Integration of Remote Monitoring Data into the Hospital Electronic Health Record System: Implementation Based on International Standards

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Abstract

Remote follow-up of implanted ICD's offers a solution to the problem of overcrowded clinics. All major device companies have developed a remote follow-up solution. Data from the remote follow-up are stored in a central database system, operated by the device company and accessible for the physician. However, the problem now arises that part of the patient's clinical information is stored in the local electronic health record (EHR) system in the hospital, while another part is only available in the remote monitoring database.

In our hospital, we have implemented the IHE-IDCO profile to import data from the remote databases from two device vendors into our self-developed Cardiology Information System (EPD-Vision). Data is exchanged via a HL7/XML communication protocol, as defined in the IHE-IDCO profile. Remote follow-up data is visible in EPD-Vision™ in the same manner as the data from the in-house follow-up.

1. Introduction

The implementation of large randomized trials showing the effectiveness of implantable cardioverter defibrillators (ICD's) has led to an exponential rise in the number of implanted ICD's.

The growing number of ICD recipients and their more complex devices are leading to rapidly increasing workload for the follow-up of these patients. A regular follow-up of a pacemaker patient is scheduled every 6 months or even over a longer period. In contrast, the follow-up period of an ICD patient is usually 3 months. Patients with a CRT-D device (CRT-ICD) often require even more frequent check-up's, again leading to a greater burden on staff and time at the clinic.

1.1. Remote monitoring of implanted devices: benefits and drawbacks

Remote follow-up of implanted pacemakers or ICD's can offer a solution to this problem of overcrowded clinics, and will bring considerable convenience to the patients since they will have to come to the clinic less frequently [1]. The clinical and health economics impact of remote monitoring however is still under discussion [2,3]. The remote monitoring system makes it possible to alternatively schedule a remote follow-up between in-clinic follow-up's. Furthermore, remote monitoring may allow the early detection of ICD leads failure without requiring any patient intervention [4].

All major device companies have developed such a remote follow-up solution. At regular moments (depending on the setup of the specific remote monitoring system) the implanted device will connect to a receiving device at the patient's home, and then send data on the status of the device to the central database system, operated by the device company. The physician can log into a secure website and check the data from the remote follow-up for each patient. However, the problem now arises that part of the patient's clinical information is stored in the local electronic health record (EHR) system in the hospital, while another part is only available in the remote monitoring database of the device company.

1.2. Need for standardized data exchange

Therefore there is a great need to be able to exchange data from the remote monitoring database systems from the device manufacturers, and then specifically in a standardized way.

Thus, there is a need for a standard set of observations, communicated in standard messages, such as:

- Therapy settings
- Events
- Device self-monitoring

Furthermore, there should be a consistent presentation of data from all devices.

2. Integrating the Healthcare Enterprise (IHE)

IHE (Integrating the Healthcare Enterprise) is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. Systems that support IHE Integration

Profiles work together better, are easier to implement, and help care providers use information more effectively. The goal is efficient delivery of optimal patient care.

In various domains, IHE integration profiles specify how for that specific domain and topic data can be exchanged based on existing standards. Therefore, IHE is not a standard; it merely specifies which standards should be used in a certain domain, and how they should be used. Systems that support IHE Integration Profiles work together better, are easier to implement, and help care providers use information more effectively [5].

Figure 1. Logo from IHE organization

2.1. IHE IDCO

To address the requirement of integrating remote monitoring data in the local EHR, the IHE Implantable Device Cardiac Observation (IDCO) profile has been developed. The IHE-IDCO profile defines a standards based transfer of device interrogation information from the interrogation system to the information management system. Strong device vendor participation in the IDCO profile development is an acknowledgement of this importance. The IHE IDCO profile is part of the IHE Patient Care Devices (PCD) domain.

Features of the IHE PCD IDCO profile are:

- Standard set of observations
- Communicated in standard messages
- Consistent presentation of data from all devices
- direct link between interrogating device and local EHR

2.2. Cardiac device in- clinic follow-up

The IHE-IDCO profile not only brings a solution to the problem of data in the remote monitoring database that is not available locally in the Cardiology Information System. The profile also brings a solution to the following problem. During in-clinic device follow-up, the measurements are performed with the use of a so-called programmer. Such a programmer system can connect wirelessly to the device implanted in the patient, and then extracts the device data (e.g., settings, status, events) from the device. Furthermore, it can also be used to reprogram the settings of the device, if necessary. However, after the measurements are performed, the information needs to be typed in by hand into CIS from a paper report printed on the prog.rammer. The IHE-PCD profile also brings a solution to this problem, by defining standards for this specific data exchange.

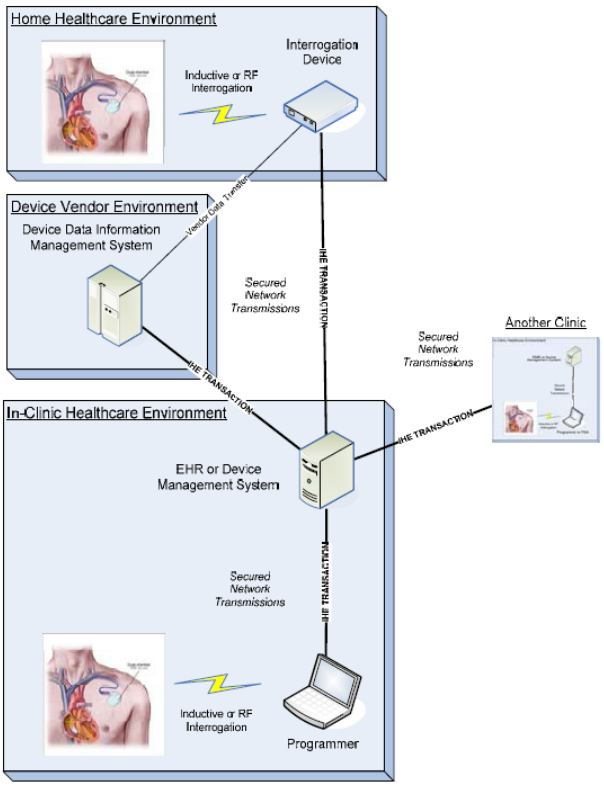

Figure 2. IHE-IDCO Architecture (St Jude Medical)

2.3. Nomenclature

An important part of the IHE-PCD IDCO profile is the nomenclature, the definition of the variables that are exchanged. Companies that implement the IHE-PCD IDCO profile not only need to exchange data in a standard way, but they also should make the data available using uniquely defined data definitions.

The IEEE Standards Association is defining sets of terminology for 'point-of-care' medical device communication. One of these sets is IEEE 11073-10103

which supports terminology for implantable cardiac devices. A draft version of this standard is available, but still subject to change. Representatives from all major device vendors are taking part in the IEEE 11073-10103 project group.

MDC_IDC_DEV_TYPE	The type of cardiac device.
MDC_IDC_DEV_MODEL	The model identifier of a cardiac device.
MDC_IDC_DEV_SERIAL	The serial number of a cardiac device.
MDC_IDC_DEV_MFG	The manufacturer of the cardiac device.
MDC_IDC_DEV_IMPLANT_DT	The implant date of the cardiac device.
MDC_IDC_DEV_IMPLANTER	The name of the physician that implanted the cardiac device.
MDC_IDC_DEV_IMPLANTER_CONTACT_INFO	The contact information of the physician that implanted the cardiac device.
MDC_IDC_DEV_IMPLANTING_FACILITY	The facility (clinic / hospital) where the cardiac device was implanted.
MDC_IDC_LEAD	The group of lead attributes.
MDC_IDC_LEAD_MODEL	The model of the lead.
MDC_IDC_LEAD_SERIAL	The serial number of the lead.
MDC_IDC_LEAD_MFG	The manufacturer of the lead.
MDC_IDC_LEAD_IMPLANT_DT	The implant date of the lead.
MDC_IDC_LEAD_POLARITY_TYPE	The number of electrodes on the lead.

Figure 3. Some variables defined in the IEEE 11073-10103 standard

3. Implementation

We have implemented the IHE-IDCO profile to import data from the remote databases from two device vendors into our self-developed Cardiology Information System (EPD-Vision™).

3.1. Implementation details

Data from the remote monitoring databases from Biotronik and Boston Scientific is transferred to our Cardiology Information System, EPD-Vision. Data is exchanged via a HL7/XML communication protocol, as defined in the IHE-IDCO profile.

Data from the remote monitoring database is transferred either automatically by querying the remote database (BSCI) or by manually exporting data from the remote monitoring database or programmer (Biotronik). In both cases, the data is available in the format as defined in the IEEE 11073-10103 standard (see figure 3 and 4).

```
<biotronik-ieee11073-export format-version="3.0" creator="BioProgrammerConverter" creator-vers
  <dataset>
    <section name="MDC">
      <section name="ATTR">
        <section name="PT">
          <value name="NAME_GIVEN" type="String">c.p.</value>
          <value name="NAME_FAMILY" type="String">Beukel vd.</value>
          <value name="DOB" type="Date">19500324</value>
          <value name="SEX" type="String">1</value>
        </section>
      </section>
      <section name="IDC">
        <section name="PG">
          <value name="TYPE" type="MDC_IDC_ENUM_PG_TYPE">ICD</value>
          <value name="MODEL" type="String">Lumax 340 DR-T</value>
          <value name="SERIAL" type="String">60425211</value>
          <value name="MFG" type="MDC_IDC_ENUM_MFG">BIO</value>
          <value name="IMPLANT_DT" type="DateTime">20080805</value>
          <value name="IMPLANTER" type="String">prof. Schalij</value>
          <value name="IMPLANTER_CONTACT_INFO" type="String">071-5196111</value>
          <value name="IMPLANTING_FACILITY" type="String">LUMC Leiden NL.</value>
        </section>
        <section name="SESS">
          <value name="TYPE" type="MDC_IDC_ENUM_SESS_TYPE">InClinic</value>
        </section>
```

Figure 4. Example of XML output file (Biotronik)

All variable names start with 'MDC_IDC' which is short for Medical Device Communication – Implantable Device Cardiac.

Variables from the remote database were mapped to the corresponding values in the EPD-Vision™ database.

3.2. Implementation details, EPD-Vision

Data that is received from the remote monitoring system is stored in a temporary location in the EPD-Vision database, and then, using the mapping definitions between the DMC_IDC variables and the EPD-Vision variables, stored at the appropriate locations in the EPD-Vision database.

Remote follow-up data is visible in EPD-Vision™ in the same manner as the data from the in-house follow-up. Combined data from in-house and remote follow-up can also be viewed as a graph, where blue dots represent the in-house follow-up and red dots the remote follow-up (figure 5).

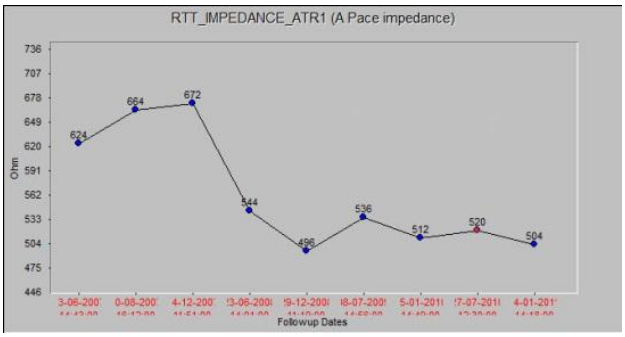

Figure 5. Screenshot from EPD-Vision™, showing graphically the atrial lead impedance over time, measured at regular follow-up visits. The measurement obtained from the remote monitoring follow-up is shown in red.

4. Discussion and conclusion

The growing number of ICD recipients and their more complex devices are leading to rapidly increasing workload for the follow-up of these patients.

All device companies have developed a system for remote monitoring of the ICD. Remote monitoring will lessen the burden of follow-up's on the clinic and staff, it will improve the efficiency of patient care.

It is also attractive from a patient's perspective, since it may lead to greater reassurance and prevents long and timely trips to the hospital.

However, as a result, part of the patient's clinical

information is stored in the local electronic health record (EHR) in the hospital, while another part is only available in the remote monitoring database.

The IHE-PCD IDCO profile is developed to bring a solution to this problem.

In our hospital, we are presently implementing the IHE-PCD IDCO profile to store data from the remote monitoring database in our local information system (EPD-Vision™). In this way, remote follow-up data can be viewed as if it was acquired during in-house follow-up.

Implementation of the IHE-IDCO profile also allows for transfer of data from the interrogation device (programmer) to the local information system, which overcomes the need for manual entry of the in-house follow-up data.

References

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