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A DESCRIPTION OF INNOVATIVE PRACTICE

Ten steps to transform ideas into product innovations: An interdisciplinary collaboration between nursing and engineering

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Abstract

Aims: To describe the development process of a device from the conception of the idea to the first contact with the commercial environment, and to demonstrate its practical application through an interdisciplinary collaboration between nursing and engineering for the design of a protective device for peripheral venous catheters.

Background: Nurses are key agents for identifying unresolved needs or problems related to nursing care. To address these needs, creative ideation processes are often triggered among nurses to seek technological answers to these challenges.

Results: The ten steps to develop a device are presented: (1) detecting an unsatisfied clinical need; (2) searching for preexisting marketed products; (3) searching for patents; (4) maintaining confidentiality throughout the process; (5) obtaining institutional support; (6) forming a multidisciplinary team; (7) developing the idea; (8) applying for a patent; (9) building the prototype; (10) marketing the device. This methodology was applied to design a protective device for peripheral venous catheters in hospitalized patients.

Conclusions: Nurses can play a key role in the promotion of healthcare innovation in their field to improve procedures, thanks to their direct contact with patients, and by providing their insight on devices that can enhance patient care. The successful interdisciplinary collaboration between nurses and engineers can provide a response to relevant clinical problems such as the manipulation or removal of peripheral venous catheters.

Implications for nursing and/or health policy: A hospital policy is required to encourage the participation of nurses in innovative actions. Furthermore, it is important to support nurse leaders who can play a pivotal role in incorporating creativity into work environments and empowering other nurses to innovatively address clinical issues.

No patient or public contribution: This article describes the process for developing a health device.

KEYWORDS

Communication, health service management, nursing, nursing capacity building, nursing care, quality assurance

INTRODUCTION

In the current era of innovation, the incorporation of technological tools or new devices in clinical environments is an essential pillar for improving the quality of care in the healthcare system.

The process for the development of a patient care device is multifaceted, as the transformation of an idea into a final product requires a series of steps and alliances. In this process, leadership and motivation of the work team are fundamental requisites (Smith et al., 2019). Despite the importance of a multidisciplinary team to successfully promote innovation (Landsman & Giuliano, 2023; Zhou et al., 2021), the recognition of inventions in the health field is mainly associated with physicians or researchers (Davis & Glasgow, 2020), in addition, the absence of nurse inventors has been noted in most of the patents registered in the U.S. Patent and Trademark Office database (Davis & Glasgow, 2020). This situation may be related to the absence of a culture or ecosystem for innovation, fostered by leaders who block new ideas, maintaining the preestablished policies and procedures in place at the healthcare centers. To achieve success in nursing innovation, it is crucial to consider the inherent characteristics of nurses, the team, and its leaders, as well as the work environment and the organization. Within nursing policy, nurse leaders must foster an environment that is conducive to creativity and interest in innovation. This involves promoting communication skills, trust, and leadership (Rylee & Cvanagh, 2023).

Other difficulties are present, such as excessive workloads, which may hamper the development of new ideas or devices, despite work environments with positive attitudes toward innovation. In this regard, the staff policy of health agencies should support its employees by considering the hospital structure, staff turnover, experience and skills, since these factors all influence innovative capacity. The organization's commitment to innovation is also important because if a center's policy includes a commitment to change, this decision will contribute decisively to fostering an innovative culture within the organization (Rylee & Cvanagh, 2023).

BACKGROUND

Nurses can play an important role in the invention of novel devices from the early stages, i.e., for requirement analysis and design, although they are often excluded from these first steps of the creative process (von Gerich et al., 2022). Nurses are ideally suited to detect needs for improvement, as they are close to the patient and their environment, they have a global vision of both the individual and society and are also one of the main agents that use health devices (Smith et al., 2019; von Gerich et al., 2022; Zhou et al., 2021). In addition, nurses have a high potential to trigger creative processes because they are intimately familiar with problems inherent to nursing care that demand innovative technological solutions and seek better health outcomes for the population (Shahsavari Isfahani et al., 2015).

The concern for ensuring patient safety may be a barrier within hospital policy for the implementation of innovative procedures. However, the adoption of new technologies and devices to address unmet clinical needs should be seen as part of the solution rather than part of the problem, provided patient safety is ensured.

Innovation in healthcare, inevitably unstoppable, requires reflection on the impact of new technologies on nursing and healthcare in general. Numerous digital technologies are already being integrated into nursing care today, such as assistive devices, sensors, and robotics, most of which have shown positive results. However, the evidence of the effects of these technologies (with large sample sizes) is limited and possibly conditioned by traditional approaches to health policy. This reinforces the need to thoroughly investigate the effects of these technologies to maximize their potential for improving the independence of people with health problems and their family members, reducing the burden of care (Huter et al., 2020).

Precisely, with the aim of improving healthcare through innovation, collaborations between nursing and engineering are increasingly common (Zhou et al., 2021). Several articles have reported the results of this interdisciplinary collaboration, especially regarding the design and evaluation of health-related smartphone applications (Gao et al., 2020; Wang et al., 2017; Zhou et al., 2021). However, the evidence on collaborations between these two disciplines for the development of devices to improve nursing care is limited (Castner et al., 2016). In addition, these initiatives should become more frequent so that nurses can assume a more proactive role in the world of innovation (Glasgow et al., 2018). Concretely, nurses can help engineers understand the clinical environment, detailing aspects that increase the effectiveness of problem-solving. Thus, the nurse–engineer partnership may lead to rapid and relevant inventions of new technologies (Giuliano & Landsman, 2022; Landsman & Giuliano, 2023). In this regard, future initiatives may be supported by a greater understanding of the steps required to develop a device for improving nursing care.

OBJECTIVES

To describe the process for the development of a patient care device from the conception of the idea to the first contact with the market, and to demonstrate its practical application, through an interdisciplinary collaboration between nursing and engineering, for the design of a protective device for peripheral venous catheters (PVC).

The ten steps for the development of a patient care device

Detecting an unsatisfied clinical need

A careful reflection and analysis of the clinical context and the nursing care provided daily is necessary, with a

fresh look that allows us to detect unresolved problems or needs, or those that could be improved through innovative proposals.

When a need is detected, the problem must be formulated in order to initiate a creative phase of proposals for its resolution. This leads to the selection of the most promising or feasible proposals. In this phase, it is enriching to incorporate elements or procedures from other disciplines that can be useful and effective, overall, in the field of health, and specifically, in the area of nursing.

Subsequently, it is necessary to know the state of the art of this problem to assess whether there is already a product or device that solves it (in the nursing field or in other fields). This search includes already marketed commercial products, scientific publications, and/or patents, corresponding to steps 2 and 3.

Searching for preexisting marketed products

At this stage, it is possible to search any internet search engine for possible devices that solve the problem, as well as gathering information from other clinical services and healthcare providers and manufacturers. Such a device may already exist and may even be marketed but unavailable at our center. This is summarized by the realization "I don't have it, it doesn't exist." Many ideas will probably fail to surpass this stage. However, it is important to avoid discouragement, as the inventive step and the active search for products feed creativity and the desire to continue improving.

Searching for patents

To verify whether our device or a similar one already exists and has been registered as a patent (industrial property title that protects an invention, its products or procedures allowing its exclusive exploitation) or as a utility model (another industrial property figure that protects products, apparatus, or technical devices, but not the procedures), specific patent search engines exist.

For a device and its development to be eligible for patent protection, it must meet three requirements: novelty, inventive step, and industrial application. If there are other very similar products or inventions, protection will not be granted for the new device.

Unlike other types of registrations, patent applications are subject to an examination at the patent office. This examination will determine whether the invention is patentable or not. The examiner conducts a background study of the invention and applies a so-called problem/solution method to verify the inventive step or whether the device obviously solves the problem identified in the patent application. This process highlights the importance of an exhaustive prior study of the background of the invention by the inventors.

In the United States, the U.S. Patent and Trademark Office provides a valuable six-step search strategy on its website (United States Patent & Trademark Office, 2022). The Patent Public Search database for U.S. patents can be accessed from its website, and it also recommends broadening the search to other global and European databases through the European Patent Office's worldwide patent publication database (Espacenet) (Espacenet, 2023).

One of the main difficulties when using these search engines is the ability to specifically define the device and, hence, limit the search, as otherwise thousands of related patents may appear, hampering this phase of the process. The use of the International Patent Classification may help perform targeted searches, characterized by a hierarchical system of symbols (independent of languages) that is established to classify patents and utility models according to the technological sector to which they belong (World Intellectual Property Organization, 2023).

In Spain, the Spanish Patent and Trademark Office (SPTO) is the public institution responsible for registering and granting different types of intellectual property. On its website (https://www.oepm.es/), it compiles different databases such as Espacenet, as well as a Spanish patent database (INVENES). Within this service, there is a bulletin where the registered medical devices are compiled by quarters, facilitating the identification of health inventions (Oficina Española de Patentes y Marcas, 2023).

Maintaining confidentiality throughout the process

If our device is eligible for patent registration, in any event, it is necessary to avoid disclosing anything about the characteristics of the product and the development process to comply with patentability requirements, particularly with those related to novelty and inventive steps.

This is important at least until the patent is filed as the dissemination of the idea to third parties outside the team of inventors invalidates the future protection of the device. All persons involved in the development of the idea, as well as external consultants and business contacts, must sign a confidentiality document.

Obtaining institutional support

During the development of the idea, the clinical agency, the research center or university where the inventor team works must be considered. Currently, many hospitals and research institutes have a multidisciplinary innovation service, which often includes nurses, doctors, engineers, and even company representatives. These services, which usually include an innovation committee and an innovation support unit, help to channel the idea by putting the inventor team in contact with other professionals who can develop the idea. Institutional support is a fundamental matter throughout the process and will be present in all subsequent steps in a cross-cutting manner.

Forming a multidisciplinary team

The challenges assumed by nurses in their clinical practice are increasingly complex and require synergies between highly qualified professionals from various disciplines such as nursing and engineering, to carry out the development of new devices and propose solutions to problems through innovation (Zhou et al., 2021). These synergies are usually established with mechanical engineers or computer engineers, although collaboration with other disciplines is also enriching. Within the work team, the knowledge that each professional can contribute to their field of work is important, as this multidisciplinary nature is a major strength. It is also necessary to define who will act as project manager or team coordinator, a role that can be assumed by one of the inventors, as well as to integrate professionals with experience in patenting.

Developing the idea (design)

For the development of the invention, it is important to accurately convey the idea to the work team, considering the object of the invention, the persons or patients who are candidates for its use (adults, children, older people), and the application environment (hospital, home). Several meetings involving the entire multidisciplinary team are necessary during the design process to evaluate the possible solutions proposed by the engineers and the steps that are being taken.

At the end of the design process, it is important to document multiple aspects, such as the general and specific characteristics of the invention, the technical problem it solves and its advantages over other devices, and whether it is a new product or an improvement of an existing product. It is always necessary to note the novelty of its characteristics and the possible applications of the device in clinical practice.

During this phase, funding is necessary, which requires applying to all possible calls for proposals from public and private entities that can contribute to the costs of the development, idea protection, and prototyping phases. Although it is difficult to obtain funding, it is important to apply to all possible calls for proposals and not become discouraged as the process of developing a device is a long process (akin to a long-distance race).

Applying for a patent

When the functional design of the device is completed, the next step is to protect the invention through intellectual property rights. In some countries, the term "intellectual property rights" is used to cover many types of intellectual property, although, in other countries, a distinction is made between intellectual property (copyright, software under European law) or industrial property (patents, designs, secrets, and trademarks). In the United States, the U.S. Patent and Trademark Office grants patents and registered trademarks (United States Patent & Trademark Office, 2023). On its web page (uspto.gov/patents), exhaustive information on patents can be consulted, as well as how to apply for and maintain the patent, along with several resources for help or consultation. To begin the patent application process, specific documentation must be gathered, which must contain the description of the device (including the background and detailed explanation of the invention) as well as the preferred manufacture of the device, accompanied by explanatory drawings. Legal recognition of the ownership of the creations is of great importance to prevent their appropriation or illegitimate use by third parties, while enabling the sale or transfer of the creation by the patent holder.

In addition, most European countries that are members of the European Patent Convention include another type of industrial property, the utility model, in their legislation. This model is not recognized worldwide, such as in the United States, Canada, or the UK. Nonetheless, this modality is applied to inventions with industrial applications that, being both novel and with inventive step, confer appreciable and practical advantages to an object, although with a lower rank of invention or innovation than a patent.

In addition, depending on the affiliation of the inventors, the ownership of the patent will be determined, which may be shared among several institutions, and which is regulated in each country according to the appropriate legislation.

Building the prototype

The process of materializing the idea into the device takes place during the construction of the prototype. This process usually consists of the following phases:

1. Elaboration of a draft that includes the dimensions, materials, and the operation of the device itself.
2. Creation of a 3D model: transferring the draft to 3D modeling software.
3. Development of a proof of concept: building the product from the draft to demonstrate the functions and feasibility of the idea.
4. Building the prototype: this stage aims to find the most efficient and marketable version. At this stage, it is essential to take all the necessary tests to reach the final result.
5. Creation of a production-ready prototype: the final step before device manufacturing.

The maturity level of a particular device can be assessed according to its technology readiness level (TRL). This tool establishes different levels on a scale between 1 and 9 according to the technological maturity of the device (Figure 1).

Marketing the device

When the technology reaches a certain degree of maturity, different possibilities exist for marketing the product:

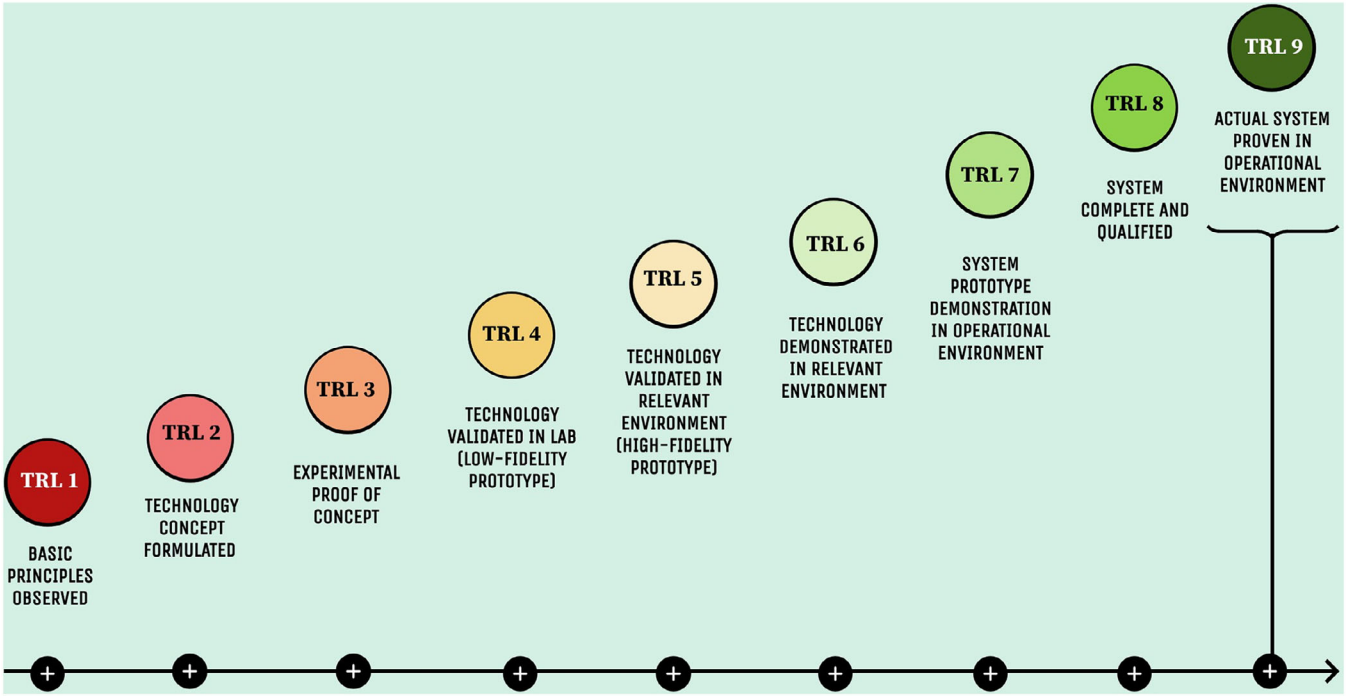

FIGURE 1 Classification and description of technology readiness level.

- *Manufacture and commercialization on behalf of the team of inventors creating a company (startup)*. Before making this decision, it is necessary to establish a business model. This business model can be developed using the Business Model Canvas (Osterwalder & Pigneur, 2010). This tool allows you to design a business model in an organized and schematic way, based on nine key sections: key partnerships, key activities, key resources, value proposition, customer relationships, customer segments, channels, cost structure, and revenue streams.
- *Joint venture*. This is another form of entrepreneurial activity that is an alternative to creating your own company. The end result is a licensing agreement, the creation of a spin-off, or another more permanent business relationship.
- *A patent license agreement with a company*. This requires finding an interested company with a solid structure and market capacity to manufacture and market the device by integrating it into its product portfolio. The exact terms of the license and the method of payment are negotiated between the patent holders, the team of inventors, and the company.
- *Sale of the patent*. A company or partnership offers to buy the industrial property rights of your invention for a fixed amount. In this case, the company is not bound for years by a license agreement.

The description of the entire process is shown in Figure 2.

The process we have detailed originated from the recommendations of the Knowledge Transfer Office or Support Units for Innovation of the centers involved. Moreover, some of these steps (e.g., steps 3, 4, and 8) coincide with the recommendations of patent offices in Europe and the United States. Finally, we also considered the experience of other professionals from our university and research institution (physicians in collaboration with engineers) who had already developed patents related to medical devices.

A PRACTICAL EXAMPLE OF AN INTERDISCIPLINARY NURSING–ENGINEERING COLLABORATION

The previously described methodology has been used in the design of a protective device for PVC named PROVIAVEN (Spanish acronym) by a team of nurses and engineers.

First, a clinical problem was detected (step 1) as most hospitalized patients require a PVC in the forearm to receive intravenous therapy; however, some of these patients, due to advanced age and/or episodes of agitation or delirium, often attempt to manipulate and pull out the PVC. Delirium usually affects 20% of patients over 65 years of age (Fuchs et al., 2020), doubling in those over 80 years of age (Marquetand et al., 2021). The loss of PVC represents a problem from the perspective of patient safety, since bleeding and extravasation of serum and medication can occur. If this situation is repeated, the patient requires multiple needle insertions, with the ensuing pain that this entails. In addition, the possible puncture sites on the forearms become increasingly limited. Also, restlessness, lack of collaboration, or psychomotor agitation are typical in these patients, which require appropriate management. To minimize the associated risks, it is essential to

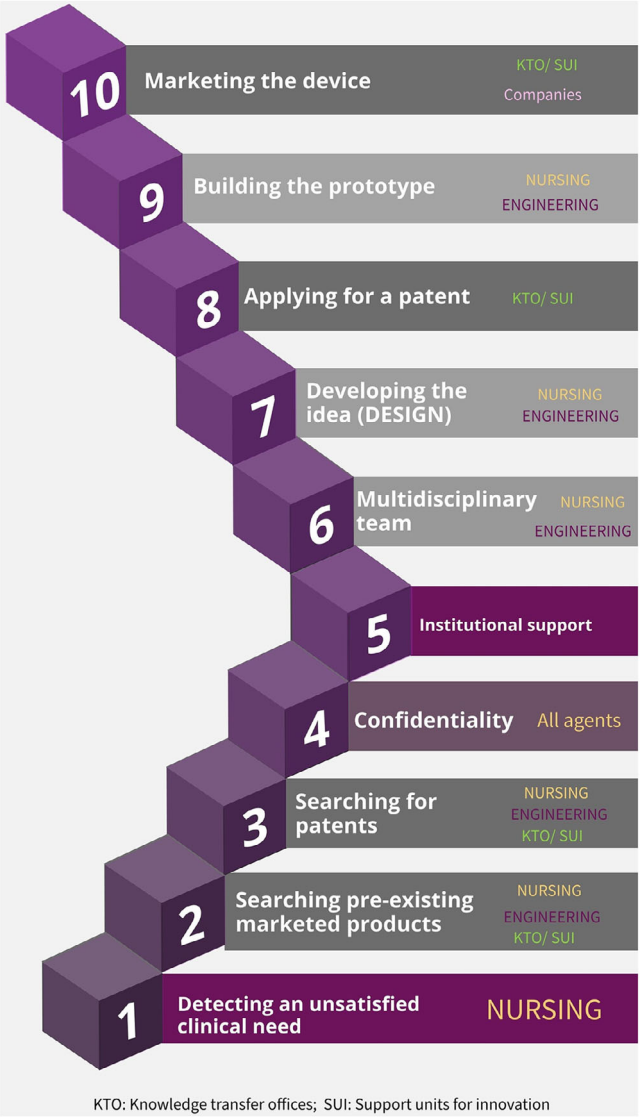

FIGURE 2 Ten-step process for design of a device and protection of the invention.

carry out specific therapeutic interventions, such as environmental and pharmacological measures, including mechanical restraint as a last resort and for therapeutic purposes only. Nonetheless, mechanical restraints are widely used and their use should be limited based on recommendations for nurses and the entire multiprofessional team to use multicomponent strategies and individualized care plans to prevent their use in patients at risk (Registered Nurses'Association of Ontario, 2012). It is crucial to consider the negative impact and the level of suffering that these therapeutic measures can cause on both patients and their families, to the point of dehumanizing health care. A search for products already on the market was carried out (step 2), detecting some devices that provide limited protection only for the PVC insertion area by means of transparent accessories, leaving the serotherapy or medication equipment accessible, which allows the venous line to be pulled out by the patient. Other proposals lacked sufficient height to protect a flow key that is usually connected to the catheter, as they were located very close to the PVC insertion in the skin.

The search for registered patents (step 3) revealed that two utility models were located in Spain. Some inventors have solved this problem by means of a larger casing that covers the catheter; however, their proposal requires adhesive strips over the insertion point that do not allow daily monitoring of the catheter's condition and fails to protect the equipment and connections (Garcia Martín, 2010). In the other utility model, the use of adhesives to fix the protective casing was proposed; however, this may pose skin problems if the casing requires removal and reattachment, as these adhesives may be damaged, and the patient can easily remove the casing as it is a fairly simple mechanism (Galván Guijo, 1995). A search was performed in the SPTO for medical devices registered in the last 10 years.

Steps 2 and 3 were performed by two nurses with clinical experience, while maintaining the confidentiality of the process (step 4). After completing the state of the art and not detecting a device marketed in Spain that solved the problem, the Health Research Institute of Asturias was contacted. The project was presented to the innovation committee of this institute by means of an ideas form and was positively evaluated. This institute subsequently put the nurses in contact with the engineering department of the University of Oviedo. All those who received information about the project signed a confidentiality document (step 4). The main institutions involved were the University of Oviedo and the Health Research Institute of Asturias (step 5).

The multidisciplinary team consisted of three nurses and three engineers with different profiles, from both hospital and university environments (step 6). The nurses contributed their professional experience in clinical and research units with numerous publications on nursing care. The engineering team had extensive experience in the development of medical devices and patents (Rodríguez-Garcia et al., 2021; Sierra et al., 2020, 2022). This team designed a protective device for PVC and its connections consisting of five elements: (1) a transparent cover placed over the PVC; (2) a means of attachment, in the form of a cuff, where the transparent cover is integrated and which is attached to the patient's forearm; (3) an outlet inserted into the cuff in the region of the patient's elbow for intravenous connections; (4) equipment for administering intravenous therapy; and (5) other means of attachment for these connections.

This device externally protects the PVC insertion site, while enabling visualization and management of complications such as phlebitis or extravasation. These two complications, as well as accidental withdrawal, are some of the most common adverse events related to PVC that should be addressed by nurses and clinical leaders to improve patient safety, quality of care, and hospital outcomes (Marsh et al., 2020). This device also protects the intravenous therapy equipment, making it difficult for patients to manipulate it and pull it out. This aspect constitutes one of the main novelties and advantages of this device.

Nurses played a major role in the process of requirement analysis, identifying the problem to be solved and the population where it could be applied, according to their clinical experience, and as designers and advisors to the engineering team during the design, construction of the prototype, and management of the patent. These two roles have previously been identified as frequent functions of nurses during interdisciplinary collaboration with engineers (Zhou et al., 2021).

After completing the design phase, the invention was protected by a utility model at the SPTO (Fernández Feito et al., 2022) (step 8).

Concurrently, the construction of a low-fidelity prototype with a TRL4 was initiated (step 9), involving testing different materials for the transparent cover, as well as for the cuff fasteners.

The team of inventors does not contemplate the creation of a startup, and therefore their proposal to market the device is to contact a company interested in acquiring the patent license and commercially exploit the idea (step 10).

IMPLICATIONS FOR NURSING PRACTICE

Today, nurses have few opportunities to develop innovation within healthcare facilities, where managers and consultants take on this role themselves and do not rely on them to develop devices or drive process innovation. To transform this reality, a change in hospital policy is needed to include nurse clinicians in the development of technology, as is done with other medical professionals. For clinical agencies, encouraging the creativity of nurses and strongly supporting the availability of their innovations in healthcare facilities can increase the quality of nursing care. Furthermore, it is important to support nurse leaders who can play a pivotal role in incorporating creativity into work environments and empowering other nurses to innovatively address clinical issues (Snow, 2019). In addition, there is a need for greater support from healthcare institutions to foster this interdisciplinary collaboration with engineering (Glasgow et al., 2018), providing examples of actions carried out by nurses (Castner et al., 2016), as well as creating ecosystems of nurse inventors in each hospital or health center. Another approach for hospital policy could be to stimulate the participation of nurses with device developers in collaboration with companies (Zhou et al., 2021) to draw on nurses' expertise and clinical experience as key agents to face the current challenges in health sciences. In addition, nursing policy should consider that the incorporation of technology into daily work could improve nurses' productivity, for example, by reducing their involvement in certain time-consuming activities (Clancy, 2020).

LIMITATIONS

This study has certain limitations. The general process for developing a device may undergo slight changes depending on the legislation of each country. In addition, some of the proposed steps may be assumed by the inventors' institutions in collaboration with the nurse–engineer team.

CONCLUSIONS

The development of a device from the conception of the idea to its market launch can be carried out following a ten-step process. During this process, it is important to collaborate with institutions and/or private companies that can provide support through human and financial resources. There is a need for hospital policies that favor the participation of nurses in innovative actions such as device design or process innovation. Nurses can and should be successfully involved in the development of devices, in close collaboration with engineering professionals, that provide answers to nursing care problems such as the manipulation or pulling out of the PVC. Nursing policy should consider the benefits of applying this device, which improves the productivity of nurses by reducing the time spent on applying new PVCs and monitoring patients with delirium and leads to savings in medical supplies.

AUTHOR CONTRIBUTIONS

Conceptualization: AFF, MRFR, PZM, MGG. Methodology: AFF, MRFR, MCC, PZM, JMSV, JLCR, MGG. Investigation: AFF, MGG. Formal analysis: PZM. Funding acquisition: MRFR, MCC. Resources: JMSV, JLCR. Validation: JMSV, JLCR. Supervision: AFF. Writing–original draft preparation: AFF, MRFR, MCC, PZM, MGG. Writing–review and editing: AFF, MRFR, MCC, PZM, MGG. All authors reviewed the different stages of the manuscript, made substantial changes to successive drafts, and approved the final version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest. The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

ETHICS STATEMENT

This study, focused on conveying the procedure for developing a device, does not require approval from the ethics committee.

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