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Information Technology Aspects of Integrated Cardiac Rhythm Disease Management

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1. Introduction

Since several decades pacemakers and *implantable cardioverter defibrillators* (ICDs) are a common therapy for patients with cardiac rhythm abnormalities. More recently developed devices like *implantable cardiac resynchronization therapy devices* (CRTs) (Anand et al. 2009) or *implantable loop recorders* (ILRs) (Boersma et al. 2003) are implanted with increasing frequency and provide promising results.

Selection and implantation of devices are only first steps in cardiac rhythm disease management. Continuous adaptation of device settings to patient's needs, monitoring of device's battery status, revision of devices and several other issues need to be considered. Additionally, the functionality of devices is closely related to other therapeutic aspects, such as medication or the patient's health parameters – assessed either by general practitioners or by the patient him/ herself (e.g. blood pressure).

In many cases a given patient needs more than one therapy: e.g. pacemaker therapy is closely related to medication monitoring; or an increasing number of remotely monitored congestive heart failure patients also have an implanted CRT device. Therefore, a system is needed which is able to handle data from various sources (from implanted devices, from patient's home, from general practitioners, from hospitals, etc.) and provide the physician with all information necessary for an optimal therapy.

While from the patient's view it is primarily essential that all data from various sources are combined in one single system, from the physician's view it is also important to have one single system for all the patients she/ he is responsible for. There are several manufacturers for each of the therapeutic tools used in cardiac rhythm disease management. Each of those provides the physician with its own proprietary data interface. And, of course, one physician's patients are not all equipped with devices of one and the same manufacturer. Therefore, it is not only necessary to combine devices supporting different therapies (pacemakers, remote monitoring, etc.), but also to combine systems from different manufacturers within one single platform.

Additionally, eHealth infrastructures with electronic health records are currently envisaged, conceived or already established in many environments (single healthcare institutions, health management organisations, whole healthcare systems, or even nation-wide) (Pfeiffer

2009). The relevance of such developments for integrated cardiac rhythm disease management also has to be considered.

A similar complex situation can be found in the field of radiology, picture archiving and communication. Though this field is rather defined by the devices used than – as for cardiac rhythm disease management – by the physiological system concerned, many aspects are very similar. Anyway, while *picture archiving and communication systems* (PACS) are nowadays state of the art, a similar system approach has not been established for the domain of cardiac rhythm disease management. While a state-of-the-art PACS can communicate with various devices (e.g. CT, NMR, PET, ultrasound, etc.) from several manufacturers, by the use of one single review station, current cardiac rhythm disease management systems are mostly isolated solutions for single applications (e.g. remote CHF monitoring) and/ or for single manufacturers.

This chapter describes the current state of the art in cardiac rhythm disease management and the theoretical requirements for an integrated solution in terms of involved information technology aspects. Finally, a ***P****latform for* ***I****ntegrated* ***CA****rdiac* ***R****hythm* ***D****isease management* (PICARD) combining the functionality of heterogeneous systems is proposed. An overview of the information ecosystem influencing PICARD is shown in Fig. 1.

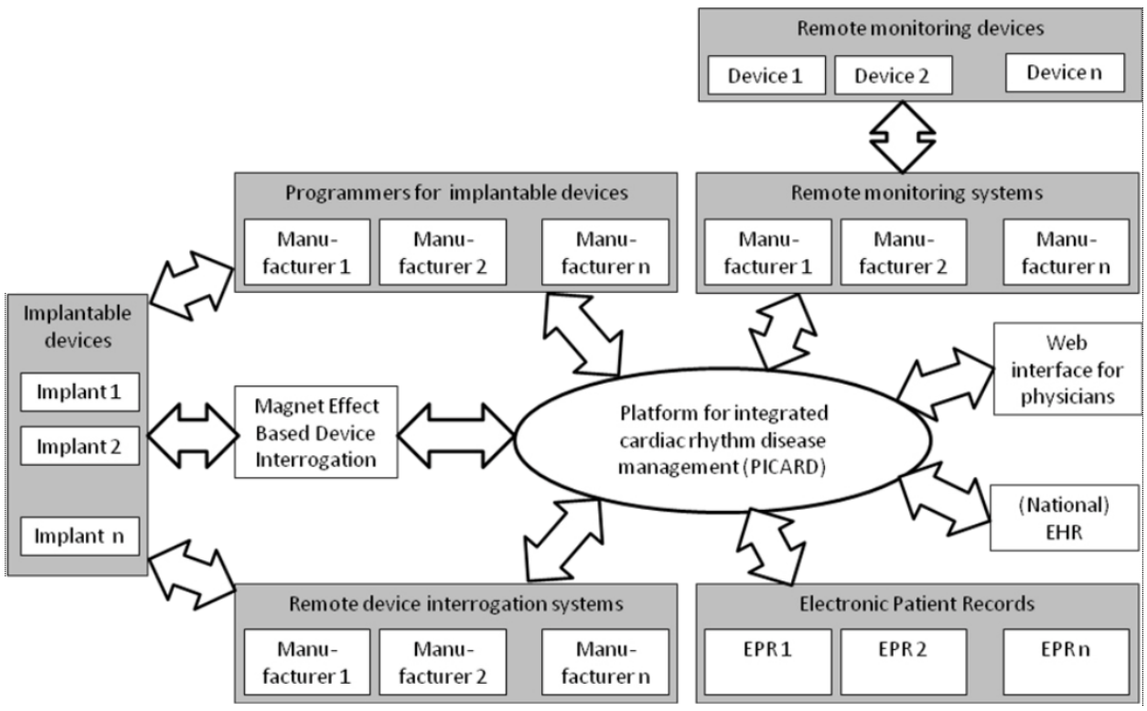


Fig. 1. Information ecosystem where a platform for integrated cardiac rhythm disease management (PICARD) is embedded. EPR...electronic patient record. EHR...electronic health record.

2. The data path

There are several data sources in cardiac rhythm disease management. Some of the sources are implanted devices (pacemakers, ICDs, ILRs, CRTs). Others are located at the patient's

home, such as devices used for remote monitoring of *congestive heart failure* (CHF) – e.g. utilising body weight scales, blood pressure meter, etc.
From these distributed, local sources, data are transmitted to more and more global systems. The data path from local data sources to a centralized electronic health record is summarized in Fig. 2. It contains the following components:

- Multiple measurement devices may be linked to each other via a *body area network* (BAN). Measurement devices can be:
  - implanted devices (pacemakers, ICDs, CRTs, ILRs, etc.)
  - monitoring devices (blood pressure meter, body weight scales, etc.)
- Aggregators are devices that collect data from several measurement devices. Aggregators are located at the patient's vicinity. Data are exchanged between measurement devices and aggregators via a so called *personal / local area network* (PAN/ LAN).
- Within an electronic patient record (often also called electronic medical record), data from different dislocated sources of information can be stored – linked via a *wide area network* (WAN). Electronic patient records can be parts of *hospital information systems* (HISs), telemonitoring platforms of single device manufacturers or disease management platforms such as PICARD, etc.
- Data from different electronic patient records may finally be linked to each other on the level of an *electronic health record* (EHR), which summarizes all health information e.g. on a national level.

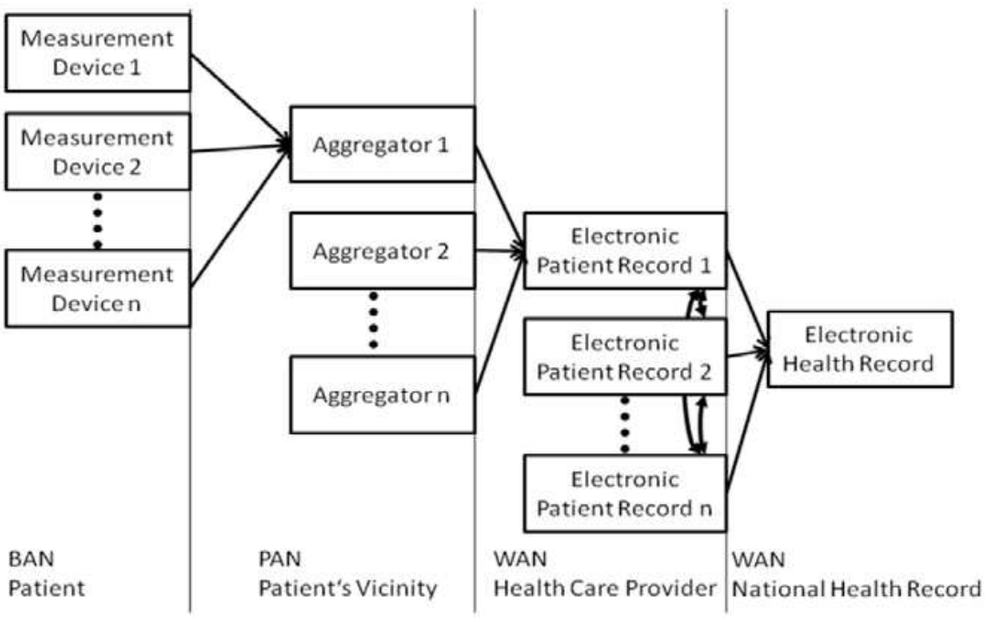


Fig. 2. Data path for cardiac rhythm disease management.

Aggregators need to be in the patient's "vicinity", a term covering several locations such as:

- Operating room – right after or even during implanting a measurement device
- Operating room – after surgeries that may influence the device's functionality (American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Rhythm Management Devices, 2005)

- Follow-up centre during regular follow-ups of a measurement device (e.g. programmers)
- Doctor's practice
- Patient's home (e.g. remote monitoring)
- Acute day wards in case of emergency situations (e.g. myocardial infarction).
- Anywhere in case of emergency situations

Some of the most common data acquisition situations which are currently used in cardiac rhythm disease management are described in the following chapter. Each of those is typically associated with a particular data source.

3. Data sources

3.1 Data source 1 – In-clinic follow-up with manufacturer-specific programmers

The aim of a follow-up is to optimise the condition of the patient and of the implanted device, to identify abnormal system function as well as lead problems, and to detect critical battery depletion (Sutton, 2006). According to international guidelines, patients with implanted pacemakers are usually requested for follow-up every 6 to 12 months, depending on patients' general condition and type and configuration of the pacing system (Task Force on Practice Guidelines, 2002 ; Kainz 1999, European Society of Cardiology & European Heart Rhythm Association, 2007). After first signs of battery depletion, the follow-up interval is decreased to every 3 months until the device is replaced.

There are two types of in-clinic follow-ups:

a. Basic follow-ups (sensing, pacing, battery, patient contentedness)
b. Extended follow-ups (additional check and optimization of pacemaker parameters)

All pacemakers provide a bidirectional telemetric interface that enables the implant to communicate with a special vendor-specific programmer. For this purpose, a so-called "wand" is connected to the programmer and placed above the implanted device. Using this wand, pacemaker data can be read out (e.g. electrode impedance) and settings of the pacemaker can be updated (e.g. pacing pulse amplitude) if necessary.

Since up to now each manufacturer provides a proprietary interface in between his implanted devices and his programmer, programmers from all manufacturers need to be available at in-clinic follow-up centres (see Fig. 3, left). Today, data read out by the programmers are usually printed out and archived in paper based patient records (Fig. 3, right). If an electronic patient record is available, manual data input is required and the data recorded electronically are mainly restricted to administrative aspects (Niederlag, 2001).



Fig. 3. Current state of in-clinic follow-ups using various programmer devices from different manufacturers (left) and paper based patient records (right).

3.2 Data source 2 – Remote device interrogation

The initial telemedical concept of so-called *Transtelephonic Monitoring* (TTM), is widely used in the US and Canada to evaluate battery depletion of pacemakers remotely (Calisto et al., 1993; Dreifus et al., 1986). Patients are asked to record an ECG in predefined intervals and to transmit the data via the standard telephone line to a service centre where the ECG is analysed by a cardiologist (Platt et al., 1996). If patients put a magnet close to their pacemaker simultaneously, the ECG will be recorded while their pacemaker is in magnet mode. This ensures that the pacemaker paces in a predefined way that can later on be analyzed by a specialist. The patient is requested for an in-clinic follow-up only in case of detected abnormalities.

New generations of implantable pacemakers available from various manufacturers support data transmission from the device to a remote monitoring centre automatically, e.g.:

- Home Monitoring (Biotronik, Berlin, Deutschland) (Nielsen et al, 2008)
- CareLink Network (Medtronic, Inc., MN, USA) (Raatikainen et al., 2008)
- Latitude Patient Management system (Boston Scientific, St Paul, USA) (Saxon et al., 2007)
- Merlin.net (St. Jude Medical, Sylmar, USA)

Depending on the particular system, the pacemaker may send diagnostic, therapeutic and technical information wirelessly to an external aggregator using a proprietary protocol. The aggregator forwards the data to the manufacturer's database using different transfer methods (SMS, https, FAX, etc.). At the monitoring centre the incoming data are analyzed and filtered. Pre-processed data are provided to the physician via a web-interface.

The data flow of such a remote device interrogation system is shown in Fig. 4.

Using such systems, remote follow-ups can be performed and/ or remote monitoring can be realized: For remote follow-ups the interrogation can be triggered by a physician or by the patient him/ herself whenever a follow-up seems necessary. During remote monitoring, device interrogation is done automatically according to a predefined schedule – usually once per day in the night time. Additionally, in case of arrhythmic episodes *intracardiac electrograms* (IEGMs) can be recorded and transmitted to the monitoring centre.

Up to now, remote device interrogation is used for reading out data only, and not for remote system updating or re-programming.

An overview over the properties of remote device interrogation systems from four manufacturers is given in Table 1.

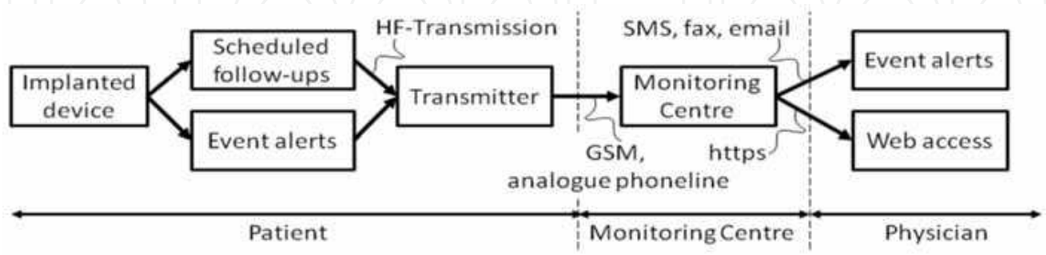


Fig. 4. Remote device interrogation system. Data from the implanted device are sent to an aggregator (transmitter) at the patient's home either regularly (scheduled follow-up) or event triggered (event alerts). The transmitter sends the data via GSM or analogue phone line to a monitoring centre where the data are analyzed. If necessary, an alarm is sent to the physician via SMS, fax or email. All data can also be accessed via a web interface.

	Biotronik Home Monitoring	Medtronic CareLink	Boston Scientific Latitude	St. Jude Merlin.net
Transmitter	GSM network	Analogue phoneline	Analogue phoneline	Analogue phoneline
FUs	Daily	Scheduled	Scheduled	Scheduled
Physician notification	SMS, e-mail, fax	SMS, e-mail	Fax, phone	Fax, e-mail, SMS
Feedback to patient via transmitter	LED indicating normal status or call to clinic	LED indicating normal status or call to clinic	Colored lights and indications	LED indicating call to clinic, automated phone calls
IEGM (real-time at remote FU)	30 s (monthly periodic EGMs)	10 s	10 s	30 s
Configurable alerts	All	Red and yellow	Red and yellow	All
Threshold adaptation	Automatic RV and LV thresholds (only Lumax 500/ 540)	Automatic RA, RV and LV (only Consulta) pacing thresholds	-	Automatic RA, RV and LV pacing thresholds (next generation of ICDs)
Heart failure monitoring support		Optivol lung fluid status alert	Weight scales and blood pressure cuffs	
Special features	GSM network – mobile transmitter		Configurable data transmission to associated caregivers Data export to electronic health records	Possibility of sending automated phone calls to patients Events visible on the transmitter's display

Table 1. Comparison of the remote device interrogation systems of Biotronik, Medtronic, Boston Scientific and St. Judes – based on (Burri et al., 2009). FU...follow-up.

3.3 Data source 3 – Magnet effect based device checks

An "intermediate" solution in between in-clinic follow-ups and telemedical device interrogation was presented in (Kollmann et al., 2005) using the pacemaker's magnet effect: To be compliant with international standards, battery depletion level and basic pacing function of any pacemaker must be accessible by applying a magnet to the pacemaker, which forces the pacemaker to switch to magnet mode (Task Force on Practice Guidelines, 2002). One motivation for this feature is to ensure that a physician can easily check – without any special equipment – whether the pacemaker is still working properly. In magnet mode, a predefined sequence of pacing pulses is applied to the patient's heart. These stimulation patterns depend on the manufacturer and the type of the pacemaker, as well as on the depletion level of the pacemaker's battery (Lampadius, 2010).

Hence, the basic working status and the depletion level of the battery can be determined by the means of a surface ECG recording during magnet application and looking for specific stimulation patterns within the signal. Additionally, possible lead malfunctions with respect to sensing and pacing or arrhythmias can be detected (Schreier et al., 2004; Kollmann et al., 2007a; Kollmann et al., 2005).

For magnet effect based device checks, the following units are necessary (Fig. 5):

- A mobile ECG recording unit, that can e.g. be situated at a general practitioner
- A monitoring centre that receives the data from the mobile ECG recording units. The monitoring centre needs access to a pacemaker database containing the properties of all pacemakers currently available.
- An ECG analysis unit comparing the received ECGs with all possible magnet mode pacing patterns of the implanted device – as stored in the pacemaker database.

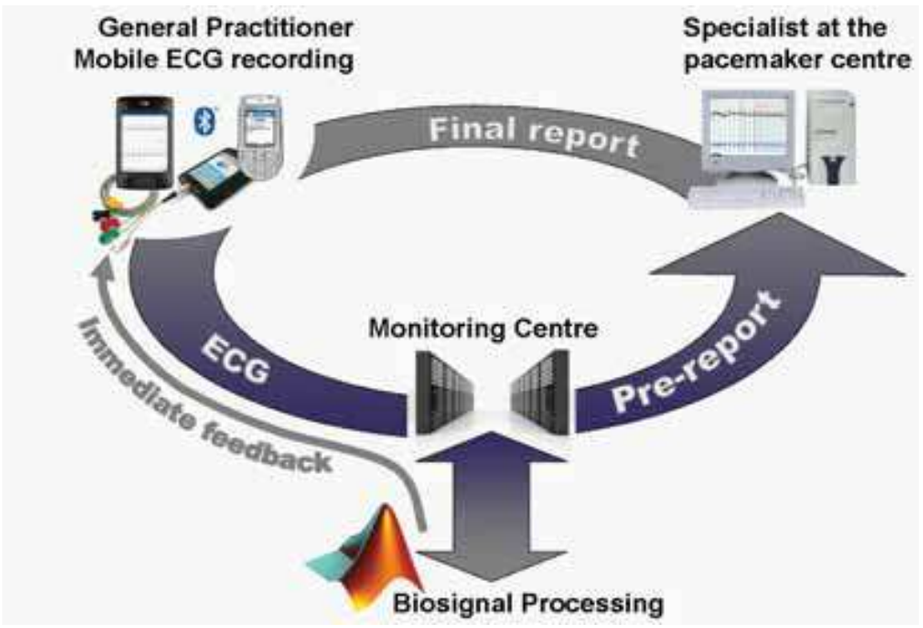


Fig. 5. Magnet effect based device checks consisting of mobile ECG recording units at the general practitioner, a monitoring centre with biosignal processing units and reviewing units for specialists at the pacemaker centre.

Depending on the results of the biosignal analysis, a preliminary report is generated and provided to a physician at the pacemaker centre. The ECG is shown to the physician, including data from the pacemaker database and the result of the ECG analysis (Fig. 6). The physician uses the ECG and all data entered by the general practitioner to review the preliminary report and finalize it. The final report is then returned to the general practitioner. In case of detected malfunctions, battery depletion, uncertainties, or if the patient reports any problems possibly related to the pacemaker, the patient is assigned to the specialized follow-up centre. If no such problems are detected, no additional actions are necessary.

Advantages of this method compared to in-clinic follow-ups and remote device interrogation are:

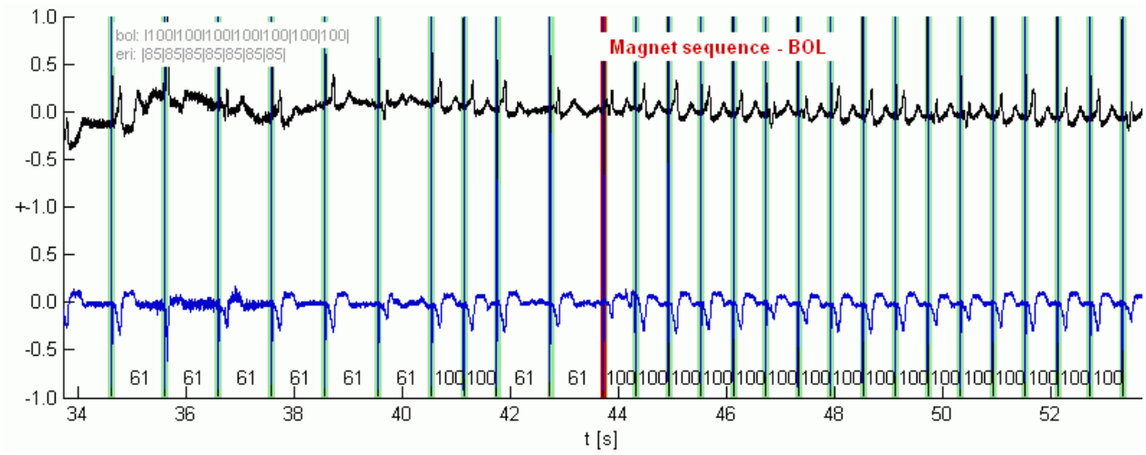


Fig. 6. ECG with magnet pattern (starting at second 44) as presented to the specialist. Possible magnet patterns for the present pacemaker in Begin-Of-Life (BOL) and Elective Replacement Indication (ERI) state are shown (upper left). Pacemaker spikes as detected by the biosignal analysis unit are marked with green lines. The beat-to-beat pacing rate [bpm] is written in between each two spikes. The suggested pacemaker state ('Magnet Sequence – BOL') is shown in red.

- Part of the in-clinic pacemaker follow-ups can be moved from specialized in-clinic follow-up centres to extramural physicians such as cardiologists or general practitioners, who a) do not need various programmers and b) need not to be pacemaker specialists.
- Specialized follow-up centres can be disburdened
- Travel costs and burden for patients can be reduced
- This method can be used for all pacemakers currently available on the market with no need for special transmitters, programmers, adaptations of the pacemaker etc. All that is needed is a magnet, an ECG recorder with an interface to a PC and Web-access.

Drawbacks of this method are:

- Device parameters cannot be adapted (equal to remote device interrogation)
- ICDs and complex device features cannot be assessed

3.4 Data source 4 – Remote monitoring systems

In recent years several systematic reviews indicate that remote monitoring concepts may be a valuable tool to optimize therapy of patients with several diseases such as CHF with respect to mortality, morbidity, quality of life, and costs (Schmidt et al. 2010; Inglis et al. 2010). Remote monitoring is already used in several scientific studies (e.g. Scherr et al. 2009) as well as in routine care (e.g. Kastner et al. 2010), and its importance is likely to increase within the next years. During remote monitoring, patients need to collect relevant data of their therapy, such as medication, blood pressure, body weight, well-being etc. and transmit them to a monitoring centre where they are accessible for the physicians.

An overview over a typical system for telemonitoring of CHF is given in Fig. 7. Measurement devices used during remote monitoring are either real devices like blood pressure meters etc. or "virtual" devices, representing data entry by the patient, such as well-being or medication intake. Mobile phones, PCs, laptops, and special devices are used as aggregators. The telemonitoring service centre provides an electronic patient record.

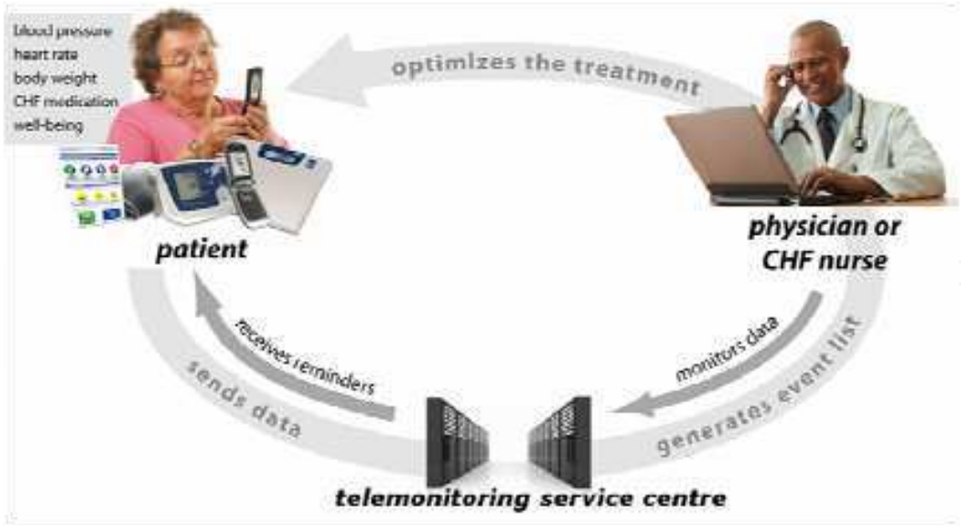


Fig. 7. Typical remote monitoring system as used for the monitoring of congestive heart failure. Several health parameters (e.g. blood pressure, heart rate, body weight, medication and well being) are recorded at the patient's home and sent to a data centre, over which the physician has access to the data (Kastner et al., 2010).

Boston Scientific has already introduced the system "Latitude" (Saxon et al., 2007). It combines telemedical device interrogation with a remote monitoring system for congestive heart failure. The system is expected to improve congestive heart failure therapy and help physicians in getting more of the information necessary for therapy optimization provided by different measurement devices at the patient site. Due to proprietary interfaces at the physician's site, however, no combination with similar systems of other manufacturers is possible – forcing the physicians to deal with several different systems.

4. Standardization aspects

Due to these heterogeneous data sources and since there are various systems data are stored in, standardized interfaces in between all partners concerned in cardiac rhythm disease management are essential. There are several standards that deal with a) information exchange in between heterogeneous information systems and b) structured information archiving. Many aspects need to be considered, such as a consistent nomenclature, data access, data transmission, data formats, where to save which data, safety and security, etc. Several consortia such as the *Continua Health Alliance* (Piniewski et al., 2010) or *Integrating the Healthcare Enterprise* (IHE) (IHE, 2010) aim to improve interoperability by forcing standardization in different health environments.
In the following, selected standards will be presented, which play an important role in cardiac rhythm disease management.

4.1 Standardized nomenclatures

Standardization begins with the vocabulary used for describing the thing one is talking about. For example, "breathing frequency", "breathing rate", "respiratory frequency" or "respiratory rate" may all mean one and the same observation term but are often labelled differently by different manufacturers. The nomenclature concerns all aspects of cardiac

rhythm disease management – measurement devices, aggregators, electronic patient records, electronic health records, etc. Examples for common medical nomenclatures are:

- *Logical Observation Identifiers Names and Codes* (LOINC) is a database and universal standard for identifying medical laboratory observations. It is widely used, especially (but not only) for laboratory values. A formal, distinct and unique 6-part numerical name is given to each term for test or observation identity. Currently, over 58,000 observation terms (e.g. blood oxygen saturation, systolic blood pressure, etc.) can be accessed and understood universally.
- *Systematized Nomenclature of Medicine – Clinical Terms* (SNOMED CT) is similar to LOINC but covers a larger area of terms – currently there are more than a million terms available. SNOMED CT is the most comprehensive and complex clinical vocabulary available today. It crossmaps to other terminologies such as LOINC.
- *ISO/IEEE X73* nomenclature was especially developed for remote monitoring.

4.2 Messaging standards

Soon as terms (words) are found that describe medical findings, a standard for how to combine these words (to sentences) is needed. These aspects are covered by messaging standards. Messages are sent in between all partners of cardiac rhythm disease management (from measurement devices to aggregators and back, from aggregators to electronic patient records and back, and from electronic patient records to electronic health records and back). The most common messaging standard is *Health Level Seven* (HL7).

HL7 v2.x is the most commonly used medical messaging standard worldwide. It has the aim to support hospital workflows by enabling different systems to communicate with each another. HL7 v2.x messages use a textual, non-XML based syntax based on delimiter.

HL7 v3 was introduced in 1995 to upgrade HL7 v2.x. HL7 v3 messages are XML-based.

XML (Extensible Markup Language) is a general open standard for encoding documents in a format which is readable by both machines and humans.

4.3 Communication standards

Of course, communication is more than just expressing a sentence. Communication starts with some kind of indicating that one has something to tell. Next, someone else has to acknowledge she/ he is ready to listen. Only then the transmission of information can begin and every now and then the speaker will expect some kind of confirmation that the receiver is still listening. Finally, the speaker will indicate the end of data transmission and the communication is terminated.

Communication standards concern these and similar aspects of communication in between different systems or devices. Since the requirements for communication standards depend on their application, there are different standards for different applications.

- The *ISO/IEEE X73* standard consists of different ISO, IEEE and CEN joint standards addressing the interoperability of medical devices. It defines parts of a system, with which it is possible to exchange and evaluate vital signs data between different medical devices, as well as remote control of devices. E.g., by the use of this standard, data can be sent from a measurement device such as a blood pressure meter to an aggregator such as a mobile phone. Data transfer can be done via different media, such as USB or Bluetooth and either wired or wireless.

- The *IHE Implantable Device Cardiac Observation* (IHE IDCO) profile is used for the communication of programmers with their environment. It defines a standard based translation and transfer of summary device interrogation information from the interrogation system to the information management system. It specifies a mechanism for the creation, transmission, processing, and storage of discrete data elements and report attachments associated with cardiac device interrogations.
- *IHE Patient Care Device Domain* (IHE PCD) was developed for use cases in intensive care units and also concerns remote monitoring workflows. Due to these applications alarm management or patient identity binding are important topics of this standard.
- The *Health Informatics - Electronic Health Record Communication standard EN 13606* is a standard especially designed for accessing, transferring, adding or modifying EHRs.

4.3 Document standards

Medical information is often transferred from one location to another via medical reports, laboratory reports, etc. In the past such reports were usually printed out or sent as PDF files. Since content within PDF files does not have a standardized format, automated analyses of the data within PDF documents is not possible. It is the aim of document standards to structure the data stored within a document in a way that specific content can automatically be found, analyzed, visualized and so on.

Unlike HL7 v2.x, HL7 v3 is not only a messaging standard, but – among others – also contains a standardized format for storing documents: *Clinical Document Architecture* (CDA) is a commonly used document standard that is part of HL7 v3. For each examination a CDA document can be generated within which the information of that examination is stored in a structured way. The CDA document consists of a header containing patient data, author and document type, and a body within which the medical data is stored.

There are three levels of CDA documents:

- Level 1 can easily be implemented. Only the document header needs to be coded as specified in the standard, while the body contains the data as free text. Parsing and automated processing of the data themselves is not possible.
- Level 2 structures the body in sections such as anamnesis, diagnostic findings, laboratory values etc. The different sections can be defined using a coding system, such as LOINC, SNOMED CT or IEEE/ ISO X73.
- Level 3 is used for storing each single parameter in a standardized way and therefore enables automated algorithms to parse the whole document and further analyze the data stored in the document. That way, e.g. the evolution of parameters over time can be visualized etc.

4.4 EHR standards

Apart from interfaces to various aggregators and due to the involvement of several healthcare actors, a platform for integrated cardiac rhythm disease management may have the need to be connected to storage systems with a wider scope in terms of health data management aspects like an electronic health records (EHR). It is the aim of EHRs to systematically collect health information about individual patients or populations over a longer period of time – so as to facilitate continuity of care. The data can be stored centrally within the record itself, or they can only be referenced in a registry while the data themselves are stored elsewhere – e.g. in distributed electronic patient records. Therefore,

specification of an EHR not only considers the way data are stored, but also which data are stored within which record. Additionally, privacy and security concerns as well as authorization and encryption issues are an important part of each EHR as well.
Two common EHR concepts are described in the following:

- *IHE Cross-Enterprise Document Sharing* (IHE XDS) (IHE, 2010) is an integration profile which facilitates the registration, distribution and access across health enterprises of electronic patient records. It focuses on standardized sharing of documents in between healthcare enterprises, ranging from a private physician office to clinic to an acute care patient facility and personal health record system. This is managed through federated document repositories and a document registry to create a longitudinal record for information about a patient within a given clinical affinity domain. Among others, IHE XDS makes use of HL7 CDA documents which has the advantage, that all medical documents can easily be shared and read among different systems. Anyway, due to CDA's rather undefined data structure, information may be hidden within the vast amount of documents belonging to each patient.
- *openEHR* (Heard & Beale 2010) is an open standard that describes management and storage, retrieval and exchange of health data in an EHR. EN 13606 is used for exchanging data in between different openEHR-compliant EHRs. While IHE XDS stores data as CDA documents, openEHR is based on so called *archetypes*, computable expressions of a domain content model in the form of structured constraint statements, based on the openEHR reference model. That way, data can easier be accessed, processed, visualized etc. Anyway, implementation of such a system and – probably more important – adaptation of existing systems to the openEHR standard are more complex than for the IHE XDS standard.

4.5 Standards – Overview

Fig. 8. summarizes standards mentioned in this chapter and the environments they concern.

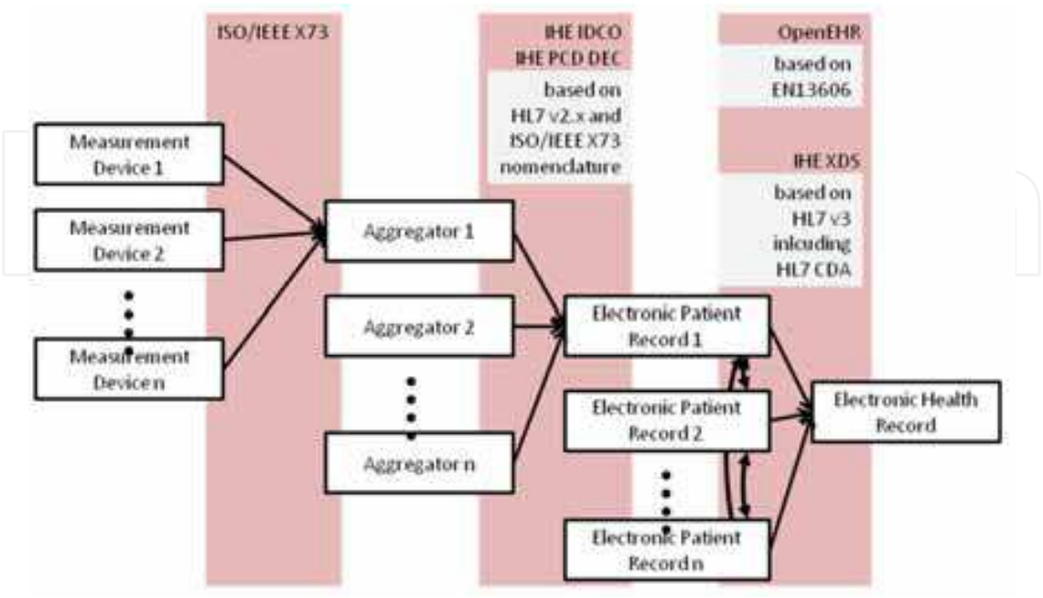


Fig. 8. Standards in cardiac rhythm disease management and environment they concern.

5. Platform for Integrated Cardiac Rhythm Disease Management (PICARD)

There are many different data sources from many different manufacturers available on the market, transmitting data to many different data storage systems like HIS or EHRs from which all data should be accessible by authorized caregivers. Additionally, there are many different standards involved, each of them developed for different sub-aspects of cardiac rhythm disease management, partly complementing, partly contradicting one another. And there are devices and systems that support the standards mentioned while others don't.
Within this complex environment, we have developed a web-based platform for integrated cardiac rhythm disease management (PICARD). Throughout the last years we have implemented several interfaces to different devices and systems involved in cardiac rhythm disease management. Some of these interfaces were standard conform, others were not. Some of the solutions were implemented prototypically, others were used in clinical studies, and some were used in routine care already.
In the following, the current state of implementation is described in details.

5.1 PICARD – Architecture

A three-tier client-server architecture was designed (Fig. 9), which consisted of a web/ application server, application specific services, data management and data storage components, a database adapter, an FTP server, an SMS gateway, data security components, and various clients.

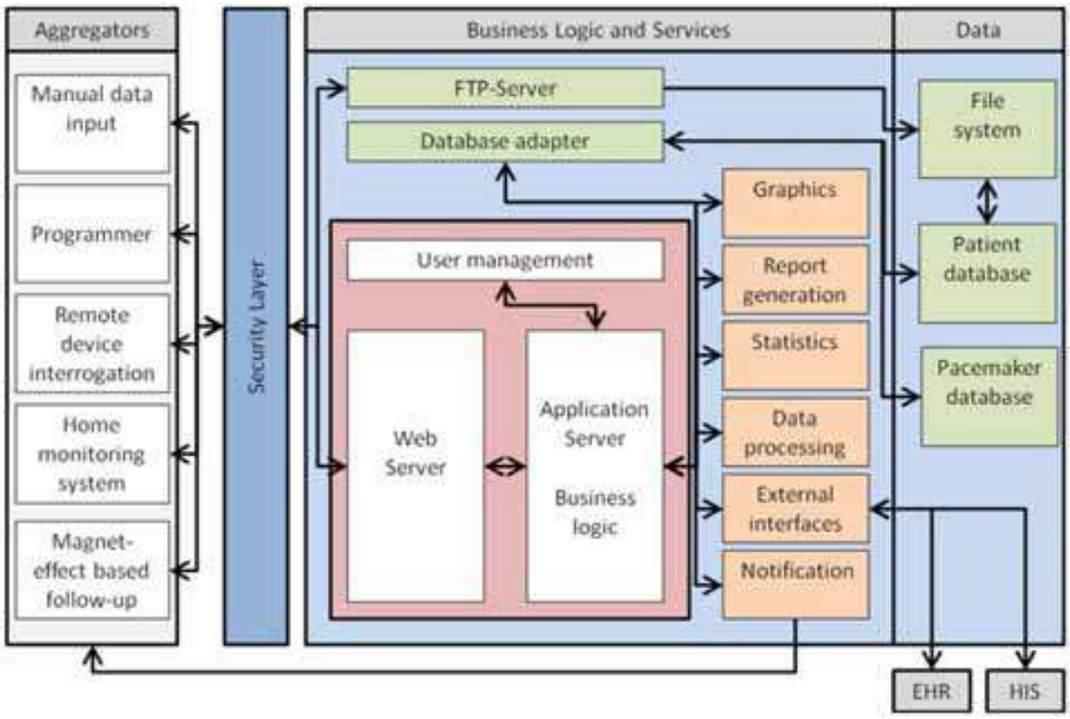


Fig. 9. Three-tier client-server architecture comprising web/ application server (red box), special services (orange boxes), interfaces to electronic health records (EHR) and hospital information systems (HIS), data management and data storage components, database adapter, FTP server, security layer and communication capabilities to various aggregators.

5.2 Web interface

Via a Web-interface physicians were able to

a. inspect data of their patients and
b. enter data relevant for the patient's rhythm disease management.

Therefore, the physician had to login to the Web-server using username and password. Personal data about the patient, about his/ her anamnesis, diagnosis, and medication etc. could be entered, as well as data read out from the patient's implanted device via a programmer. Several services were used for supporting the physician in inspecting the data as well as optimizing and documenting the therapy, such as graphical representations, report generation, statistics, data processing (e.g. ECG analysis) or notification services.

5.3 Programmer integration

The physician had the possibility to manually enter data read out from an implanted device by a programmer. Since programmers usually interrogate a large amount of data from the implanted device, the physician either had to spend lots of time on entering all these data via the web-interface, or she/ he decided only to enter selected data. We found that usually a few parameters were entered via the Web-interface and additionally, reports from the programmers were printed out and stored in a paper based patient record.

In order to simplify the process of entering data read out by the programmer into PICARD, a standardized interface to a pacemaker programming device (Biotronik ICS 3000 DS, Biotronik SE & Co. KG, Berlin, Germany) was implemented, which allowed for automated integration of the data read out by the programmer into PICARD.

Fig. 10 shows the workflow of the programmer interface. From the programmer's RS232 interface, a proprietary XML file could be exported including all information read out from the implanted device by the programmer. This XML file was sent to the client-PC's RS232 interface. Thereafter, a Java application running on the client-PC received the data and

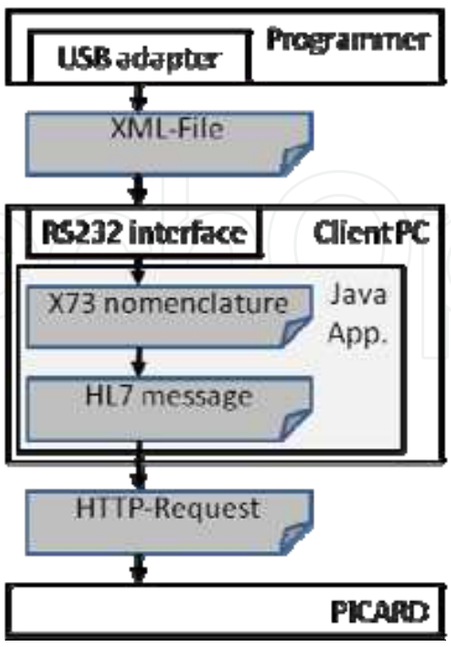


Fig. 10. Programmer integration as realized prototypically for the Biotronik programmer.

processed it. The proprietary data structure of the programmer's XML file was mapped to a standardized data format according to the *ISO/IEEE* X73 nomenclature. A mapping table was generated that translated each parameter of the programmer to a standardized *ISO/IEEE* X73 parameter. In the next step, the standardized data were included into an HL7 v2.5 message and sent to PICARD via HTTP.
The interface was prototypically implemented and its functionality was tested in the course of an interoperability showcase at the eHealth2008 conference (Sabutsch et al., 2008).

5.4 Upload of data form magnet effect based remote device checks

In the course of a clinical study (Kollmann et al., 2007a) PICARD was used for managing data achieved during magnet effect based remote device checks as described in chapter 3.3. It could be shown that integration of magnet effect based device checks to PICARD is feasible and that the proposed follow-up concept has the potential to work as an efficient screening method. It may also spare a significant number of patients the burden of having to travel to specialized follow-up centres.

5.5 Interface to remote device interrogation systems

Up to now, no electronic interface to remote device interrogation systems has been implemented. Parameters transmittable by the system of one manufacturer have been included to PICARD's database and to the Web-interface. However, only manual input of the data was possible so far.

5.6 Upload of data from remote monitoring systems

PICARD was designed so as to be able to receive data from remote monitoring systems and was already used in several studies concerning heart failure (Scherr et al., 2009), psoriasis (Hayn et al., 2009), diabetes (Kollmann et al., 2007c), and adipositas (Morak et al., 2008). Currently it is also used in a routine remote monitoring scenario (Kastner et al., 2010).

5.7 Interface to hospital information systems (HISs)

Interfaces to HISs are necessary for two basic purposes:
- To read out selected patient data from the HIS
- To write back selected data (reports) to the HIS

So far, we implemented an interface to a single HIS. Since this HIS was not completely standard based, the following proprietary workflow was used (Fig. 11).
In the course of patient registration, patient's demographic data and unique PID were requested from the HIS. For this purpose, a unique case ID generated by the HIS was entered to PICARD and sent to the HIS using an HL7 v2.3 Admission Discharge and Transfer (ADT) query (1). The communication server mapped the case ID to the corresponding patient ID (2), which was returned to PICARD in addition to patient demographic data (3). Via several sources (e.g. Web-portal, ECG upload, etc.) data from different aggregators were uploaded to PICARD (4). Consequently, data were reviewed (5) and a PDF report was generated (6). Besides the PDF file, a description file was generated that contained metadata including the patient ID. The FTP server fetched both files (7) and stored the report to the file archive of the HIS (8). The description file provided information for the registration of the document in the HIS database.

According to the proposed concept, the PDF report summarised the most important findings of a particular follow-up session, whereas source data remained in PICARD. The layout of the report and its content was designed in cooperation with our clinical partners and was structured as following:

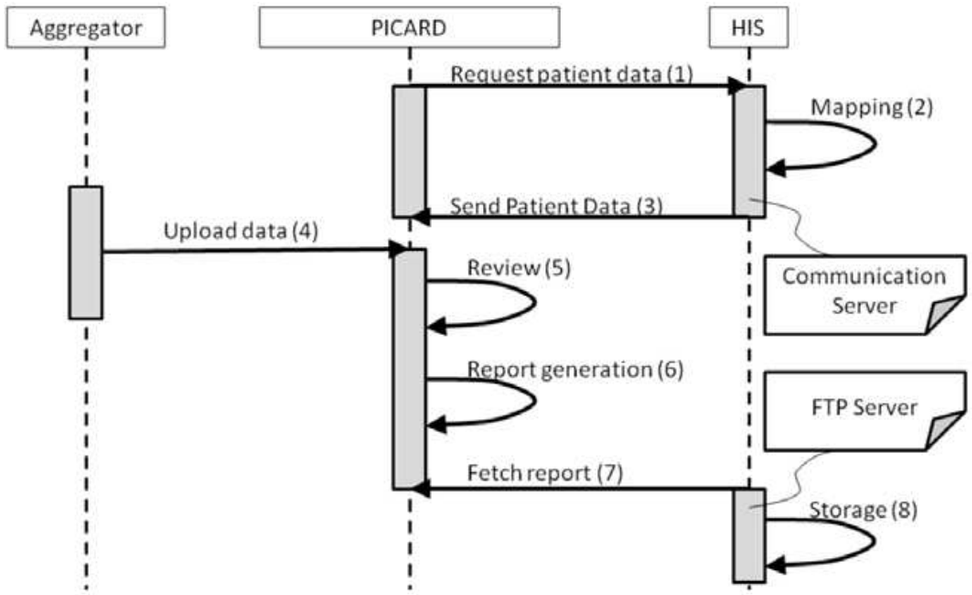


Fig. 11. Information exchange between aggregator (e.g. programmer), PICARD, and Hospital Information System (HIS).

- *1st Page:* A header provided information about the document itself, information about the patient, and information about the responsible physician and the responsible institution. Additionally, important data and crucial clinical observations were summarised on the first page including information about the implanted device, its functional status, and therapy regimen. In general, the first page contained observation data that was applicable for the primary care physician.
- *2nd Page:* Additional observation data (e.g. specific interrogation data, device settings, etc.) were summarised on the second page. This information was important for documentation and advanced therapy management. Data summarised on the second page was targeted primarily to the cardiologist.
- *3rd Page (optional):* Here, a list of current medication was provided.

5.8 Integration of PICARD into an IHE XDS conform EHR

In Austria, a national EHR is currently developed. It will be based on the IHE profile XDS and the content itself is stored as HL7 CDA documents (ARGE ELGA, 2009).

Fig. 12 shows the concept of Austria's IHR XDS based EHR. The patient index provides a unique identifier for each patient. Several case IDs can exist, and each case ID refers to several document IDs for a given patient. These IDs together with a small set of meta-data are stored within the national EHR document registry. The data itself (CDA documents) are stored in decentralized document repositories within electronic patient records. Only data that are registered in the central document registry can be found in the national EHR, while all other data are visible to the decentralized electronic patient records only.

Integration of PICARD into an IHE XDS conform EHR required a) patient cross identification and b) document registration. While only a basic version of patient cross identification has been implemented so far, document registration was implemented comprehensively. Since Austria's future EHR will use HL7 CDA documents, an HL7 CDA document was generated whenever an examination was registered within PICARD.

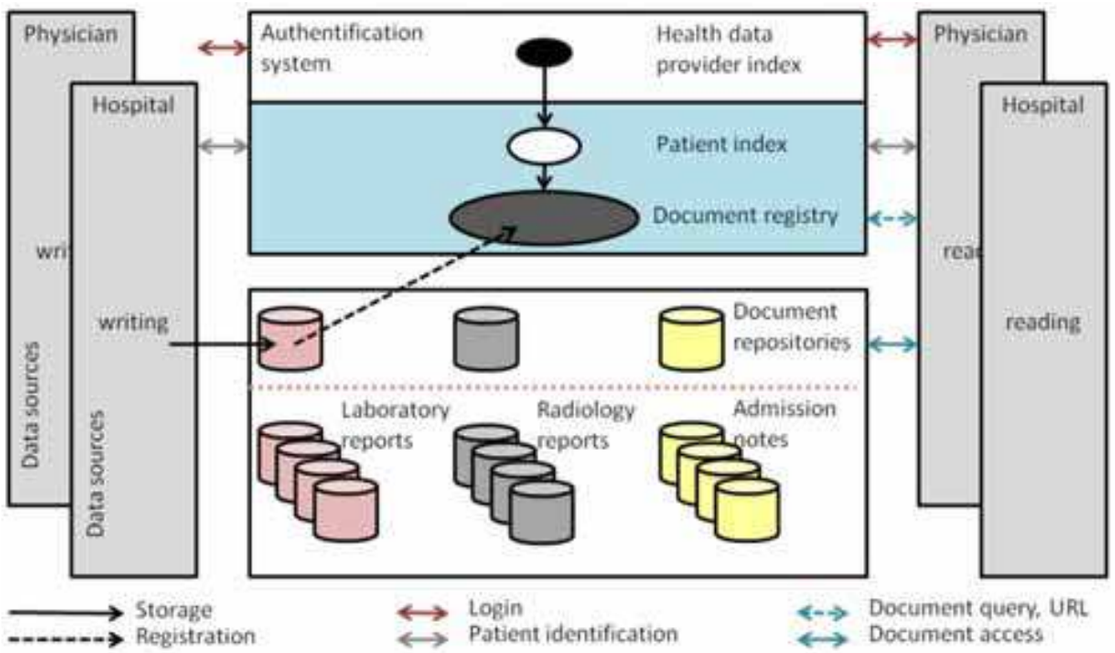


Fig. 12. Concept of the Austria's future IHR XDS based EHR (based on ARGE ELGA, 2007). The upper most two boxes build up Austria's EHR. The lower box represents electronic patient records that can be adapted to the EHR. The red dotted line represents the border in between data that can be seen from out of the EHR and data that are only visible within each single electronic patient record.

CDA level 2 was used for most of the data, and additionally, selected parameters were included in CDA level 3. Within PICARD's document repository, all the CDA reports were stored and meta-information about these reports was registered to the EHR's document registry.
Integration of PICARD into an IHE conform EHR infrastructure such as Austria's future national electronic health record has been demonstrated in a virtual environment (Kollmann et al. 2007b).

6. Discussion

Cardiac rhythm disease management represents a complex medical domain with many requirements concerning information management. A variety of systems must be handled by the cardiologist and telemedical aspects are rapidly gaining importance.
Healthcare manufacturers in this domain have focused on the devices, since, up to now, those were the most complex elements in the whole ecosystem. With constantly evolving new devices and systems for diagnosing, treating and monitoring of cardiac rhythm

disorders new concepts for more integrated approaches are desperately in need. Information and communication technologies are important enablers of telemedicine-based new ways to re-organise the care of cardiac patients and to move from a predominately device-centred follow-up concept to a patient centred system (Boriani 2008).

6.1 PICARD – State of implementation and outlook

Resulting from the analysis of the involved sub-domains we presented a platform for integrated cardiac rhythm disease management (PICARD) designed to fulfil those requirement.

Fig. 13 outlines those components of PICARD our activities addressed so far. Some elements have already been implemented to work in routine clinical environment whereas others have so far only been demonstrated in the lab, in clinical studies or in course of interoperability showcases:

Up to now, an interface to the pacemaker programming device of one manufacturer has been implemented. Interfaces to programming devices of other manufacturers are currently under consideration. Additionally, magnet effect based device interrogation was enabled.

An interface to one telemedical follow-up system has also been implemented. In order to disburdening cardiologists, it is necessary to implement one single event and alarm management for all telemedical and remote monitoring systems available. Therefore, interfaces to other home-monitoring systems will be needed.

An interface to the electronic patient record of a local HIS was implemented and PICARD was also connected to an IHE XDS conform EHR.

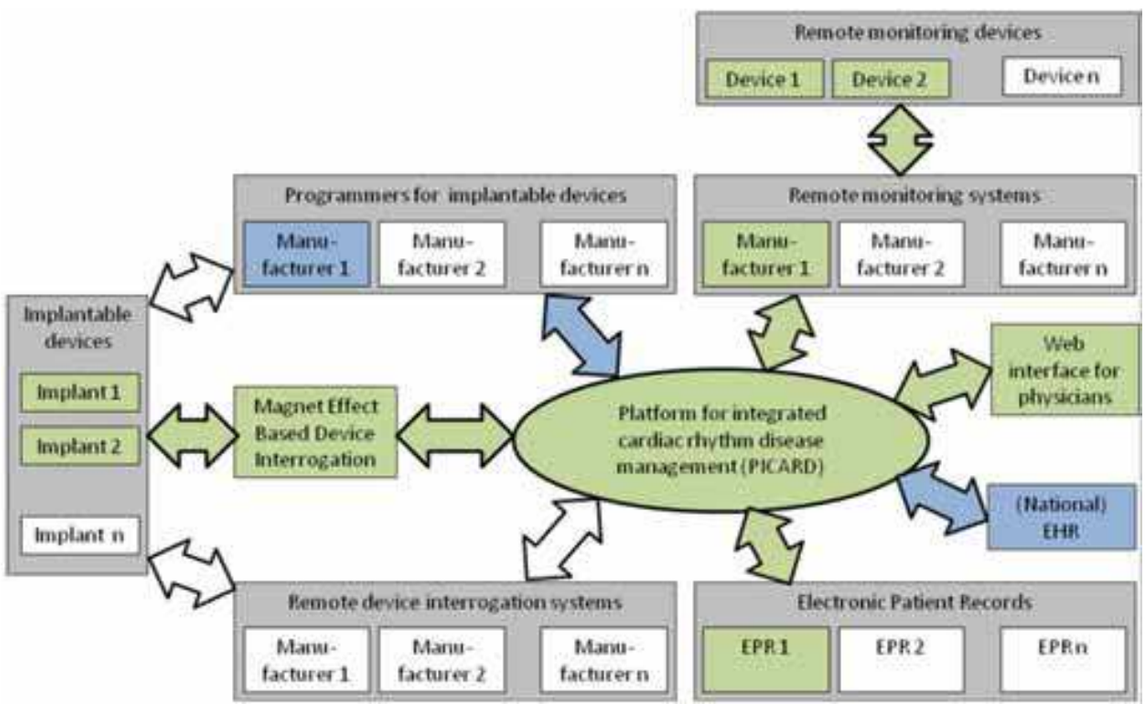


Fig. 13. Information ecosystem of PICARD. Interfaces, that have already been implemented, are plotted in green. Interfaces that have been implemented in a prototypical way are plotted blue.

The solutions developed so far have been implemented and operated in different scenarios. For most of these scenarios a separate clone of PICARD was developed. Though the same core components were used in all these clones, none of the implementations combined all modules described in chapter 5. Rather, most specialized modules were used in one single cone of PICARD only. Therefore, implementation of a clone that contains all modules is still outstanding.

6.2 State of standardization

In the future it is likely that all (or at least most) interfaces in between the various partners of the data chain will be standardized.

The most promising standard for connecting measurement devices to aggregators is currently specified by the Continua Health Alliance. Standardized communication from programmers to electronic patient records is defined in the IHE IDCO standard. And standardized communication from remote monitoring systems to electronic patient records can be implemented using the IHE PCD profile (Kumpusch, 2009). Upcoming standards for communication in between different EHRs and electronic patient record are openEHR and IHE XDS.

However, up to now only very view devices and systems fully support these upcoming standards. Therefore, proprietary interfaces are needed in the meantime.

6.3 Outlook

As Niederlag stated in (Niederlag, 2010), cardiac rhythm disease management is a fast moving topic. 1958 the first pacemaker was implanted and initially each patient received one and the same type of device. The next step was selection of the most suitable pacemaker for a patient out of four different groups. Thereafter, programmable pacemakers were developed and the same type of pacemaker could be implanted for each patient, while after implantation the device was programmed for optimally fit to the patient. The next step was rate adaptive pacemakers, where the pacemaker itself was able to adapt to the patients momentary needs. Remote monitoring of pacemakers followed, enabling the physician to check pacemaker status, no matter where she/ he is or where the patient is. Since 2005, pacemakers can individually and automatically adapt their parameters to the patient's current state.

While even modern devices currently only react on changes affecting themselves or their "direct contact" to the patient, in future it is likely that implanted devices will also consider other information – received from external sources. By that way, the devices will become more and more integrated into the whole rhythm disease management process.

Therefore, a future system for cardiac rhythm disease management needs to be able to handle data from various sources (from implanted devices, from patient's home, from general practitioners, from hospitals, etc.) and from different manufacturers – all of them communicating with one another.

7. Conclusion

Since cardiology in general and cardiac rhythm disease management in particular is still a field with a strong innovation process, new methods and devices are entering the scene all the time. Doing things in a different and better way is part of this innovation process and

standardisation will always be one step behind. As far as basic and routine procedures and follow-ups are concerned, however, for the sake of safety and efficiency, neither the patient nor the physician should be forced to deal with multiple systems and multiple interfaces that are not related to one another. Information and communication technologies can help to bridge the gap between both standardisation and innovation and will increasingly become a key technology for cardiac rhythm disease management.

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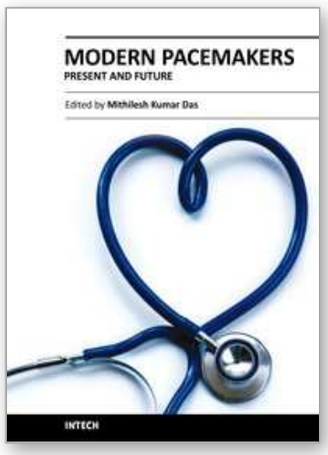
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Modern Pacemakers - Present and Future

Edited by Prof. Mithilesh R Das

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The book focuses upon clinical as well as engineering aspects of modern cardiac pacemakers. Modern pacemaker functions, implant techniques, various complications related to implant and complications during follow-up are covered. The issue of interaction between magnetic resonance imaging and pacemakers are well discussed. Chapters are also included discussing the role of pacemakers in congenital and acquired conduction disease. Apart from pacing for bradycardia, the role of pacemakers in cardiac resynchronization therapy has been an important aspect of management of advanced heart failure. The book provides an excellent overview of implantation techniques as well as benefits and limitations of cardiac resynchronization therapy. Pacemaker follow-up with remote monitoring is getting more and more acceptance in clinical practice; therefore, chapters related to various aspects of remote monitoring are also incorporated in the book. The current aspect of cardiac pacemaker physiology and role of cardiac ion channels, as well as the present and future of biopacemakers are included to glimpse into the future management of conductions system diseases. We have also included chapters regarding gut pacemakers as well as pacemaker mechanisms of neural networks. Therefore, the book covers the entire spectrum of modern pacemaker therapy including implant techniques, device related complications, interactions, limitations, and benefits (including the role of pacing role in heart failure), as well as future prospects of cardiac pacing.

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