Work Package 5
Building The National Arthroplasty Registry of Slovenia in the Parent Project

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Building The National Arthroplasty Registry of Slovenia in the Parent Project

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### Abbreviations

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<tr>
<td>PARENT</td>
<td>Cross-border PAitent REGistries iNiTiative</td>
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<tr>
<td>RES</td>
<td>The National Arthroplasty Registry of Slovenia (in Slovene: Register endoprotetike Slovenije)</td>
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<tr>
<td>OBV</td>
<td>Valdoltra Orthopaedic Hospital (in Slovene: Orotropska bolnišnica Valdoltra)</td>
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<tr>
<td>NIJZ</td>
<td>National Institute of Public Health (in Slovene: Nacionalni inštitut za javno zdravje)</td>
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<tr>
<td>HZJZ, CIPH</td>
<td>Croatian Institute of Public Health (Hrvatski zavod za javno zdravstvo)</td>
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<tr>
<td>AR</td>
<td>Arthroplasty Registry</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>WBS</td>
<td>Work Breakdown Structure</td>
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<td>VAD</td>
<td>Value-Added Chain Diagram</td>
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<tr>
<td>EPC</td>
<td>Event-driven Process Chain</td>
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<tr>
<td>CDS</td>
<td>Common Data Set</td>
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<tr>
<td>SDLC</td>
<td>The Systems Development Life Cycle</td>
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<tr>
<td>EPIRARE</td>
<td>European Platform for Rare Disease Registries</td>
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<tr>
<td>EAR</td>
<td>European Arthroplasty Register</td>
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<tr>
<td>EFORT</td>
<td>European Federation of National Associations of Orthopaedics and Traumatology</td>
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<tr>
<td>epSOS</td>
<td>European Patients - Smart open Services</td>
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<tr>
<td>ENCR</td>
<td>The European Network of Cancer Registries</td>
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<tr>
<td>CARDS</td>
<td>Cardiology Audit and Registration Data Standards</td>
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<tr>
<td>B.I.R.O.</td>
<td>Best Information through Regional Outcomes</td>
</tr>
<tr>
<td>TREAT-NMD</td>
<td>Translational Research in Europe – Assessment &amp; Treatment of Neuromuscular Diseases</td>
</tr>
<tr>
<td>EUReMS</td>
<td>European Register for Multiple Sclerosis</td>
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<tr>
<td>SZD</td>
<td>Slovenian Medical Association (in Slovene: Slovensko zdravniško društvo)</td>
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<tr>
<td>CRP</td>
<td>Central population register (in Slovene: Centralni register prebivalstva)</td>
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<td>CKM</td>
<td>Clinical Knowledge Manager</td>
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<td>Abbreviation</td>
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<tr>
<td>UKZ</td>
<td>Slovene Clinical Knowledge Manager (in Slovene: Upravljavec kliničnega znanja)</td>
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<tr>
<td>CSV</td>
<td>Comma separated values</td>
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<tr>
<td>ICD</td>
<td>The International Statistical Classification of Diseases and Related Health Problems</td>
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<tr>
<td>SNOMED</td>
<td>Systematized Nomenclature of Medicine</td>
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<tr>
<td>ACHI</td>
<td>The Australian Classification of Health Interventions</td>
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<tr>
<td>ZZZS, HIIS</td>
<td>Health Insurance Institute of Slovenia (in Slovene: Zavod za zdravstveno zavarovanje Slovenije)</td>
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A joint EU and Member States response to poor cross-border availability of health data for public health and research. PARENT (PAtient REgistries iNiTiative) brings added value by providing Member States with recommendations and tools for implementation of interoperable and cross-border enabled patient registries.

The overall objective of PARENT Joint Action is 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 rationalize 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, we need 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 in the 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 rationalization 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. (Parent, 2015)

Patient registry is an organized system that collects, analyses, and disseminates the data and information on 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 (Parent Guidelines, 2015).

One of the main deliverable of the Parent JA is the "Methodological guidelines and recommendations for efficient and rational governance of patient registries" (Parent Guidelines, 2015, hereinafter The Guidelines). While working with Guidelines we wanted to test theoretical bases in practice. As a practical example, we chose the building of The National Arthroplasty Registry of Slovenia (RES – Register endoprotez in Sloveniji), which was stated to be needed in Slovenia for a long time. Valdoltra Orthopaedic Hospital (OBV – Ortopedska bolnišnica Valdoltra) expressed great interest and affection to this process as well as the readiness to cooperate.
2 Value-Added Chain for Building the new Registry

For the purpose of building the new registry, we produced a Process Model. First we made Value-Added Chain Diagram – VAD (see Figure 1).

![Figure 1: VAD for building the new registry](Diagram1.png)

We researched "Creating a Registry" in detail and produced a Value-Added Chain Diagram - VAD for it. (see Figure 2).

![Figure 2: VAD for Creating a Registry](Diagram2.png)

You can read more about these processes in The Guidelines, 2015.
I. Planning a registry

3 Defining the Purpose, Objectives and Outputs of the Registry
(for more see document Parent ARM 2014)

3.1 Reasons for the Arthroplasty Registry (AR):
The Arthroplasty Registries 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 of the implants. The health system in Slovenia allows very good control of the patients with implanted endoprosthesis, since the patients use the hospital inside Slovenia for primary and revision operations. But as they are free to choose the hospital and the doctor, where they want to be operated, the hospital registry, like in Valodoltra, is not good enough 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) and will come into force in 2015. That is why we want to establish a model for minimal dataset as a framework for The National Arthroplasty Registry of Slovenia (RES). We used the OpenEHR methodology, because it can be upgraded for different national needs.

3.2 Initiator:
- NIJZ and OBV
- Payer of the AR project: PARENT – NIJZ
3.3 Purpose of the AR:

The purpose of AR is to enable better control and data integration of implanted endoprostheses (hip and knee endoprostheses in the first step) in individual health care centres on national and international level. In AR Model, we followed the PARENT Methodological Guidelines and we used The National Arthroplasty Registry of Slovenia as a pilot study to get the AR Model started. AR offers the possibility of an immediate reaction of the profession on 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 and to improve the orthopaedic profession as well.

AR is an infrastructure that allows the assessment of:

- The effectiveness of different implants in 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.

3.4 Objectives of the AR:

First objective: to establish the OpenEHR Framework for AR Model based on EAR Minimal Dataset Forms. English version is available on foundational Clinical Knowledge Manager (CKM): http://www.openehr.org/ckm/.

Second objective: to use the same archetypes for AR in Slovene language for the interested stakeholders in Slovenia with the possibility to expand the forms. Slovene version is available on the Slovene web page: http://ukz.ezdrav.si/ckm/OKM_sl.html.

General objectives:

- 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.

These objectives will be reached through the model of neutral European Arthroplasty Registry (EAR) Minimal Dataset, used in the pilot study for The National Arthroplasty Registry of Slovenia RES.
3.5 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 would be a common interest to have a model for the main issues regarding all arthroplasty registries. The European Federation of National Associations of Orthopaedics and Traumatology (EFORT) – the platform organization linking Europe’s national orthopaedic associations – has its web page for European Arthroplasty Registry: [http://www.ear.efort.org/](http://www.ear.efort.org/) which includes Minimal Dataset Forms. This dataset is also the template for The National Arthroplasty Registry of Slovenia (RES). Slovene Orthopaedic Association accepted and translated it into Slovene language in 2010, but it was never brought to live until now. Few hospitals in Slovenia still collect the forms for their own purposes. On the other hand, we have an active hospital registry – Valdoltra Arthroplasty Registry in Valdoltra Orthopaedic Hospital, Ankaran, Slovenia, founded in 2002 – which is an important pool of information for different studies concerning the survival time of prostheses also on the European level. As Valdoltra surgeons perform about 40% of all arthroplasty procedures in Slovenia, this hospital registry already works as a regional one. Anyway, there are another eight orthopaedic departments in Slovene clinics and hospitals and eight more traumatology departments where endoprostheses are implanted. This is the reason why establishment of RES remains a challenge.

4 Performing stakeholder Analysis

We prepared a draft of a Conceptual diagram, which was completed in a working meeting (see Figure 3). This Conceptual diagram was included in The Guidelines as a practical example.
**4.1 Primary stakeholders of the Arthroplasty Registry Model are:**

National Institute of Public Health (NIJZ): controls the use of secure internet connections between hospitals in Slovene secure healthcare network zNET, is the owner and manager of the server, has its representative in the Slovenian Board for Endoprosthetics;

Valdoltra Orthopaedic Hospital (OBV): as the holder of RES collection gets the data, aggregates them for analytics purpose, has an important role in Board for Endoprosthetics, is the reviewer in the implementation of the RES in OpenEHR platform, writes the reports about procedures and implants;

Ministry of Health: adaptation of the Healthcare Databases Act (ZZPPZ), helps to provide the use of the server, has its representative in the Slovenian Board for Endoprosthetics.

Slovene Orthopaedic and Traumatology Clinics and Departments/Divisions in Hospitals where arthroplasty is performed: help to implement RES in their environment, supply the data to the RES holder, get the aggregated data about the success of their operations, their hospital and the implants they use in comparison to the Slovenian average;

**4.2 Secondary stakeholders:**

Medical doctors from the above listed hospitals: provide the data on the procedures; get the aggregated data about the success of their operations, their hospital and the implants they use in comparison to the Slovenian average. Orthopaedic surgeons from other Slovenian clinics, hospitals and divisions will be invited in the implementing process as reviewers;

Health Insurance Institute of Slovenia (HIIS): gets the information of most successful implants, therefore the overall cost of treatment is reduced;

Central Population Register at Ministry of the Interior: provides the data on vital status of the patients;

Patients – implants users: get useful information on implants of their concern;

EAR: provides minimal dataset forms, helps with analytics, involvement in other projects and studies;

Manufacturers: provide the information about the material, standards and operative technique of the implant they make for Slovenian market, get the data about the success of the implants they manufacture, they are possible donators for the financial support of RES;
Distributors: provide the information about the material, standards and operative technique of the implant they sell in Slovenia, get the data about the success of the implants they distribute, they are possible donators for the financial support of RES;

Importers: they can use the RES to select the most successful implants to be imported;

Authorized representatives (Slovenian Board for Endoprosthetics) will be established when RES will start to function.

4.3 Outputs of AR Model

- Arthroplasty Registry Model document that is following PARENT Methodological guidelines and recommendations for efficient and rational governance of patient registries.
- Conceptual Model of the National Arthroplasty Registry of Slovenia.
- Process Model of the National Arthroplasty Registry of Slovenia: Description of the process and a process flow diagram - WBS. (See attached document: THE NATIONAL ARTHROPLASTY REGISTRY OF SLOVENIA – REGISTER ENDOPROTETIKE SLOVENIJE (RES) - Description of the process)
- Data Model of the National Arthroplasty Registry of Slovenia.
- The National Arthroplasty Registry of Slovenia as a pilot study.

4.4 Work Breakdown Structure (WBS), list of activities:

We produced a Work Breakdown Structure (WBS) - deliverable-oriented decomposition of a project into smaller components (see Figure 4).

- Defining a research question, purpose, objectives, outputs, funding and risks in ARM document
- Defining a Conceptual Diagram;
• Defining a Business Process:
  o Getting the approval of Slovenian Orthopaedic Association
  o Establishing the financial support – PARENT project
  o Checking the status in all interested healthcare institutions as stakeholders in the process
  o Preparation of the proposal for amendment of the Healthcare Databases Act (ZZPPZ)
  o Use of uniform RES forms as the base for dataset model
• Defining a Data Model using OpenEHR:
  o Comparison of EAR, OpenEHR and Valdoltra datasets
  o Mind map drawing
  o Use of EAR Minimal and RES Dataset in English language and
  o Use of the dataset for RES in Slovene language
  o Validation of the model
• Defining a Process model:
  o Textual document (Description of the process)
  o Landscape process model
  o Event Process Change (EPC) model
• Creating the Arthroplasty Registry Model and RES as an IT solution:
  o Specifications
  o Developing IT solution
  o Solution testing
  o Pilot set-up of RES in Valdoltra Orthopaedic Hospital.

4.5 Defining the scope and limitation of the Registry
• The scope of creating the Arthroplasty registry Model is to build a uniform model based on the EAR Minimal Dataset, so it can be applied to different national Arthroplasty Registries in Europe and abroad. The RES is the AR Model put into life in Slovenia;
• The limitations: it includes only a minimal data set, but it can be expanded by different national requirements. Compliance with data protection is required. The stakeholders needed for implantation process in Slovenia will cooperate on voluntary basis since the Healthcare Databases Act (ZZPPZ) does not include RES. For the pilot study in Valdoltra, the legal basis is satisfying but for other hospitals, the patient informed consent is to be obtained.

4.6 Legal Aspects and confidentiality
For the purpose of the analysis based on the registry data, we need first the legal basis, relying on the Healthcare Databases Act (ZZPPZ) since the patient’s personal identification number (EMŠO), which unambiguously identifies patients, is needed. At this moment, we do not have clear legal bases for the national RES collection but the amendment of the Healthcare Databases Act (ZZPPZ) is planned in the near future.

The personal data: patient name and address, Identification number of the health insurance card holder (HIIS), personal identification number (EMŠO), name and number of the surgeon, name and number of the healthcare institution.
For the analysis purposes, pseudo anonymisation will be performed at the holder of RES. Since some sort of patient identification is necessary and sensitive personal data are involved in the Registry, pseudo anonymisation (patient name and address, identification number of the health insurance card holder (HIIS), personal identification number (EMŠO), name and number of the surgeon, name and number of the healthcare institution) of these data is needed for the purpose of RES. Data protection policy will be guarded after the modifications of the Healthcare Databases Act (ZZPZV) will be approved. Since then the opinion of the Information Commissioner of The Republic of Slovenia is required.

4.7 Defining team members and roles for AR building

- Matic Meglič: Matic.Meglic@nijz.si PARENT Coordinator till 9.10.2014
- Marija Magajne: Marija.Magajne@nijz.si PARENT Coordinator from 10.10.2014
- Metka Zaletel: Metka.Zaletel@nijz.si as WP5 leader
- Vesna Levašič: Vesna.Levasic@ob-valdoltra.si to organize and provide clinical input into registry data model and process model; implementation at OBV. Provides additional contacts of clinicians for data reviews.
- Živa Rant: Ziva.Rant@nijz.si data modelling, business process definition
- Vesna Lešnik Štefotič: vesna.lesnik@triera.net writes the guidelines on establishing a registry in accordance with this guideline, data modelling.
- Mate Beštek: Matebestekpro@gmail.com PARENT Framework specification development and coordinator of registry implementation, consultant of OpenEHR framework, contact with Infonet.
- Marcel Kralj: Marcel.Kralj@nijz.si writes the guidelines on establishing a registry and gives these guidelines as the example of good practice
- Alen Vrečko: Alen.Vrecko@nijz.si the leader of the Framework activity in WP5
- Ivan Drvarič: Ivan.Drvaric@nijz.si data modelling
- Heather Leslie: heather.leslie@oceaninformatics.com and
- Ian McNicholl: ian@freshehr.com registry data modelling (have already started comparing existing models: http://www.xmind.net/m/cfyn/). They provide implementation into archetypes of Open EHR and review of the model
- Gerold Labek: Gerold.Labek@i-med.ac.at responsible for the Arthroplasty Scenario in PARENT - providing the EU wide safety dataset. As the leader of EARN (European Arthroplasty Registry Network) supports the work of Valdoltra Arthroplasty Registry
- Ingrid Milošev: ingrid.milosev@ijs.si the Research Assistant Manager of Valdotra Orthopaedic Hospital is the tutor of the Contract between NIJZ and Valdoltra, her contribution is the knowledge about materials used for arthroplasty implants

4.8 Arthroplasty Registry Model and The National Arthroplasty Registry of Slovenia (RES) holder

The holder of the Arthroplasty Registry Model is defined in the Cooperation Agreement (Pogodba o sodelovanju - 19.9.2014) between National Institute of Public Health (NIJZ) and Valdoltra Orthopaedic Hospital (OBV). The registry holder of The National Arthroplasty Registry of Slovenia
dataset, proposed in the amendment of the Healthcare Databases Act (ZZPPZ), is Valdoltra Orthopaedic Hospital.

4.9 Resources

4.9.1 Human Resources:
- All the team members listed above (project management, data management)
- Person for designing questionnaires and graphic design
- Support from the Ministry of Health for legal data protection
- Administrators in stakeholders’ hospitals to provide input via secure internet connections to the server
- 1 statistician
- 2 full time high educated persons for creating outputs
- Board of stakeholders for decision making
- Translator and proof-reader for English language

4.9.2 IT Resources (technical and logical infrastructure, location etc.):
- NIJZ for study design and statistical support
- OceanInformatics (defining the OpenEHR models)
- Slovene IT Company for the programming of Slovenian version of RES
- IT workers from the hospitals
- Contact to Infonet group – provider of Hospital Information Systems in most Slovenian hospitals
- Secure internet connections between hospitals, NIJZ and zNET
- Server at Ministry of Health, Ljubljana, Slovenia or at NIJZ if possible
- SPSS program for designing Kaplan-Meier curves (Valdoltra)

4.9.3 Financial Resources
- PARENT Project – NIJZ
- Additional resources from Valdoltra
- Application to the Ministry of Health for long-term sustainability of The National Arthroplasty Registry of Slovenia
- Possible donations from manufacturers and distributors of implants

4.9.4 Other Resources (office space, equipment):
- Place for meetings at NIJZ
- Office of Vesna Levašič at Valdoltra Orthopaedic Hospital
- Use of PC-s (one for each team member and for fellows included in the project)
- Phone, internet connections
- Barcode Readers (optional in the hospitals, where are already in use))
- Secure internet connections between hospitals, NIJZ and the server, zNET
- We are planning the server at Ministry of Health, Ljubljana, Slovenia
- Printers for printing reports
4.10 Data sources for The National Arthroplasty Registry of Slovenia

4.10.1 Primary data sources:

Data for Arthroplasty Registry Model will come from Valdoltra Orthopaedic Hospital. When RES will have legal basis by the amendment of the Healthcare Databases Act (ZZPPZ), all the orthopaedic clinics, hospitals, departments and the divisions in hospitals, where arthroplasty is performed will be included as stakeholders. The collected data are based on the EAR Minimal Dataset Forms.

Implants data are collected from the stickers of the implants applied to the paper forms.

4.10.2 Secondary data sources

Secondary data sources are the useful data from classifications, established for other purposes. The sources to fulfill the datasets are diagnosis collection Australian modification of ICD-10, version 6 (Slovenian MKB-AM) and procedures collection ACHI (KTDP), because they are already implemented in Slovenian Health Informatics System.

Data for Outputs (Kaplan-Meier Curve to design Implant Survival Curve) need to be censored by the data of patient deaths. The connection to Central Registry of Population at Ministry of the Interior is needed.

Additional data on the parts of the implants come from Implant Library in Valdoltra Hospital.

4.11 Data Quality Considerations for AR

The use of data for secondary purposes, such as research, typically requires explicit consent from patients or full anonymity. Data for AR Model will be collected in the pilot study in one hospital only (OBV) and will be expanded to other healthcare institutions when legislation for national RES will be in order.

Data quality and completeness is often compromised. Inadequate registry staff training may cause data quality issues as well as security breaches and/or privacy violation. Training is not only important for registry staff, but also for the staff of the healthcare unit that provides data for the registry, in order to increase data quality. A sustainable workflow that can be integrated into everyday clinical practice of doctors, nurses, pharmacists, and patients will be followed.
5  Action Plan for the implementation of AR

We prepared a detailed plan, which was completed and confirmed in the group (Parent, 2015 – see Working plan).

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<td>Živa Rant, Vesna Lešnik</td>
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4.5.1. Translation to Slovene

Vesna Levašič

5. IT solution developing (see document VD_Parent_ang.pdf)

5.1. Development and testing of the IT solution

Marand Vesna Levašič, Živa Rant, Alen Vrečko 20.3.2015

5.2. Pilot implementation - Valdoltra database

Marand Vesna Levašič, Živa Rant, Alen Vrečko 30.3.2015

5.3. Final version

Marand Vesna Levašič, Živa Rant, Alen Vrečko 31.3.2015 postponed - the legal circumstances
5.1 Data Modelling
- Collection of data elements from EAR Minimal Dataset Forms
- OpenEHR data modelling in CKM in English
- Translation of Data Model to Slovene in UKZ Slovenia
- The subcontractor for the Slovene Framework should include NIJZ and OBV in the modelling process
- Validation of the Model

5.2 Process Modelling
Based on the text description about RES
- Specification of the process:
  - Conceptual Diagram
  - Process Diagram

5.3 IT solution development
- development and testing of the IT solution
- pilot study on Valdoltra database starting in February 2015
- final version at the end of March 2015

5.4 Control points following the Diagram of activities (WBS)
First, we will implement the model for the hip implants. The implementation will start in Valdoltra Orthopaedic Hospital. In the implementation process, orthopaedic surgeons from other Slovenian clinics, hospitals and divisions will be invited as reviewers.

The second step is to implement the model for knee implants in the same way.

The control points are
- The input data (from the forms, stickers, selecting right diagnosis and procedure form collection) – is there anything missing, are there any misunderstandings?
- The data on the implants (Slovene Implant Library, Implant Library from other European and foreign countries)
- The output forms
- Analysis (the statisticians’ and reviewers’ opinions)

5.5 Funding
Actual funding: PARENT (NIJZ), Valdoltra Orthopaedic Hospital

Possible funding: Ministry of Health, Slovenian Orthopaedic Association, manufacturers and providers of medical implants, other donations
5.6 Risk and feasibility

5.6.1 Assumptions
To build an efficient AR Model to solve main issues regarding all Arthroplasty Registries. The RES serves as a base study of how this AR model works. The planning process is to be undertaken under the guidance of experts familiar with the process of registry and with the stakeholders.

5.6.2 Feasibility
The objectives and the purpose of the RES are likely to be met within the timeline considered, the budget available, the scientific model proposed and within the environment the proposed registry is due to be implemented in.

5.6.3 Risks
- Working with CKM program is a new methodology process for most of the team members
- A Research Fellow help is needed for more time consuming work – translation of the existing forms, filing the implant data into the Library, testing the RES at implementation
- The existing secure internet connections between public institutions may not work properly
- The collaboration with other European and International Arthroplasty Registries is needed
- The stakeholders needed for the implantation process in Slovenia could not cooperate
- Some legal aspects of data protection can slow down the implementation process
- The funding cannot be sustainable

5.7 Content of AR

5.7.1 Research questions and hypotheses:
Questions: Are different types of implants performing the same way after being implanted in the patient? What are the reasons and risks for implant failure – i.e. very short time in situ? What is the influence of different materials, bearing surfaces, cementation? Is there any difference between the hospitals and the surgeons?

Hypotheses: The Arthroplasty Registry Model is an efficient tool to answer the questions listed above.

5.7.2 Study design
The RES is based on the principals of a cohort study. The final product will be built in CKM mode.

5.7.3 The population covered by a registry:
Target population – the Slovenian citizens who undergo the procedure of implantation of the endoprosthetic material. They are divided to groups with similar implants in order to compare the different groups to each other and to normal population of Slovenian citizens.
5.7.4 Inclusion criteria:

RES will include data of orthopaedic implants inserted in Slovenian citizens with arthroplasty procedure performed from the orthopaedic and traumatology clinics, hospitals, departments and all the divisions in which either primary or revision surgery was done. First, patients with total hip replacement will be involved. The patients with knee replacement will come second.

Other joints like shoulders and ankles can be included afterwards. The identification number could be the Identification number of the health insurance card holder – HIIS - (KZZ in Slovenia), however due to the possibility of self-payment operations also for Slovenian citizens, it is necessary to use the Personal Identification Number (EMŠO in Slovenia).

5.7.5 Exclusion criteria:

Patients from foreign countries will receive a special code, which will allow the traceability; however, they will not be included in the annual report. These patients are of great interest for data comparison between different countries, when possible.

5.8 Assumptions

The expectancy of RES: Open-ended. In the pilot study, we expect to cover around 40 % of all arthroplasty procedures, after the amendment of the Act near to 100 %

The follow up point will be established every end of the year. The follow-up of the implant ends when any component of the prosthesis is removed or replaced. The data of deceased patients are censored events in Kaplan-Meier curve.

The data in the hospitals will be collected from the stickers with electronic barcode readers, or typed in from the paper forms to the holder’s computer and then automatic export from each Hospital Information System (BIS) to registry holder (Valdotra) for needs of the national registry RES.

5.9 The expected Outputs of RES:

- Number of different implants, used in the stakeholders’ hospitals
- Bearing surfaces (between head and acetabulum in hip implants)
- Implant survival time: AR on national or international level makes tracking of the implant possible
- Reasons for revisions of the implants
- Revision burden for different hospitals
- Number of revisions per 100 observed component years
- Demonstrating that a device or surgical technique is associated with increased post-postoperative complications
- Fulfilment of post-marketing obligations
- Validation of the realization of expected value by innovations and/or premium products
- Transparent ranking of quality achieved by implants and health care provider practice.

The basic methodology used in the preparation of the solution was the Systems analysis and Design (Dennis, 2014) methodology. We considered Systems Development Life Cycle (Dennis, 2014) methodology and Predictive Software Project Life Cycle (PMBOK SW, 2013) methodology – see Figures 5 and 6.

![Figure 5: The Systems Development Life Cycle, source: Dennis (2014, p. 10)](image)

![Figure 6: Predictive Software Project Life Cycle, source: Source: PMBOK SW (2013, p. 29)](image)
6 Planning

We used The Guidelines (Parent Guidelines, 2015) and Project Management methodology (PMBOK, 2008; PMI, 2008; Rant, 1995; IVZ, 2009) in the phase of planning which is described in chapter 1: Planning a Registry.

Main dilemmas and decisions:

ProjectPlace tool will be used for better documentation and communication between participants (https://www.projectplace.com/). ProjectPlace provides powerful collaboration tools.

We decided on the registry’s name: Register endoprotesike Slovenije; in English: The National Arthroplasty Registry of Slovenia. After some coordination, we decided that the acronym – RES – will be the same in both languages.

We will start with hip implants and later include knee implants and the rest of endoprostheses.

Orthopaedic Association of Slovenian Medical Association (SZD) confirmed the collection of minimal dataset, which is in line with EAR. Valdoltra hospital is collecting the extensive dataset; however, the agreement on national level has not been reached yet. The OpenEHR model offers the possibility to include the additional data (used in Valdoltra) in the maximum dataset.

We have found that it is essential to have a language editor for English who would regularly answer our questions and translate the materials when necessary. Parent project leader ensured one.
7 Analysis

7.1 Process Modelling

This part of the document describes the Process Model for building RES. The model is made with ARIS Express, (http://www.ariscommunity.com/aris-express). ARIS Express is a free-of-charge modelling tool for business process analysis and management for occasional users and beginners in Business Process Management and is a member of the Aris community. We use the Value-Added Chain (VAD) and Event-driven Process Chain (EPC) Diagram.

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

**Primary arthroplasty** is the first surgical procedure when a total or partial endoprosthesis is implanted

**Revision arthroplasty** is the surgical exchange or removal of any component (or all components) of an artificial joint replacement

The team responsible for the creation of RES data model:
- Vesna Levašič, MD, Head of Valdoltra Arthroplasty Register, Valdoltra Orthopaedic Hospital
- Matevž Topolovec, MD, PhD, Valdoltra Orthopaedic Hospital
- Živa Rant, M.Sc., information specialist, National Institute for Public Health Slovenia

Co-workers from Valdoltra Orthopaedic Hospital prepared textual process description. The working group analysed the proposals.
In pilot phase, the RES will only include data for hip endoprostheses from Valdoltra, which has a legal basis according to current legislation. Later, RES will include data from other Slovenian hospitals as well.

We used the first draft to prepare a new process model, which is comprised of the following:

- Textual description: RES procedures specification,
- Value-added Chain Diagram (VAD) and
- Event-driven Process Chain Diagram (EPC).

7.1.1 RES procedures specification

1. **Orthopaedic Surgeon** indicates the surgery and records it in a Medical Report.

2. **Patient** comes to the hospital to be admitted for surgery (insertion/replacement of endoprosthesis)

3. **Administrator (or reception nurse)** completes the Register Form (for example primary hip, revision hip, primary knee, revision knee operation) and inserts it in the Medical Record map, which is a hospital document. The Form can be pre-printed or printed directly from Hospital Information System (BIS in Slovenia), with included Social Security Number (KZZ) and number of the hospital (from the registry of public institutions). When entering the operation also the number of the hospital, which will carry out the operation, is entered. By entering the operation, identity card (Social Security Number (KZZ) or Personal Identification Number (EMŠO) is required.

4. **Reception nurse** enters patient’s body height and weight data into the form and/or in the Hospital Information System (BIS) – for maximum dataset.

5. For **revision surgery**: Reception **doctor** inserts in the form, if it is possible, the precise date and hospital name where the primary surgery and/or other previous surgeries of the index joint were undertaken.

6. The same at **primary surgery**, the reception doctor marks which surgeries have been done on the index joint before the primary implantation.

7. Before the surgery, the operation room nurse, enters the following information into Hospital Information System (BIS): the surgical team members, side of the operation, type of the procedure (primary/revision; hip/knee). When entering the operation, the application adapts to the planning procedure (hip primary, hip revision, knee primary, knee revision).

8. **Surgeon** performs the operation with his team.

9. After the operation, unscrubbed operation room nurse puts the labels (stickers) of individual components of the endoprosthesis on the appropriate form. (Labels with catalogue number – REF and serial number – LOT are necessary for all implanted materials; not-implanted materials are not labelled, because they are only subjected to material accountancy). If there is no label, the unscrubbed nurse writes the REF and LOT number down from the packets of endoprosthesis.
10. After the surgery, the surgeon fills all the remaining sections in the form.

11. The operation room nurse forwards the form to the person responsible for collecting Register Forms in the Hospital or she/he enters the data from the form to OpenEHR application directly. When possible the surgeon fills the form into the OpenEHR application directly.

7.1.2 RES Value-Added Chain Diagram - VACD
(see Parent RES Process Model, Parent Process, 2015)
We have found that the process of data provision can roughly be divided into the following phases:
- Data entry prior to procedure,
- Surgery procedure,
- Post procedure Data entry, and
- Forwarding data from hospital to the keeper of national registry.

Based on that we produced the Value-Added Chain Diagram – VAD (see Figure 7):

![Figure 7: Data Assurance Process for RES – VACD](image)
7.1.3 RES Event-driven Process Chain Diagram (EPC)
(see Parent RES Process Model, Parent Process, 2015)
We divided basic sub-processes in more detail and produced the Event-driven Process Chain (EPC) Diagram for data assurance process for RES (see Figure 8):
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- Previous operation data
  - Entering the data of previous operation
    - Data of previous operation are entered
      - Orthopaedic surgeon
      - OR staff
      - Operating room nurse
      - Patient EHR

- Endoprotetic procedure
  - Procedure finished
    - Operating room nurse
    - Patient EHR

- Implant library
  - Postoperative data entry
    - Operating room nurse
    - Patient EHR

- Medical procedure data entry
  - All data of procedure are entered
    - Orthopaedic surgeon
    - Procedure report
    - Final registry form
    - Patient EHR
Figure 8: EPC Diagram for RES
7.1.4 Use Case 2: Data Search and Retrieval (EPC)

For describing Data Search and Retrieval process, we produced EPC diagram for Data Search and Retrieval (see Figure 9):
Figure 9: EPC diagram for Data Search and Retrieval
7.2 Data Modelling

For the needs of data modelling, we chose 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 (OpenEHR, 2015).

We have encountered several dilemmas:

1. What should represent the record? Implant exchange? The patient? Treatment?

2. Should we model EAR or the data collected in OBV (Valdoltra Orthopaedic Hospital)?

3. Do we have a legal basis for the establishment of national arthroplasty registry?

We have decided:

1. What should represent the record? Implant exchange? The patient? Treatment? We chose 'Implant exchange' unit for the first version.

2. Should we model EAR or the data collected in OBV (Valdoltra Orthopaedic Hospital)? We have decided on the following: The model, that we are building in OpenEhr, consists of two branches:
   1. minimal EAR collection data elements, which we use in Slovenian forms (EAR + Additional data) All data that could be accepted by Europe go into maximal collection. We decided to prepare maximum dataset for the RES too.
The national RES will only include EAR dataset from the form. The Orthopaedic Association of SZD confirmed the collection of minimal dataset, which is line with EAR. Valdoltra hospital is collecting extensive dataset; however, the agreement on national level has not been reached yet. Because of the long-lasting procedure to confirm the extensive dataset, we will prepare everything needed for minimal dataset in the following documents, while we will present the extensive dataset in Annex (Additional data).

3. Do we have a legal basis for the establishment of national arthroplasty registry?
To answer this question, we have spoken with Information Commissioner of the Republic of Slovenia. We have learned that there is no legal basis for national arthroplasty registry yet. We have proposed the amendment of the Healthcare Databases Act of the Republic of Slovenia, which is currently under revision. Valdoltra Orthopaedic Hospital has the legal basis for collecting data on its patients so the pilot solution will be made for the patients of this particular hospital and later on, the procedure will spread to national level.

7.2.1 Starting
In September 2013, we started building the Data Model with the mind map from the data set from the definition of EFORT/EAR (European Arthroplasty Register), http://www.ear.efort.org/.

We used the Xmind, professional and popular mind mapping tool, available free from: https://www.xmind.net/.

We produced a mind map (see Figure 10).

Figure 10: Implant Change Mind map from September 2013

We found out we do not have enough knowledge do make this Mind Map. We contacted and asked for help the European Arthroplasty Register (EAR). Dr. Gerold Labek, EAR Coordinator and Ivan Pristaš, MD, public health specialist from Croatian Institute of Public Health contributed.
Despite that, we still did not have enough knowledge. As prof. Labek did cooperate successfully with Valdoltra Arthroplasty Registry, guided by the physician Mrs. Vesna Levašič, MD from Valdoltra Orthopaedic Hospital, we invited her to cooperate in the
We were very happy that she accepted the invitation and unselfishly shared her knowledge with us.

We have prepared a comparison between EAR, OpenEHR existing archetypes and Valdoltra Orthopaedic Hospital’s data for revision. We discussed this comparison during a workshop where a set of questions arose. We needed much coordination regarding identifiers. We concluded to include all proposals into the model and then later decide on the ones we will actually use in the registry.

We produced the Mind Map to ensure greater clarity.

In March 2015, we made a final version of the Mind Map for The National Arthroplasty Registry of Slovenia for Hip replacement – primary operation and revision.

The team responsible for the creation of RES data model:
• Vesna Levašič, MD, Head of Valdoltra Arthroplasty Register, Valdoltra Orthopaedic Hospital
• Vesna Lešnik Štefotič, M.Sc., information specialist, ISP, Vesna Lešnik Štefotič s. p.
• Živa Rant, M.Sc., information specialist, National Institute of Public Health Slovenia
• Ivan Drvarič, information specialist, National Institute of Public Health Slovenia.

We discovered that constructive input from clinicians is very important for the production of good data model and that involvement of informatics specialists is very useful.

7.2.2 The final version of the Mind Map
In March 2015, we finished our Mind Map in Xmind.

First, we made the Mind Map for primary operation (see Figure 11):
After primary operation, we continued to work with the revision. We made a Mind Map for the revision and primary operation of hip replacement (see Figure 12):
Figure 12: The National Arthroplasty Registry of Slovenia (RES) Mind Map for HIP replacement from March 2015
7.2.3 The Medical Device Archetype

In that time, we investigated data elements for implants. Finally, we made a Mind Map for arthroplasty component (see Figure 13):

![Mind Map for Arthroplasty Component](image)

Figure 13: Mind Map for Arthroplasty Component

This work was included into updating of the archetype Medical device on CKM (CKM 2015). We contributed the review of the clinical content of Archetype Medical Device (openEHR-EHR-CLUSTER.device.v1). 30 reviewers from Norway, New Zealand, Slovenia, Spain, Australia, Sweden, United States and United Kingdom, contributed 47 reviews. Finally, the Archetype is following (see Figure 14):

One can see the archetype on the [http://www.openehr.org/ckm/](http://www.openehr.org/ckm/) find openEHR-EHR-CLUSTER.device.v1. Here you can also see the data about the review process.
7.2.4 Building the RES OpenEHR model

After the Mind Maps were done, we started building an OpenEHR model.

Most of OpenEHR modelling was made by:

- Dr Ian McNicoll, Co-Chair, OpenEHR Foundation Management Board and Director, FreshEHR Clinical Informatics, and
- Heather Leslie, Consulting Lead, Ocean Informatics & Clinical Programme Lead, OpenEHR Foundation.

The final version was made in cooperation with Marand d.o.o, a solution provider in healthcare offering products, who made the computer application for RES.

We use the Archetype Editor (AE) and Template Designer for making archetypes and templates for RES (OpenEHR, 2015).

Finally, we have two models, one for primary hip operation and another for hip revision.

The OpenEHR models are available on the following links:

Slovenia RES Primary Hip Arthroplasty Report:

Slovenia RES Revision Hip Arthroplasty Report:
7.2.5 OpenEHR Model for Slovenia RES Primary Hip Arthroplasty Report

An OpenEHR Model for Slovenia RES Primary Hip Arthroplasty Report is available on: http://openehr.org/ckm/#showTemplate_1013.26.33 CKM RES1 (2015). You can view it in several ways (see Figure 15 and 16):

7.2.5.1 Mind Map

Figure 15: Slovenia RES Primary Hip Arthroplasty Report – Mind Map
7.2.5.2 Template Hierarchy

7.2.6 OpenEHR Model for Slovenia RES Revision Hip Arthroplasty Report
An OpenEHR Model for Slovenia RES Revision Hip Arthroplasty Report is available on: http://openehr.org/ckm/#showTemplate_1013.26.34, CKM RES2 (2015). You can view it in several ways (see Figure 17 and 18):

7.2.6.1 Mind Map

Figure 17: Slovenia RES Revision Hip Arthroplasty Report – Mind Map
7.2.6.2 Template Hierarchy

Figure 18: Slovenia RES Revision Hip Arthroplasty Report – Template Hierarchy

7.3 Data sources for registries

We have planned that RES will include the reports of all health care providers in Slovenia that perform arthroplasty surgeries. These institutions are the following: Valdoltra Orthopaedic Hospital, Brežice General Hospital, Celje General Hospital, Izola General Hospital, Jesenice General Hospital, University Medical Centre Ljubljana – Division of Surgery, University Medical Centre Ljubljana – Department of Orthopaedic Surgery, University Medical Centre Maribor, Murska Sobota General Hospital, Novo mesto General Hospital, dr. Jože Potrč General Hospital Ptuj, Slovenj Gradec General Hospital, dr. Franc Derganc General Hospital Šempeter pri Novi Gorici, Trbovlje General Hospital and Surgical Centre Rožná dolina.

We have prepared all the necessary forms and an online platform for the data on hip implants, knee implants will follow in the second phase and all other arthroplasty in the third.

Orthopaedic association of SZD confirmed the minimal dataset collection, which was proposed by the EAR in 2010. The members of the Association confirmed at a meeting in 2014 that OBV and NIJZ could cooperate in PARENT project with the aim to bring the RES model to the point where data collection will be possible whereby and OBV will be named registry holder.

In the phase of the analysis, we have found that according to the Healthcare Databases Act of the Republic of Slovenia OBV does not have a legal basis for data collection on national level for all data elements yet.

We had two options for data collection. One of the options would be to collect the data with individual consent of each patient but we chose the second option: we have proposed an amendment to the Healthcare Databases Act of the Republic of Slovenia, which is currently in progress. Since Valdoltra Orthopaedic Hospital has the legal basis for collecting data on its patients, the pilot solution will be oriented to the patients of this particular hospital while we plan to spread it to national level in later stages.
7.4 Terminologies and Code lists

During the process of data model creation, we also had to choose which commonly renowned code registers to use. Shall we use the ICD, one of its versions or the SNOMED. Finally, we found that none of them is suitable therefore we kept the list of diagnoses proposed by the EAR.

We had the similar dilemma regarding the procedures code register where the ACHI does not cover everything we need.

We will use Slovenian Implant Library in RES, which is the property of the Valdoltra Orthopaedic Hospital.

For the reporting providers we will use HealthCare Provider code register, which is based on the Slovene HealthCare Providers Database.

7.5 Common Data Set (CDS)

There are many different registries in the EU. Some of them we analysed in the Parent project. We liked to find the data elements, which are the same or similar in all registries we deal with. We called them Common Data Set (CDS).

We started this activity in February 2014.

We considered European Arthroplasty Register - EAR, European Platform for Rare Disease Registries - EPIRARE, European Patient Smart Interoperable Services - epSOS and The European Network of Cancer Registries - ENCR.

We have formed maximum dataset for all registries for which we were able to obtain the list of data elements (see Figure 18).

We found out that there are only few common data elements. (see ParentCDS.xlsx and ParentCDS2.xmind). Therefore we have delayed this thought for a while.
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Figure 19: Maximum data set from February 2014
In April 2015 we started this activity again. We analyzed the following registries:

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<td>CARDS Data Standards</td>
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<tr>
<td>Multiple Sclerosis</td>
<td>EUReMS</td>
<td>EUReMS Core data set</td>
<td><a href="http://eurems.eu/attachments/article/93/EUReMS%20Data%20Mask_August2014.pdf">http://eurems.eu/attachments/article/93/EUReMS%20Data%20Mask_August2014.pdf</a></td>
</tr>
<tr>
<td>RES-The National Arthroplasty Registry of Slovenia</td>
<td>Parent</td>
<td>RES-data model for primary operation</td>
<td></td>
</tr>
</tbody>
</table>

We selected EpSOS Patient Summary as a starting point. We compared all other datasets with this one. We merged all our analyses in one table (see Annex CDS-final table.xlsx).

Our analysis shows that common datasets of observed registries are very small. Further results are discussed in document PARENT CDS (2015).

Only Gender and Date of Birth are present in all registries; most of them also include: Primary Patient Identifier, Healthcare Facility’s identifier, Problem/diagnosis description.

We came to a conclusion that registries in the EU have very different structures, so common dataset is very small and badly usable.
8 Design

The topic is discussed in the Guidelines in the chapter Patient Registry Information System Development and Implementation.

We designed our requests for programme software in the document entitled Functional Requests of The National Arthroplasty Registry of Slovenia, (Parent functionality, 2015):

1. Defining more user types and allocating access rights accordingly
2. Data entry into register
   a. Importing data from existing HIS
   b. Data entry through e-forms
3. Data control
   a. control (syntactic and semantic control)
      i. automatic syntactic and partly semantic
         1. within the package
         2. according to data already in the registry
      ii. control by registry holder
   b. browsing
   c. data correction
   d. making the request for data correction and new sending
   e. marking records, which will not be included in the analysis
4. Linking: recalling previous surgeries of this patient (patient ID, joint, side), comparing revision records with previous surgeries in the registry and pairing
   For all new revisions, computer shows me the window with appropriate primary surgeries. If there are no such surgeries, computer shows similar surgeries.
5. Inclusion of holder’s Central Implant Library and import from distributors’ or producers’ databases.
6. Linkage with the Central population register of Slovenia, i.e. the dead
7. Possibility of linkage with causes of death and cancer registries?
8. Pseudo anonymization
9. Tools for dynamic inquiries (e.g. on the implant, doctor, hospital, region, etc.) in accordance with existing legislation and different user types
10. Enabled patient inquiries on the prostheses success
11. Data exports – at least in CSV format
12. Reports
For the Patient Registry Information System Development we selected the Marand programming firm, which was selected based on the call for tender in the framework of Parent project. Marand is a Slovene solution provider in healthcare offering products.

First, we looked through the Functional Requests of RES, and then we harmonized them, complimented and additionally defined them.

We delivered process and data models. Together we went through OpenEHR data model, which was completed based on previous experiences. Then we harmonized it between NIJZ, Valdoltra Orthopaedic Hospital and Marand. Oceaninformatics was also included in the harmonization who published final archetypes and templates on CKM (CKM, 2015).

### 9 Implementation

#### 9.1 Registry set-up

Registry set-up was divided into four sets:

- Infrastructure establishment
- Establishment of secure connection and accesses
- Software installation and testing
- Data preparation

#### 9.1.1 Infrastructure establishment

First, we needed to establish operating infrastructure.

We made a decision to install the registry on the NIJZ server, while Valdoltra Orthopaedic Hospital will be its holder.
We established the infrastructure at NIJZ. We gathered technical inquiries from the software provider. After some harmonization, we were able to establish adequate infrastructure.

9.1.2 Establishment of secure connections and accesses

The next challenge was to establish secure connections and accesses.

NIJZ and Valdoltra Orthopaedic Hospital are health 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 data security. We decided to use the existing network of secure connections between hospitals – zNet. This caused some problems and access provision took us a lot of time. We finally solved the problem when IT experts of all three partners (NIJZ, Valdoltra Orthopaedic Hospital and Marand) met in Valdoltra and cleared all obstacles on the spot.

9.1.3 Software installation and testing

Marand prepared a pilot version of IT solution. They installed the software on the NIJZ server. During the user testing, Marand 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 in Marand. The main testing was performed in Valdoltra Orthopaedic Hospital.

The first software solution takeover was held in May 2015 in Valdoltra Orthopaedic Hospital, but it did not succeed due to failure of secured connections. The experience was especially unpleasant since the management of the hospital was invited to the event. The testing, harmonization and updating continued until the final takeover of the solution in November 2015.

A 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 analysis, called a Tableau (http://www.tableau.com/). We installed the tool on the NIJZ server. Valdoltra Orthopaedic Hospital prepared the proposals for the data display and the Marand used this proposition to prepare graphic displays in Tableau programme.

Several installations and accesses are foreseen for the Tableau programme, depending on user rights. The server offers a version where advanced user can create or correct the proposals for displays. Using the internet, the users can access the graphs, which are prepared based on these proposals. RES application can also access these graphs.

9.1.4 Data preparation

We came across two challenges during the data preparation:

- Initial data entry
- Ensuring regular electronic data entries
9.1.4.1 Initial data entry

Initial data entry was an extensive job, which took us more time than expected.

Since Valdoltra Orthopaedic Hospital already had a similar registry in hospital’s information system Birpis21 that included data from 2014 on, the users requested that data are transferred from this registry. This made sense since most of the Slovene hospitals use the same hospital information system. This meant that we needed to motivate the software provider who developed the solution to enable export from HIS. This needed a lot of work since additional contract had to be signed between them and the contractor (Valdoltra Orthopaedic Hospital).

It was necessary to define which data to transfer, how to register them and which data in the hospital registry were compatible with data in RES.

The users from Valdoltra Orthopaedic Hospital, system analysts from NIJZ and the experts of old and new software providers firstly designed the content of the transmission table, and later the table itself.

9.1.4.2 Ensuring regular electronic data entries

Since all data in reporters’ information systems are saved in electronic forms, it makes sense that these data are sent electronically. We have foreseen this method in this solution.

We needed to define 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 CSV file, which is prepared by reporters from there IS.

Hospitals, which have the same IT solutions as Valdoltra Orthopaedic Hospital can directly enter data into RES application prepared by Marand company.

9.1.4.3 RES and the connection with the Central Population Registry (CRP):

Functional Requests of The National Arthroplasty Registry of Slovenia foresee the connection with the Central Population Registry (CRP). Eventual patient’s death is a very important data in the survival of the prosthesis. This is the reason why we wanted to receive the data on the date of patient’s death from CRP.

We were not able to develop this function the way we wanted, but the application allows the manual entry of the date of death.
9.2 Running the registry

After the registry setup, which included the infrastructure establishment, establishment of secure connections and accesses, software installation and testing, data preparation and user training, we started to run the registry.

The application allows us to add new persons, surgeries (revisions and primary surgeries), we have access to Implant Library and we are able to browse and update the data.

Some screen images and applications are shown below – see Figures 20–22.

![Application's screen image 1 – patient data](image-url)
Figure 21: Application's screen image 2 – basic view

Figure 22: Application's screen image 3 – revision data
9.2.1 Data dissemination

The Tableau tool allows us to perform data analyses and make graphic presentations.

Some graphic presentations, made with Tableau from RES data are shown below (see Figures 23 - 25).

Figure 23: The cause for the revision for all years – test data

Figure 24: Burdening surfaces for primary hips in Valdoltra for 2014 and 2015:
Figure 25: Kaplan-Meier's curve of the survival for Profemur stem in Valdoltra Orthopaedic Hospital
10 Outcomes

Parent project outcomes, which were produced in the process of building The National Arthroplasty Registry of Slovenia:

- working plan
- Parent ARM
- Conceptual diagram
- Healthcare Databases Act amendment proposal
- Data model
  - Comparison table of EAR, OpenEHR, Valdoltra for primary surgery and revision
  - CDS
  - mind map for primary surgery and revision
  - OpenEHR model EAR
  - OpenEHR model RES
  - Implant Library (holder: OBV)
- Process model
  - Tekstual description
  - VAD diagram / Aris
  - EPC diagram / Aris
  - EPC diagram for Data Search and Retrieval /Aris
- documents to support the software solution development
  - Functional Requests of The National Arthroplasty Registry of Slovenia

11 Outcomes' annexes

Next to the operating registry itself, the following outcomes are also the result of our work:

- PARENT Arthroplasty Registry Model - PARENT ARM (2014) (VL_AR_Model.docx)
- Conceptual diagram of The National Arthroplasty Registry of Slovenia (RES) (VLS_Conceptual diagram.pptx)
- Healthcare Databases Act amendment proposal (Zbirka_RES_Priloga1_ZZPPZ.docx)
- PARENT RES Data Model (RES Data Model-v1.docx)
- Parent RES Process Model (RES Process Model-v1.1.docx)
- Functional Requests of The National Arthroplasty Registry of Slovenia (funkcionalnostiRES.docx)
We used the following tools when building The National Arthroplasty Registry of Slovenia:

1. We used **ProjectPlace** for the communication between project participants, for controlled posting, monitoring and updating. Projectplace provides powerful collaboration tools ([https://www.projectplace.com/](https://www.projectplace.com/)).


3. We used **Microsoft Excel** for the work with tables - a spreadsheet application available on: [https://products.office.com/en-us/excel](https://products.office.com/en-us/excel).


5. For the creation of mind maps, we used **Xmind** - professional and popular mind mapping tool, available free on: [https://www.xmind.net/](https://www.xmind.net/) (6.10.2015).

6. We used **OpenEHR** for data modelling - open domain-driven platform for developing flexible e-health systems, [http://www.openehr.org/what_is_openehr](http://www.openehr.org/what_is_openehr) (6.10.2015)

7. We used **CKM – Clinical Knowledge Manager** for harmonization and publishing of OpenEHR Archetypes and Templates - a system for collaborative development, management and publishing of a wide range of clinical knowledge governance within and across the health enterprise. For reviewing, [http://www.openehr.org/ckm/](http://www.openehr.org/ckm/) (31.8.2015).

8. We used Slovenian version of **UKZ - Upravljavec kliničnega znanja** for publishing OpenEHR Archetypes and Templates in Slovenia: [http://ukz.ezdrav.si/ckm/OKM_sl.html](http://ukz.ezdrav.si/ckm/OKM_sl.html) (6.10.2015)

9. For the creation and editing of archetypes, we used **Archetype Editor (AE)** - currently the main tool in use for authoring openEHR ADL 1.4 archetypes as found on openEHR CKM and elsewhere. [http://www.openehr.org/downloads/archetypeeditor/home](http://www.openehr.org/downloads/archetypeeditor/home) (6.10.2015).

10. For the definition of templates, we used **Template Designer** - based on the open .oet format in use with ADL 1.4 archetypes, [http://www.openehr.org/downloads/modellingtools](http://www.openehr.org/downloads/modellingtools) (6.10.2015).

11. We are using **Tableau** for graphical presentations of data from The National Arthroplasty Registry of Slovenia (RES) - Business analytics anyone can use [http://www.tableau.com/](http://www.tableau.com/) (6.10.2015).
13 Challenges

1. We were glad that we had financial resources assured. Parent covered the expenses. Despite that, we had many challenges.

2. 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 Mrs. Vesna Levašič, MD, Head of Valdoltra Arthroplasty Register. Finally, we composed the project team of medical experts, informatics team and an expert for business processes. We used the OpenEHR methodology, which is user friendly for medical experts and informatics specialists and helps them to talk between themselves.

3. 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).

4. What to include into the data set? Should we model EAR forms or the data collected in the Valdoltra hospital? We decided we would model on the one side the EAR minimal data set and, for extension, the Valdoltra dataset.

5. Do we have a legal basis? We asked the Information Commissioner of the Republic of Slovenia for the opinion. She replied that we did 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. Valdoltra Orthopaedic Hospital 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 will spread to national level.

6. To reach as much interoperability as possible, we asked ourselves which standards could be included. First, we started with diagnosis. Shall we use the ICD10, ICD10 Australian modification that is standard in Slovenian hospitals, SNOMED or something else? None of these could fulfill our needs, so finally we used the list from the EAR form. 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 Slovenian Implant Library, which is produced in the framework of Valdoltra Orthopaedic Hospital, which is its holder.

7. RES includes sensitive personal data that is obliged to guarantee 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 on the NIJZ server within the zNet.

8. Since all data in reporters’ information systems are saved in electronic format, it makes sense that these data are sent 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 IS.

9. To import the data from existing registry in other software solution we made the agreement with the hospital software provider and together we imported the data form existing solution.
10. Some implants have to be excluded from the analysis. For this, we need to get the date of patient’s death. We now can type it in or import it from the Central population register by following the special procedure.

14 Advantages

RES, The National Arthroplasty Registry of Slovenia, contains the real world data. Data are imported in the registry from the EHR in the hospital information system (HIS). All data from the HIS are included.

We use 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 in the CKM (CKM 2014).

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 the update of business processes.

We have the Slovenian Implant Library, which was produced in the Valdoltra Orthopaedic Hospital and is its holder. It helps us to fulfill the implant's data automatic from the key input.

Patients and surgeries can be added in the RES, we can browse and update the existing data. The implant traceability is assured.

The reports and analyses with nice graphs can be made in the Tableau tool.

15 Conclusion

The building of The National Arthroplasty Registry of Slovenia was a great challenge but we were successful. There were many unforeseen situations, which showed that building a registry in practice is very different from theoretical bases. The Methodological Guidelines and Recommendations for Efficient and Rational Governance of Patient Registries (Parent Guidelines, 2015) were very helpful and we developed them simultaneously. Despite the fact that we precisely started the planning, we encountered many unforeseen complications during the implementation. It was once again proved 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 informatics team – system analysts, system engineers and developers of new IT solution and experts for the update of business processes is also very important. Building of the registry lasted a lot longer than expected. We also had to carry out some unplanned activities.

We gained many new experiences and became more qualified for building new registries during the process of building this one. This document is intended to help anyone that will encounter similar challenges in future.
16 References


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