

Implementation of a National Database Infrastructure for Registration of Clinical Procedures and as Tool for National Benchmarking

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Abstract

In the past years, organizations worldwide have put many efforts in establishing guidelines for the medical practice. However, it has become clear that in order to improve patient care it is necessary to check and ensure the adherence to the established guidelines.

Therefore, in 2007, the Dutch Society of Cardiology (NVVC) has implemented a structure for national databases that will serve as benchmark tool for the quality assurance of the clinical outcome of cardiology procedures in all hospitals in the Netherlands. For this, the NVVC has instituted an independent foundation: the National Cardiovascular Data Registry (NCDR). The goal is implementation and management of various national databases. These databases will contain data on incidence and prevalence of various cardiovascular diseases, in combination with registration of numbers and results of procedures and interventions.

1. Introduction

Started in 2007, the Dutch Society of Cardiology (NVVC) has implemented a structure for national databases that will serve as benchmark tool for the quality assurance of the clinical outcome of cardiology procedures in all hospitals in the Netherlands. For this, the NVVC has instituted an independent foundation: the National Cardiovascular Data Registry (NCDR). The goal is implementation and management of various national databases.

Purpose of the NCDR is to measure and improve the

quality of care for patients with cardiovascular diseases. This will be realized by initiation, implementation and management of national databases.

In these national databases, numbers and results of cardiovascular procedures will be registered. Furthermore, data on incidence and prevalence of various cardiovascular diseases will be collected and made available. With the contents from these databases, it will be possible to compare the results from a hospital or cardiologist with national averages. It is expected that this information will improve the quality of care.

The NCDR databases have been initiated in close cooperation with Dutch Ministry of Health, and meet the requirements from the Government.

The NCDR databases are supported by Government mandates: NCDR participation has been added as performance indicator for all hospitals.

The following quality tools will be developed:

- Report tools on individual and group results.
- Benchmarking tools of local results compared with national averages.
- Standardized reports on procedures and outcome based on pre-defined parameters.
- Outcomes reports to drive quality initiatives.

2. Methods

2.1. Databases

The following NCDR databases have been planned:

- DIPR (Dutch ICD and Pacemaker Registry) *now LIVE*

- Registration of percutaneous interventions: **Q3-2008**
- Registration of catheter ablation procedures: **2009**
- Registration of clinical complications: **2009**

2.2. Implementation

All NCDR databases are hosted by the 'ProMISe' system, developed by the department of Medical Statistics in Leiden, the Netherlands (see figure 1). ProMISe already hosts many other national and international scientific and clinical registries [1,2].

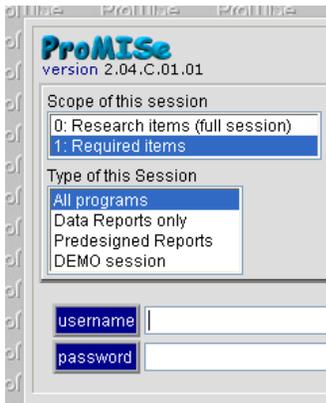


Figure 1: Part of Promise login screen

ProMISe is based on a secure Web application and underlying Microsoft SQL server database. All NCDR databases will comply with NEN-7510 standard on Information Security in Healthcare.

2.3. Data definitions

Starting point for data definitions of the NCDR databases are the CARDS data definitions, as developed by the ESC.

For each database, a focus group is responsible for the complete set of data definitions.

2.4. Data entry

Data entry is facilitated in two ways: on-line via web-forms, and off-line via export from local Electronic Health Record System or Pacemaker/ICD database. See figures 2 and 3.

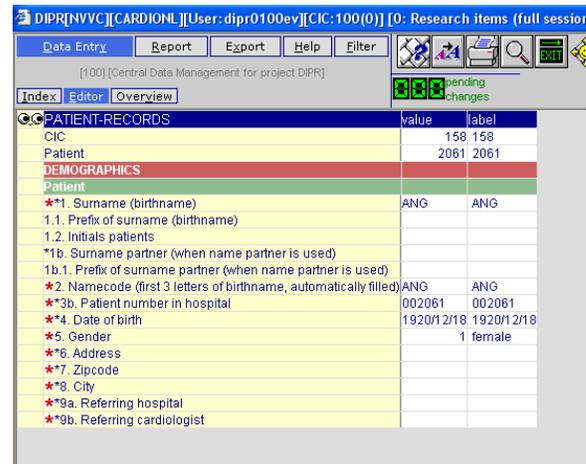


Figure 2: On-line data entry via web-forms

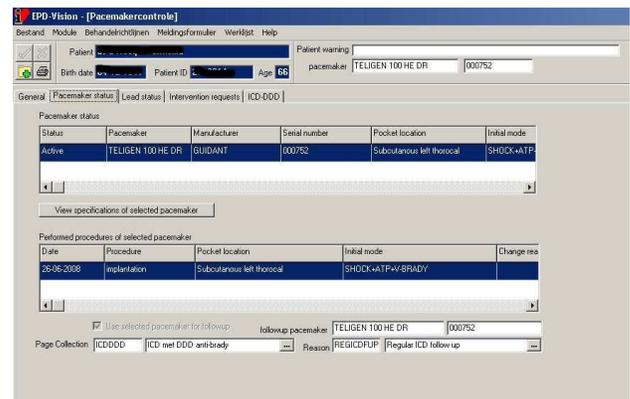


Figure 3: Off-line data entry via export from local Electronic Health record system or Pacemaker/ICD database

2.5. Data exchange format

Data from the local Electronic Health Record (EHR) system must be exported in XML format, as specified by the NCDR data definitions group. See (part of) an example of the XML export file below.

```

<Implant>
<Hospital>ZWOLLE, Isala Klinieken, lok. S</Hospital>
<Code>ZYP19370419M</Code>
<Initials>D</Initials>
<Prefix></Prefix>
<Birthname>ZYP</Birthname>
<Totalname>D ZYP</Totalname>
<Birthday>19-4-1937</Birthday>
<Gender>M</Gender>
<Address>GROENENDAEL 139</Address>
<PostalCode>8271 EH</PostalCode>
<City>IJSELMOUIDEN</City>
<FirstImplantHospital>ZWOLLE, Isala Klinieken, lok. S</FirstImplantHospital>
<FirstImplantDate>ZWOLLE, Isala Klinieken, lok. S</FirstImplantDate>
<HospitalCode>67</HospitalCode>
<Cardiologist>00013</Cardiologist>

```

Figure 4: Example of part of DIPR XML export file (implant section)

```

<Device>
<Implantatiedatum>15-12-2006</Implantatiedatum>
<Fabrikant>Medtronic</Fabrikant>
<DeviceCode>D164VWC ICD Virtuoso VR</DeviceCode>
<Serienummer>PUP601775S</Serienummer>
<OtherSurgery1></OtherSurgery1>
<OtherSurgery2></OtherSurgery2>
<OtherSurgery3></OtherSurgery3>
<OtherSurgery4></OtherSurgery4>
<UnsuccessfulApproachForLead></UnsuccessfulApproachForLead>
<Vervangingdatum>30-12-2008</Vervangingdatum>

```

Figure 5: Part of example of DIPR XML export file (device section).

3. Results

3.1. DIPR registry

The DIPR registry has gone live in March 2008. All 120 hospitals in the Netherlands can enter data on pacemaker and ICD procedures and follow-up on-line.

At the start the DIPR database has been filled with historical implant data from the SPRN registry (> 140.000 patients, > 180.000 device procedures, > 200.000 leads) [3].



Figure 6: Screenshots of the DIPR homepage, with link to the DIPR database [4]

The DIPR registry contains various chapters and sections, such as:

- Patient demographics
- History & risk factors
- Symptoms & indications
- Admission & procedures
- Testing & settings
- Follow-up
- Adverse events

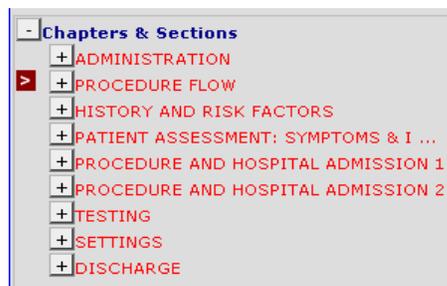
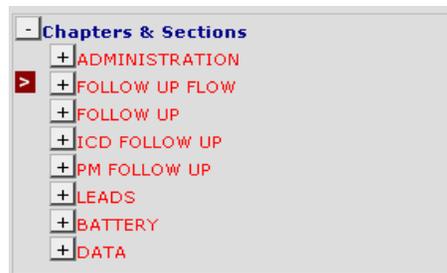


Figure 7: Screenshots of DIPR database sections.

Many hospitals are already entering pacemaker and ICD data on-line. Furthermore, a number of hospitals that have been using the local SPRN application (GRIT) will be facilitated so that they can still send their GRIT export files which then will be imported in the DIPR database.

3.2. PCI registry

In October 2008 the second NCDR registry, the PCI database, will start. Four centers: the Academic Medical Center Amsterdam (AMC), the Leiden University Medical Center (LUMC), the Isala hospital Zwolle and the Amphia hospital Breda will first start a pilot for data entry and retrieval.

Data on the angiographic results of coronary artery evaluation, on the PCI procedure and PCI results will be collected. In addition, information on past history, risk factors, indication, medication and follow-up, including possible immediate and late adverse events will be collected.

3.3. Data export/import pilot project

Many hospitals are already using some kind of database or Electronic Health Record System to store data on pacemaker/ICD or PCI procedures. As can be understood, these hospitals are reluctant to retype all the information in another database. Therefore it will be made possible to import data from the local databases.

Presently, a number of hospitals are collaborating to test the off-line data export/import facilities as described above. In the database system that is used locally to register pacemaker and ICD implant and follow-up data export capabilities will be implemented. Data export from the following local systems will be tested: EPD-Vision (Leiden University Medical Center, Leiden), Tiel system (Erasmus Medical Center Rotterdam), GE Healthcare Carddas (St Radboud Medical Center, Nijmegen) and SAP (Maastricht University Medical Center).

4. Discussion and conclusions

- Data registries are essential to improve patient care.

- In the event of a device or lead recall, patients can be traced easily.
- Benchmarking of results will improve performance of individual hospitals and individual clinicians.
- Reimbursement should become dependent on participation in the registry.
- The facility to export data from local databases is very important

References

- [1] Eur J Epidemiol 2005;20(6):549-57
- [2] <http://www.mbsi.nl/promise>
- [3] <http://www.sprn.nl>
- [4] <http://www.dipr.nl>

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