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Research Article

Epidemiology of multi-resistant organisms – challenges to a regional data management system

Epidemiologie multiresistenter Erreger – Herausforderungen an ein regionales Daten-Management-System

Abstract

The health care region Baltic Coast is within the framework of the joint project HICARE (Health, Innovative Care & Regional Economy) to be developed from January 2011 to December 2014 into a model region to combat the spread of multi-resistant organisms (MRO). The concept of the project area "IT & Epidemiology" will be introduced here. An IT system is to be developed and implemented consisting of two interconnected elements, a central data management and a web-based support system for information and decision. Particular challenges are the consolidation of data decentrally collected from numerous and heterogeneous data sources, compliance with the data privacy protection laws and the complex management of patients' informed consent. The information collected by the central data management will be the basis of epidemiological evaluations. Prevalence and incidence of MRO in patients and staff of medical facilities, single risk factors as well as risk profiles, the range and extent of treatments including their effectiveness and sustainability will be investigated. Furthermore, cost and cost-utility analyses will be performed.

Keywords: multi-resistant bacteria, epidemiology, data collection, data management, information system, data privacy

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Zusammenfassung

Die Gesundheitsregion Ostseeküste soll im Zeitraum Januar 2011 bis Dezember 2014 im Rahmen des Verbundprojektes HICARE (Health, Innovative Care & Regional Economy) zu einer Modellregion entwickelt werden, um die Ausbreitung multiresistenter Erreger (MRE) einzudämmen. In diesem Beitrag wird das Konzept des Projektfeldes „IT & Epidemiologie" vorgestellt. Es wird ein IT-System konzipiert und umgesetzt, das aus zwei miteinander verknüpften Elementen besteht, einem zentralen Datenmanagement und einem web-basierten System zur Information und Entscheidungsfindung. Besondere Herausforderungen bei der Realisierung dieses Vorhabens sind die zentrale Zusammenführung dezentral erfasster Daten, die zahlreichen Quellsysteme mit jeweils eigener Datenstruktur, die Notwendigkeit einer datenschutzgerechten Patientenidentifikation über verschiedene Einrichtungen und Datenerfassungssysteme hinweg und ein komplexes Management zum Informed Consent.

Die im zentralen Datenmanagement erfassten Angaben bilden die Basis für epidemiologische Auswertungen. Es soll dabei die Prävalenz und Inzidenz von MRE bei Patienten und bei den Mitarbeitern der beteiligten Einrichtungen untersucht werden, der Einfluss einzelner Risikofaktoren sowie von Risikoprofilen auf das Auftreten von MRE. Zudem werden die Methoden der Sanierung erfasst und deren Wirksamkeit und Nachhaltigkeit verfolgt. Zusätzlich werden Kosten- und Kosten-Nutzwert Analysen durchgeführt.

Schlüsselwörter: multiresistente Bakterien, Epidemiologie, Datenerfassung, Datenmanagement, Informationssystem, Datenschutz

Introduction

Multi-resistant organisms (MRO) continue to be a significant health threat in spite of numerous and diverse counter-measures. Both nationally and internationally every year about 4–9% of all inpatients suffer from nosocomial infections acquired during a hospital stay [1]. Treatment of these infections is being hampered by the increasing number of antimicrobial resistant organisms and in many cases patients will succumb to their infections. In Germany, it is estimated by the German society of hospital hygiene (DGKH) and further societies that up to 30,000 patients die yearly due to nosocomial infections. This number includes patients in rehabilitation centres and in outpatient surgical [2].

Multi-resistance is an increasing problem in a range of pathogens. For example, of all present *Staphylococcus aureus* isolates, presently 20–25% are Methicillin resistant (MRSA) [3], [4], [5]. Increasing resistance to antibiotics is also being seen in other organisms such as Vancomycin resistant enterococci (VRE) and enterobacteria that are capable of producing extended-spectrum beta-lactamase such as *Escherichia coli* and Klebsiella strains. Especially the development of gram-negative multi-resistant bacteria is alarming [6], [7], [8]. Main reasons for this increase are the shift in patient populations to older, multimorbid patients with weakened immunologic resistance as well as the increasing number of invasive diagnostic and therapeutic procedures. Additionally, antibiotics are widely prescribed [1]. The total consumption of antibiotics per year can be estimated to 250–300 t, while 85% percent of all prescriptions are in the community setting. Compared to other European countries the outpatient prescription rate of Germany is placed in the lower third of the range [3]. A wide prescription leads to selective pressure favouring resistant organisms with increased pathogenic potential. Most available data on prevalence, incidence, means of propagation, prevention and costs focus on MRSA. However, as recently shown, the quality of studies on MRSA differ widely [9].

The goal of the joint project HICARE (Health, Innovative Care & Regional Economy) is to counter the spread of MRO at the regional level and at the same time to depict the clinical importance and epidemiological peculiarities of these infections, especially in the case of multiple infections. The organisms that will be considered are listed in Table 1.

Transmission of MRO occurs most frequently in hospitals. There is a particular abundance of cases in intensive care units, with a large heterogeneity between individual units dependent upon the types of intervention performed and the age distribution of the patients [6]. It is imperative that MRE colonised or infected patients are identified upon admittance (prevalence) to lower the probability of potential complications by early treatment as well as to prevent potential transmissions to other patients via the environment or hospital staff (incidence). Carrier status for MRE often persists after discharge from the hospital. The project must, therefore, embrace the complete sphere of interacting healthcare facilities, in particular at the interfaces of admittance and of discharge (Figure 1).

Between January 2011 and December 2014 the healthcare region Baltic Coast (Figure 2) within the framework of HICARE is to be developed into a model region, including integrated, sustainable patient-centred care, healthcare products and services.

The following partners are responsible for the project:

- The University and University Medicine Greifswald
- The University and University Hospital Rostock
- Gensoric GmbH, Rostock
- BioCon Valley GmbH, Greifswald

The joint project comprises a total of more than 40 cooperating partners: Hospitals and their affiliated laboratories, healthcare companies, statutory health insurances, the state office of health and social affairs Mecklenburg-Western Pomerania, the *Kassenärztliche Vereinigung* (association of statutory health inscurance physicians), the *Medizinischer Dienst der Krankenkassen* (medical review board of the statutory health insurance) and the animal disease fund of Mecklenburg-Western Pomerania. The clinical partners include of 11 hospitals with in-patient wards and four inpatient rehabilitation facilities. Three study centres (AMEOS Hospital Ueckermünde, ASKLEPIOS Hospital Pasewalk, Unfallkrankenhaus Berlin UKB) are located outside of the geographically defined area of the healthcare region Baltic Coast (Figure 2). Since these centres provide care for the population within the study region to a relevant extent, however, they participate as associated partners in the joint project. In addition, efforts are being made to include resident physicians in private practices or health centres, with the ultimate goal to consider the complete circle of healthcare services.

The HICARE project comprises 6 project areas. The concept of project area 4 “IT & Epidemiology” will be introduced here. This project is attached to the Institute for Community Medicine, Section Healthcare Epidemiology and Community Health.

The planning and implementation of an IT system consisting of two interconnected elements will take place here. The two elements are:

- A central data management system to support research
- A web-based information and decision support system.

The information collected by the central data management will form the basis of the epidemiological evaluations. The data will serve to answer the following central questions:

Table 1: Organisms that will be considered in the HICARE project

Pathogenes	Abbreviation
Methicillin resistant *Stapyhlococcus aureus*	MRSA
Vancomycin-intermediate *Staphylococcus aureus*	VISA
Vancomycin-resistant *Staphylococcus aureus*	VRSA
Vancomycin resistant enterococci	VRE
Pathogenes which are capable to produce extended-spectrum beta-lactamase, for example *Escherichia coli, Klebsiella pneumoniae*	ESBL E-coli
Clostridium difficile	CDIFF
Non-fermentative gram-negative bacteria (e.g. multi-resistant pseudomonas, multi-resistant *Acinetobacter baumannii*)	MRP A. baumannii

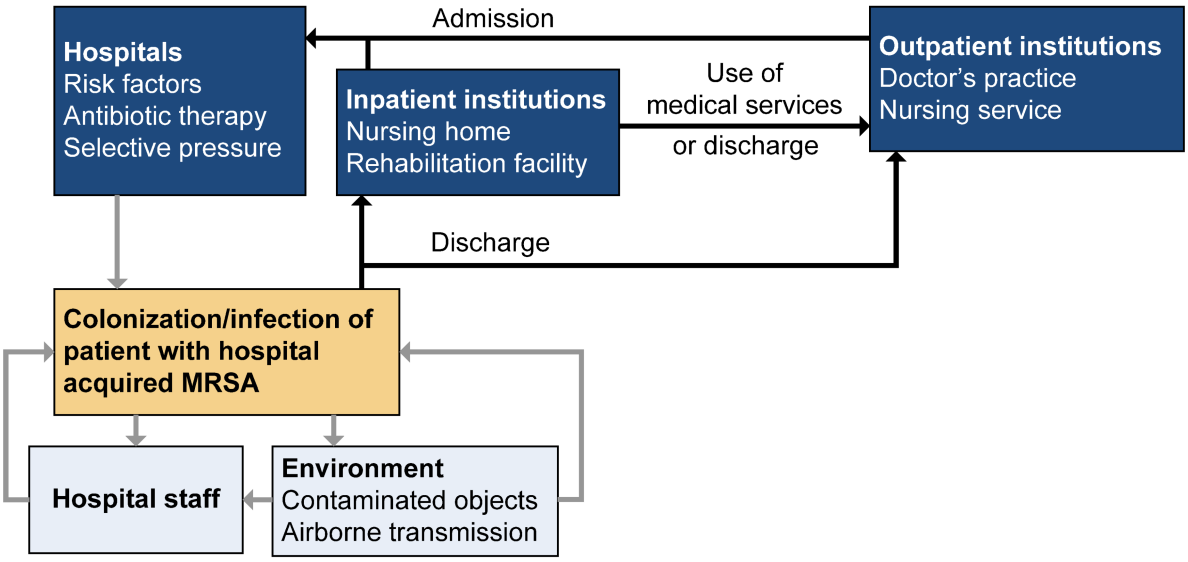

Figure 1 (modified after [12]): Interfaces in health care, using hospital acquired MRSA as an example

- How high is the prevalence and incidence of MRO in the patient population as well as by the staff of the medical facilities in the region?
- Which causative agents are involved?
- How important are single individual risk factors, e.g. chronic wounds, artificial respiration, antibiotic therapy, length of stay, chronic illnesses (e.g. diabetes) and co-morbidity?
- What are important combinations of single risk factors (risk profiles) with regard to prevalence and incidence for patients and staff in the institutions involved?
- Which methods of treatment are being carried out and how effective and sustainable are they?
- What are the costs and the cost-utility ratio?

Methods

Due to the large number of partners involved in the joint project HICARE the data sources are highly heterogeneous and diverse. In order to consolidate the data it is therefore necessary to convert them into a common format. Particular care must be paid in order to guarantee the privacy of sensitive patient data as required by data protection legislation, during both data integration and in storage and evaluation.

Results

Since the requirements of data management and change over the project time it was necessary to design a system (Figure 3) that can handle data from different source systems and feed them into a joint, generic integration process. Thus, for the central data management a service-oriented system architecture was created that is composed of 6 principle components:

- Processing begins in the "Extraction Layer". This component primarily serves to implement the required data privacy protection by separating the medical (MDAT) from the identifying patient data (IDAT).
- The IDAT are sent to the "Trusted Third Party", and are pseudonymised before they are sent to the "Persistence Layer." The pseudonymised data are then stored together with the MDAT.

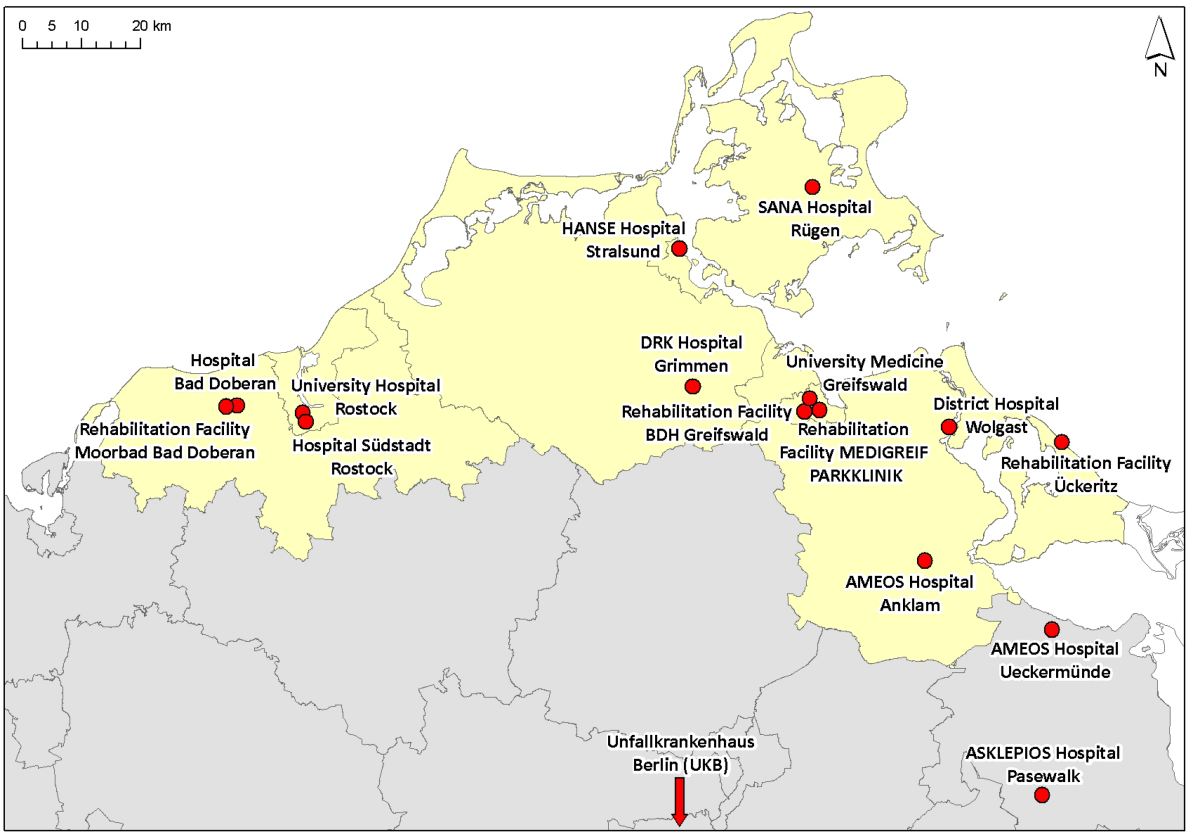

Figure 2: Healthcare region Baltic Coast

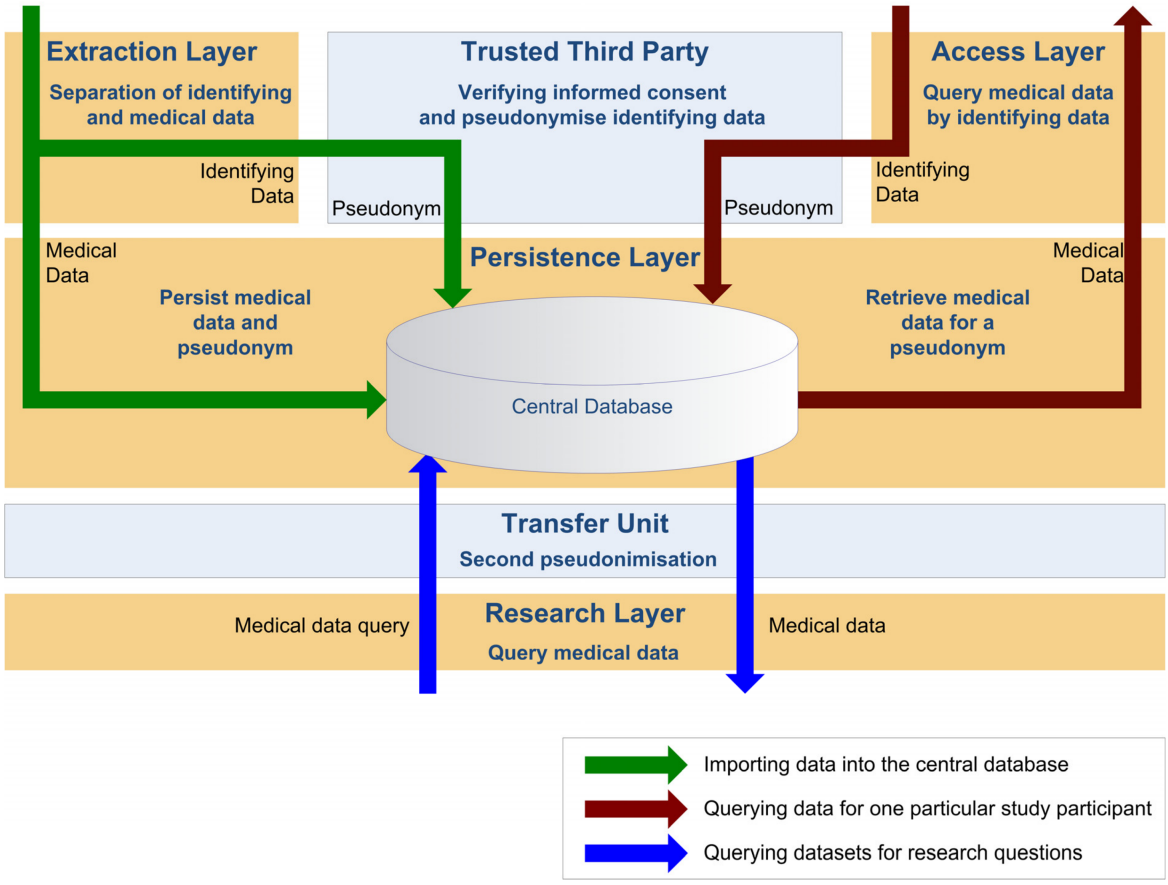

Figure 3: HICARE IT & Epidemiology: Principal system design and data flow

For data access, the system offers two ways:

- The "Access Layer" may provide medical data on an individual study participant. Therefore a MDAT query is made for this particular person and sent to the trusted third party. Here it is transformed to a pseudonymised MDAT query and passed to the persistence layer, where the medical data are collected and upon success sent back to the access layer.
- In contrast to this process, the "Research Layer" provides pseudonymised medical data for researchers. For this purpose a data query is sent to the persistence layer. The resulting data are processed by the "Transfer Unit" and sent back to the research layer.

When implementing a platform as described, several aspects have to be considered. From the IT point of view, the vast divergence of the source systems is a major challenge. The high number of different types of participants leads to an equal number of system configurations. The clinical context requires a high security level throughout the whole system, e.g. encrypted data connections. As a result two parts may be identified in the central data management: a rather individual part for each source system for the basic data connection and a common part, where data from all the source systems are integrated for the actual data processing. Therefore the system is designed to easily adapt to new source systems by a separation of data acquisition, processing and storage. Acquisition of data for the research platform requires processes which fit in clinical routine and cause only a minimum of extra work. A part of the data such as laboratory results can be acquired fully automatic from the existing IT-management system in the partners' institutions. Others may be entered in a standardised data collection software [10]. This software is thus also designed in a way that allows ready implementations with only minimal changes to the existing systems and workflows. Essential aspects of the whole system are privacy and data security. Especially in the context of a joint project a number of risks have to be considered carefully:

- To assure study participants data privacy, the system is oriented on the generic data protection concepts A and B of the *TMF – Technologie- und Methodenplattform für die vernetzte Forschung e.V.* [11]. Aspects such as pseudonymisation administered by the central trusted third party as described in concept B are combined with the early separation of IDAT from MDAT as in concept A. This hybrid of concept A and B provides an optimal solution for the specific requirements in HICARE. Additionally, the informed consent of the study participant has to be considered and be checked in every step of data processing, such as storing or giving away data to researchers. For this purpose, the consent is recorded digitally and can be verified automatically any time needed. The system accommodates to consent changing over the course of the project.
- The economic competition of some of the participating hospitals and laboratories has to be regarded. The data used for analyses or given to cooperating researchers have to be pseudonymised in a way that no economic disadvantages may arise for any of the participating institutions.

The system thus developed is capable to collect and combine standardised data, making it available both for cooperative, intersectional research and for tracking a particular, individual patient with adequate data protection.

Development of a web-based information and decision support system

A web-based system which dynamically generates regional prevalence and resistance maps will process the collected information. General information on organisms and treatments will also be provided. Additionally, existing guidelines are used to establish a rule set for a knowledge-based system. This system shall assist clinicians and general practitioners to find the correct antibiotic therapy. Focus points of the development are an ergonomic and intuitive user-interface as well as a high utilisation rate among involved partners. After the roll out the existing rule set will be refined in a feedback loop with users and experts allowing for the timely implementation of project results.

Discussion

In the HICARE project, healthcare region Baltic Coast, relevant personal and pseudonymised data on infections with multiresistant bacteria in a large array of healthcare facilities in the region are tracked, processed and evaluated epidemiologically in a central data management system. The particular challenges involved are:

- Consolidation of decentrally collected data
- Compilation and integration of numerous and heterogeneous data sources with unique individual data structures (hospitals, rehabilitation facilities, doctor's practices, laboratories, etc.)
- Patient identification and record linkage spanning data from various facilities with diverse data acquisition systems that meets the requirements of data privacy protection laws
- Complex system for management and update of individual informed consent.

In addition to the technical and organisational realisation that requires the cooperation of all the partners involved, the acceptance of the patients will play a primary role. This will, in turn, require that the patients be timely and adequately informed. Careful planning of data privacy protection and a comprehensive ethical concept are key elements.

Notes

Authorship

The two first authors Gerlich MG and Möller A contributed equally.

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Competing interests

The authors declare that they have no competing interests.

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