Managing Collaborations between Medical and Engineering Actors in Case of Prosthesis Implantation: A PLM-Based Approach

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ABSTRACT

Medical sector is a dynamic domain that needs continuous improvement of its business processes. The purpose of this research focuses on the treatment process requiring prosthesis. This type of process requires knowledge reuse and data sharing for collaboration between various business stakeholders. Such treatment process makes connection between two separate lifecycles that belong to medical and engineering fields respectively. In this case, several problems of communication and collaboration already appear due to heterogeneity of semantics and business practices. In this perspective, this paper proposes a conceptual framework for analyzing the connection between disease lifecycle (Medical) and prosthesis lifecycle (Engineering). Based on this analysis, a combined KM-PLM based approach is proposed and implemented in AUDROS software solution to support the involved stakeholders by assistance functionalities along the treatment and prosthesis realization processes.

Keywords: Collaborative work, PLM, medical surgery, prosthesis engineering, knowledge management.
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1 INTRODUCTION

During the last decades, huge technological developments are supporting the human being by proposing new ways and methods for working, consuming and communicating. Medical and healthcare are one of critical domains where the application of technology is challenging at both technical and social dimensions. This is because the medical devices must interact with humans in various sensitive and risky situations. Furthermore, they are strongly regulated by standard policies. In addition, every patient should be considered as a unique case study even if he suffers from a common pathology and the patient data is covered by confidentiality. This second

specificity also makes difficult to assess the real performance of the devices during its usage stage and, consequently, to guarantee the completeness and the accuracy of the related requirements.

This assumption is particularly important in the case of medical devices implanted in human body such as prosthesis. Prosthesis can be standard or customized and could be implanted for a permanent or temporal usage. However, in all case, the prosthesis should be suitable to the patient morphology and guaranty a maximum of flexibility and safety for him throughout his different life situations. Thus, the accuracy and completion of the device requirement has a strong influence on the success of the whole treatment process. For example, the quality of the prosthesis reduces the risk of incidents during surgery process. Post-treatment and related costs can be also reduced if the geometry of the prosthesis is perfectly adapted to the patient morphology. Consequently, the patient will be recovered after surgery quickly in this case [37, 38]

To obtain such results, strong collaboration between several stakeholders is required. The list of stakeholders includes the patient, medical doctors, engineers but also all other professional that could interact with the patient during his recovery. Focusing on the design and realization stages, medical doctors have to share their knowledge in a comprehensible way so that the engineers start designing the prosthesis based on accurate requirement. Conversely, the medical doctor has to aware about the capacity and constraints of each type of prosthesis when deciding the right treatment for a given patient pathology. This co-decision should be taken in very short time in emergency situation.

As a consequence, improving the medical treatment process with prosthesis implantation could be possible through an efficient assistance to actors for knowledge reuse, data sharing and collaborative activities. The new generation of information and communication technology (ICT) systems might foster better consideration of these aspects by supporting the management and the traceability of relevant data and information. It might facilitate stakeholders' collaboration among the whole product lifecycle in a context of virtual organizations [2]. From these categories of ICT, Product Lifecycle Management (PLM) approach are distinguished by their capacity to manage in a consistent way all product-related information and processes through the entire lifecycle, from the initial idea to end-of-life [25, 30]. It also provides the support for the interoperability between heterogeneous information systems and computer aided applications in the company [26].

Thanks to its integration capacities, PLM approach can be adapted from industrial domain to support the medical treatment processes and, similarly, the connection of these processes with prosthesis related engineering processes. Furthermore, as a common repository of shared information in the organization, PLM system can be also used for the management of useful knowledge and its capitalization in a consistent format. These assumptions are at the aim of this research work. In the following, a global solution is defined and implemented in an industrial PLM software to support data sharing and knowledge reuse along the medical treatment process requiring prosthesis. To do so, a conceptual approach is developed to analyze the connections between the patient disease and the prosthesis lifecycles. This analysis conducts to the formal representation of shared knowledge at every life stage following the Product-Process-Resource perspectives [18]. Collaborative and knowledge-based assistance functionalities are then derived as operational solutions to implement the connection between the above-mentioned lifecycles.

The remaining of the paper is organized as follow: the next section provides a review of the main characteristics of the medical domain requiring prosthesis implantation. The problem statement of collaboration and knowledge management is refined. The literature review is completed by a short description of PLM approach and its advantages regarding to the scope of the research. Section 3 setups the main foundations of the proposed conceptual framework while section 4 develops the main implementation steps in the PLM tool.

2 LITERATURE REVIEW AND PROBLEM STATEMENT

Medical sector is a wide field that can be divided into 4 main areas: diagnostic service, treatment service, healthcare service and medicine field. In which, diagnostic service includes blood exams, X-ray, blood pressure measurement, CT/MRI scan, etc. Treatment service includes surgery,

prescribe a medicine or only give an advice from doctor, etc. Healthcare service includes recovery service, home care service. The treatment process requiring prosthesis is one of the important medical fields that includes complex processes with the participation of various stakeholders [6]. Generally, this process starts by patient interviewing and initial exams allowing the medical doctor to create a preliminary opinion on the patient pathology (Figure 1). After which, the radiologist will scan the concerned part of body. Medical imaging can be provided with several mechanisms depending on the identified symptoms. Conventional radiology (CR), computed tomography (CT), magnetic resonance imaging (MRI), X-ray, ultrasound imaging, positron emission tomography, thermography and different types of microscopy are the most known data acquisition methods [14, 27]. These methods can produce sets of two-dimensional (2D) images and three-dimensional (3D) reconstructions for interpretation [15]. Among them, CT and MRI are currently the two most popular methods for producing computerized images of patients [32]. CT and MRI produce pixel-based images in a series of slices.

For the analysis of the collected data, 3D Medical Image Processing software became important tools for supporting medical images analysis and diagnosis purposes [20]. Such kind of software reduced cost and quality problems associated to conventional radiology, where doctors and secretary lost lot of time and money for the printing, reading and archiving in good conditions huge quantity of documents [29]. The 3D Medical Image Processing (3DMIP) software applies various automatic analysis and processing algorithms to accurately segment and visualize the data described on the 2D/3D images [10].

Generally, DICOM file is the main standard format that could be generated by scanners and that can be supported by 3DMIP viewers [34]. DICOM (Digital Imaging and Communications in Medicine) is a standard format that allows the exchange, sharing and processing of medical images information easily. In medical applications, DICOM is the leading standard for storage and transfer of image data [21]. This standard format provides a protocol for sharing across many different medical devices and systems. It is widely used in hospitals as well as the output format of medical imaging devices such as MRI, ultrasound, X-rays and CT scans. The DICOM file exists as a series of many hundreds of cross-sectional slices taken through an area of the patient's body via a CT scan, MRI scan.

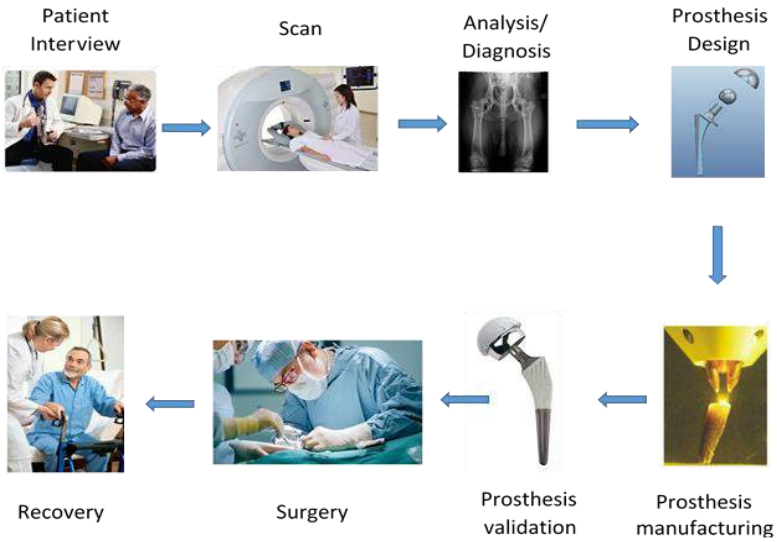

Figure 1: The medical treatment process requiring prosthesis.

After the analysis of medical images obtained from the scan, the design and realization of the needed prosthesis is achieved. 3DMIP tool like MIMICS software (Materialise's Interactive Medical

Image Control System) proposes the conversion of the scanning data (presented in DICOM format) into the highest possible quality STL (STereoLithography) data or VRML (Virtual Reality Modeling Language) files. STL files are easily imported into the CAD software [5, 14, 31]. They can support (semi-) automatic representation of bone morphology and help designers in the conception of the prosthesis based on a set of technical specifications. The same type of files can be used to accelerate the prosthesis manufacturing, which is the next step of the treatment process. Several technologies are currently used for the manufacturing of prosthesis depending on its kind and material. It can be fabricated by using conventional CNC (Computer Numeric Control) machines, or more recently, using additive manufacturing through 3D printing machines [1, 28]. Finally, before implanting the prosthesis on the patient's body, a strong quality approval process is achieved, involving engineers, medical doctors and surgeons [32]. The last process after implantation is then rehabilitation and recovery.

During the above process, several types of data and knowledge are created and shared between stakeholders. This data concerns: medical reports and other patient data, surgery procedures, medical images and prosthesis data among others. However, there are no optimum methods to achieve the efficient collaboration between stakeholders. They often use ad-hoc network and email to share the data together or even the data is archived to CDs/DVDs, then supply for related sub-processes. These data sharing practices usually lead to potential errors and delays [7]:

- Potential errors: The data size is normally very large (up to 300 MB) and several technical and human factors are influencing the accuracy, the completion and the exploitation of the generated. Therefore, using ad-hoc network or email can increase the problems linked to corrupted or incomplete data. This is because of the low capacity of data structuring and searching as well as the high risk of losing details in the big mass of emails.
- Interoperability failure: because of the variety of standards and tools, several problems of data exchange can occur during the import/export of files in/from tools.
- Delays: The stakeholders in one sub-process want to receive the data from another sub-process. They must send a request and wait for accepting from another stakeholder. The data is then sent by the internet or saved to a CD/DVD. This method is not optimal. It causes delay in the data exchange between the sub-processes. Consequently, the completion time of the whole process is lengthened.
- Knowledge capitalization failure: doctors and engineers generally focus in their interaction on the descriptive data for the current medical treatment of a patient and the prosthesis under development. Less interest is given to the capitalization and the sharing of decision taken and respective business rules. This results in time loosing for the future cases.

In this context, there is the need to provide stakeholders by: (1) common standards for data structuring and easier communication, (2) interactive workflows for easier collaboration, (3) knowledge-based supports for decision-making and (4) robust finding mechanisms to make easier the exploitation of saved knowledge. These elements are among the most important development pillars within the information perspective and should be considered as part of a global framework in order to ensure the consistency of the whole medical treatment process requiring prosthesis.

As part of the modern Information and Communication Technology (ICT) systems in industrial companies, the product lifecycle management (PLM) approach might have great advantages to implement the above needs since it provides interesting mechanisms for supporting different levels of inter-enterprise collaboration [22] and associated data sharing [33]. Regarding the integration of PLM and KM issues, many research works aim to support the capitalization of product engineering and manufacturing process knowledge within a PLM approach [3, 35]. For example, Jałowiecki, et al. [13] showed a popular process of knowledge acquisition that includes different stages from identification, acquisition, expansion and validation of knowledge base, then compared various techniques to acquire the different types of knowledge. In addition, Hellebrandt, et al. [12] explained the importance of knowledge reuse. The authors proposed a framework to transfer the complaint knowledge to the product manufacturers and developers. Bissay, et al. [8] have

proposed a methodological approach to capitalize knowledge in PLM systems. The proposed approaches integrate the knowledge generated by a business process into PLM based on two main phases: process integration and knowledge integration. Similarly, the work of Bertin, et al. [4] aimed to integrate a lessons learnt system (REx) into PLM. The authors demonstrated how to couple PLM-REx in order to enhance the capacity of PLM in knowledge capitalization.

Based on KM methods, Bosch-Mauchand, et al. [9] have used PLM capabilities to achieve semi-automated capitalization of heterogeneous knowledge from various enterprise information systems (EISs). The authors used this set of knowledge in order to assess the manufacturing process performance. The authors developed a framework to support this manufacturing process assessment based on three main modules: knowledge capture, knowledge structuring and performance assessment. Kiritsis, et al. [16] introduced the concept of a closed-loop PLM, a system that enable all people who play a role during the life cycle of a product to track, control and manage product information. Within the multi-agent-based approach, Monticolo, et al. [23] developed a knowledge engineering module integrated into a PLM system with the aim of capturing knowledge and technical data related to design projects. In the same perspective, Mahdjoub, et al. [19] proposed a knowledge engineering system embedded in a PLM environment in order to capture knowledge emanating from information generated during collaborative activities carried out by the designers. The authors apply the captured knowledge to a virtual reality system in order to help the designers in their daily tasks.

Therefore, the main issue in this research work is to propose new solutions mixing facilities coming from PLM approach on one side and knowledge engineering on the other side to support the above cited pillars. The target is to assist and support collaboration between large variety of stakeholders, including medical doctors, surgeons, radiologists, design engineers, prosthetists, manufacturers, and nurses. In addition, knowledge capitalization and reuse facilities are needed as part of the PLM approach to support medical problems resolution. The next section describes the main foundations of the conceptual framework behind the proposed PLM-KM approach.

3 THE CONCEPTUAL PLM-KM APPROACH

3.1 Lifecycles Connections

The development of the prosthesis follows the classical steps of design and manufacturing processes of mechanical products. However, some particularities should be pointed in this context. First, the product (prosthesis) is completely linked to its final user (patient). Generally, the geometry of prosthesis depends on the morphology of the patient. Second, all decisions taken about the prosthesis lifecycle depend on the concerned patient disease data. Thus, the prosthesis lifecycle management is strongly linked to the disease lifecycle. Base on this analysis, two concurrent lifecycles is identified: "disease lifecycle" for medical point of view and "prosthesis lifecycle" for engineering point of view as shown in Figure 2.

The lifecycle of disease is a closed loop including stages: Health problem, disease checking, treatment definition, treatment realization, recovery and end of treatment. The lifecycle of prosthesis includes stages: prosthesis request, requirement analysis, prosthesis design, prosthesis manufacturing, using and end of life. The above processes imply a lot of linkages between these lifecycles stages. These linkages can justify the need of collaborative actions between heterogeneous stakeholders.

At a macro analysis level, there are some semantic connections between the two lifecycles. For instance, the stage of requirement analysis (prosthesis lifecycle) refers data, information, and requirement from the stage of treatment definition (disease lifecycle). Prosthesis manufacturing is based on the requirements coming from the stage of treatment realization. From the treatment process described in detail using process models, we can identify the relation between stages of two lifecycles. This relation is described by links that connect the stage of one lifecycle to the stage of another one. Figure 2 shows six links numbered from L1 to L6. The arrows indicate that the stage is receiving or providing data. For example, Link L1 implies that after analysing medical data

at stage "treatment definition", medical doctor will decide patient needs prosthesis or not. The decision will send to stage "prosthesis request". This link demonstrates the connection and data exchange between medical doctors belong to "disease lifecycle" and design engineer from "prosthesis lifecycle".

This double lifecycles connection is the kernel element of the proposed conceptual framework. An important step for the definition and the implementation of the proposed PLM approach consists of the understanding and the modeling of each life stage as well as the main linkages between these lifestages, following a coherent modeling framework.

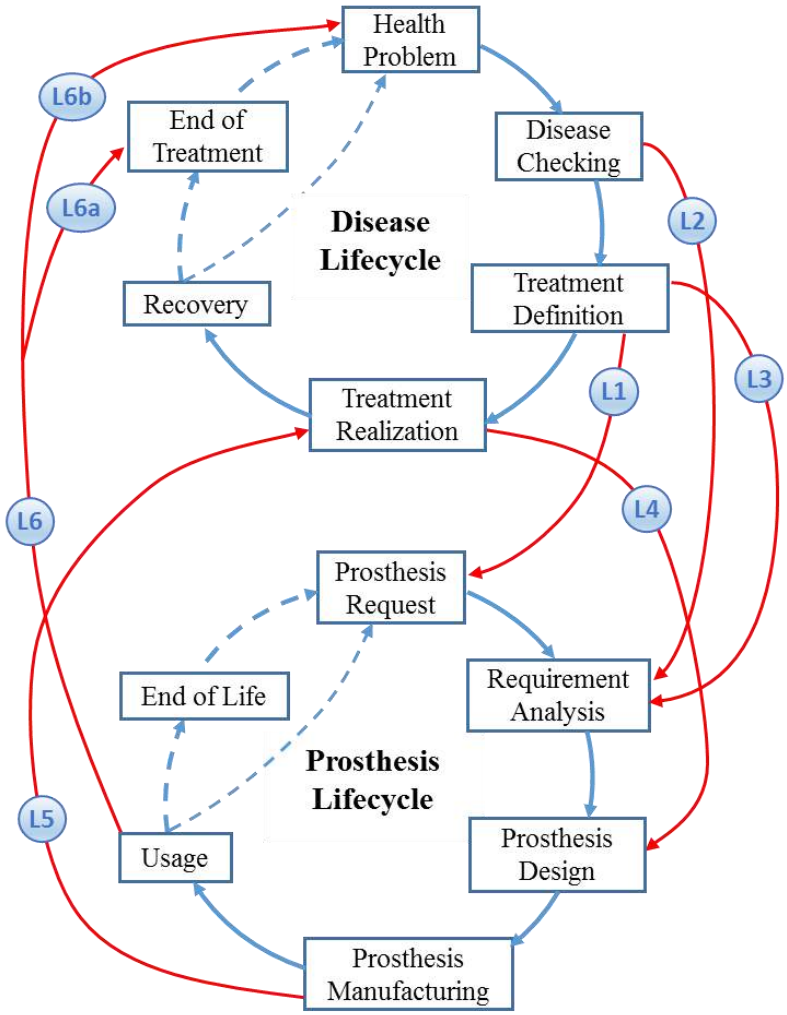

Figure 2: Linking between disease lifecycle and prosthesis lifecycle.

Several modeling frameworks and methods already exist in the literature. Some of them are generic offering guidelines and semantic to describe heterogeneous business domains and other ones are specific for supporting some applications. For instance, the collaborative aided design framework proposed by Nowak, et al. [24] is based on the concepts of Product, Process and Organization as main modeling axis for engineering process. Product model consists on the definition of the functional, structural and behavioral dimensions of the product, while process

model focuses on the various activities around the product. The organization view is interested to the resources and their roles in the process. Similar concepts are used in the P4LM methodology [11], where the product data are conjointly managed with process and project as well as proceeds. Project dimension includes the organization of resources as well. FBS-PPRE (Function, Behavior, Structure – Process, Product, Resource, and External) is another modeling framework proposed by Labrousse, et al. [17] for the description of large variety of enterprise artifacts. Based on this, Le Duigou, et al. [18] uses the PPRO (Product-Process-Resource-Organization) meta-model for the specification of PLM systems dedicated to SMEs (Small and Medium Enterprises). Inspired from such modeling frameworks and others, the proposed modeling framework suggests analyzing every life stage and every potential link between life stages according to five complementary dimensions: Flows, processes, stakeholders, tools and requirements (Figure 3).

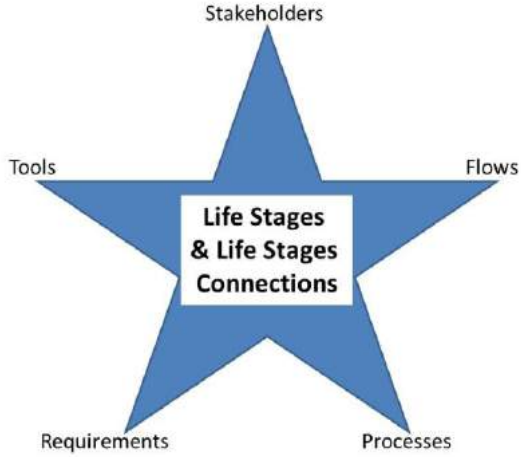

Figure 3: Main concepts in the treatment process.

For instance, the requirements dimension aims to summarize the different objectives of the life stage (as well links), the needs expressed by stakeholders and any additional constraints of integration. The classical resource dimension is divided into material resources (tools in our model) and human/organizational resources (stakeholders). Stakeholder is more suitable in this case in order to include the patient as well (object of some activities). Process dimension describes the different activities while the Flow dimension is compared to the classical product dimension. However, using the flow concept helps the representation of both physical and informational entities concerned by the medical processes. The final result of the proposed framework is the building of the whole semantic model for medical sector. Ontology based modeling approach is used to develop the proposed models to be used for the structuration of the common knowledge repository. The next section illustrates the main elements of the proposed model.

3.2 Ontology Modeling of Medical and Engineering Related Knowledge

As analyzed and introduced, there is always the exchange and re-use of knowledge among stakeholders during treatment process. So using ontology is necessary to facilitate the reuse as well as updating and developing of knowledge. Figure 4 describes the main steps of the ontology building process. This process begins by identifying the main concepts from the treatment process, then indicating the properties and relationships of all concepts in the conceptual model. Finally, taxonomy is constructed by extending these concepts in detail. With each main concept, we build a corresponding taxonomy. The whole ontology is developed using the Protégé tool. For instance, the following taxonomies are developed as part of the semantic model:

- Flow taxonomy to express different types of exchanged objects between stakeholders. Information and physical flows are distinguished. The first category includes mainly medical knowledge while physical flow focuses principally on prosthesis data among others.
- Prosthesis taxonomy to describe the main types of prosthesis, their characteristics and especially indications on their usage context according to the disease pathology.
- Process taxonomy includes all necessary processes from medical and engineering domains as well as the key collaborative activities connecting these processes.
- Stakeholder taxonomy is complementary to the process taxonomy and aims to identify different involved actors in the processes as well as their roles and authorities in the treatment process.
- Tool taxonomy syntheses the main categories of tools used during the treatment process. The tool section of the proposed ontology gives additional information about their characteristics.

In addition, generic taxonomy of main pathologies is defined to make possible the linkage of every prosthesis type to the concerned usage context.

During the treatment process, in order to perform a sub-process, it is necessary to refer and collect the data, information, knowledge from other sub-processes. In other words, there is always an exchange and sharing of data between the sub-processes together. This sharing plays an important role not only enhancing the accuracy, quality, making the right decisions but also shorten completion time of the entire process. For example, through the collaboration and data sharing, the surgeon can propose some requirements for design and manufacture process of prosthesis. Moreover, from the data collected, he can comment and adjust these processes as suitable as possible.

From the problems identified, the proposition is that using PLM approach to enhance efficiency of collaboration, information and, knowledge sharing between stakeholders related. The idea is that all disease data, prosthesis data, actors, tools of both sub-processes inside hospital (interview patient, do exam, do surgery, etc.) and outside hospital (design and fabricate prosthesis) will be connected through a PLM hub as shown in Figure 5. With this proposition, actors can share data, knowledge to each other. They can view, modify data or only give comments depending on their roles.

The last dimension of the proposed conceptual framework concerns the identification of knowledge-based assistance and data sharing facilities that are able to support the involved stakeholders with the KM-PLM approach. To do so, an operational scenario is built based on the different processes and for each step, medical and engineering experts are interviewed to identify their main needs. The next section gives the key issues for the implementation of the proposed approach in the PLM tool.

4 SOFTWARE IMPLEMENTATION IN A PLM TOOL

The chosen solution is a French PLM solution named AUDROS because it proposes a set of flexible tools able to be adapted to any functional domain through an intelligent merge of the business process model, the data model generator and the user interface design [36]. These functionalities are implemented throughout various software modules for database and workflow administration and connectors to manage the interoperability with legacy Computer Aided Applications. For instance, the main Audros modules are used as follows:

- ModelShape: to create all classes (objects), attributes, actors and the relationship between them. This module also grants access right for actors depending on their role.
- View designer: to design the interface of classes according to the attributes created by ModelShape.

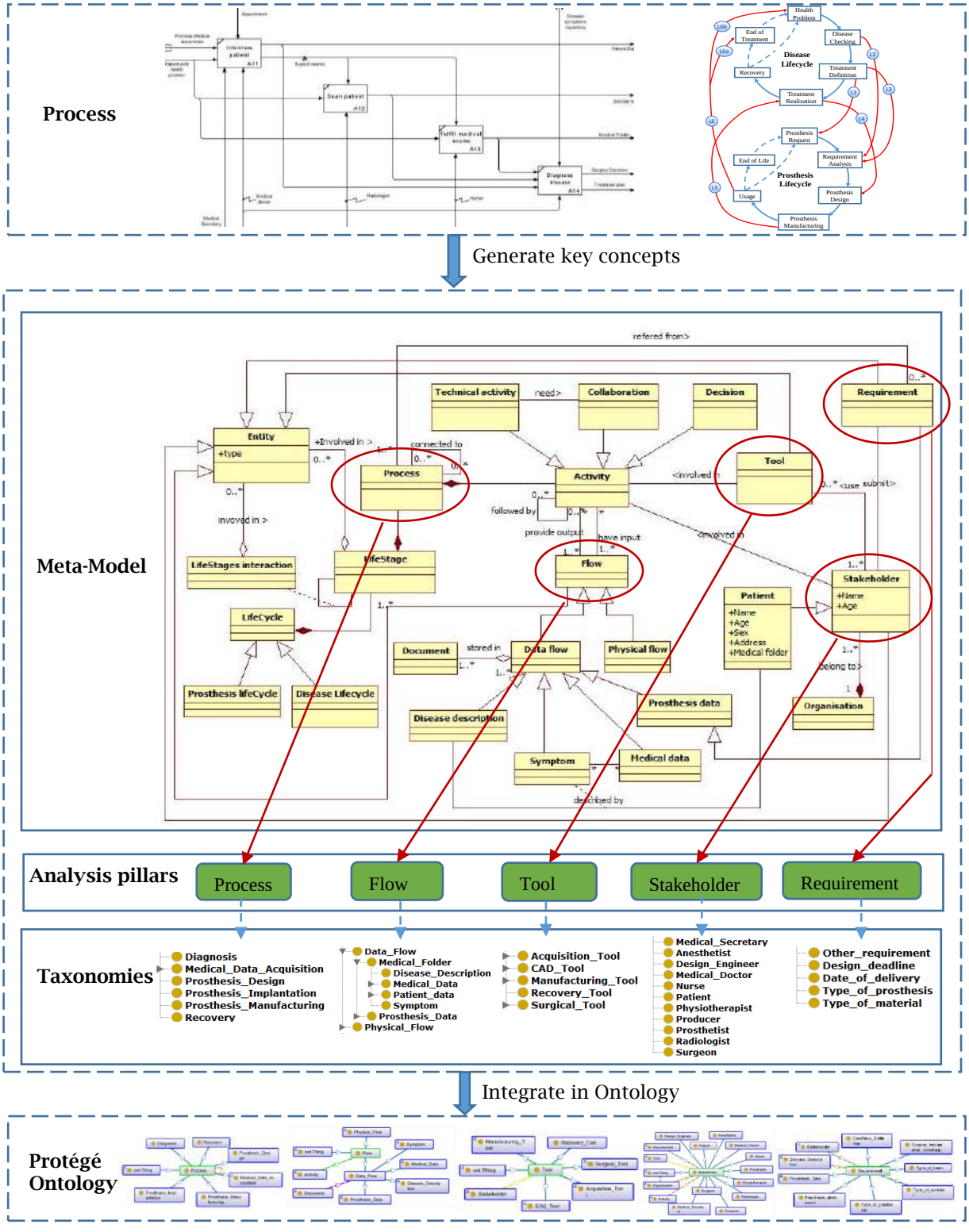

Figure 4: Ontology building process.

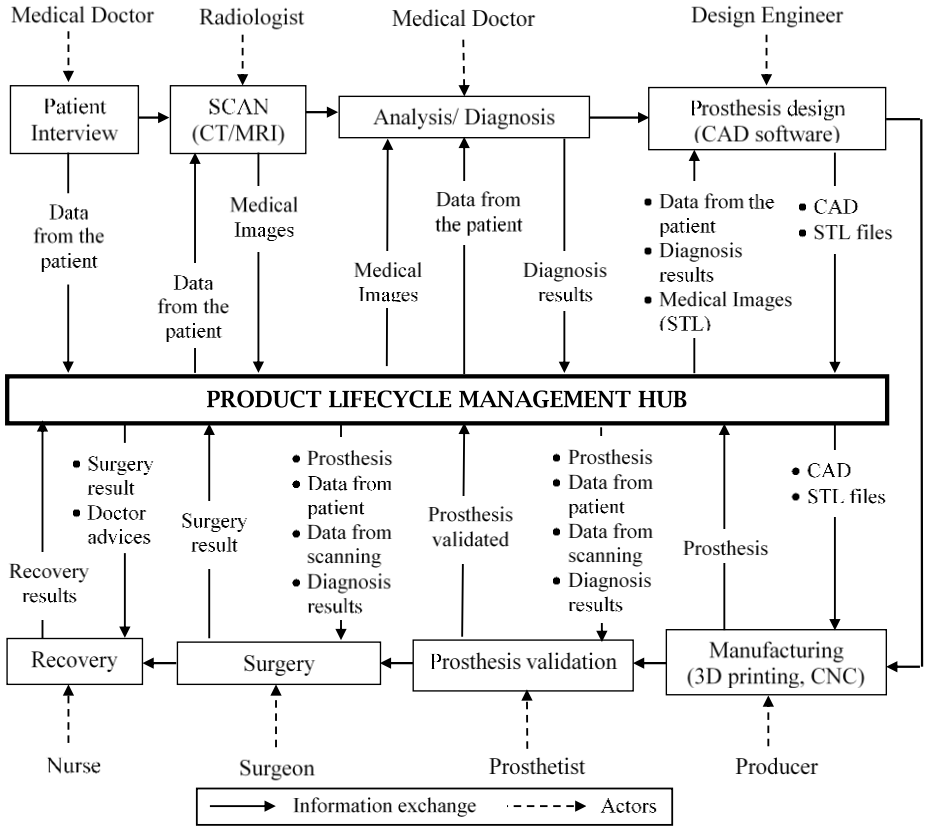

Figure 5: The PLM solution as a hub.

- SE manager to create medical and engineering objects' lifecycle and to structure all shared data in folders and files.
- Audros Applet: to implement the variety of medical sub-processes in terms of PLM workflows. In each workflow, it shows series of activities as well as the actors involved. In this research, the system operates base on six workflows: Medical folder workflow (for the management of data collection), Disease workflow (for the identification and the treatment of disease), Requirement workflow (for the management of functional and technical specifications), Prosthesis workflow (for the management of prosthesis design data, Prototype validation and Prosthesis fabrication), Surgery workflow (for the management of prosthesis implantation procedures), and post-surgery workflow (for the continuous traceability of aftercare patient data)

The main functions implemented in the Audros applications are summarized in the following use case diagram (Figure 6). These use cases can be classified into four main categories: (1) update and extract disease knowledge, (2) update and extract prosthesis knowledge, (3) create prosthesis and pathology catalogs for decision making support and (4) manage notifications and emails. The manipulation of the stored knowledge and the exploitation of the developed functions are possible by means of the AWS creation module.

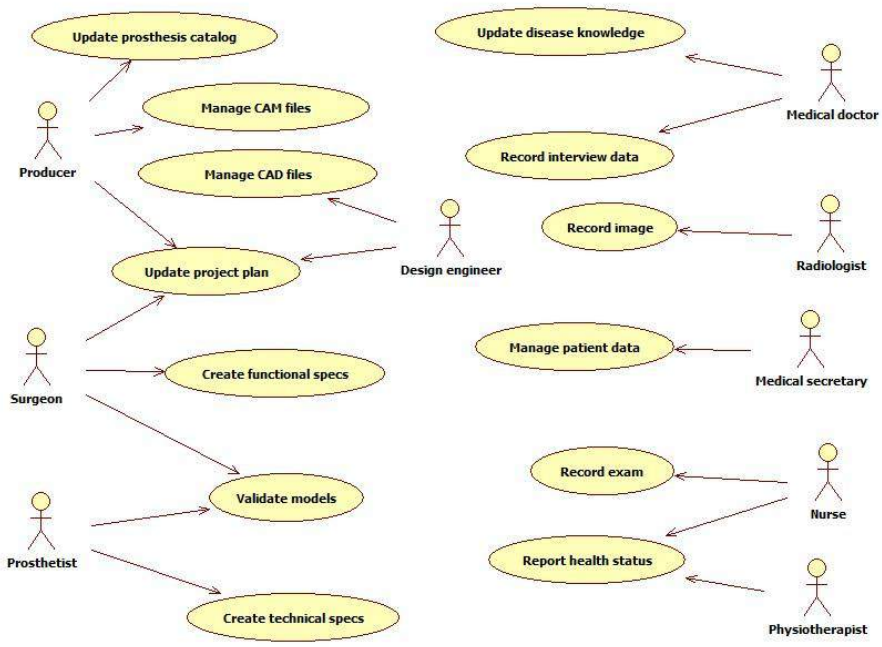

Figure 6: Use case diagram.

The implementation scenario of every use case is described using UML sequence diagram. For example, Figure 7 shows the scenario of medical knowledge update. Following this scenario, Firstly, the medical doctor collects and analyzes medical data of patient. Then patient symptom is identified. From the description of symptom, it is compared with the symptoms in pathology catalog to select the suitable pathology of patient (the graphical user interface of disease description is shown in Figure 8). The pathology will appear in the main interface of PLM object "DISEASE" and the doctor can use pathology catalog to identify the suitable pathology based on the identified symptoms (the graphical user interface of the pathology catalog is shown in Figure 9). After selecting the suitable pathology, the medical doctor completes the disease description process and the system automatically notifies the new problem to the surgeon. The surgeon will receive the notification by email using the standard AUDROS mailing facilities.

Similarly, the prosthetist and prosthesis designer can exploit similar knowledge catalog describing the characteristics of various prosthesis types. The catalogs are defined as an implementation of the proposed ontology explained in section 3.2.

While the technical specifications are defined and validated, the design process is started.

Figure 10 illustrates the role of design engineer from the beginning to end of design process and how he collaborates via the PLM with the prosthetist and the producer as well as the surgeon in charge of the validation of the prototype.

Concretely, after receiving email, the design engineer will log in with his account and create PLM object "PROSTHESIS" (Figure 11). He converts medical image to STL file. Based on requirement (functional and technical requirement), he begins to design prosthesis. After completing the design process, the design drawing model will be attached in this PLM object (Figure 12). Finally, the system notifies prosthetist to validate the virtual model and notifies producer to prepare the manufacturing process.

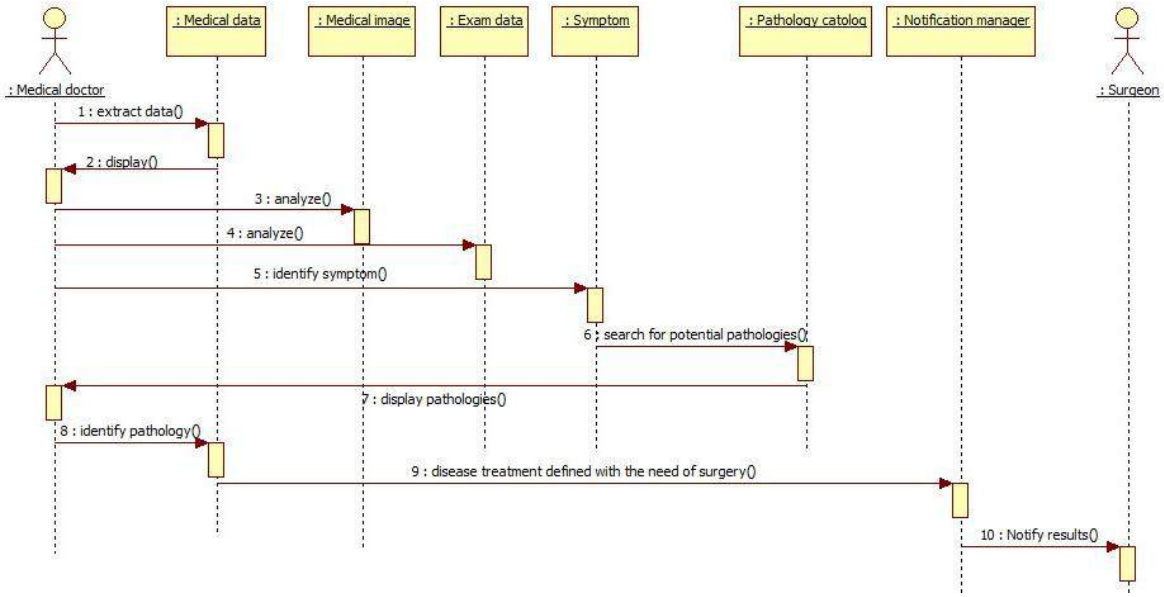

Figure 7: Scenario of disease knowledge update.

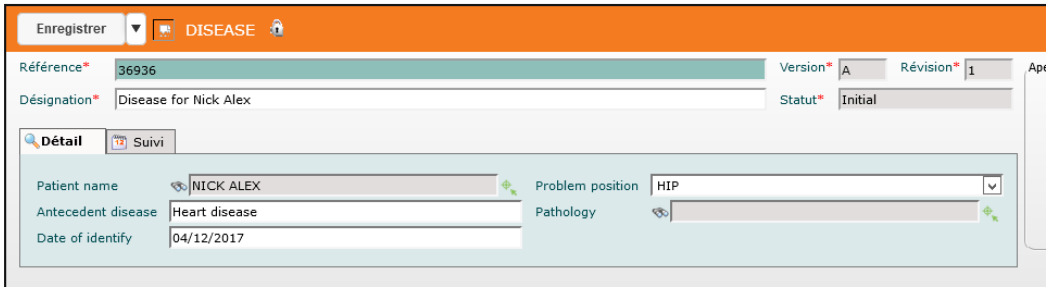

Figure 8: Main interface of PLM object "DISEASE".

Figure 9: Identify pathology of patient from symptoms.

The collaborations between the actors involved in the prosthesis design process are managed in the PLM by means of automatic workflows. Figure 13 presents an example of workflows developed in the PLM to follow the process of prosthesis creation and validation. In this workflow, the design engineer begins to design prosthesis that will be validated by prosthetist. If it is not satisfactory, prosthetist requests redesign it. If prosthesis 3D model is validated, producer will receive a notification and begin to prepare the manufacturing process.

After finishing the preparation for manufacturing process, the system sends a notification to anesthesiologist, medical secretary, and surgeon to prepare the surgery process. At the same time, producer begins to fabricate prosthesis. It will be validated by prosthetist before sending to

hospital. Finally, the PLM will notify the result to anesthesiologist, medical secretary and surgeon to begin the surgery process.

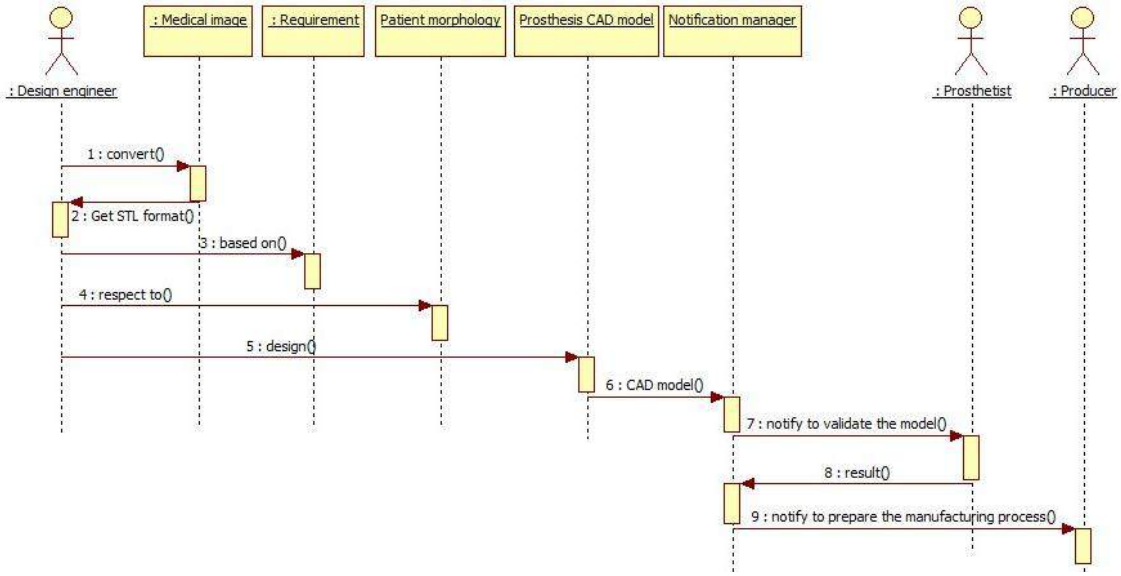

Figure 10: Scenario of prosthesis design.

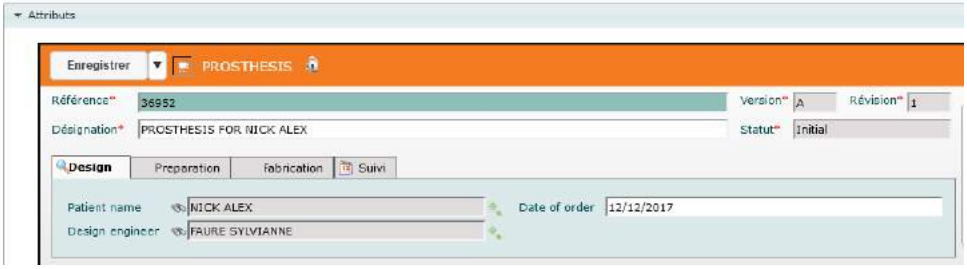

Figure 11: Main interface of PLM object "PROSTHESIS."

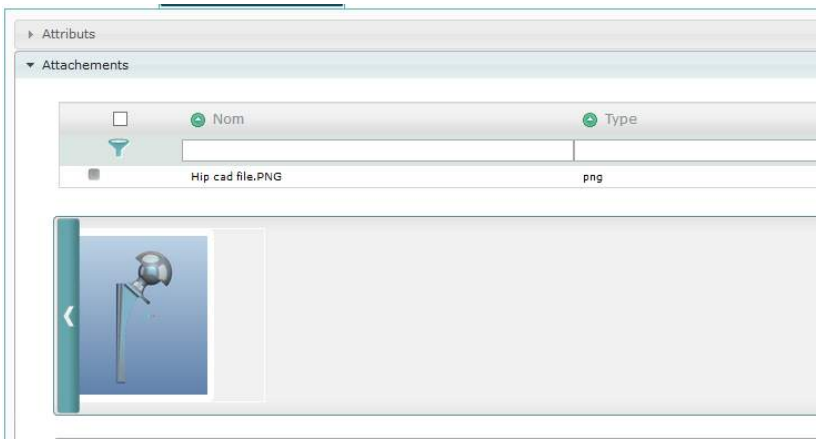

Figure 12: 3D design drawing attachment.

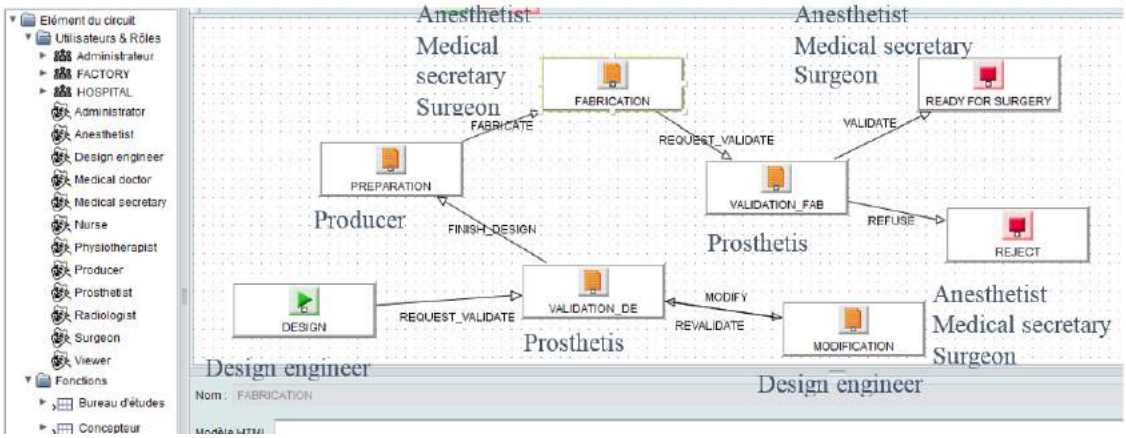

Figure 13: Prosthesis creation and validation workflow in Audros.

5 CONCLUSION

The paper pointed out a critical problem that can strongly affect the processes' performances in the medical sector. The problem concerns the information exchange and collaboration between actors. It also indicates the main problems to be solved to develop the appropriate PLM approach. Then a collaborative model is presented based on PLM approach. It connected all actors and processes through a PLM hub. All actors can send and receive the information and data through this HUB. Consequently, it minimizes errors during the data exchange, improves the quality of prosthesis and shortens completion time of the whole process. Besides that, Actors can monitor the progress of other processes, so they can make their own plan actively. In addition, the links between the patient treatment lifecycle and the prosthesis lifecycle are identified as part of the conceptual framework to analyze the medical treatment process requiring prosthesis from a collaborative point of view.

Based on this framework, a set of collaboration and knowledge-based functionalities are implemented in industrial PLM software. The main advantage is to provide a common repository to manage both technical and medical data in the same manner. For this, a new medical-oriented ontology is proposed to classify the characteristics of main elements involved in the studied process. The first results give a great proof to validate the hypothesis that it is possible to extend the software applications generally developed in industrial domain to manage other types of service businesses like the medical treatment.

Further work is planned to make the proposed prototype exploitable in real context. The main development works concerns principally: the extension of the knowledge repository by including among others the existing standards, the interoperability with other legacy CAX tools for direct extraction of useful data, and the creation of intelligent engines for intuitive research and finding of knowledge at every step of the process. Societal aspects should be also studied to analyse what kind of patient data can be stored and how this storage will be managed looking to the current policies.

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