STAKEHOLDERS' MANAGEMENT FOR TRULY IMMERSIVE CDIO EXPERIENCES IN BIOMEDICAL ENGINEERING

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ABSTRACT

When education is faced with a Project-Based Learning (PBL) approach, understanding and managing subjects considering project management principles help better achieving project objectives and hence improving the learning outcomes. Within the project management field, stakeholders’ management has been considered a key element for project success. It is one of the main knowledge areas identified in the standards of the Project Management Institute (PMI), within PMBOK (Project Management Book Of Knowledge). Stakeholders’ management is of great importance since it enables to improve benefits and probabilities of success of a project, by considering the impact and interest from different points of view and consequently defining an appropriate strategy. In this study, stakeholders’ management approach is presented in a course devoted to the biomedical engineering field, namely "Bioengineering Design and Medtech", included in the Master’s Degree in Industrial Engineering and in the Master’s Degree in Engineering Management, both at the ETSI Industriales from Universidad Politécnica de Madrid. Students from the course collaborate in teams and live through the complete project life cycle of innovative medical devices. For stakeholders’ management, different phases are carried out, such as stakeholders’ identification, engagement planning, engagement managing, and monitoring. In this course, oriented to the biomedical field, participation and management of hospitals, patients, students, professors, innovation units, open innovation initiatives, potential users, associations, and health professionals, among others, are presented. Main results, difficulties, benefits, and conclusions of the experience are included in this work. The experience and its systematic assessment shows that students, feeling part of a whole system, by interacting with all key stakeholders, demonstrate higher commitment to achieve learning objectives and live through more realistic, complex, and transformative PBL-CDIO learning experiences. As a result, they become more professional engineers, which is one of the CDIO implementation benefits.

KEYWORDS

CDIO as Context, Project Based Learning, Project Management, Stakeholders’ Management, Biomedical Engineering, Standards 2,3,4,7, 8
INTRODUCTION

In this study, a Project-Based Learning (PBL) approach following CDIO principles is applied to allow students to learn necessary Project Management (PM) and Biomedical Engineering competences. Students in this experience belong to two courses devoted to the biomedical engineering field, namely "Bioengineering Design" and "MedTech," included in the Master's Degree in Industrial Engineering and the Master's Degree in Engineering Management.

From the beginning of the courses, students are provided with specific knowledge, tools, and exercises to improve their capabilities for building strong teams and achieving their biomedical project goals. In this case, supported by the integration of the Stakeholders Management approach with a defined strategy, it has been possible to provide an effective learning experience for improving students’ skills.

The learning approach, results, difficulties, lessons learned, and conclusions of this experience during the 2019-2020 course are presented in this paper.

LITERATURE REVIEW

Project-Based learning approach

Project-Based Learning (PBL) is a model in which learning opportunities are organized around projects. Projects are complex tasks that are based on challenging questions or subjects that involve the students in design, problem-solving, decision making, or investigative activities. In regard to students and Higher Education (HE), dealing with projects gives the former an opportunity to work relatively autonomously over extended periods. This culminates in the creation of realistic products or presentations (Thomas, 1999; Turner et al., 2002; van Rooij, 2009). In PBL, the project is the central teaching strategy. Students encounter and learn the fundamental concepts of the discipline by means of the project.

Some studies have shown that students retain minimal information in the traditional, didactic, teaching environment and frequently have trouble in transferring the acquired knowledge to new experiences (Schmidt, 1983). In contrast, PBL has proved to be an excellent method for developing new forms of competencies (Graaff and Kolmos, 2003; Kolmos and Kofoed, 2002). A PBL environment enables students to draw upon their prior knowledge and skills, brings a real-world context to the classroom, and reinforces the knowledge that they acquired by both independent and cooperative group work (Schmidt, 1993). To be considered an example of PBL a project should have centrality, a driving question, constructive investigation, autonomy, and realism (Thomas and Mergendoller, 2000). Projects should have characteristics that provide a feeling of authenticity to students. These characteristics can involve the topic, tasks, the roles that students play, context within which the work of the project is carried out, collaborators who work with students on the project, products that are produced, an audience for the project's products- or criteria by which the performance or products are judged.

Earlier studies suggested that project management skills are core to the leadership attributes of engineers (Hamilton, 2006; Wearne, 2004). Some interrelated research streams are available for an understanding of the challenges in teaching and learning both engineering (Zhou, 2012) and project management education (Ashleigh et al., 2012; Louw and Rwelamila, 2012). Students’ experiences have remained a major theme of interest to scholars, especially in the engineering and project management areas (Dietrich and Urban, 1998; Heer et al., 2003).
Stakeholders' Management

The importance that is attributed to the strategic role of project management in organizations has led in recent decades to the growing development of frameworks of international competencies and professional standards. Within normative project management literature (PMI, 2017), stakeholders management is proposed as a knowledge area to support project success.

Freeman (1984) defines stakeholders as "any group or individual who can affect or is affected by the achievement of the organization's objectives." Since then, the stakeholder concept has become a salient part of project management (Eskerod and Vaagaasar, 2014; Cleland, 1985; Crawford, 2005; Aaltonen, 2010). The main idea of project stakeholder management is that the project team can increase the possibility of project success by influencing stakeholders to define an appropriate strategy (PMI, 2017).

Savage et al. (1991) recommend that the project management team should be in charge of identifying and diagnosing the stakeholders in order to build a specific strategy for interacting with all of them (Eskerod and Vaagaasar, 2014). In line with Freeman (1984), it is suggested that the analysis should be based on each stakeholder's potential to cooperate with the organization and the stakeholder's potential to threaten the organization on a particular issue. This approach defines four different types of stakeholders' strategies: Supportive, Mixed Blessing, Nonsupportive, and Marginal (Table 1).

Table 1. Project stakeholder type framework. Source: Eskerod and Vaagaasar (2014).

<table>
<thead>
<tr>
<th>Stakeholders' potential for cooperation with the projects (help potential)</th>
<th>Stakeholders' potential for threatening the project (harm potential)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>High</td>
<td>Mixed Blessing strategy: Collaborate</td>
</tr>
<tr>
<td>Low</td>
<td>Nonsupportive strategy: Defend</td>
</tr>
</tbody>
</table>

Stakeholders' management is especially relevant in biomedical engineering since there is a wide variety of actors implied in decisions and technology development, considering the interconnected nature of the health field.

DESIGN OF THE LEARNING EXPERIENCE

Description of the course

Industriales Ingenia is a compulsory subject (12 ECTS) of the Master's Degree in Industrial Engineering and the Master's Degree in Engineering Management. There are 12 Industriales Ingenia different initiatives designed to cover most of the profiles of the Master's Degree in Industrial Engineering composed of approximately 300 students. 31 of these students selected "Bioengineering Design," which is the most demanding option. The students of the Master's Degree in Engineering Management are 41, and they could choose between three different tracks for studying Industriales Ingenia. "MedTech" was the first option for 13 of them, who
were all accepted. Therefore, a total number of 44 students are participating in these two subjects, working together in seven teams. These teams were formed with an average of 4-5 people from "Bioengineering Design" (technical profile) and two persons from "MedTech" (business and management profile). Although one project manager was required at the beginning of the course for every team, all the teams decided to work with a shared leadership for managing the project, giving an opportunity to a horizontal approach. Table 2 shows the characteristics of engineering students and their projects.

Table 2. Teams and projects participating in the experience.

<table>
<thead>
<tr>
<th>Team members</th>
<th>Logo and Name</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 MT* + 4 BD*</td>
<td>Ingesapiens</td>
<td>Crutches with support meter</td>
</tr>
<tr>
<td>1 MT + 5 BD</td>
<td>Health Solutions</td>
<td>Radiology collaboration with a Hospital</td>
</tr>
<tr>
<td>2 MT + 5 BD</td>
<td>MedBeetle</td>
<td>Sock muscle treatment</td>
</tr>
<tr>
<td>2 MT + 5 BD</td>
<td>Sejmet</td>
<td>Device for Herniated Disc</td>
</tr>
<tr>
<td>2 MT + 4 BD</td>
<td>Hybmed</td>
<td>Redesigned Speculum</td>
</tr>
<tr>
<td>2 MT + 5 BD</td>
<td>L.I.F.E.</td>
<td>Arthrocentesis Device</td>
</tr>
<tr>
<td>2 MT + 4 BD</td>
<td>Dr. Gear</td>
<td>Multi-compartment refrigerator</td>
</tr>
</tbody>
</table>

*M = MedTech; BD = Bioengineering Design

Lecture sessions, together with some specific conferences led by professionals of the Bioengineering arena, allow the teams to improve their capabilities and achieve their project goals. Furthermore, for three sessions, the teams were divided to deal in depth with prototype design, on the one hand, and into the marketing and entrepreneurship on the other hand. The rest of the sessions were shared and dealt with teamwork, project management, and sustainability. Based on the PM style, some deliverables are required for the teams along the course. PBL methodology and techniques used for reinforcing the PM and Bioengineering skills are the following:

- **Teamwork and team development:** Multidisciplinary teams, Team agreements, Personality assessment, Interviews, Organization charts, Competency assessment, Teambuilding activities.
- **Deliverables:** A set of deliverables is scheduled with deadlines. Some examples are CAD designs, Simulations, Prototyping, Usability, Business Plan, Team performance, Project Management Plan.
• **Oral presentations:** An interim presentation for assessing the progress and a final presentation is scheduled. They include technical, management, business, and sustainable aspects.

• **Complementary workshops:** Arduino-Matlab, Simulations, Sustainability, Biomechanics, Electronic design, Biomaterials, Leadership and communication skills, Entrepreneurship.

**Description of stakeholders’ management overall strategy**

Professors, along with students, identified stakeholders regarding the projects proposed. Identification of stakeholders helps to define an appropriate strategy as well as gather useful information for ideas generations concerning bioengineering devices and business modeling.

Being aware of this, during the course, students and professors integrated different activities to manage stakeholders for the projects. Main activities and description are shown in Table 3:

<table>
<thead>
<tr>
<th>Stakeholders management activities</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholders’ identification</td>
<td>Identification and diagnosis of stakeholders in order to build a specific strategy for interacting with all of them. Main stakeholders identified were: Universities Students; Hospitals; Patients; Innovation units; Open innovation initiatives; Potential users; Entrepreneurs; Spanish Agency of Medicines and Health Products; Business schools</td>
</tr>
<tr>
<td>Meetings</td>
<td>Several meetings were developed with stakeholders (practitioners, hospitals, clients, doctors, regulators, etc.); and Professors (by means of Mentoring activities). As an example, two professors went with one team to one of the principal hospitals in Madrid, in the radiology area to coordinate the activities of students and health professionals.</td>
</tr>
<tr>
<td>Interviews with professionals</td>
<td>Project teams were responsible for interviewing professionals from the field, depending on the medical device they were in charge of. Special emphasis was put on potential users, hospitals, and patients since they are relevant stakeholders in these projects.</td>
</tr>
<tr>
<td>Surveys</td>
<td>Some project teams considered the opportunity to develop a survey for different health professionals and potential users to better get the main requirements for medical devices design and business plan.</td>
</tr>
<tr>
<td>Round tables</td>
<td>Professors organized round tables with practitioners, university professors, hospitals, clients, doctors, regulators, students, entrepreneurs, etc. These sessions served to share different perspectives and allow project teams to understand principles and truly practice of biomedical engineering, open innovation initiatives, and business strategy.</td>
</tr>
<tr>
<td>Multiplier events</td>
<td>At the end of the course, several presentations were organized showing results with stakeholders and students from other PBL experiences in the school.</td>
</tr>
</tbody>
</table>
RESULTS AND LESSONS LEARNED DURING THE PROJECT

Some conceptual designs proposed by the students are shown in Figure 1. The first lesson learned is to afford the students to choose their project and to invite them to manage stakeholders from the beginning. It allows students to become more involved in their designs, results, understanding of the field, and definition of realistic objectives. In addition, it allowed them to choose a project that responds to a close need, often lived by a stakeholder. Then, the ability to obtain first-hand information also increases, and it is easier to align their entrepreneurship strategies with the stakeholders' needs. The skills related to the business and project management are developed at the same time as the technical skills, which remain essential for current and future engineers.

![Arthrocentesis Device](image1)

![Device for Herniated Disc](image2)

![Redesigned Speculum](image3)

Figure 1. Examples of conceptual design proposals from different projects.
- a) Arthrocentesis Device.
- b) Device for Herniated Disc.
- c) Redesigned Speculum.

The second learning is that working with this methodology allows the students to manage their time better and to share the tasks properly. With project and stakeholder management activities, students are really committed to the subject and motivated to achieve the objectives as a team. Professional competencies of engineers are implemented for the first time for most of the students. It brings them a little closer to the future work that awaits them once they finish their masters.

The third lesson learned is that when an appropriate follow-up of stakeholders' management is done, the project trend is to advance itself progressively, without needing to pressure students. Probably, it is due to the natural way of working in a project that requires not only a team and a set of deliverables with deadlines but also the commitment to respond to stakeholders' needs. In the beginning, students were not much comfortable with the idea of interacting with different stakeholders, but during the course, they demonstrated an improvement in this area, becoming more confident and feeling professionals when doing it.
**Personal competencies strengthening**

For personal competencies strengthening, an interpersonal competencies questionnaire was implemented by the students during the learning experience. This helps to identify specific difficulties of students and focus on them in order to be improved. The main feedback received by students (n=41) during the course is shown in Table 4.

<table>
<thead>
<tr>
<th>Improvements areas</th>
<th>Strengths</th>
</tr>
</thead>
</table>
| Students have general difficulties for time management, emotional management, and conflict management. Main specific improvements areas detected by students were:  
  - Stress management and patience  
  - Delegation  
  - Active listening  
  - Shyness  
  - Ambition  
  - Empathy  
  - Communication  
  - Flexibility  
  - Organization  
  - Proactivity  
  - Self-confidence | On the other hand, they generally feel they were very good at showing professionalism and commitment to the projects and the subject. Main specific strengths detected by them were:  
  - Working capacity  
  - Results orientation  
  - Generosity  
  - Team working  
  - Respecting others  
  - Loyalty  
  - Perseverance  
  - Innovation  
  - Analytical thinking  
  - Problem-solving  
  - Responsibility |

As an additional challenge during the second half of the course, students had the need to boost team working and collaborative engineering due to the COVID-19 scenario. They really made a rapid transition from normal classes to online working conditions by having more frequent meetings through MS Teams and with the support of the UBORA platform.

At the end of the course, students will give their feedback again to analyze differences and, therefore, the impact of this approach on students' performance, allowing identifying as well actions for the next courses.

**CONCLUSIONS**

The learning experience following the PBL approach and CDIO principles is showing to be effective for future engineers and professionals. In this case, when applying principles of project management, and specifically stakeholders' management function, project teams become committed, feeling professionals and being part of something bigger. Stakeholders' participation in this experience allows a better understanding of market needs, restrictions, and project threats. Project success is very linked to how the team manages stakeholders. Sometimes, as engineers, we tend to focus mainly on technical and design aspects of biomedical devices, which is essential, but not enough.
PBL and CDIO have demonstrated how to support students in competences strengthening and learning by doing. Now, the focus should be to identify good practices in order to become excellent in CDIO implementation.

The main difficulties that raised during the experience were in the first place the effort needed by professors to be well-coordinated, taking into account the participation of several stakeholders and the combination of two different master students in one project. As well, some difficulties have to do with the limitation in time and experience of the students, since they have several subjects with additional work and different agendas that make it difficult for them to work always together as a team.

Some limitations of this study have to do with competencies quantitative assessment since the course has not finished yet, and it was not possible to assess differences at two different moments (at the beginning and the end of the course). As well, the pandemic scenario (COVID-19) at the end of the course had an impact on prototyping and team working.

A new way of teaching future engineers is spreading in our university. If we focus on maintaining the spirit of CDIO initiative as well as continuous improvement of its implementation, we think we could be an example and a reference in our engineering school, leading the change of learning approaches for more subjects in several degrees.

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