an ICIS
1. Financial cost for initial implementation, maintenance and upgrading;
2. The need for dedicated IT personnel for configuration and end-user training;
3. Integration with the hospital information system;
4. Reliability;
5. Confidentiality issues;
6. Need for infrastructure adaptations.

Table A.4: Main drawbacks to buying an ICIS.

There are several limitations to our study. First, the response rate of the 2005 survey was only 57.5%. Nevertheless, this is in accordance with other response rates of similar written questionnaires [13, 17]. We should also note that there was probably an important responding bias to the initial written questionnaires in 2005, which appear to include among the respondents particularly ICUs which had already implemented an ICIS. Furthermore, the non-respondents in this first survey admitted later in the telephone survey of 2008 that they did not return the questionnaire especially because they were not computerized. This means that the perceived implementation rate of 16.1% in 2005 was clearly an overestimation, and was actually only 9.3% (i.e. 5 out of 54 ICUs). Therefore, we can draw the relevant conclusion that the ICIS implementation rate in Flemish ICUs doubled from 2005 to 2008 to the level of 19% and increased further in August 2010 to 25.3%.

Second, we did not use a validated questionnaire. This implies limited applicability for parallel follow-up study. Finally, the responses indicate self-reported IT implementation rather than direct observation.

A.5 Conclusions

Nearly all ICUs in Flanders use hospital-wide available IT applications such as computerized laboratory and radiology displays, although the computerized request for laboratory and radiology is still an exception. Furthermore, the adoption level of medication CPOE and ICIS remains relatively low. The implementation rate of ICISs has nearly doubled over the last three years, and has the potential to increase to 50% by the end of 2011. Major obstacles to implement specialized IT solutions are the high initial costs and maintenance costs, the complexity of integrating ICISs with existing hospital-information systems, and the unclear return on investment.

List of abbreviations

IT: Information Technology; ICU: Intensive Care Unit; PACS: Picture Archiving and Communication System; CPOE: Computerized Physician Order Entry; ICIS: Intensive Care Information System.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Kirsten Colpaert has made substantial contributions to the original concept, coordination and design, acquisition of the data, analysis and interpretation of the data, and drafting of the manuscript. Sem Vanbelleghem participated in the design and the coordination of the study, the acquisition and analysis of the data, and drafting the manuscript. Christian Danneels participated in the design and coordination of the study. Dominique Benoit participated in the design and helped to draft the manuscript. Kristof Steurbaut, Sofie Van Hoecke and Filip De Turck participated in the design of the study, and have been involved in revising it thoroughly. Johan Decruyenaere made substantial contributions to the concept and design, analysis and interpretation of the data, and has revised the manuscript thoroughly. All authors have reviewed and approved the final manuscript.

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B

Use of web services for computerized medical decision support, including infection control and antibiotic management, in the intensive care unit

In this appendix, we summarize the COSARA research project and describe the general objectives and benefits. A detailed description has already been given in chapter 4.

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Abstract The increasing complexity of procedures in the intensive care unit (ICU) requires complex software services, to reduce improper use of antibiotics and inappropriate therapies, and to offer earlier and more accurate detection of infections and antibiotic resistance. We investigated whether web-based software can facilitate the computerization of complex medical processes in the ICU. The COSARA

application contains the following modules: Infection overview, Thorax, Microbiology, Antibiotic therapy overview, Admission cause with comorbidity and admission diagnosis, Infection linking and registration, and Feedback. After the implementation and test phase, the COSARA software was installed on a physicians office PC and then on the bedside PCs of the patients. Initial evaluation indicated that the services had been integrated easily into the daily clinical workflow of the medical staff. The use of a service oriented architecture with web service technology for the development of advanced decision support in the ICU offers several advantages over classical software design approaches.

B.1 Introduction

Every year more than 100,000 patients suffer from nosocomial infection in Belgium. Nosocomial infections are those which are not present before the patients admission but are acquired in hospital. The symptoms usually appear after 48 hours in hospital. Patients who are particularly at risk are those who have mechanical ventilation or invasive procedures. Nosocomial infections produce significant morbidity and mortality in patients in the intensive care unit (ICU). European and Belgian reports state that the prevalence of nosocomial infection in ICUs is 2025% [1]. Studies have shown that 2030% of these infections might be prevented [2] [3].

Ghent University Hospital is a tertiary care facility in Belgium. The ICU was founded in 1980 and has a total of 56 beds. The ICU admits about 4000 patients each year and consists of a surgical, medical, cardiac surgery, paediatric and burns unit. The ICU has been using an information system with computerized physician order entry (CPOE). Although this commercial Intensive Care Information System (ICIS) was able to replace the paper-based ICU patient record, the level of advanced ICU medical decision support is still moderate. Extending the ICIS with support for nosocomial infection studies and creating an efficient integration process of monitored, laboratory and radiology data were major requirements of the medical staff. By combining and mapping available data sources, data can be exploited in advanced decision support services.

The aim of the present study was to enable Computerbased Surveillance and Alerting of Nosocomial Infections, Antimicrobial Resistance and Antibiotic Consumption (COSARA) in the ICU by providing computerized support at the point of care. The COSARA platform will be used in the daily follow-up of infections and antibiotic therapies. It has the potential to improve the quality of care, time efficiency and cost-effectiveness of critical care infection control.

B.2 Methods

The COSARA project started in April 2007. Both physicians and software developers were involved in the design and implementation of the computer-based infection control and antibiotic management system.

B.2.1 Multidisciplinary approach

Despite the potential of information technology (IT) to support complex medical decision-making, few IT applications have been adopted to assist medical staff. One of the reasons is poor communication between ICU users and software developers. At the start of the COSARA project we established regular discussions between physicians, data managers and software developers to identify their expectations about the infection control application. Based on their experiences and previous studies [4], the application was adopted by the medical staff. Physicians started to use the application routinely because it was integrated with their current tasks and it was designed for their specific needs. The involvement of physicians in the design phase was crucial.

B.2.2 Infection control and antibiotic services

Physicians and nurses perform time-consuming, complex data analyses in order to make decisions based on the individual patients data. Previously, information was only accessible through multiple, vendor-specific applications. Therefore, we developed a data collection process that collected and integrated the relevant infection data within a single software application (Figure B.1).

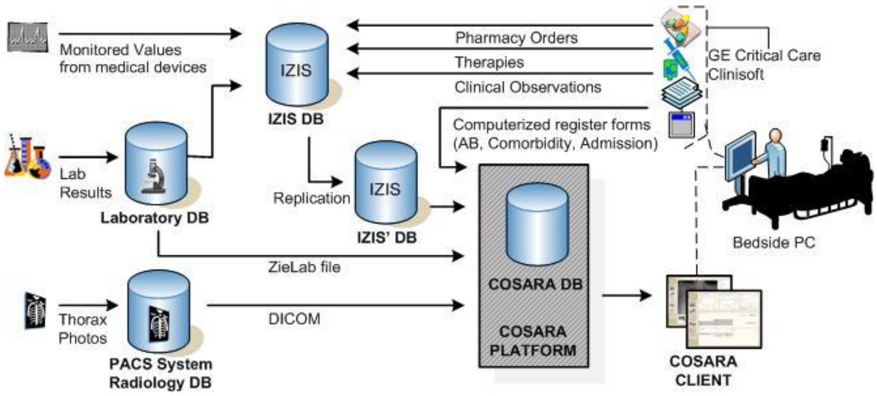

Figure B.1: Collection and integration of data from the hospital's data sources

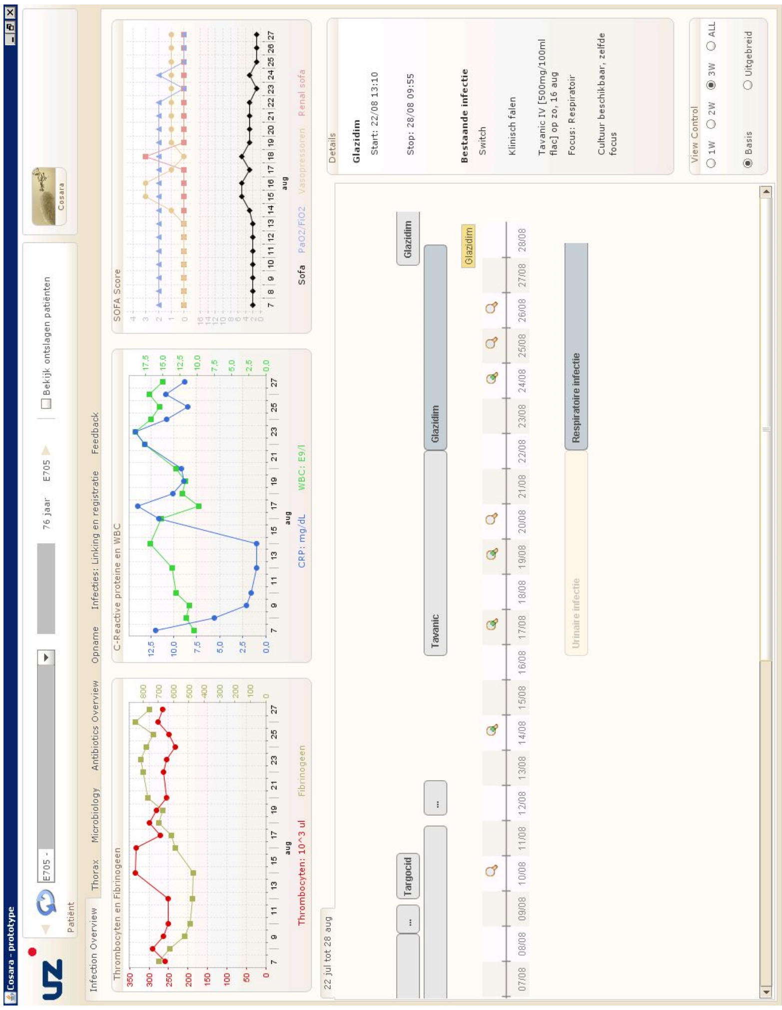

Figure B.2: Overview of the client with modules for infection control and antibiotic management

Monitor and therapeutic data are retrieved from the ICU, while laboratory data is collected from the hospital laboratory system and the patients chest X-ray images are identified in the Picture Archiving and Communication System (PACS). All these data sources have a specific structure which makes it difficult to integrate them. Some sources, such as the microbiology reports, are entirely text-based and have no structured format. By creating additional parsing techniques and a data model we were able to collect and integrate all clinical data automatically. The COSARA application [5] contains the following modules: Infection overview, Thorax, Microbiology, Antibiotic therapy overview, Admission cause with comorbidity and admission diagnosis, Infection linking and registration, and Feedback. The infection overview, as shown in Figure B.2, presents the important laboratory values and the current antibiotic therapy. Figure B.3 shows the thorax module which gives an overview of the patients latest chest X-ray images. Figure B.4 shows the susceptibility reports (antibiogram) and microbiology data. The infection linking module allows the physician to link all infections with microbiological resistance patterns and antibiotic orders. Prior to the COSARA study, this information was not present in the information system database. Furthermore, the reasoning for making an antibiotic prescription with associated therapy indications (such as empiric, prophylactic therapy), available microbiology data and the level of diagnostic certainty is registered in a new antibiotic pop-up screen. This captures the diagnosis and judgement of the physician while initiating or changing the antibiotic order. By combining all these data with advice from antibiotic services (such as an antibiotic dose, antibiotic switch and Sequential Organ Failure Assessment (SOFA) service) we are able to modify the antibiotic prescriptions and create alerts.

Both antibiotic services check whether the current antibiotic therapy complies with the standard clinical guidelines in the ICU. The SOFA service gives an indication of the organ failure of the individual patient. The client (Figure B.2) shows graphs of the patients laboratory values, such as thrombocytes and fibrinogen (left), C-reactive protein and white blood cells count (middle). It also shows the SOFA score (right). The client presents a timeline with ordered antibiotics and occurring infections. The box at the right shows the details of a selected antibiotic with a given start and endtime (in this case we selected an antibiotic Glazidim, a switch from Tavanic. This antibiotic was prescribed for a respiratory infection).

B.2.3 Implementation

We investigated whether web-based software can facilitate the computerization of complex medical processes in the ICU. Using a service oriented architecture, new medical services can be plugged in easily [6]. Service-orientation expresses an architectural style that defines the use of loosely coupled services, which serve

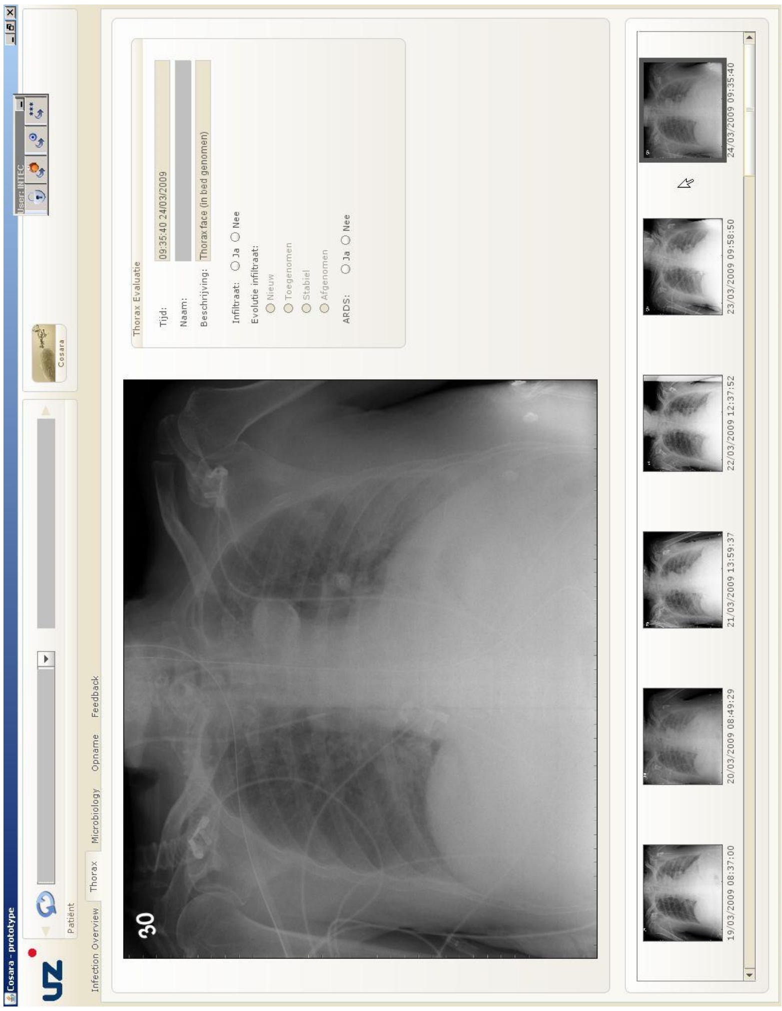

Figure B.3: The client shows a history of chest X-ray images and an evaluation form. The form on the right is used to calculate the Clinical Pulmonary Infection Score (CPIS) based on occurence of infiltrate (and its evolution), indication of acute respiratory distress syndrome (ARDS) and other laboratory values.

as building blocks for distributed software applications. The services are plugged into a service execution platform that offers data collection, event handling and medical service management. Thus the developer and physician can concentrate on the design of the decision support function itself. After the implementation and test phase, the COSARA software was installed on a physicians office PC. At this stage, the multidisciplinary team met to discuss updates or changes. Subsequently the application was also installed on the bedside PCs of the patients.

B.3 Results

Initial evaluation indicated that the services had been integrated easily into the daily clinical workflow of the medical staff. The involvement of medical experts in the development of the application probably helped to establish user-acceptance in the hospital. The additional recording of the physicians reasoning when making antibiotic prescriptions was not seen as additional workload. In September 2009, 93% of the prescribed antibiotics were recorded using the new antibiotic pop-up screen. It is expected that this percentage will increase after configuration of all bedside PCs. The complete application is currently being evaluated in a clinical study. Because of the service oriented approach, it was also possible to generate real-time alerts such as alerting for early kidney injury [7], to implement advanced Computerized Physician Order Entry (CPOE) such as advice for adapting the antibiotic dosage according to renal function and to set up an automated infection surveillance computerized system.

B.4 Discussion

The initial clinical evaluation showed three main benefits:

(1) The service platform allowed more accurate investigation of the impact of infection control programmes and antimicrobial exposure on the incidence of nosocomial infection and microbial ecology, taking into account potential confounders;

(2) The services produced time savings because manual calculations (e.g. SOFA score service) are timeconsuming and therefore expensive;

(3) The client gave physicians accurate data for daily patient care using a simple graphical user interface with data from several data sources. Using only one application able to integrate all data sources also saved time.

The use of a service oriented architecture with web service technology for the development of advanced decision support in the ICU offers several advantages

Figure B.4: The microbiology module shows the patient's antibiotic susceptibility reports and list of lab sample results. These reports (A-D) (below) can be compared by highlighting an antibiotic element.

over classical software design approaches. For example, it was possible to offer a P/F service calculating the PaO2/FiO2 ratio (based on partial pressure of oxygen in the arterial blood, PaO2, and the fraction of inspired oxygen, FiO2, after checking mechanical ventilation). This is used as a building block in the composed SOFA and CPIS services. The efficient distribution of the web services over the available workstations spread the workload and thus avoided overload failures. Finally, the involvement of the physician in the software specification process improved communication between the physicians and the software developers.

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