Article

Design process for a birthing bed, based in user hierarchy: Promoting improvement in user satisfaction

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Abstract: Medical Device Design process carries a high responsibility when defining the characteristics of the object for its correct interaction with users. This study presents a proposal for the improvement of the medical device design processes, in order to increase user acceptance, considering two key factors: the hierarchy of users and the relationship with the patient's health status. The goal of the study seeks to address this research gap and raise design factors with practical suggestions for the design of new medical devices. The results obtained will help medical device designers in the development stage to make more informed decisions about the functions and features required in the final product; As well, in the design process didactics, demonstrating the importance of the correct execution of the process, and how the factors considered can generate an impact on the final product. An experiment was carried out with Forty design engineering students, who designed birthing beds, with two design processes, the traditional product design process, and the new design process based on hierarchies (proposed in this study). The results showed that there is a significant increase in user acceptance with the new birthing bed that was developed with the hierarchical based design process.

Keywords: Design; birthing-bed; user-centered-design; medical-device-design; user-hierarchies; design-process; design-education; hierarchies.

1. Introduction

User-Centered Design in health care has been applicate in different studies, however research has had limitations: firstly, few articles focus on future design guidelines and methods in relation to improvement of the patient experience, as well as the specific needs of patients within hospitals [1]. Best practices in the medical device industry seek increasingly informed innovation process developments, with the understanding of all stakeholders, seek to maximize effectiveness and reduce patient risk and cost of execution to provide comprehensive solutions that work for the health area and the business [2]. Companies must be rigorous in their search for innovation, seeking the ultimate goal of developing new products in a more effective, efficient and profitable way [3]. As well as systematic approaches are necessary for product development, as they guarantee safe and effective devices for users, economic successes for manufacturers, and reliable and profitable investment for consumers [4].

The correct care of patients is based on the medical devices available, currently, clinical professionals have to adapt to the functionality of the devices to avoid errors and risks in patients. The reports of errors in medical devices have generated an emphasis on the

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implementation of user centered design processes [5]. Research in the US and UK suggests that many usage errors are due to poor device design [6], which is not suited to user needs. Unfortunately, many investigations into medical errors are superficial, as they do not report the error in depth. usually the fault lies with the user of the device. there is a link between poor device design and what was traditionally classified as user error. The FDA and the courts of law recognize the importance of poor device design in contributing to such "misuse". To reduce errors, designers must follow a human factors engineering approach to understand user needs throughout the design process [6].

1.1 Design Process

Design is the human power to conceive, plan and realize all the products that serve human begins in the achievement of their individual or collective purposes [7]. The design of medical devices begins with a brief, a problem to be solved. For a new device to hit the market and reach the clinical setting, certain procedures such as verification / validation must be carried out. In addition, the integration of human factors in the design process, to reduce risk and improve patient safety. Design control is a fundamental requirement to comply with regulatory approval of international standards, as it ensures that any decision made during the process is verifiable, in order to improve the ability of designers and auditors to determine safety and efficacy of a product, the frame of this model complies with the United States (US) federal regulation 820.30 for design control [8].

Traditional design processes focus on prioritizing evaluation criteria and shaping use-value. They may not address all of the interaction between systems such as: users, context, and meet general design expectations. [9]**.** Traditional design approaches have been accused of failing to involve users in the design process, compromising business opportunity and user experience and interaction. Eilkinson and De Angelli, explain that the importance of considering users as individuals with their individual needs, capabilities and desires throughout the design process increases user acceptance [10].

In a typical design process, the designers must consider the complexity of the context and the users, just as they must balance the conflicting needs of end users with business approaches that influence the entire design process. However, in the case of medical device design, this problem is further complicated, detailed investigation of user needs and end-use environments remain difficult for development, it is often unclear how the design process can be improved, and it is unclear how improvements in these domains could affect the usability of the final product itself, or how end users might or might not accept the product. These challenges require further study of medical device design [11]. In the past, there were two directions to approach the development of product concepts: the marketing perspective and the engineering perspective, marketers focused on product attractiveness, engineer's perspective is on appropriate product features. Methods and approaches, that support product development teams early in the process include: the Kano model or joint analysis, the perspectives of engineers and salespeople complementing each other, considering both perspectives. These methods have in common that their objective is to identify the current or obvious desires and needs of the clients [12].

Some authors have considered hierarchical analysis in their design process, such is the case of Hierarchy of Needs according to Ulrich and Eppinger: The concept development process involves, a distinction between customer needs, and product specifications; this distinction is subtle but important. According to this, the authors propose 5 steps to identify the needs of the clients, among which are: Collect, interpret, organize the needs in a hierarchy of primary, secondary and tertiary if necessary, reflect it in the result. It

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thus defines that the primary needs are the most general, while the secondary and tertiary needs express more detail. The procedure for organizing the hierarchy is intuitive, survey-based, and for practicality limited to only a small group of needs that result in difficult or costly technical trade-offs in product design [13].

Therefore, Hierarchical Task Analysis (HTA) is a central ergonomic approach, it is based on a performance theory, it is a way of representing a hierarchy of sub goals of the system for an extensive analysis [14]. Hierarchical Task Analysis (HTA) is one of the most widely used methods [15]. In this study, the tasks are ranked under the criterion of health status and care needs, basing the hierarchies on user needs and user types.

There are several models of design processes. Models are continually changing, yet the foundation of the design process is constant. There are two well know models: Those proposed by Pahl and Beitz and the one developed by Stuart Pugh. Both are configured around engineering design, as they are medical devices. Both posit that medical devices are products that at the end of the day have to be manufactured because they are needed, and they have a more technical vision. Pahl and Beitz model, allows the designer to become fully aware of the need and the environment in which he/she operates, it also gives the designer time to discuss with the end users, before the conceptual design phase. Model by Pugh: Total design model, fundamentally assumes, that the process begins at one end and progresses in a straight line to the final result; Pugh incorporated manufacturing into the design process. While these models are important, they focus on visualizing the process but not the activities [16].

Designers since 1990 have explored design thinking and practice. The pioneers were the IDEO design studio at the Stanford University School of Design; tried to map the process in different ways: rounds, cycles, double diamond, etc., however there are two fundamental values or principles that they cannot avoid: Design thinking must be human centred, beginning with the needs and the creative stage [17].

The design process was initially described as a problem-solving activity [18]. This instance is typical of the first generation of the design methods movement. The idea of human needs and the subdivision of the process were the natural way to approach a design problem, as described in figure 1.

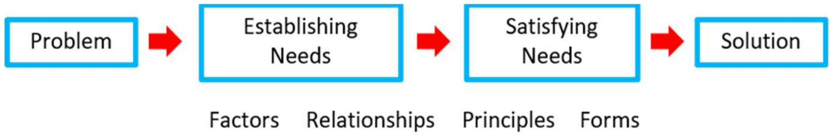

Figure 1. Design as a process to solve human needs [18].

Today, the traditional design scheme is implemented in product design [19]. This method is a linear process that consists of researching the design requirements, defining concepts, developing the design product itself, manufacturing it, and launching it on the market as we show in figure 2. However, such scheme has notable shortcomings: The lack of definition at prototypes based on adaptation in requirements and needs of its end user, and lack for an evaluating stage of the usability of the product itself.

Figure 2. Design as a linear process [20].

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For Rodríguez Morales [20]. The traditional design process, also understood as the form-oriented design, has its main objective to make functional objects mass-produced and base its indicators mainly on quantitative data.
On the other hand, the user-centered design process presents an alternative path where, beyond defining design requirements, designers seek to understand and explain the actual users of the products to be designed and their needs and context of use. Once these variables are established, user testing allows the design to be redefined based on the end-user requirements and prototypes before manufacturing, as shown in Figure 3.

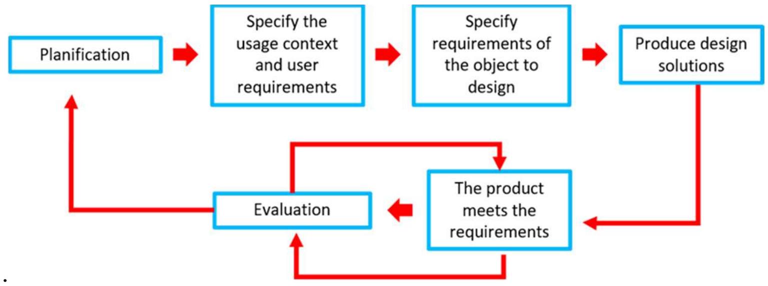

Figure 3. The user-centered design process [21].

The user-centered design focuses on generating practical and attractive proposals for its users and creating aesthetically pleasing and functional objects. Its main objective is to provide a correct user experience, basing its indicators on quantitative data and in-depth ethnographic studies of the profiles of users, who interact with the product under development, and the understanding of the requirements that may need.

Based on the above, we can conclude that user centered design seeks to generate products that improve users' quality of life, by exploring their ethnographic diversity. Thus, the user-centered process aims, to create innovation, and tends towards smaller consumption niches [22]. This way of implementing the design, provides humanistic aspects, commercial objectives, and a renewed vision to the execution processes from the designers.

Traditional design processes mostly address the typification of users in three groups, as Eason (1987) identifies three categories of users; Primary those who frequently use the system, Secondary: those who occasionally use the system, Tertiary: all those affected by the introduction of the system or influencing your purchase. Identifying all users allows designers to make reasonable decisions about their degree of involvement in a project to be successful. However, he/she does not specify that the hierarchies of the three groups can constantly change during the product's end-use, as it happens with a medical device [23].

According to the Federal Drugs Administration, there is a definition of the design standards for medical devices. The current design process combines engineering disciplines, government regulatory agencies (national and international), independent certification, and compliance companies. The objective of the techniques is to ensure that a new product meets user expectations, is safe and effective in providing its stated benefits [24].

A study by Bikina O. et al. in 2020 Kwangwoon University in Seoul Korea, analyzed 88 scientific sources related to the usability and UX of medical device design were analyzed. The studies examined the concept of medical device usability from three points of view: patients, physicians / medical staff, and caregivers. The main documents were up

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to international standards. The authors presented the main UX analysis methodologies. One of the three main future challenges for human factors in medicine are user-product interaction, the technology and medical device design process, and aspects of clinical research. They concluded in the first place that, usability can be considered as a subset of UX. Second, the assessments can be applied differently for medical devices and consumer goods. Third, usability can be evaluated differently, depending on the type of product. Fourth, there is a distinctive difference in the evaluation of the usability of medical devices compared to the case of consumer goods [25].

A study by Maguire at the Research Institute in Loughborough University 2001, analyzed the importance of human-centered design systems and processes as a way to achieve them. Adopting the framework of ISO 13407, each process is considered together with a set of usability methods to support it. Usability is now widely recognized as critical to the success of an interactive system or product [26]. An analysis of the literature has shown that the main benefits of user participation, in the design and engineering of a medical device technology, include relevant information about the user's perspectives, and with this: the design of the user interface, the functionality, therefore usability and quality of medical devices improves [19]. The application of human factors, standards, and the practice of user centered design, remains a priority in the industry for the development of medical devices to be safe, effective and usable. Despite the challenges, the industry respects the rules, and values user recommendations [8].

Participatory design aims to develop products with the participation of end users, in order to capture information, and user feedback at each stage of the design and development process, these participatory design approaches try to better understand real users. designing easy to use products is essential [10]. Studies have shown that user research can be done in a rigorous way, this type of research is necessary if we are to demonstrate the benefits of adopting user-centered principles for medical device developers. When developing any new medical device, the user's requirements must be correctly specified. This will increase the likelihood of producing a device that is also easy and satisfying to use. These processes are a risk from a business point of view, as developing a new medical device is expensive. Therefore, it is essential that the correct device is developed, a device that is safe and meets the needs of users [27].

The application of human factors (HF) to the design of medical devices is indispensable for the development of new products The publication of ISO 62366: 2008 Medical devices: Application of usability engineering to medical devices (ISO 62366: 2008) details how the developers must formally address usability. Any medical device that is marketed must be safe (ISO 14971: 2007) and developers must demonstrate evidence of the device's clinical efficacy [28].Currently, there are different design methodologies and processes that highlight the value of users' knowledge, and indicate the importance of involving them during the design process of a new product; for example, user centered design process (UX council), Design Thinking (Ideo), Medical device design process (FDA), Double diamond design process (Design Council) User interaction design process (interaction design foundation) among others [29].

In the article "hospital bed designs "by N. Wiggermann et al., they mentioned user centered design processes. However, their design process does not consider or make mention of users hierarchy, and the fluctuation of the patient health status [30], which could be important to make design decisions during the development, ignoring them, could lead to errors of use, and reduce users' acceptance.

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Users of medical devices must be defined and classified effectively, a study by Ghulam S, et al. In 2008, review 556 articles, and the results showed that, in 29 studies the involvement of different users types was part of the process for developing medical devices. They found, that health users are not the only users, also the user's definition and classification was unclear. They concluded that medical device users are heterogeneous, and are composed of different classes, groups and types, they have different needs and requirements. Without acknowledging this problem, the development of medical devices will be less effective [31]. An example shows it's figure 4. this figure represents how many users could be in a new born procedure, therefore the different type of users that could be present in this procedure are not represented.

Figure 4. Example of different possible users, who could be in a new born process.

The lack of knowledge about the focus on users in the design processes and the strict regulations for the design of medical devices, have overshadowed the importance of implementing ergonomic factors during the design process [19], such is the case of birthing bed´s that, although they are the product of a professional design process, lacks factors that should be thoroughly investigated during its development. One of these factors, is the importance of hierarchies of users, whose interaction with the object will be influenced by the patient's health status fluctuation [35].

An experimental study was carried out in the design of a new birthing bed, to evaluate the results of each process, and to seek a final comparison, of the design proposals, and determine whether the design process based on hierarchies increased or not the satisfaction of the final Users. At this project, we consider a Class 1 medical product, which does not represent a potential risk of disease or injury, which had a frequent and specific use in a single condition. For this reason, we chose a birthing bed, since It is a complex process, in which one of the main factors within the hospital context is: the medical equipment that helps carry out the work, such as a birthing bed. It is around it, that the activities are carried out to allow efficient work [38].

1.2 Birthing bed

When a medical device designer starts designing a new product, they need to understand the problem and what the emotions of the users are. Empathy is a priority, the ability to share experiences. ¿What is it like to be on the receiving end of a pelvic exam? uncomfortable, and daunting, this is even worse in emergency rooms, where 6.3 million pelvic exams are performed annually, and gynecological beds are rarely available [17]. Creating an efficient delivery environment in a hospital setting, entails meeting the needs of medical technical safety, and ensuring a physiological and emotionally safe environment for women during labor. The psychosocial environment has fundamental effects on the women´s birthing experience, and the design aspects of the delivery room indirectly influence maternal and neonatal outcomes. The study concludes that maternity facilities must incorporate a personalized, woman-centered approach to delivery. More research is required on how this approach could be implemented in maternity care facilities, to reduce power imbalances and increase women's sense of organization and satisfaction with childbirth [32].

A hospital bed, for example, is generally is located at the center of the delivery room, the position is common, although it is due in large part to the practicality so that doctors can access women in case an intervention is required. The bed in the center of the room is an approach that contributes to the feeling of vigilance in the delivery room, placing the bed in the center also makes the woman feel that this is where she "should" give birth [33]. The traditional environment of childbirth, affects women's experience of labor. A common feature of the modern birth space is the bed. Knowledge about the use of the bed, about the perceptions and attitudes of women in labor and doctors is limited [34]. The modern hospital bed is a sophisticated medical device and its users represent a diversity of skills and needs. To develop a new bed, a company studied users in almost 500 hours of observation in 29 hospital units, the different needs and capabilities of users are a complex challenge for the design of a new hospital bed. [35]. Therefore, in their study they didn't refer about hierarchical fluctuation of the users.

At present, the obstetric team does not meet the proper characteristics for adequate care of pregnant patients in the labor room, in the expulsion room, In its different phases, the deficiencies of the equipment cause various conditions in patients [36].

Industrial designer or medical device designer should be prepared from their fundamental training in school. Since traditional design processes are not enough to face the challenge, the booth must be familiar with the importance of ergonomic factors in the design process, mainly in user-centered design [37]. However, both the traditional design process, user-centered design, and the medical device design process do not specify the importance of defining user hierarchies, and their correlation with the possible health status of the patient.

1.3 Project description

This research compares the improvements obtained in a design process based on hierarchies, taking reference to the traditional design process. It is proven that multiple medical errors within hospitals could be solved with prevention activities that reduce risks for people and the unnecessary expenditure of resources. Preventive medicine should prioritize health policies and the proper design of devices, as set by quality standards in the medical field [18].

This study focuses on studying the design process of birthing bed, mainly at several users around the object, types of users, the hierarchy of users in the use of the thing, and in a fluctuation of the patient's health status, which causes constant changes in rankings of users, to improve the design of the birthing bed and turn to meet the needs of each user during the delivery process. Also is based on the education of process design based on the hierarchies of the users. In the final year of engineering design bachelor's, the students demonstrate the impact of didactics information of the project and the evaluation of results in prototypes [38].

2. Materials and Methods

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A cross-sectional comparative study was carried out with a convenience sample consisting of two groups of students, from Design and Innovation Engineering at the Universidad Panamericana of Guadalajara, Mexico, a total of 40 students in the 5th semester of the degree (half career), 88% were women, and 12% men. To check whether the hierarchical design improves the final product. The students were asked to design a bed for natural births.

The study was carried out in 3 stages:

- Stage A - Traditional Design Process
- Stage B – Hierarchy Design Process
- Stage C -Comparison of acceptable levels of the proposals

2.1 Stage A: Traditional Design Process

The objective was to determine the design's characteristics and evaluate if the students identified the potential users of the product. They carried out three different activities:

a) Dynamics of creativity, with which they generated concepts from different sources of inspiration. Each team developed ten design proposals.

b) Article research, they were asked to investigate databases of scientific texts to add the information to the previous results and improve the previous proposals. We selected three proposals per team.

c) Field research participated in five teams selected for their best performance in the previous stages in this step. The points to consider in the visits were: identify the number of users around the birthing bed, the equipment inside the room, times and movements, Movement hierarchy, the birthing bed functions; they were collecting data and problems. Participants generated three proposals per team, including this information.

This process allowed us to analyze the proposals based on the consideration of the product's users and the inclusion of 13 criteria: safety, convenience, efficiency, attractiveness, shape, pleasantly color, adaptability, easy to use technology, material suitability, comfort, consideration of needs, easiness to use, agreeability to use, users feeling of inclusion of particular needs during design.

2.2. Stage B: Hierarchy Design Process

Regarding the proposals obtained in Stage A, we produced new designs integrating the design process based on hierarchies. As showed at the figure 5 scheme. The objective of this stage, was to modify the previously elaborated proposals, based on, the analysis of the various users who interact with the birthing bed. In this stage 20 students participated.

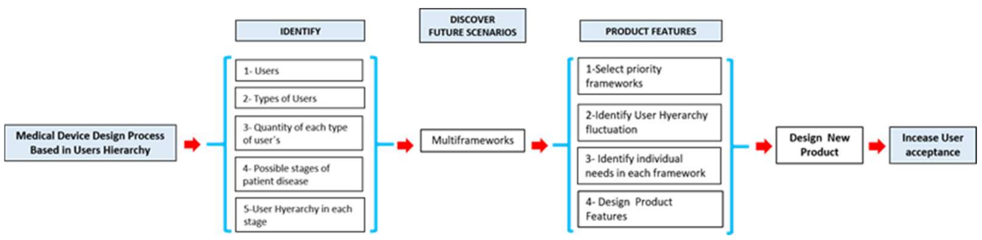

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Figure 5. Hierarchy design process, proposed in this study.

At the beginning of this stage, an information session was held on the hierarchical approach. We follow the scheme of Figure 5, and explained the importance of correctly identifying the number and type of users involved around the stretcher during the delivery process.

With this information, they are to analyses 32 birthing videos, collected through the online YouTube platform, videos previously selected based on their duration and type of shot. The information they had to obtain from videos was: user type, number of users, woman in a labor position on the birthing bed during the expulsion process, and interactions with each one of them [19].

Subsequently, they indicated several possible scenarios and analyzed each user's tasks again, depending on the stage of labor and the patient's health status

2.3. Comparison of acceptable levels of the proposals

This stage aims to compare the level of acceptance of the models designed with a traditional design process and with the models designed with the design process based on user hierarchies. As we show at figure 6.

The evaluation was carried out by 453 participants, corresponding to 11 user profiles: pregnant mother, father, obstetrician-gynecologist, nurse, maitenance staff, technical staff, anesthesiologist, pediatrician, newborn, midwife, parents. From a sample of 40 subjects per profile.

A survey was designed using a Likert scale to evaluate the best proposals of Stages A and B, considering the quality of the graphic representation of the ideas the proposal justification. The survey was conducted online, evaluating the 13 design factors considered at the beginning of the process: safety, convenience, efficiency, attractiveness, shape, pleasantly color, adaptability, easy to use technology, material suitability, comfort, consideration of needs, easiness to use, agreeability to use, users feeling of inclusion of particular needs during design.

The survey was applied to eleven different user groups, comparing the proposals made in pairs. For the statistical analysis, the Friedman [39], test was used, which allows the comparison of results. Friedman's test is a quadratic statistic, and helps in studies where the direction of deviations between treatments of alternative hypotheses is not known [39].

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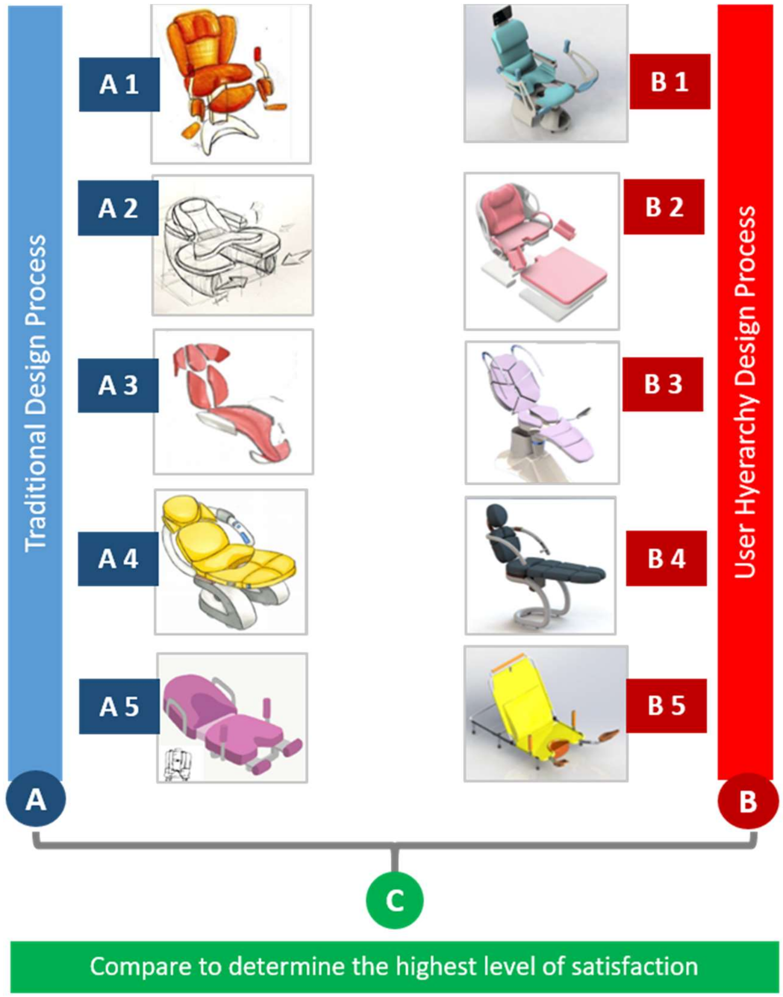

Figure 6. Comparison of Stage A and Stage B sketches

3. Results

3.1. Results stage A

The results were 130 sketches, from which teachers were discarding all proposals that did not meet requirements and those of low-quality idea representation in each step.

3.1.1. Step 1: Dynamics of Creativity

A total of 68 different characteristics were identified, in which only 22 were repeated in a percentage of 10% or more, as we show in figure 7.

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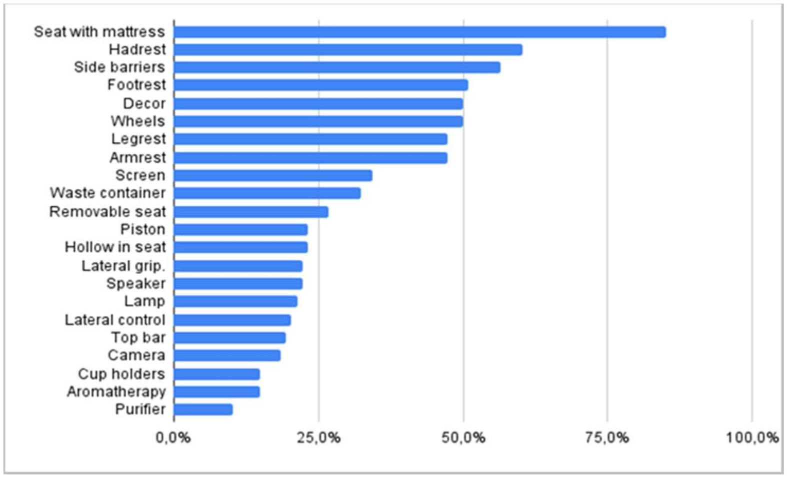

Figure 7. Result Graph step 1, The 22 characteristics repeated in a percentage greater than 10% or more in a total of 108 different designs are shown.

3.1.2. Step 2: Article Research

The repeated design characteristics are primarily identified according to the elements in the previous step. A study was carried out, resulting in 22 different aspects, of which 17 were present in a percentage greater than 10%. This can be seen in the figure 8.

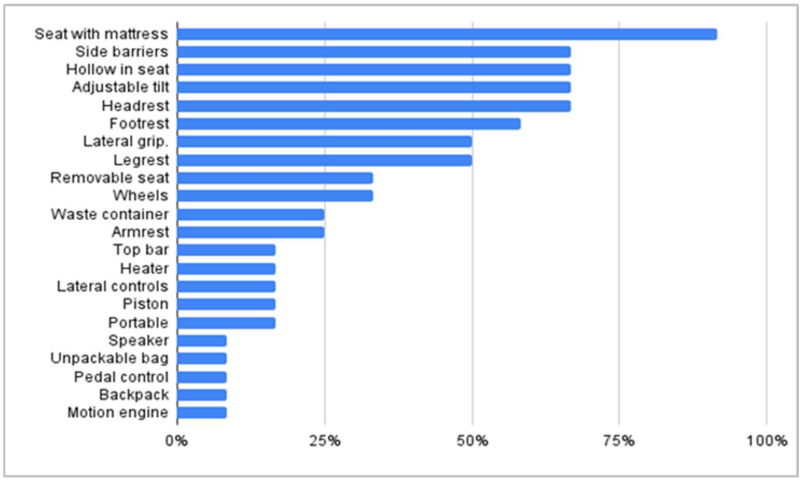

Figure 8. Results of step 2, of the experiment show the 17 characteristics mentioned in a percentage greater than 10%.

3.1.3. Step 3: Field Research

From the information collected in the fieldwork and considering the characteristics obtained from step 2, 15 new proposals were designed, an obtained with the criterion of quality of representation of the idea and design argument, choosing the three best proposals of each team, to be analyzed.

This time, the number of characteristics was 21, repeated in more than one concept, as we represent in figure 9.

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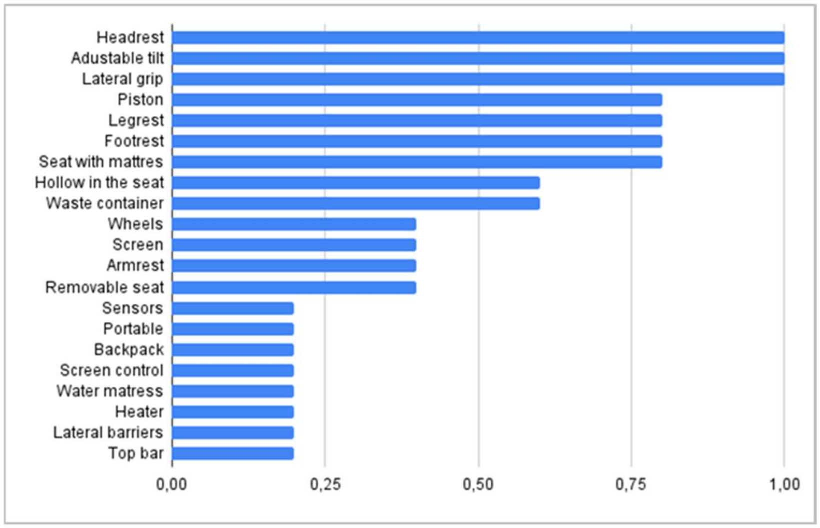

Figure 9. Result of step 3, of the graph showing the 21 most frequently mentioned characteristics.

With these three steps, Stage A of the study is completed, which focuses on designing under the traditional process; the figure 10 shows the final designs of this stage

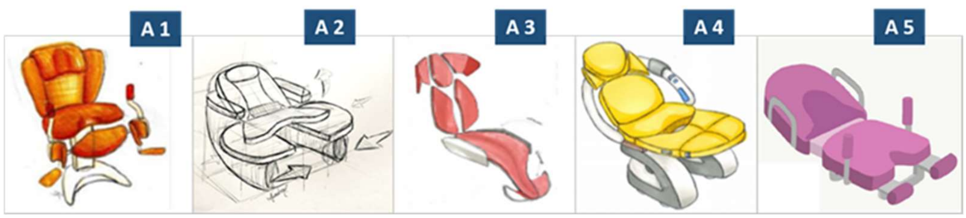

Figure 10. Final results of designs in Stage A

The number of characteristics identified reduced to 20, of which 13 repeated in more than one concept. Five different types of users were identified: pregnant mother, father, obstetrician-gynecologist, nurse, and anesthesiologist.

3.2. Results stage B

Table 1 represents all users classified according to had the most significant interaction with the product.

Table 1. Examples of video analysis, task analysis, and user hierarchy.

VIDEO SCREENSHOT AND SOURCE	USER	HIERARCHY	TASK ANALYSIS
 Video #25	Mother	2	Leaning almost sitting, soles of feet supported
	Family	5	Accompaniment
	Specialist	1	Delivery, cleaning the baby
	Pediatrician	4	Delivery assistance, baby cleaning, mom cleaning
	Baby	3	Cleaning on the mother's belly

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Table 2 represents the analysis of the videos allowed us to identify that in each one of them, the average number of users was between 6 and 8 people with different activities. And the frequency at which users appear in videos it shown is classified according to their greater or lesser interaction with the birthing bed.

Table 2. Results of users that appear in the 32 videos during the delivery phase.

USER´S	PERCENTAGE	VIDEOS
Specialist, Mother, Baby, Nurse, Family member	100	32
Pediatrician	59,4	22
Technician	31,3	10
2nd Family member	28,1	5
3rd Family member	18,8	9
2nd Nurse	15,6	2
4th Family member	9,4	1
2nd Doctor	6,3	1
2nd Technician	3,1	6
3rd Nurse	3,1	3

Figure 11 represent a top view of different user´s positions observed in the videos, it shows the specialist at the bottom of the bed, the nurse assisting and also the specialist or family members on the both sides of the birthing bed.

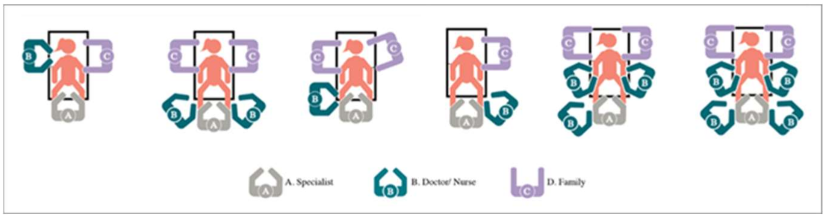

Figure 11. Example of the user's hierarchy around the birthing bed, depending on the phases of labor. In gray, the specialist staff, the nursing staff, and assistant doctors in green, and in purple the patient's relatives [40].

Figure 12 represent the positions most used by mothers to have their babies. The most used ones were reviewed since, it was found that a specific position allows nurses better access from the side of the bed, giving them more space to carry out their tasks.

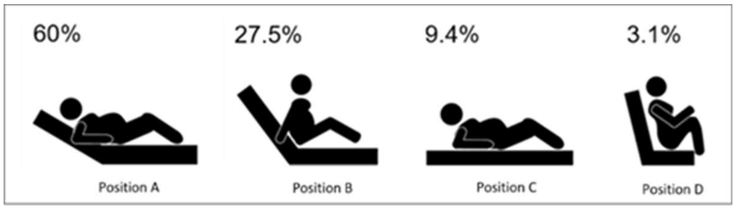

Figure 12. [40] The figure that exemplifies the results of the positions most used by the mother. Position A being the most used with 60%, and position B with 27.5%, position C with 9.4%, and finally position D with 3.1%

3.2.1 Future scenarios

Students are shown examples of possible scenarios where the patient could have a health problem during labor and how this event could affect user fluctuation and interactions around the birthing bed [41].

Scenario design is one of the most used techniques in the activity known as prospective, this being a tool to reduce the level of uncertainty that affects decision-making in the medium and long term [42].

The design of frameworks is a fundamental concept intended to serve as a guide for the construction of a structure that leads us to the most optimal solution to a problem. The number of possible scenarios or frameworks that could be generated in each situation was explained to them; this was exemplified with a permutation combinatorial calculation analysis, as we show in figure 13 [41].

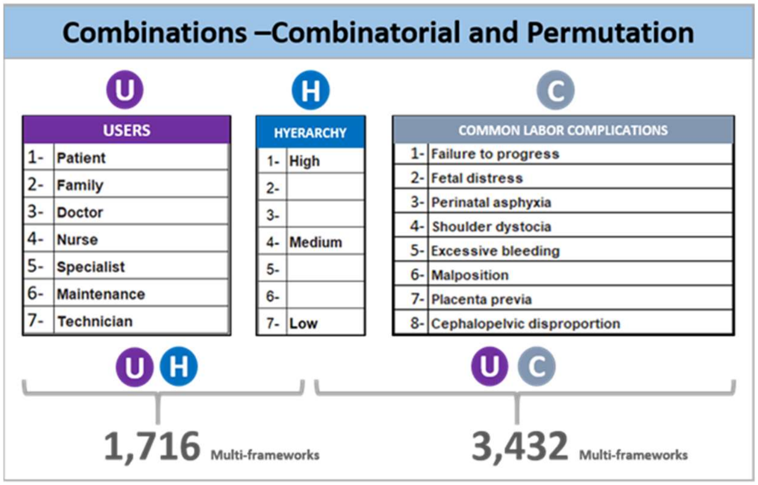

Figure 13. Image showing the combinatorial calculations[41], exemplifying only seven hierarchies with seven types of users, generating an estimate of 1,716 possible Frameworks, and calculating the seven users with eight different stages of the patient's health, which would yield 3,432 possible frameworks.

Once this information is shown to students, the following scheme figure 14, was designed to exemplify possible movement of hierarchies with a graphic depending on a complication during delivery to reinforce learning of the subject, based on the study of multi frameworks [43].

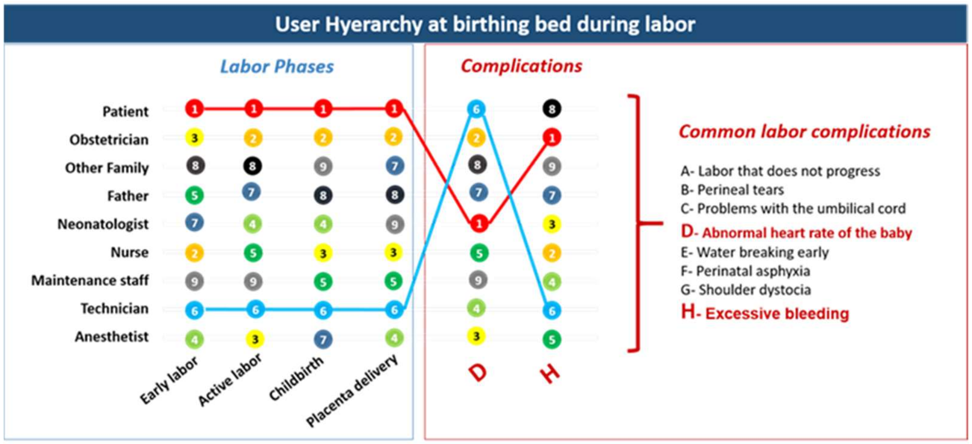

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Figure 14. Graph exemplifies the movements and interactions between different users around a birthing bed when a complication appears during childbirth [43].

Several possible scenarios were indicated to them, and they were asked to perform an analysis of each user's tasks, depending on the different possible complications of the patient.

With the data mentioned above, the participants were asked to design a new birthing bed. As a result, they developed 15 proposals, of which the teachers chose the best five as we show in Figure 15. With the selection criteria of the best-arguments design and quality of idea representation.

The design proposals were analyzed to identify the most frequently mentioned characteristics and all the users involved in developing the delivery who had interaction with the birthing bed.

The following Figure 15 shows the result of the final designs of Stage B.

Figure 15. Final results of proposals in Stage B

The features that were included in these models are shown in figure 15.

3.2.2 Analysis

Figure 16 represents the results of twenty design characteristics more significant than 10% were identified, and 11 different types of users: pregnant mother, father, obstetrician-gynecologist, nurse, cleaning staff, technical staff, anesthesiologist, pediatrician, neonate, midwife, another relative.

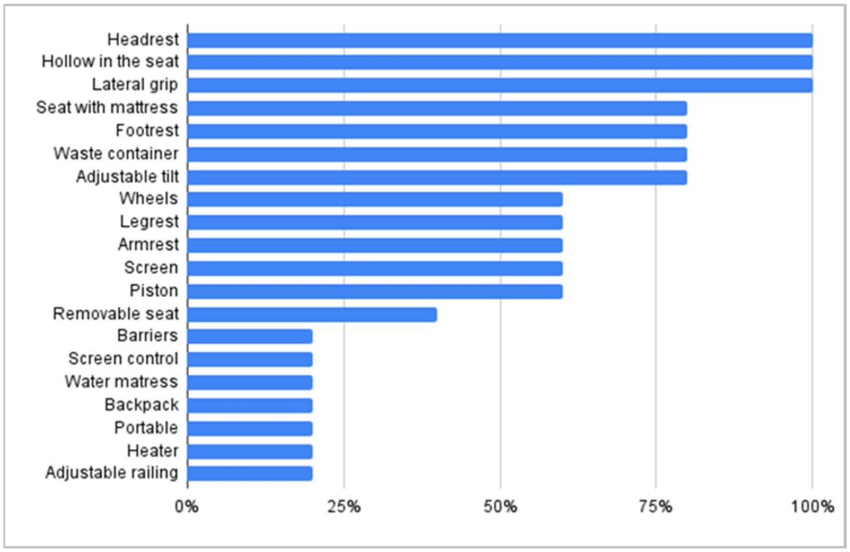

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Figure 16. Results of stage 2 of the experiment graph showing the 20 most frequently mentioned characteristics.

The designs presented evolved satisfactorily, the teams detected all the users involved and in turn analyzed the needs of each one, making the problem to be solved increase its complexity, and in turn, the final proposals had design elements focused on the solution from them.

3.3 Stage C:

Based on the survey results, an average of the score acquired in each category was calculated. The results are shown in Table 3 and helped determine which birthing bed obtained the best scores.

Table 3. The survey results with users determined the best evaluation between Stage A and Stage B of the design proposals.

A		B	
A1	51.12	B1	51.51
A2	41.97	B2	55.79
A3	55.21	B3	54.48
A4	49.67	B4	50.99
A5	40.67	B5	56.45

3.3.1 Analysis

The Friedman test was applied to check whether the differences found between the two design stages were statistically significant since those were ordinal data. The result indicates that Stage B scores were higher. They are shown in Table 4.

Table 4. According to the users, the comparison between the characteristics of the designs of birthing beds is compared (n = 453).

	A		B		Friedman Test
	Mean	s.d.	Mean	s.d.	
Safe	3,81	1,05	4,27	1,00	57,25***
Convenient	3,74	1,09	4,02	1,05	22,37***
Efficient	3,73	1,14	4,07	1.02	17,75***
Atractive Shape	3,77	1,14	4,23	1,02	48,13***
Color	3,74	1,22	4,32	0,98	70,00***
Adaptable	3,78	1,14	4,17	0,99	23,22***
technology Easy to use	3,87	1,12	4,11	0,96	8,73**
suitable material	3,89	1,11	4,13	0,94	15,02***
Comfort	3,65	1,21	4,27	11,1	43,84***
Consideration of needs	3,77	1,26	4,1	0,98	34,59***
Easy to use	3,74	1,19	4,23	0,99	32,00***
I would agree to use it	3,68	1,23	4,09	1,1	33,53***
consider my special needs	3,54	1,24	3,92	1,15	28,45***

*** p<0.001

**p<0.01

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In Stage C, the results of Stage A of the traditional design process are compared with Stage B, the hierarchy-based design process, which is exemplified in Figure 17.

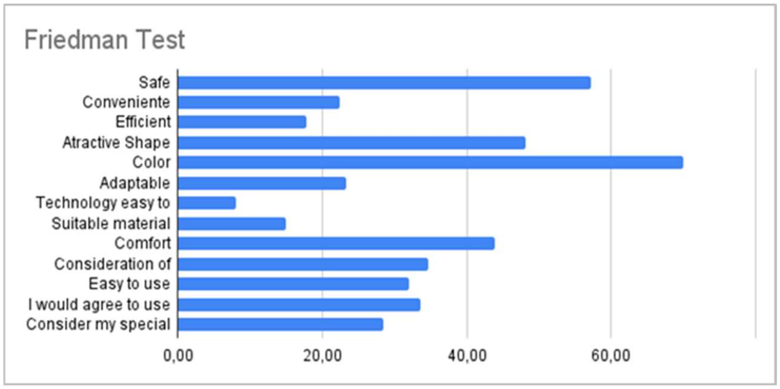

Figure 17. Graph that exemplifies the results of the Friedman test

3.3.2 Conclusion Stage C:

Figure 18 represents the conclusion of comparison the Stage A and Stage B proposals shows how the Stage B designs had better acceptance by users in the different factors.

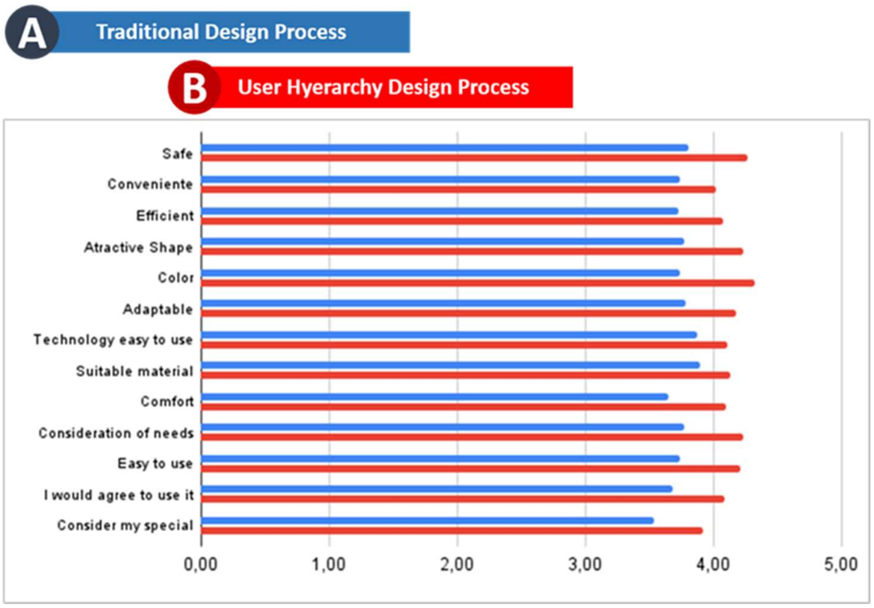

Figure 18. Graph that exemplifies the results of the surveys of 453 subjects.

4. Discussion

The research results reveal that the hierarchy-based design process effectively increases user acceptance, more than the traditional design process, however, some factors may be determining factors for the execution of a new project. Among them, the survey presented to users with the final design (birthing bed), it would be advisable in the following projects, to present the proposals at the same rendering level, even without color, all in white and without the application of textures, to give uniformity to all the designs,

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so the user can choose more objectively without being influenced by the colors, the level of representation or the impact of a render, to exemplify correctly just the shape. and the main characteristics of the design.

Stage B, which is the hierarchical design process, presents better results than traditional design, however, it is a longer process, but the increment of work time represents an area of opportunity for the hierarchical design process.

It is important to mention that stage B is consecutive in stage A, that means it could be a risk in the experiment, because some might argue that the results of the first stage A, could help to improve the results of stage B. Although this could be discussed further in the future, with more experiments.

The experiment was developed with 40 Mexican students, of which the majority were women, an information gap was detected with the male participants, showing at evident cultural issue where they watching birthing bed due to the graphic content of the videos since Mexican male are not familiar with the content. For the majority, both women and men, it was their first time observing this type of procedure, and it caused a shock that could generate an area of opportunity for design, giving them more empathy when designing their products.

The literature and the authors lack in off information on who are the users of medical devices, as well as their classification only indicates two groups, those who are from the health area and those who are not. This information is a gap that needs to be studied further. If the medical device designer does not know the users, they cannot previously classify them, thus making it impossible to design a product effective in usability, on the contrary, it will only be designed based on function and this will exclude the users, and with this, the essential information to design the interaction efficiently, consequently bringing products with a high risk of use error to the market, which will undoubtedly be a commercial failure, but more importantly, they can considerably harm the patient, as well as make incorrect diagnoses.

5. Conclusions

The study focuses on pointing out the importance of a new design process for medical devices, which can improve the characteristics of the product design and thereby increase user satisfaction. The main contribution of this new process focuses on showing medical device designers the importance of considering the hierarchy of users around a medical product, considering the fluctuation of the patient's health status since depending on the progression of the disease, the patient needs the attention of various users. In turn, final users need to solve specific problems in each phase, and design needs to be prepared for each user's particular needs around the birthing bed and the patient.

The results obtained will help medical device designers and healthcare professionals understand the main trends in medical research and improve the design process. In addition, they will help increase the level of satisfaction among users of medical devices [44].

The final results showed a significant difference in the acceptance of the products of stage B (design based on hierarchies), expressed by users. At birthing bed design processes, different aspects were considered in the development. However, the users showed a significantly greater preference for the design that concentrated on the satisfaction of their individual needs, that is, the proposals of Stage B.

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They concluded, that the hierarchy-based design process enables the designer to better understand user’s needs, and integrate them during a new birthing bed design process. It generates an increase in acceptance by users, unlike the traditional design process.

As evidence of this study, it was shown that the consideration of the needs of the different stakeholders is fundamental for the design process of a medical device to ensure the information that will determine the final characteristics of the design and better integration of aesthetic factors: ergonomic, functional, and their correct correlation with the context.

The user-centered design process describes the phases throughout a design development lifecycle, all while focusing on gaining a deep understanding of who will use the product, how, and when, allowing for a better understanding of the design process and its control at any stage, and as an interactive process, keep researchers and designers aware of the real needs of all users who will interact with the final device

The design process based on evidence or theoretical and field research helps, in the development of products at design process, by increasing the functionality and decision-making. The design process supported by user centered design, increases the value of users involved, as well as its importance by considering multi frameworks that could happen if the patient's health deteriorates during the use of the object. The constant fluctuation of users during childbirth, should be significant and indispensable information for medical device designers, and must be consider during the design process: This information will help develop designs that significantly increase the acceptance of the object for final users.

Derived from this study, the five final designs of stage B were sent to participate in the design contest: Design Mexico 2020 student category design B5 achieving the honorable mention award, and design B1, B2, B4. were also selected as finalists, Figure 19 represents the images of the contest.

Figure 19. Design winning the Honorable Mention award in the Design Mexico 2020 contest, student category.

Two prototypes were donated to indigenous communities of the Lacandon jungle in Chiapas, Mexico as we show in the Figure 20. They were send it through the IXIM association, and to the association of Mother Earth midwives, to be evaluated in the Tzeltal community and the Tzotzil community, the investigation is ongoing, we are collecting information from midwives, intending to design a second prototype that is even more adapted to the needs of the communities, to manufacture it at an industrial level and take it to more than 800 registered midwives in the Lacandon area, such as in the border area of Mexico and the USA, to support the problem of childbirth in migrant communities.

Figure 20. Prototypes were being tested by the midwives of the Casa Madre Tierra in San Cristóbal de las Casas in Chiapas, Mexico.

6. Patent

Currently, the B5 design proposal is in the patent process, being the winner of the Call for the Jalisco Program for the Promotion of Intellectual Property (PROPIN) 2021, issued by the State Council of Science and Technology of Jalisco (COECYTJAL) in collaboration with the Jalisco Science and Technology Innovation Secretariat (SICYT).

7. Ethical Considerations

The students were informed about their participation in the study; but they were unaware of the analysis carried out on sketches, as to not to modify the experiment. Likewise, users were informed about their voluntary participation in the study and how the results would be handled. At the end of the project, they were informed of the results.

8. Author Contributions: Conceptualization, F.C. and A.R. and E. G.; methodology, F.C. and A.R. and E. G.; software validation F.C. and A.R. and E. G.; formal analysis F.C. and A.R. and E. G.; investigation F.C. and A.R. and E. G.; resources F.C.; data curation F.C. and A.R. and E. G.; writing_ original draft preparation, F.C. and A.R. and E. G.; writing, review and editing F.C. and A.R. and E. G.; visualization, F.C. and A.R. and E. G. ;supervision, E.G. and A. S.; project administration, F.C., Funding acquisition, F.C.; All authors have read and agreed to the published version of the manuscript.

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10. Institutional Review Board Statement: Ethical review and approval were waived for this study because any kind of invasion to human subjects was not involved

11. Informed Consent Statement: Patient consent was waived because any kind of invasion to human subjects was not involved

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13. Conflicts of Interest: The authors have no conflict of interest to declare.

14. Data Availability Statement: Not applicable

15.Sample Availability: The data used to support the findings of this study are available from the corresponding author upon request

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