Interest of PLM for data sharing in the patient treatment process requiring prosthesis implantation

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Abstract: The medical sector is a wide and complex field that needs continuous improvements in its efficiency. This paper deals with the problem of collaboration and the data sharing in the medical field. The focus is on the case of treatment processes requiring prosthesis implant. Several actors from both medical and industrial sectors are involved in these processes. They need to collaborate during the whole process of prosthesis creation and implantation. From this perspective, this paper presents a discussion about the advantages of the current PLM-based approaches to deal with these issues. A first proposal of the conceptual approach is also proposed.

Keywords: Product Lifecycle Management, Prosthesis, Medical sector, Collaboration, Information sharing.

I. INTRODUCTION

In the current social, the medical sector is more interested and looking for the better ways to improve it, especially in the context of the life quality is increasingly improved.

Medical sector is a wide and complex field that includes many different areas, however this paper is only focus on the treatment process requiring prosthesis that includes a series of closely related sub-processes.

In the patient treatment process requiring prosthesis, it is necessary to design and fabricate prosthesis based on not only the symptom but also morphology of patient. There are two lifecycles that cover all stages of the treatment process: the patient disease treatment lifecycle and the prosthesis lifecycle. In other words there is always an exchange of information and knowledge sharing between business sub-processes and stakeholders.

In fact, the prosthesis lifecycle management is strongly linked to the patient disease treatment lifecycle and several interactions between heterogeneous experts, different applications from both medical and industrial sectors are required.

This paper describes the first results of a study that aims to develop new PLM approach for the management of prosthesis lifecycle. The main idea is to adapt currently used approaches in industrial domain by taking into account the specificities of the product and its lifecycle described above. It indicates some limitations in the patient treatment processes in terms of data sharing and collaborations between different actors involved in the treatment process. Based on this analysis, the paper discusses the main advantages of the PLM approach that can improve these issues. The main conceptual pillars of the PLM approach are then proposed.

For this goal, the nextsection of this paper gives a general description of medical sector in this research work. Besides that, this part also indicates the need of collaboration and information sharing. The third part focuses on the definitions and some applications of PLM in industry and in medical sector.

The fourth part of this paper proposes the patient treatment process and relative actors. After that, this part also indicates the problem in the context and proposes the PLM approach to solve that problem. Finally, the paper exposes the conclusions and future work.

II. COLLABORATION AND DATA SHARING ISSUES IN THE MEDICAL SECTOR.

The 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 test, X-ray, blood pressure measurement, CT/MRI scan, etc. Treatment service includes: Surgery, prescribe a medicine or only give an advice from doctor… Healthcare service includes recovery service, home healthcare…

In the specific case when a prosthesis implant is needed, the treatment process of a patient includes many sub-processes such as: the patient data acquisition, prosthesis design, manufacturing, surgery and recovery. The accuracy and completion time of these sub-processes have a strong influence on the success of the treatment process. For instance: with better quality of the prosthesis, it reduces the incidents may occur during surgery process. Post-treatment and related costs can be also reduced if the geometry of the prosthesis is completely adapted to the patient morphology. The patient will be recovered after surgery quickly in this case [1, 2] Therefore, enhancing the accuracy of all sub-processes in the patient treatment process and shortening the development time of the prosthesis are emergency problems that can find new solutions by using new generation of ICT (Information and Communications Technology) systems.

There are many factors influencing accuracy and completion time of the patient treatment process. Some of them can be mentioned such as: the collaboration, information sharing, and data integration between all actors, sub-processes during the patient treatment process. For example, during the cycle of the prosthesis, the surgeons always want to monitor, check information, data of prosthesis and patient. Based on the data acquired, he can effect, adjust the prosthesis design process or modify the parameters of manufacturing process. Therefore, it will contribute to reduce the production time of the prosthesis and enhance quality, shape of prosthesis matching with the patient treatment data.

However, there are no optimum methods to achieve the efficient collaboration between actors. They often use ad-hoc network, email to share the data together or even the data is archived to a CD/DVD, then supply for related sub-processes. These data sharing methods usually lead to potential errors and delays [3].

Therefore, the main issue in this research work is to propose new solutions based on PLM concept to improve the collaboration and information sharing between all actors including doctor, Radiologist, design engineer, manufacture engineer, surgeons, administration services, etc.

The main assumption is that the concepts of PLM approach can provide several advantages to this problematic. The main question is then how to adapt these concepts to deal with the specificity of the studied domain. The next section presents an overview about the concept of PLM.

III. PRODUCT LIFECYCLE MANAGEMENT (PLM)

A. Definition of Product lifecycle management

A product system’s life cycle include all stages from inception, through engineering design and manufacture, to service and disposal. It can be divided into 3 phases [4]: Beginning of Life (BOL), Middle of Life (MOL) and End of life (EOL). BOL includes [5] concept development, Product design, Prototyping& testing, process planning, supply chain planning and production. MOL includes delivery& installation and maintenance& other services to the customer. Finally EOL includes removal& disposal and recycling.

In the literature, PLM is defined as an integrated approach managing all product information, engineering processes and applications along the different phases of product lifecycle [6]. The PLM approach has the ambition to covers all product lifecycle stages.

The PLM is also defined as a systematic concept for the integrated management of all product-related information and processes through the entire lifecycle, from the initial idea to end-of-life [7]. It works in collaboration with other business softwares as SCM, ERP, CAD, CAM… (Figure 1) [8].

Using a PLM system to manage product data, it helps the company to: develop more new products, shorten time to market, reduce risks, reduce costs, drive innovation, accelerate revenue growth, increase productivity and improve the quality of products and procedures. [9]

Figure 1. PLM AND BUSINESS APPROACH

B. Some PLM applications in industry and in medical sector

In general, PLM is used in all sizes of companies, ranging from large corporations to small and medium enterprises. It is applied across a wide range of industrial sectors such as in automotive and aerospace industry, as well as in research, education, medical, military and other governmental organizations.

However, PLM technology is primarily used in automotive and aerospace industry, because the products of these areas have long lifecycles, high complexity and nearly no possibility of physical prototyping.

Several applications of PLM approach can be found in the literature. For example,[10, 11]presented the modelling framework to support a new PLM approach to improve information sharing in collaborative design at the conceptual level. The data model is applied for a case study in aeronautic industry. In another case, Tang and Qian [12] proposed a PLM framework to connect Automotive OEM and supplier in collaboration. He presented an automotive case study to illustrate the PLM implementation (Nanjing-Fiat, an automotive company, Products are designed in Italy while the manufacture and assembly are performed in China).

About applying PLM in SMEs (Small and medium-sized enterprises), [13, 14]pointed out some difficulties to apply PLM and proposed a meta-model that can be applied for the SMEs that have the same product data problematic. The main function of the general data model: externally, to facilitate the information integration and exchange between different enterprises with different modeling frameworks; internally, to realize the information integration and exchange between PLM and other information systems such as CAD, ERP.

Besides the automotive and aerospace industry, PLM has now been widely adopted by the whole manufacturing industry world, including pharmaceutical domain. Nevertheless, it has not widely set up in medical sector except for prosthesis design, manufacture and healthcare companies[15]

One of the rare application is the proposition of Allanic et al [15, 16] who constructed a Meta model for PLM in bio-medical imaging (BMI). Authors used the workflow module to manage the processing of BMI data between phases in lifecycle. Workflow is also used to launch the data check processes, data calculation and follow how data has been computed. Author proposed a BMI data model, it can store and manage all BMI data from specification study phase to published result phase. This data model has been implemented to PLM software tool to verify the results.

IV. TOWARDS A PLM APPROACH

The main issue in this research work is to improve the collaboration and information sharing between all actors including Radiologist, design engineer, manufacture engineer, surgeons…

PLM has proven its large capabilities to deal with such kind of problematic. The implementation of any PLM approach requires a crucial step of business process analysis and roles identification in order to identify the main data to be connected and workflows to be automatized. The next sub section proposes a global description of the patient treatment process in case of prosthesis implant.

A. The patient treatment process

The patient treatment process requiring the prosthesis implant is a complex process that includes many sub-processes with different actors [17]. It can be summarized as follows:

After interviewing and conducting some initial checking on the patient, the radiologist will scan the patient using 3D computed tomography (CT) or Magnetic resonance imaging (MRI) [18, 19]. The scanning data is stored and send to medical doctor who will diagnose and make the treatment plan. After that, the scanning data is exported in DICOM format in order to be suitable with the input of MIMICS software which converts the scanning data into the highest possible quality STL data files. Then, the STL files are imported into the CAD software [20, 21]. At this stage, surgery plan will be simulated by using the software tools. Until all specifications are satisfied, the design engineer will begin to design prosthesis.

The final design model will be then exported to the high quality STL file for prosthesis manufacturing process. Depend on kind of prosthesis, it can be manufactured by different technologies (3D printing, CNC…). Before going into surgery, the prosthesis must be approved by medical doctors and surgeons [18]. Then surgical process will be carried out on the patient. The final process is rehabilitation and recovery.

B. PLM Hub

During the treatment process, in order to perform a sub-process, it is necessary to refer and collect the information, data from other sub-processes. In other words, there is always an exchange and sharing of data between the sub-processes together. It plays an important role in not only enhancing the accuracy, quality but also shorten completion time of whole process. Therefore, the collaboration and data sharing during the patient treatment process must be interested.

Through the collaboration and data sharing, the surgeons can monitor the progress of the design process as well as manufacturing prosthesis. Moreover, from the data collected, he can comments and adjust these processes as suitable as possible. Consequence, this improves the quality prosthesis and shortens time of the whole process.

However, nowadays the data is often archived to a CD/DVD, then supply for related actors. Or shared based on the Internet (ad hoc network, Email), but it usually occurs potential errors and delays [3]:

- Potential errors: The data size is normally very large (up to 300 MB). Therefore, using ad-hoc network or email can cause the corrupted or incomplete data.
- Delays: The actors in one sub-process want to receive the data from another sub-process. They must send a request and wait for accepting from another actor. The data then is sent based on 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, lengthening the completion time of the whole process.

From the problems above, in this research, the paper proposes PLM approach to enhance efficiency of collaboration and information sharing between sub-processes in the patient treatment process.

Following the treatment process described in the previous section, all actors, patient treatment data, and prosthesis data will be connected through PLM hub like it is shown in Figure 2.

This figure illustrates the need to connect heterogeneous tools that are used in different business sectors. This implies a complex interoperability to be resolved as a part of this research work.

C. Need of lifecycles integration

After the prosthesis is implanted on the patient, there are 3 possible cases that may occur as follows:

- Case 1: The patient adapt well to the new prosthesis. Prosthesis will exist forever along the rest of the patient's lifetime.
- Case 2: This case concerns the temporary implants used by the doctors to fix some problems. In this work the implants are considered as particular kind of temporary prosthesis. After recovery, the surgeons will perform another surgery to remove the prosthesis. Prosthesis will be then recycled at its last life stage.
- Case 3: During the recovery process, some problems may occur such as: Patient has an accident in daily life; prosthesis is unsuitable with the patient's physical condition, defective design or even in case the prosthesis is replaced according to the predefined calendar. At this

case, the patient will be cured again with a new prosthesis.

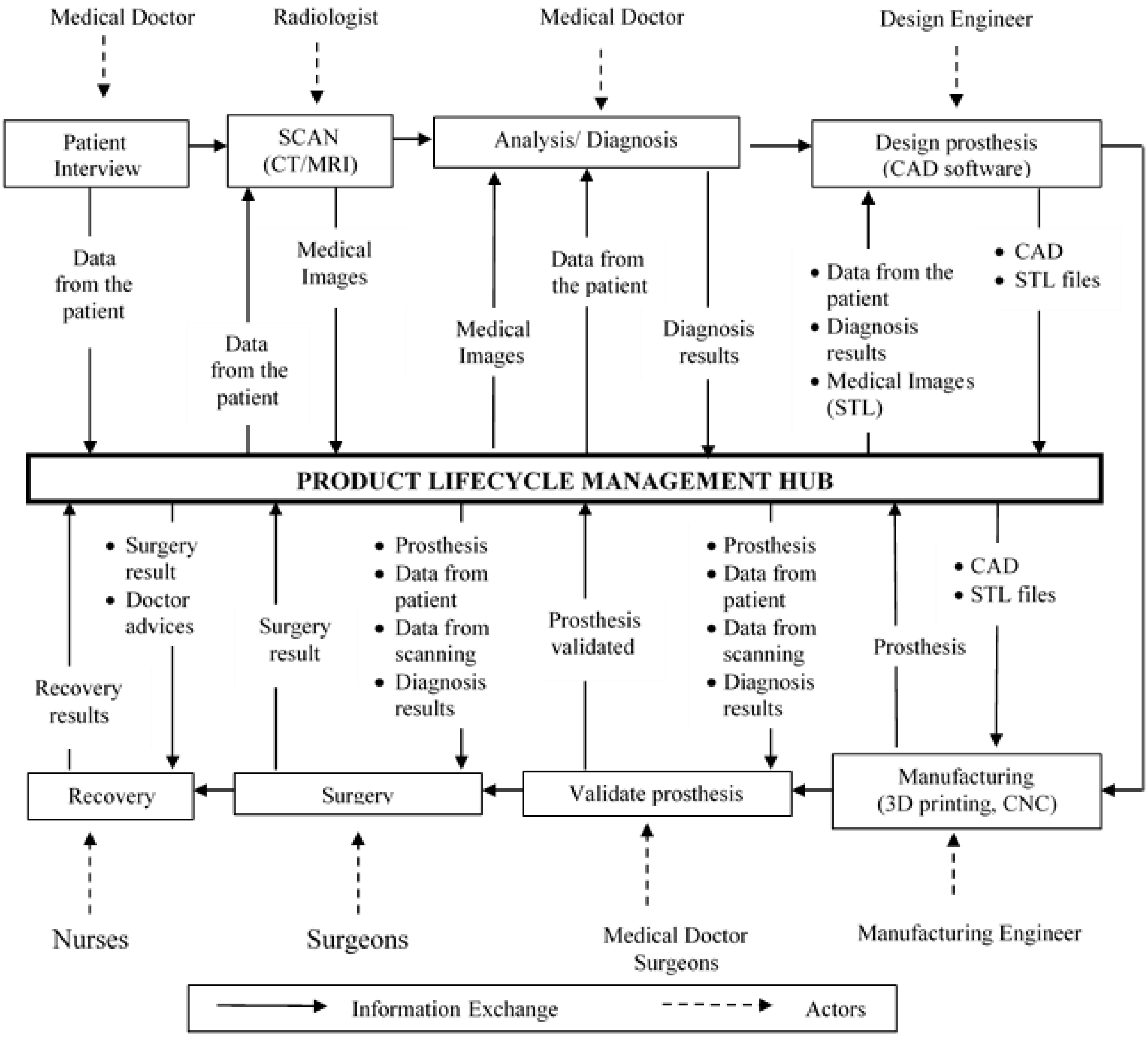

Figure 2. CONNECT THE ACTORS, PATIENT TREATMENT DATA AND PROSTHESIS DATA THROUGH PLM

With 3 cases above, the patient treatment process will only repeat corresponding to case 3. In this case, there are two lifecycles that exist in parallel: The patient disease treatment lifecycle and the prosthesis lifecycle.

This research intends to propose a management solution of the prosthesis integrated to the patient disease treatment lifecycle through the identification of different links between these two lifecycle (Figure 3). One of the main challenges for the definition of the PLM approach is then to analysis all these links in terms of data, tools, processes and actors.

After recovery stage, it has two possibilities (Figure 3):

- Prosthesis is unsuitable with the patient. Therefore, prosthesis is extracted from the patient. Then, they will be cured with all stages like the previous loop. New prosthesis is redesigned and manufactured more suitable. It will be implanted on the patient again.
- The patient needs a new prosthesis to cure the new health problem (maybe: they have an accident or other problems). So, the new treatment process will continue the same as old loop.

Figure 3 describes the linking of processes between the patient disease treatment lifecycle and the prosthesis lifecycle. The data acquisition process is affected by three other processes in the patient disease treatment lifecycle (Patient interview, CT/MRI Scan and Diagnosis). On the other hand, design and manufacturing process influence prosthesis implantation process.

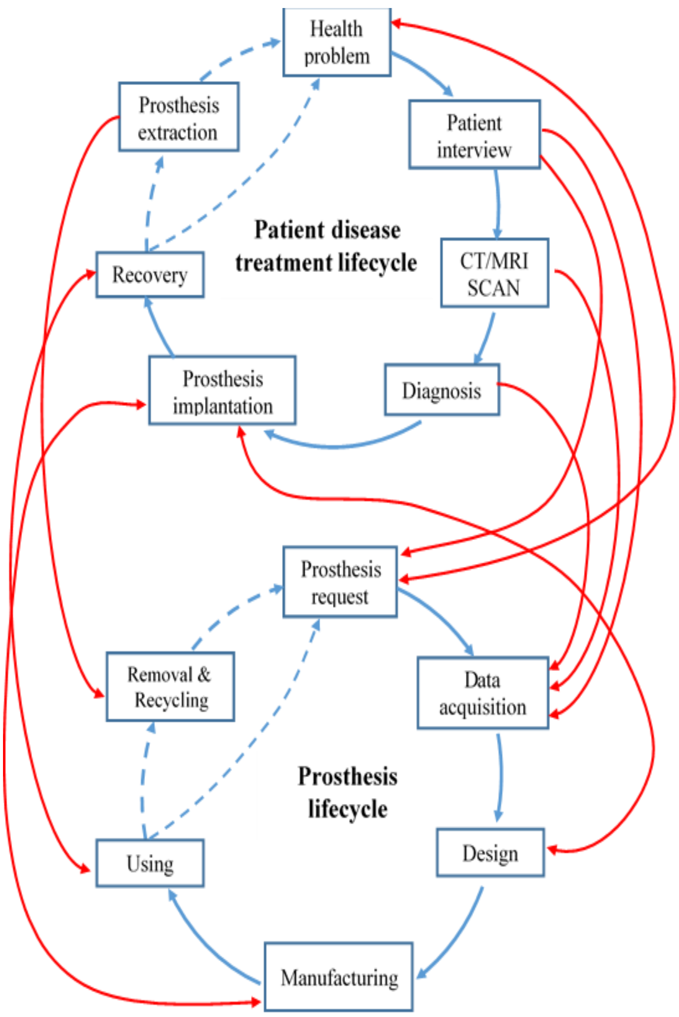

Figure 3. LINKING BETWEEN THE PATIENT DISEASE TREATMENT LIFECYCLE AND THE PROSTHESIS LIFECYCLE

The data linking of "Using, removal & recycling, recovery, prosthesis extraction process" influence and interact with each other. At these processes, the doctors will monitor compatibility of the prosthesis and the patient based on their data. From these results, doctors will propose next suitable treatment directions for the patient.

The PLM approach will propose a common repository associated to several collaborative functionalities like notification, light model viewing, automatic update of connected information, etc. This figure illustrates the need to connect different business processes and heterogeneous tools that are used in different business sectors. This implies a complex interoperability to be resolved as a part of this research work.

This research presents the global approach described at conceptual level. It proposes a management solution of the prosthesis lifecycle integrated to the patient disease treatment lifecycle through the identification of different links between these two lifecycles (Figure 3). These links are used to guide the identification of all collaborative situations, data exchange, processes, PLM functionalities, etc.

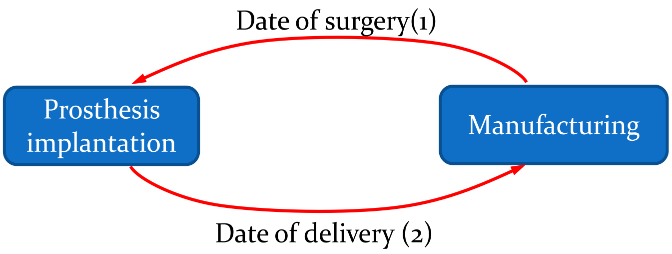

Figure 4. THE LINKS BETWEEN PROSTHESIS IMPLANTATION AND MANUFACTURING PROCESS.

Figure 4 shows an example to clarify the links between two sub-processes: prosthesis implantation and manufacturing process. Link 1 is used for the non-emergency situations. The date of surgery is decided by manufacturing process. The prosthesis order is considered by the supplier with a high priority. On the contrary, link 2 is in emergency situations, the prosthesis will be manufactured as soon as possible so that the date of delivery will be considered in the definition of the surgery date.

V. CONCLUSION

The paper pointed out a critical problem that can strongly impact on 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, receive the information and data through this HUB. It minimizes errors during the data exchange, improves the prosthesis quality and shortens 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 paper also proposes the links between the patient treatment lifecycle and the prosthesis lifecycle.

Future research work will continue to develop the initial proposition. We will analyze in detail the data exchange tools and collaboration in the treatment processes. Knowledge models will be built to describe, in an organized way all concepts and constraints that can be involved in the relationship between the actors and sub-processes.

The development of specific processes based on the meta-modeling framework is constructed to demonstrate the communication between different processes and actors.

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