■ *Research paper*

Živa Rant, Vesna Levašič

Building the National Arthroplasty Registry of Slovenia

Abstract. National Institute of Public Health from Slovenia was the project leader of the PARENT Joint Action, which was co-funded by the European Commission. One of the deliverable of the PARENT Joint Action are Methodological Guidelines and Recommendations for Efficient and Rational Governance of Patient Registries. To test them in practice, we built the pilot version of the National Arthroplasty Registry of Slovenia. Its goal is to support quality and safe health care for the patients and to improve the orthopaedic profession as well. We encountered many challenges during the implementation. This article summarises our experiences with a view to help others who meet similar challenges in the future.

Izgradnja Registra endoprotetike Slovenije

Povzetek. Nacionalni inštitut za javno zdravje je vodil Skupni ukrep PARENT, ki ga je sofinancirala Evropska komisija. Eden glavnih izdelkov projekta so Metodološka navodila in priporočila za učinkovito in racionalno upravljanje z registri pacientov. Za preverjanje njihovih teoretičnih izhodišč smo zgradili pilotno verzijo Registra endoprotetike Slovenije. Cilj registra je nuditi podporo kakovostni in varni zdravstveni oskrbi za paciente ter izboljšati samo ortopedsko stroko. Med delom smo se srečali z mnogimi izzivi. Svoje izkušnje smo zapisali, ker upamo, da bodo v pomoč vsem, ki se bodo v prihodnosti srečali s podobnimi izzivi.

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Institucije avtorjev / Authors' institutions: National Institute of Public Health (NIJZ), Slovenia (ŽR); Valdoltra Orthopaedic Hospital (OBV), Slovenia (VL).

Kontaktna oseba / Contact person: Mag. Živa Rant, NIJZ, Trubarjeva 2, 1000 Ljubljana, Slovenia. E-pošta / E-mail: ziva.rant@nijz.si.

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Introduction

The establishment of the pilot version of the National Arthroplasty Registry of Slovenia (Register endoprotetike Slovenije, RES) was made within the PARENT Joint Action (JA). PARENT (PAtient REgistries iNiTiative) brings added value by providing Member States the recommendations and tools for implementation of interoperable and cross-border enabled patient registries. The project coordinator was the National Institute of Public Health from Slovenia. The contributing experts were form 25 countries.

The overall objective of PARENT JA was to support the EU Member States in developing comparable and interoperable patient registries in clinical fields of identified importance (e.g., chronic diseases, medical technology). Its aim is to rationalise the development and governance of interoperable patient registries, thus enabling the use of secondary data for public health and research purposes in cross-organizational and cross-border setting. To do so, it helped to improve the ability of patient registries to share data as well as improve the process of feeding data to the registries from their primary sources, such as Electronic Healthcare Records (EHRs).

The Joint Action objective is also to support the EU Member States in providing objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy, as well as short-term and long-term effectiveness, of health technologies. This information should be effectively exchanged among the relevant national authorities or bodies. This will enable the rationalisation of the Health Terminology Assessment (HTA) processes. It will avoid the duplication of assessments and increase availability and quality of previously localized patient registries data.[1]

One of the main deliverables of the PARENT JA were the Methodological Guidelines and Recommendations for Efficient and Rational Governance of Patient Registries[2] (hereinafter The Guidelines). While working with the Guidelines, we wanted to test theoretical bases in practice. As a practical example, we chose the building of the National Arthroplasty Registry of Slovenia (in Slovenian: RES – Register endoprotetike Slovenije), which had been needed in Slovenia for a long time. The Valdoltra Orthopaedic Hospital (OBV) expressed great interest and the readiness to cooperate because of their experience with the Hospital Registry.[1] The Slovenian Orthopedic Society gave OBV full support to establish the RES collection within this project.[3]

The definitions from PARENT that affect patient registries are:

- The patient registry is defined as an organised system that collects, analyses, and disseminates the data and information on a group of people defined by a particular disease, condition, exposure, or health-related service, and that serves a predetermined scientific, clinical or/and public health (policy) purposes.[2]
- Primary arthroplasty is the first surgical procedure when a total or partial endoprostheses is implanted.[4]
- Revision arthroplasty is the surgical exchange or removal of any component (or all components) of an artificial joint replacement.[4]

Overview of the Current State

On the European level, there are many active national and regional Arthroplasty Registries, each with its own source of data, mode of analysis and reporting. It is of common interest to have a model for the main issues regarding all arthroplasty registries. Few hospitals in Slovenia collect the relevant forms only for their own purposes. On the other hand, there is an active hospital registry – Valdoltra Arthroplasty Registry at the OBV, founded in 2002, which is an important pool of information for different studies concerning the survival time of prostheses also on the European level.[5] As OBV surgeons perform about 40% of all arthroplasty procedures in Slovenia, this hospital registry already works as a regional one. There are eight other orthopaedic departments in Slovenian clinics and hospitals, and eight more traumatology departments where endoprostheses are implanted. This is the reason why establishment of the RES remains a challenge.[4]

Reasons for the Arthroplasty Registry

The Arthroplasty Registries (ARs) around the world are efficient instruments for the detection of success or failure of implants used for joint replacement. Some countries in Europe, including Slovenia, still do not have such control over the implants. The health care system in Slovenia allows very good control of the patients with implanted endoprosthesis because the patients use the hospital inside Slovenia for primary and revision operations. As they are free to choose the hospital and the doctor where they want to be operated, the hospital registry, like in Valdoltra, is not sufficient to cover the national needs. The implementation of national registries as tool to

medical device control is also one of the EU Directives COM2012/542 (article 83), which applies also to directives 2005/50/EC in 93/42/EEC. V) that came into force in 2015.[4]

Purpose of the Arthroplasty Registry

The purpose of an AR is to enable better control and data integration of implanted endoprostheses in individual health care centres at the national and international level. AR offers the possibility of immediate reaction of the profession to the possible increase in the number of revision surgeries due to failed implants. The goal is to support quality and safe health care for the patients, as well as to improve the orthopaedic profession.

AR is an infrastructure that allows the assessment of:

- Effectiveness of different implants in the real world;
- Safety and cost effectiveness of a new and existing device;
- Outcome monitoring of performance and potential safety issues over the entire lifecycle;
- Early signal detection of inferior outcome of device and surgical techniques;
- The impact of patient profile/ comorbidities/ risk classes on patient side of the outcome;
- Market monitoring concerning implants and health care providers;
- Feedback to health care providers;
- Comparison of different national registries;
- Identification of fields for improvement and monitoring of effects of the treatment.

Objectives of the Arthroplasty Registry in the PARENT JA[4]

The first objective was to establish the OpenEHR Framework for an AR Model based on European Arthroplasty Register (EAR) Minimal Dataset Forms. The second objective was to use the same archetypes for AR in Slovene language for the interested stakeholders in Slovenia with the possibility to expand the forms.

General AR objectives were:

- To achieve the traceability of implants used in Slovenia;
- To define the implants' survival in the human body;
- To identify all possible factors and events that influence the implants' survival in the human body;
- To define all the post-operative complications related to the device insertion;
- To facilitate feedback to stakeholders in order to support decision-making;
- To improve risk management;
- Other opportunities.

Methods

We designed the RES as a proof-of-concept of the Guidelines.[2] We knew that good project management is essential for successful software solution implementation. For project management, we used the Project Management methodology.[6-9]

The basic methodology used was Systems Analysis and Design.[10] We also considered Systems Development Life Cycle[10] methodology and Predictive Software Project Life Cycle[11] methodology (Figures 1 and 2).

For Process Model development and presentation, we used the Business Process Management (BPM) methodology on the ARIS Business Process Analysis platform.[12] We used the Aris Express – a free-of-charge modelling tool for business process analysis and management for occasional users and beginners in Business Process Management.[13] We made Process Landscape – the Value-Added Chain (VAD) and Event-driven Process Chain (EPC) Diagrams.

For data modelling, we used the OpenEHR methodology. OpenEHR is a virtual community working on interoperability and computability in e-health. Its main focus is electronic patient records (EHRs) and systems.[14] Usage of the existing OpenEHR archetypes and templates helps improving semantic interoperability because of using the same data models in different databases. We used CKM – Clinical Knowledge Manager for harmonisation, reviewing and publishing of OpenEHR Archetypes and Templates.[15] For the creation and editing of archetypes, we used Archetype Editor (AE) and for the definition of templates, we used Template Designer.

We created mind maps before we made the data model in the OpenEHR. We used the popular XMind[16] professional mind mapping tool, which is user friendly and helps medical experts and informatics specialists to talk to each other. We used Tableau[17] commercial business analytics software for the reports and analyses with graphical presentations of data from the RES.

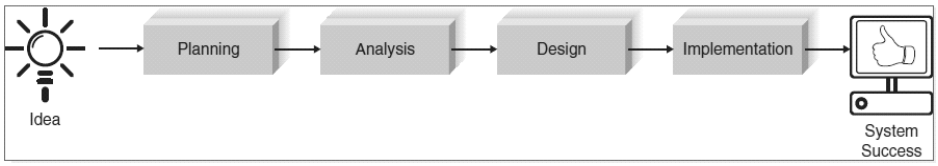

Figure 1 The Systems Development Life Cycle. Source: Dennis.[10 p. 10]

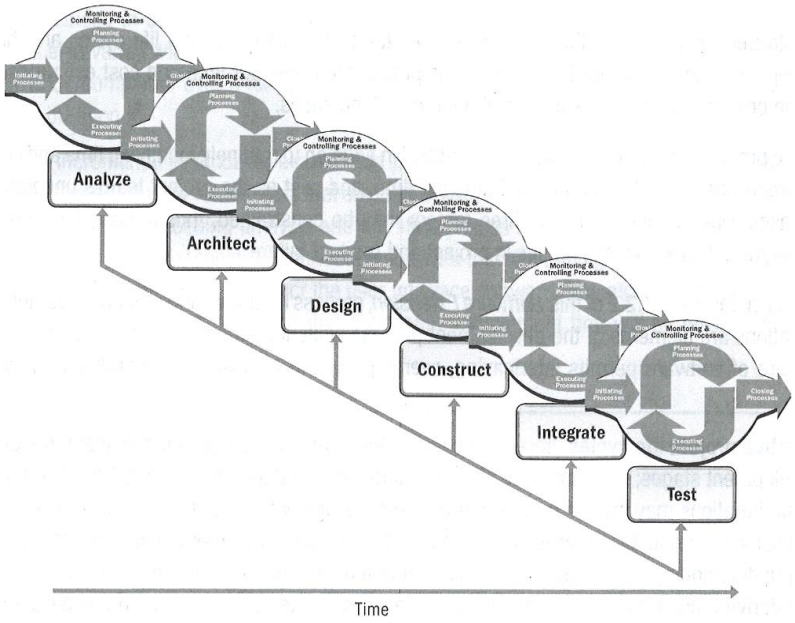

Figure 2 Predictive Software Project Life Cycle. Source: PMI.[11 p. 29]

Figure 3 VAD for building the new registry.

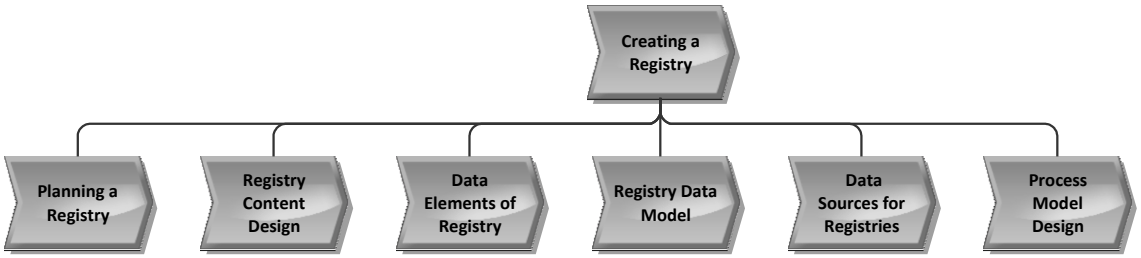

Figure 4 VAD for Creating a Registry.

Results

First of all we, decided to define the new registry process. We made the VAD[4] (Figure 3).

We had to define the purpose, objectives, circumstances, project limitation and other topics that are including in the planning. After that, we were able start with creating a registry. Than we set up the registry and started running it. The process of building a registry ends by changing and stopping the registry, but we have not considered those issues.

When creating the registry, we relied on the VAD[4] in Figure 4, which includes planning a registry, registry content design, data elements defining, registry data model, data sources for registry and process model design. These activities are not sequential; they can take place at the same time.

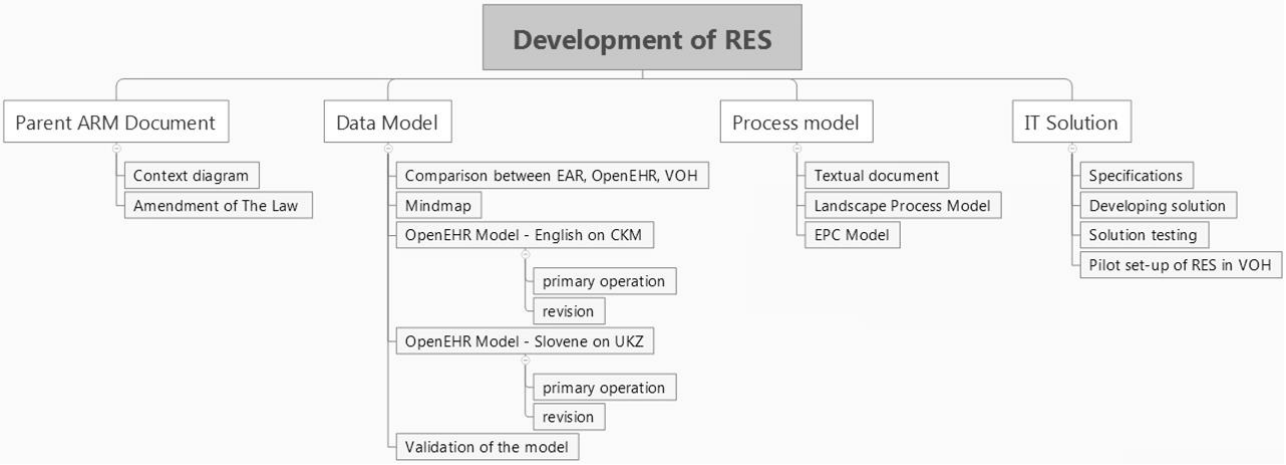

Figure 5 Work Breakdown Structure.

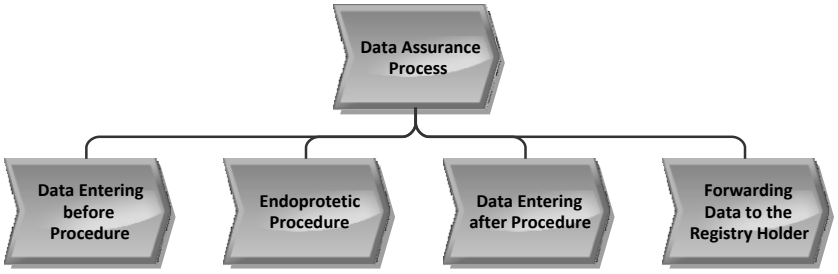

Figure 6 Data Assurance Process for RES – VAD.

Planning

We defined the reasons for the AR, its purpose and objectives. The reasons for ARs and the purpose of our AR have already been outlined above. As already stated, the goal was to support quality and safe health care for the patients and to improve the orthopaedic profession.[18] We followed two main objectives within the PARENT project: to establish the OpenEHR Framework for an AR Model based on EAR Minimal Dataset Forms, confirmed by the European Federation of National Associations of Orthopaedics and Traumatology (in 2015, it transformed into NORE – Network of Orthopaedic Registries of Europe)[19] and to use the same archetypes for AR in Slovenian language for the interested stakeholders in Slovenia with the possibility to expand the forms. We also had to follow the general objectives stated above. The stakeholder analysis was made in the form of a conceptual diagram. We made the Work Breakdown Structure (WBS, Figure 5) with the list of activities. It consist of PARENT ARM document, data model, process model and IT Solution.[18]

We defined the scope and limitations of the registry, the legal aspects and confidentiality. We described the resources (human, IT, financial and other resources) and the project team members. We discussed data sources for RES. We planned that data from all orthopaedic clinics, hospitals, departments and the divisions in hospitals in Slovenia where arthroplasty is performed will be included. We also made the Action Plan for the implementation of AR, risk and feasibility, and wrote down the assumptions of the inclusion and exclusion criteria, and made a list of the expected outputs of RES.

Analysis

We performed process and data modelling simultaneously, because they are interdependent. First, we simultaneously prepared a draft of data model and process model for primary operation.

Process modeling

Two medical experts and two informatics experts contributed to process modelling. Staff from OBV prepared textual data assurance process description. The working group analysed the proposals. We worked with Aris Express.[13] First we made VAD[4] (Figure 6).

We divided basic sub-processes in more detail and produced the Event-driven Process Chain (EPC) Diagram for data assurance process for RES.[4] For

describing Data Search and Retrieval process, we produced EPC diagram for Data Search and Retrieval.[4]

Data modeling

For data modelling, we chose the OpenEHR methodology.[14] We started with the mind map produced using XMind.[16] We included the Minimal data set from European Arthroplasty Register (EAR) form.[19] We contacted and asked for help the former vice-president of EAR, who was very supportive. Despite that, we still did not have enough knowledge until the medical expert from OBV contributed actively. First, we made a mind map for primary operation of hip replacement and after that for revision.[4] It took a lot of time, collaboration and synchronisation to produce the final mind map.

The Medical Device Archetype

We investigated data elements for implants and made a mind map for the arthroplasty component[4] (Figure 7).

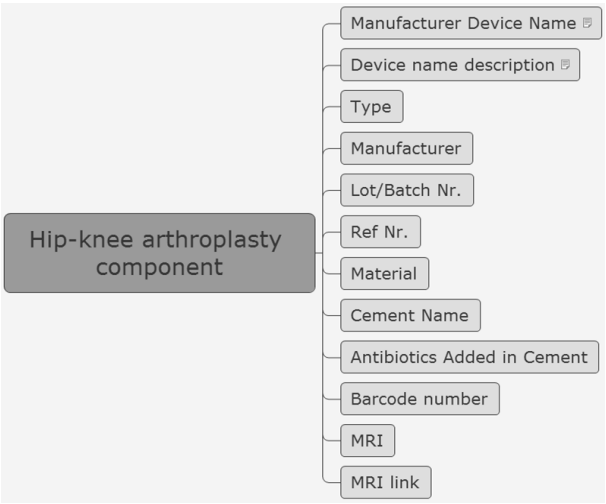

Figure 7 Mind Map for Arthroplasty Component.

The medical device archetype had already existed in OpenEHR methodology. Therefore, we decided to use the existing archetype, but it did not fulfil all our needs. Hence, we decided to review the clinical content of the Archetype Medical Device on the CKM. Thirty reviewers from Norway, New Zealand, Slovenia, Spain, Australia, Sweden, United States and United Kingdom contributed 47 reviews.[15] The archetype is available on the CKM webpage.[15] One can also find the data about the reviewing process there. The final version of the archetype is in Figure 8.[4,15]

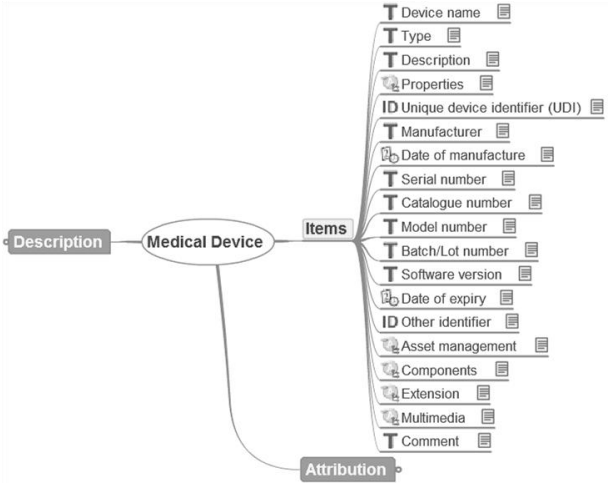

Figure 8 Archetype Medical Device.

Building the RES OpenEHR model

After the mind maps were done, we started building the OpenEHR model. The participants were Experts from OBV, informatics experts from NIJZ, OpenEHR experts from Ocean Informatics and Marand. We used the Archetype Editor (AE) and Template Designer for making archetypes and templates for RES.[14] Finally, we produced two models, one for primary hip operation and another for hip revision (Figure 9). The OpenEHR models are available on the CKM webpage.[20]

Data sources

We found out that in the analysis phase that OBV did not have a legal basis for collecting the required data at the national level yet. Therefore, the data for the RES will come from OBV alone in the initial phase. When the RES gets a legal basis by the Amendment of the Healthcare Databases Act (ZZPPZ), data from all orthopaedic clinics, hospitals, departments and the divisions in hospitals in Slovenia where arthroplasty is performed will be included. At that point, the whole target population, i.e., all Slovenian citizens who undergo the procedure of implantation of the endoprosthetic material, will be included. The data for estimating the survival curve need to be censored due to patient deaths. Therefore, a connection to the Slovenian Central Population Register (CRP) is also needed. Additional data on the implant parts came from the Implant Library from OBV.

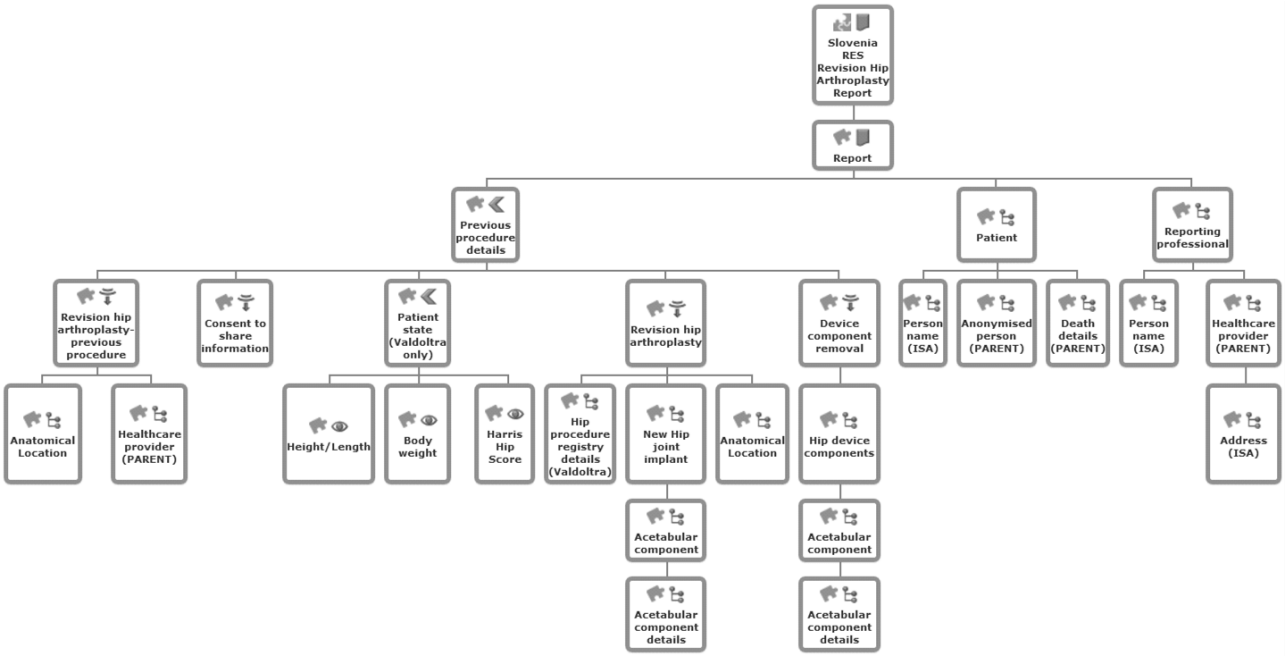

Figure 9 Slovenia RES Revision Hip Arthroplasty Report – Template Hierarchy in OpenEHR.

Design

We defined our requests for software solution. For the Patient Registry Information System Development we selected the Marand software company, which was selected based on the call for tender in the framework of thePARENT project. Marand is a Slovenian solution provider in healthcare offering products.

Implementation

A good implementation process is essential for a good solution and user satisfaction. The implementation comprised registry set-up and running the registry.

Registry set-up

Registry set-up was divided into four steps:

- Establishing the infrastructure
- Establishing secure connection and accesses
- Software installation and testing
- Data preparation

First, we needed to establish the operating infrastructure. We established the infrastructure at the NIJZ. We gathered technical inquiries from the software provider. After some harmonisation, we were able to establish adequate infrastructure.

The next challenge was to establish secure connections and accesses. NIJZ and OBV are health care institutions that work with sensible personal data and, according to the Personal Data Protection Act of the Republic of Slovenia, they are obliged to guarantee the highest level of data security. We decided to use the existing network of secure connections zNet between health providers in Slovenia. This caused some problems and access provision took a long time. We finally solved the problem when IT experts of all three partners (NIJZ, OBV and Marand) met in Valdoltra and cleared all obstacles on the spot.

The software provider prepared a pilot version of the IT solution and installed the software. During the user testing, the software provider continued to improve the solution. We are aware that a good testing is key for user's satisfaction and consequently for all developers of the solution. The testing guarantees that the system performs as expected. The first testing was performed at the software provider's place. The main testing was performed in OBV. The testing, harmonisation and updating continued until the final acceptance of the solution. User training was also implemented and short user's guidelines were supplied. In the framework of the PARENT project call for tender, we also bought a tool for business analytics. OBV prepared the proposals for the data display (the outputs) and the software provider prepared templates for graphic displays. The RES application allows access to these graphs.

Two challenges appeared during the data preparation: initial data entry and ensuring regular electronic data entries. Because OBV had a similar registry within its hospital information system with data from 2014, the users requested that data to be transferred. This made

sense because most of Slovenian hospitals use the same hospital information system (HIS). For this purpose, we needed to motivate the software provider who developed the HIS solution to enable export from it. The users from OBV, system analysts from NIJZ and the experts of previous and new software providers first designed the content of the transmission table, and later the table itself. This coordination was very time consuming for the project, but proved to be worthwhile.

As all data in reporters' information systems are saved in electronic forms, it makes sense that these data are sent electronically. We defined the form of sending which we will forward to reporters and include the electronic data entry in the register. The IT solution for RES allows the possibility of importing data from file, which is prepared by reporters from their HIS.

There are two possibilities for entering data into the RES. One possibility is to type in the data for each patient manually. The other possibility is to export the data from the local HIS to the CSV file and then import it into the RES.

Functional Requests of the National Arthroplasty Registry of Slovenia foresee the connection with the CRP. Eventual patient's death is a very important piece of data for estimating the survival of the prosthesis. We can now type it in or import the data from the CRP by following a special procedure.

Running the registry

After the registry setup, we started to run the pilot version of registry for hips. The application allows us to add new persons, surgeries (revisions and primary), and we are able to browse and update the data. Screenshot from the application are shown below (Figures 10, 11).

Discussion

Challenges

The main advantage was that the financial resources were assured by the PARENT project. Despite that, we had many challenges.

First, we had to decide who would be invited into the project team. The informatics experts are usually not enough. We were very happy to cooperate with the Head of the Valdoltra Arthroplasty Register. Finally, we composed the project team of medical experts, informatics team and experts for business processes. We used the OpenEHR methodology, which is user friendly for medical experts and informatics specialists and helps them to communicate between. We had to decide what should represent the records in the new registry. Our options were implant exchange, patient, treatment, and we chose operation (surgery).

What to include into the data set? Should we model EAR forms or the data collected in the Valdoltra hospital? We decided to take the model of the EAR minimal data set, because this dataset was accepted by the Slovenian Orhopaedic Society as well, and for extension, the Valdoltra dataset.

Having access to the Implant Library, we can make informative graphics presentations (Figures 12, 13).

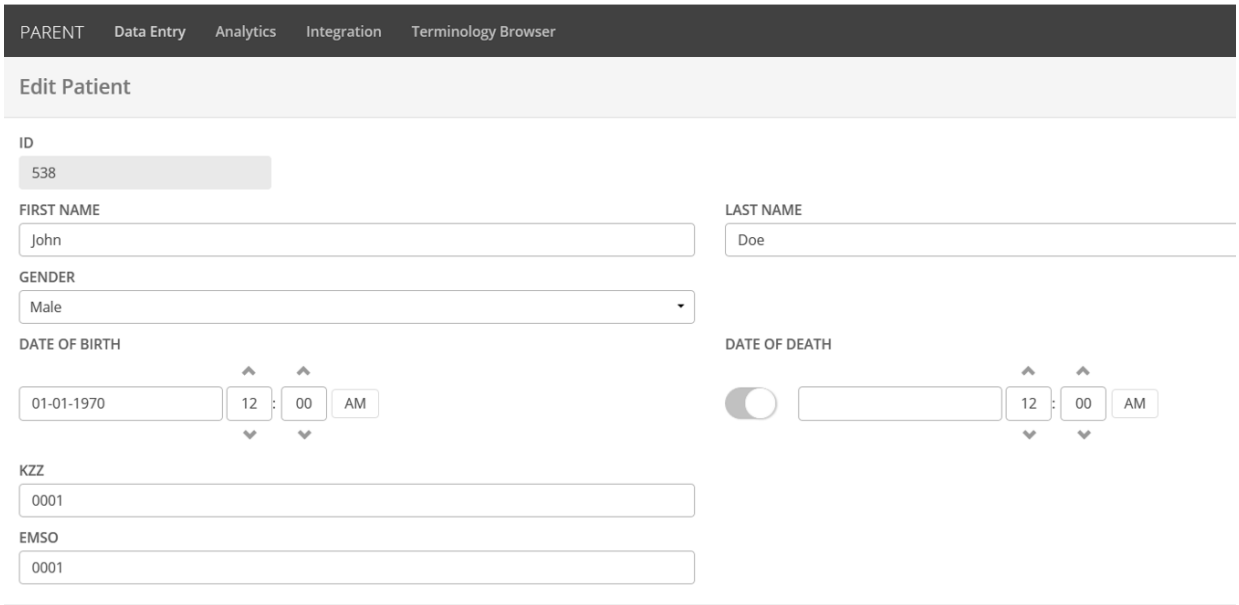

Figure 10 Application's screenshot – patient data.

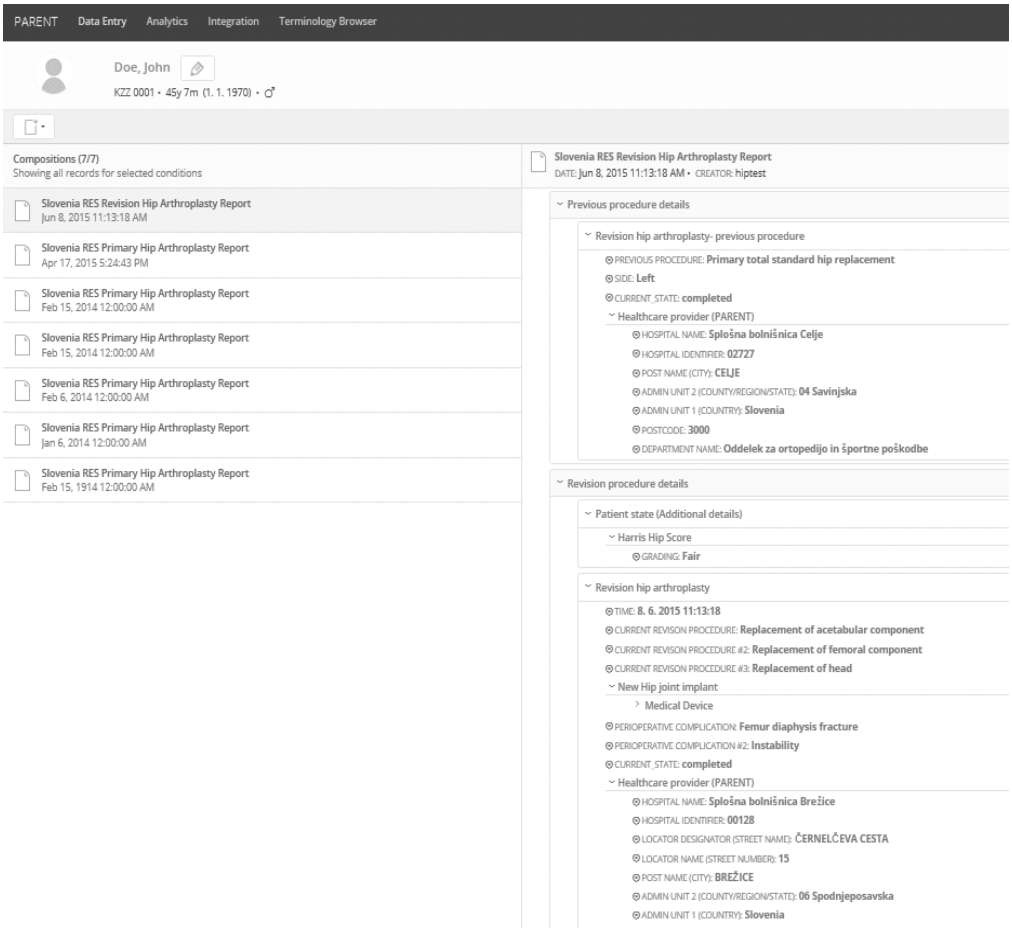

Figure 11 Application's screenshot – basic view.

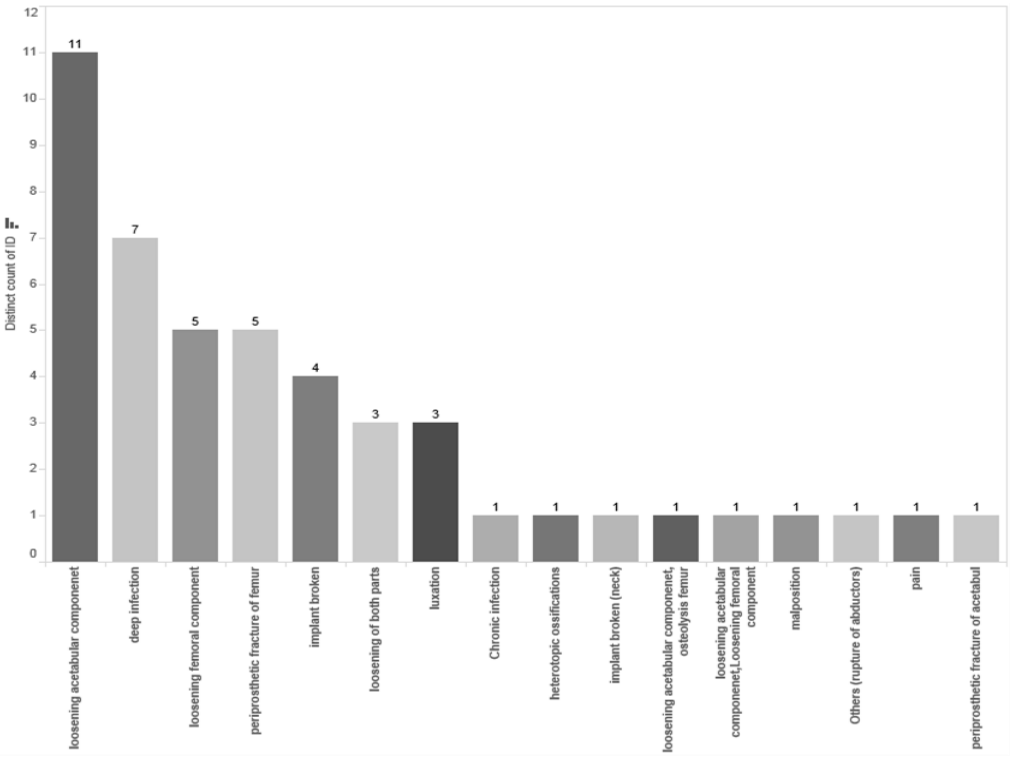

Figure 12 Reason for revision.

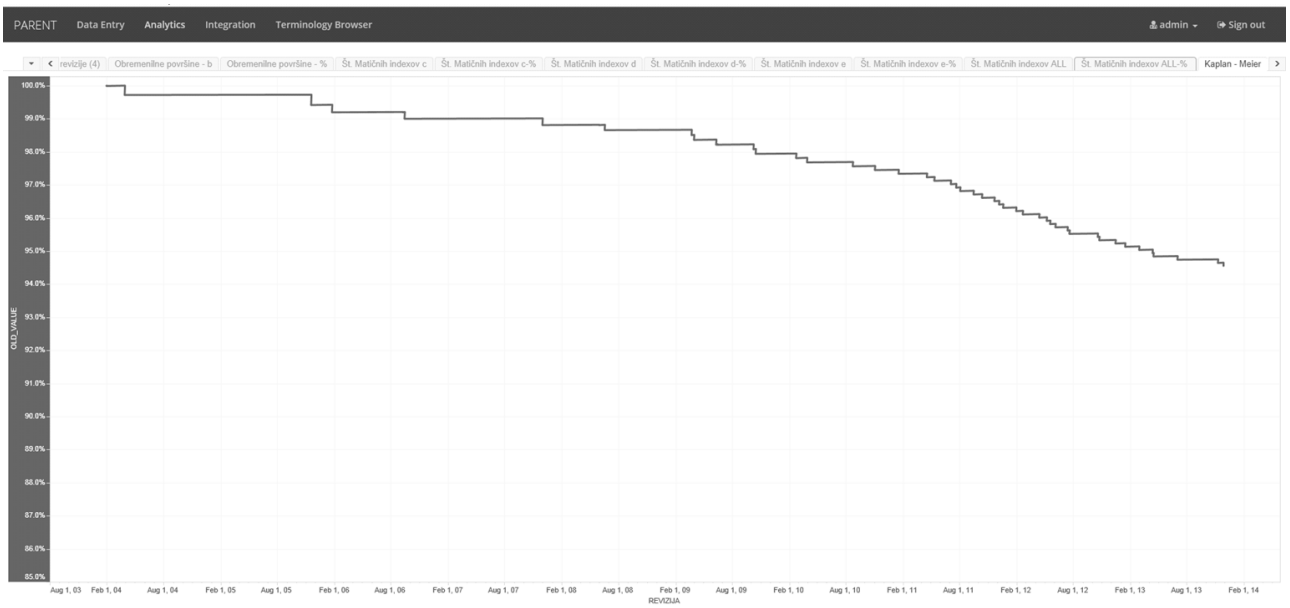

Figure 13 Kaplan-Meier curve of the survival of Profemur stem in the Valdoltra Orthopaedic Hospital.

Do we have a legal basis? We asked the Information Commissioner of the Republic of Slovenia for the opinion. She replied that we do not have a legal basis according to the existing legislation. Therefore, we prepared the Amendment of the Healthcare Databases Act of the Republic of Slovenia, which is currently under revision. We had three possibilities: to stop with our work, to make a data register based on subject's consent, or to start with Valdoltra patients. OBV has the legal basis for collecting data on its patients so the pilot solution was made for the patients of this particular hospital. Later, the procedure can spread to the national level.

Regarding assurance for as much interoperability as possible, we asked ourselves which standards could be included. For the set of data elements we use the EAR Minimal Dataset Forms,[19,20] which is accepted on the European level. For standardisation of diagnosis, should we use the ICD10, ICD10 Australian modification that is standard in Slovenian hospitals, SNOMED or something else? None of these could meet our needs, so finally we used the list from the EAR form,[19,20] which was coordinated on the European level. Similarly, we could not use the ACHI procedures collection, which is used in Slovenian hospitals. For the healthcare providers, we used the data from the Slovene HealthCare Providers Database. We used the Slovenian Implant Library, which is produced in the framework of OBV, which is its holder.

RES includes sensitive personal data that request the highest data security according to the Personal Data Protection Act of the Republic of Slovenia. We decided to use the existing Slovene health network of secure connections between hospitals – zNet and its security service. We located the registry data on the NIJZ server within the zNet.

All data we request is in reporters' HIS in electronic format. It will be send to RES electronically. We defined the form which we will forward to reporters and include the electronic data entry in the register. The IT solution for RES allows the possibility of typing in the data or importing data from CSV file, which is prepared by reporters from their HIS.

We would also like to import the data from existing registries in another IT solution. We made the agreement with their software provider and together we imported the data from their solution.

When a person with an implanted prosthesis dies, their data have to be excluded from the analysis of implant survival. That is why we need to get the date of the patient's death. We now can type it in or import it from the CRP.

Advantages

RES, the National Arthroplasty Registry of Slovenia, contains real-world data. Data are imported in the registry from the EHR in the hospital information system.

We used the existing OpenEHR archetypes and templates for improving and enabling the interoperability. We also had to make some new ones.

They were published and are available free on the CKM webpage.[21]

We achieved a really successful cooperation among medical experts and informatics team – system analysts, system engineers and developers of new IT solution and experts for business processes.

We have the Slovenian Implant Library, which is produced in the OBV. It helps us to fill the implant data automatically.

Patients and surgeries can be added in the RES, we can browse and update the existing data. The implant traceability is assured. Descriptive statistical analyses and informative graphics can be made using the Tableau tool.

Conclusion

The building of the National Arthroplasty Registry of Slovenia was a major challenge, but we were successful.

There were many unforeseen situations, which showed that building a registry in practice is very different from theory. The Methodological Guidelines and Recommendations for Efficient and Rational Governance of Patient Registries[2] were very helpful and we developed them simultaneously. Despite timely and comprehensive planning, we encountered many unforeseen complications during the implementation. It was proved once again that good planning is a precondition for the successful implementation of the project. The teamwork of all participants and their readiness is the clue to good joint final solution. The cooperation of medical experts with the informatics team and business process experts is also very important. We also comply with EFORT organisation regarding the definition of the dataset, and cooperated with experts in the OpenEHR community to synchronise the data model.

Building the registry lasted a lot longer than expected. We also had to carry out some unplanned activities. Unfortunately, OBV did not have a legal basis for data collection on the national level. On the other hand, OBV has the legal basis for collecting data on its own patients. Hence, as already stressed, the data for the RES come from OBV, which performs about 40% of all arthroplasty procedures in Slovenia. Their internal registry is also on the list of Arthroplasty Registries in Europe[22]. When RES will have the legal basis, the whole target population will be included.

In conclusion, we have gained many new experiences and became more qualified for building new registries during the process of building the RES. This document is intended to help anyone who will encounter similar challenges in future.

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