Prioritizing Patient Safety: Analysis of the Procurement Process

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Abstract

Background

Patient safety is a global priority and the European public procurement process is an essential vehicle for assessing the patient safety implications of new equipment, technology, and other products. One important factor contributing to patient safety issues is poor usability which is an important human factors concept measured by efficiency, effectiveness, and satisfaction. We sought to understand whether patient safety and human factors are considerations in healthcare technology procurement analyzing the case of infusion pumps as they use condition critically patient safety.

Methods

We reviewed infusion pump procurements in the Spanish Public Sector Procurement Database (PLACE). Sixty-three batches in 29 tenders for supplying 12,224 volumetric and syringe infusion pumps and consumables for an overall budget of 30.4M€ were identified. Requirements and scoring criteria for the selection of pumps were analyzed.

Results

Concepts related to “ease of use” were identified in the selection requirements of 35 (55.6%) batches and in the criteria for the selection of pumps in 23 (36.5%) batches, and related to “intuitiveness” in the selection requirements of 35 (55.6%) batches and in the criteria in 10 (15.9%) batches. No method to evaluate the ease of use, intuitiveness, or usability was mentioned. A review of the procurement teams responsible for the evaluation of the tenders showed no reported human factors or patient safety expertise.

Conclusions

Infusion pump procurement considers usability as a relevant criterion for selection. However, no human factor experts nor specific methods for evaluation of the technology in this field are usually defined. A potential room for refining the selection of healthcare technology in order to improve patient safety is detected.

BACKGROUND

Patient safety is a global priority and a central focus of the World Health Organization, as well as other oversight agencies. There are many facets to patient safety and one critical aspect is the usability of medical devices, health information technology, and other products which is the extent to which the technology or product can be used effectively, efficiently, and satisfactorily. Products that are poorly designed, developed, and implemented can have poor usability which can directly impact patient safety by resulting in errors that harm patients. For example, an inaccurately programmed infusion pump due to a confusing display can result in a patient receiving the wrong amount of medication resulting in an over or underdose.

Human factors, a multidisciplinary science focused on understanding human capabilities and designing tools and technologies to meet these capabilities, is instrumental in promoting usable and safe medical devices and technologies. Human factors methods such as direct observation, interviews, and surveys to gather user needs, rigorous user evaluation and usability testing, and heuristic evaluations all serve to improve product usability. In certain countries, there are oversight agencies, such as the United States Food and Drug Administration (FDA), that require usability testing of medical devices and other products before introduction to the market.

In Europe, a key step to assessing the usability and safety of medical devices is the public procurement process. Currently, public procurement in Europe accounts for approximately 14% of GDP and is an essential vehicle for implementing government policies and meeting national strategic objectives, as well-functioning public procurement markets contribute to improving the competitiveness of quality service strategies. Identifying usability and patient safety issues during procurement can prevent patient harm and can serve to improve medical products.
In this article, we review public procurements in Spain to identify whether usability and human factors were taken into consideration during the procurement process. We focused specifically on infusion pumps given the prevalence of these devices and the importance of usability for safe use of pumps. Infusion pumps are recognized as devices frequently involved in medication errors. From 2005 through 2009, the FDA received approximately 56,000 adverse events reports associated with the use of infusion pumps, including injuries and deaths. Manufacturers made 87 infusion pump recalls addressing identified safety concerns during this period. Seventy of these recalls were designated as Class II, which implies likely to cause temporary or medically reversible adverse health consequences. Fourteen recalls were Class I, which is, likely to cause serious adverse health consequences or death. Other studies have identified a high rate of error in the administration of intravenous medications with smart pumps, with relatively few errors that were potentially harmful. Infusion pumps provide an elevated level of control, accuracy, and precision in medication administration, and reduce certain types of medication errors resulting in improved patient care. At the same time, infusion pumps have been associated with persistent safety issues that can lead to over or under-infusion and overlooked or delayed therapy. Despite the growing support for the use of smart pumps as an element of safety strategies, the literature shows that user error, incorrect programming, and equipment failures continue to occur. Several strategies have been proposed for mitigating infusion pump safety problems and the inclusion of human factors principles and methodologies during design, implementation, and purchasing is one of the most widely accepted.

METHODS

With the aim of identifying the role of human factors and ergonomics in the selection of healthcare technology with high user dependence patient safety, represented by infusion pumps, information was retrieved from the Spanish Public Sector Procurement Database (PLACE) (https://contrataciondelestado.es/). This database is used by the Spanish Public Authorities to transparently store their tenders in compliance with the Spanish Law on Public Sector Contracts. This Law applies to all contracts for works, works concessions, service concessions, supplies, and services requested by entities belonging to the public sector in accordance with the European regulations. PLACE announces more than 11,000 new procurements per month.

For the identification of infusion pump tenders, a search was performed using the Common Procurement Vocabulary (CPV) with the code 33194110 (infusion pumps) in the PLACE database between 2002 and 2022. All the records retrieved were reviewed individually, selecting those that included volumetric and syringe infusion pumps and consumables. The records were analyzed to identify the following:

- Use of human factors related terms including “ease of use”, “usability”, “human factors”, “ergonomics” and “intuitive” in the requirements and/or evaluation criteria.
- Indication of user training requirements or mention of user training by the bidder.
- Whether the procurement evaluators had background knowledge and experience in patient safety and/or human factors.
- Whether human factors methods or principles were mentioned as part of the evaluation.

Numeric data are represented as mean (SD) unless otherwise indicated. Categorical data were compared by the chi-square or Fisher's exact test. Quantitative data were compared by Student's t-test as appropriate. A significance level of 0.05 (2-sided) was used for all tests.

RESULTS

Seventy-three tenders were identified with the infusion pumps' CPV search codes in the PLACE database, of which 44 were excluded. Causes for exclusion were emergency tenders or framework agreements (n = 20), tenders that didn't include syringe or volumetric infusion pumps (n = 19), those for only consumables (n = 2), those without enough information (n = 2), and those for animal equipment (n = 1).

The 29 selected tenders were published between July 2015 and October 2022. All the tenders for the procurement of consumable products included the use of the infusion pumps during the contract. The overall estimated budget was 30.4M € (range per procurement from 46.431 € to 12.4 M €) for an acquisition of 12.224 pumps and an average duration per procurement of 27 months.
(range 1 to 60 months). In the 29 selected tenders, 63 batches of pumps with different specifications and selection criteria were identified (19 syringe pump batches and 44 volumetric pump batches).

Requirements and criteria for pump selection

Mandatory technical requirements for the selection of volumetric and syringe infusion pumps identified in the procurement's batches are listed in Table 1. In a comparison of the requirements of syringes and volumetric pumps, no significant differences were identified, except in the proportion of batches with air system detection.
Table 1
Procurement requirements for the selection of syringe and volumetric pumps, Data represents numbers and percentages.

<table>
<thead>
<tr>
<th>Requirement aspects</th>
<th>Syringe (n = 19)</th>
<th>Volumetric (n = 43)</th>
<th>p</th>
<th>Overall (n = 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical aspects</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stackability</td>
<td>14 (73.7%)</td>
<td>24 (55.8%)</td>
<td>0.14</td>
<td>38 (61.3%)</td>
</tr>
<tr>
<td>Low noise</td>
<td>0</td>
<td>2 (4.7%)</td>
<td>0.48</td>
<td>2 (3.2%)</td>
</tr>
<tr>
<td>Weight</td>
<td>15 (78.9%)</td>
<td>32 (72.7%)</td>
<td>0.43</td>
<td>47 (74.6%)</td>
</tr>
<tr>
<td>Battery life</td>
<td>14 (73.7%)</td>
<td>33 (75%)</td>
<td>0.57</td>
<td>47 (74.6%)</td>
</tr>
<tr>
<td><strong>Alarms and safety systems</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarm adjustable volume</td>
<td>5 (26.3%)</td>
<td>18 (41.9%)</td>
<td>0.19</td>
<td>23 (37.1%)</td>
</tr>
<tr>
<td>Alarm software</td>
<td>9 (47.4%)</td>
<td>28 (63.6%)</td>
<td>0.19</td>
<td>23 (37.1%)</td>
</tr>
<tr>
<td>Pressure alarm</td>
<td>10 (52.6%)</td>
<td>32 (72.7%)</td>
<td>0.1</td>
<td>42 (66.7%)</td>
</tr>
<tr>
<td>Obstruction alarm</td>
<td>12 (63.2%)</td>
<td>26 (59.1%)</td>
<td>0.49</td>
<td>38 (60.3%)</td>
</tr>
<tr>
<td>Air detection</td>
<td>4 (21.1%)</td>
<td>24 (54.5%)</td>
<td>0.01</td>
<td>28 (44.4%)</td>
</tr>
<tr>
<td>Liquid free fall prevention</td>
<td>6 (31.6%)</td>
<td>19 (43.2%)</td>
<td>0.28</td>
<td>25 (39.7%)</td>
</tr>
<tr>
<td>Safety blocking</td>
<td>6 (31.6%)</td>
<td>14 (31.8%)</td>
<td>0.61</td>
<td>20 (31.7%)</td>
</tr>
<tr>
<td><strong>Interface</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keyboard</td>
<td>5 (26.3%)</td>
<td>12 (28.6%)</td>
<td>0.56</td>
<td>17 (27.9%)</td>
</tr>
<tr>
<td>Easy screen</td>
<td>6 (31.6%)</td>
<td>19 (43.2%)</td>
<td>0.28</td>
<td>25 (39.7)</td>
</tr>
<tr>
<td>Screen parameters</td>
<td>12 (63.2%)</td>
<td>25 (56.2%)</td>
<td>0.43</td>
<td>37 (58.7%)</td>
</tr>
<tr>
<td><strong>Programming</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easy management</td>
<td>6 (31.6%)</td>
<td>20 (45.5%)</td>
<td>0.23</td>
<td>26 (41.3)</td>
</tr>
<tr>
<td>Infusion rate</td>
<td>17 (89.5%)</td>
<td>41 (93.2%)</td>
<td>0.48</td>
<td>58 (92.1%)</td>
</tr>
<tr>
<td>Infusion programming</td>
<td>14 (73.7%)</td>
<td>35 (79.5%)</td>
<td>0.42</td>
<td>49 (77.8%)</td>
</tr>
<tr>
<td>Infusion rate medication without interruptions</td>
<td>9 (47.4%)</td>
<td>25 (56.8%)</td>
<td>0.34</td>
<td>34 (54%)</td>
</tr>
<tr>
<td>Retrobolus</td>
<td>7 (36.8%)</td>
<td>9 (20.5%)</td>
<td>0.15</td>
<td>16 (25.4%)</td>
</tr>
<tr>
<td>Keep vein open</td>
<td>3 (10.5%)</td>
<td>13 (30.2%)</td>
<td>0.09</td>
<td>15 (24.2%)</td>
</tr>
<tr>
<td>Drug library</td>
<td>14 (73.7%)</td>
<td>31 (70.5%)</td>
<td>0.52</td>
<td>45 (71.4%)</td>
</tr>
<tr>
<td>Pharmacokinetics (target-controlled infusion)</td>
<td>9 (47.4%)</td>
<td>15 (34.1%)</td>
<td>0.24</td>
<td>24 (38.1%)</td>
</tr>
<tr>
<td><strong>Interoperability</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interoperability</td>
<td>10 (52.6%)</td>
<td>14 (31.8%)</td>
<td>0.1</td>
<td>24 (38.1%)</td>
</tr>
<tr>
<td>Wifi</td>
<td>2 (10.5%)</td>
<td>5 (11.4%)</td>
<td>0.65</td>
<td>7 (11.1%)</td>
</tr>
</tbody>
</table>

The overall number of batches with any requirement referring to “ease” was 35 (55.6%) and was related to pump handling (12 cases, 19%), use (9 cases, 14.3%), cleaning (8 cases, 12.7%), programming (6 cases, 9.5%), purging (5 cases, 7.9%), visualizing data (2 cases, 3.2%), placement (1 case, 1.6%), understanding (1 case, 1.6%), and learning (1 case, 1.6%). The number of different requirements referring to “ease” in each batch was 4 in 1 batch (1.6%), 3 in 1 batch (1.6%), 2 in 5 batches (7.9%) and 1 in 28 batches.
In 18 batches (28.6%) there was at least one requirement related to “intuitive use”. None of the requirements mentioned the terms “usability”, “ergonomics”, “human factors”.

The scoring criteria for pump selection included in all cases economic and technical aspects with a total of 100 points. The mean points of economic criteria were 46.2 (14.5). Scoring criteria related to the characteristics of pumps are listed in Table 2. Significant differences among syringe and volumetric scoring criteria were detected in pump battery life, pressure monitoring, and relay systems.

### Table 2
Procurement criteria scoring for the selection of syringe and volumetric infusion pumps.
Data represents mean of points per criteria (SD).

<table>
<thead>
<tr>
<th></th>
<th>Syringe N = 19</th>
<th>Volumetric N = 44</th>
<th>p</th>
<th>Overall Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical aspects</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stackability</td>
<td>1.74 (0.67)</td>
<td>1.84 (3.87)</td>
<td>0.51</td>
<td>1.78 (3.54)</td>
</tr>
<tr>
<td>Low noise</td>
<td>0.11 (0.47)</td>
<td>0.09 (0.43)</td>
<td>0.81</td>
<td>0.1 (0.43)</td>
</tr>
<tr>
<td>Weight</td>
<td>1.50 (3.05)</td>
<td>1.65 (2.89)</td>
<td>0.72</td>
<td>1.56 (2.88)</td>
</tr>
<tr>
<td>Battery life</td>
<td>0.17 (0.71)</td>
<td>1.07 (2.88)</td>
<td>0.007</td>
<td>0.78 (2.22)</td>
</tr>
<tr>
<td><strong>Alarms and safety systems</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarm software</td>
<td>0.67 (1.50)</td>
<td>0.60 (1.58)</td>
<td>0.99</td>
<td>0.6 (1.52)</td>
</tr>
<tr>
<td>Noise and lights alarms</td>
<td>0.61 (1.97)</td>
<td>0.40 (1.56)</td>
<td>0.43</td>
<td>0.44 (1.65)</td>
</tr>
<tr>
<td>Easy to use</td>
<td>1.72 (2.95)</td>
<td>1.88 (3.59)</td>
<td>0.64</td>
<td>1.78 (3.35)</td>
</tr>
<tr>
<td>Drugs library</td>
<td>0.67 (1.41)</td>
<td>1.19 (2.95)</td>
<td>0.14</td>
<td>0.78 (2.44)</td>
</tr>
<tr>
<td>Pressure monitoring</td>
<td>7.94 (15.48)</td>
<td>1.70 (5.15)</td>
<td>0.001</td>
<td>3.43 (9.56)</td>
</tr>
<tr>
<td><strong>Programming and safety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Programming software</td>
<td>1.33 (2.89)</td>
<td>1.00 (2.49)</td>
<td>0.49</td>
<td>1.06 (2.56)</td>
</tr>
<tr>
<td>Remote monitoring</td>
<td>1.78 (3.14)</td>
<td>1.02 (2.31)</td>
<td>0.06</td>
<td>1.21 (2.55)</td>
</tr>
<tr>
<td>Infusion rate</td>
<td>0.67 (2.06)</td>
<td>0.37 (1.23)</td>
<td>0.17</td>
<td>0.46 (1.51)</td>
</tr>
<tr>
<td>Infusion volume</td>
<td>1.33 (4.28)</td>
<td>0.95 (3.59)</td>
<td>0.63</td>
<td>1.03 (3.72)</td>
</tr>
<tr>
<td>Pharmacokinetics</td>
<td>0.44 (1.46)</td>
<td>0.84 (2.08)</td>
<td>0.12</td>
<td>0.7 (1.89)</td>
</tr>
<tr>
<td>Air detection</td>
<td>0.00</td>
<td>0.70 (3.23)</td>
<td>0.06</td>
<td>0.48 (2.68)</td>
</tr>
<tr>
<td>Relay system</td>
<td>1.06 (2.48)</td>
<td>0.19 (1.22)</td>
<td>0.001</td>
<td>0.43 (1.69)</td>
</tr>
<tr>
<td>Keep vein open</td>
<td>0.28 (1.18)</td>
<td>0.91 (3.41)</td>
<td>0.12</td>
<td>0.7 (2.89)</td>
</tr>
<tr>
<td><strong>Interoperability</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interoperability with other systems</td>
<td>0.56 (2.36)</td>
<td>0.42 (1.93)</td>
<td>0.67</td>
<td>0.44 (2.01)</td>
</tr>
</tbody>
</table>

Mention of “ease” in any criteria was present in 23 of the 63 batches (36.5%). It was related to its use (12 cases, 19%), programming (12 cases, 19%), purging (8 cases, 12.7%), handling (7 cases, 12.1%), placement (2 cases, 3.2%), and cleaning (1 case, 1.6%). The number of different criteria referring to “ease” in each batch was 1 in 6 batch (9.5%), 2 in 15 batches (23.8%) and 3 in 2 batches (4.8%). Criteria including “intuitiveness” were identified in 10 batches (15.9%), and “usability” in 3 batches (4.3%). No criteria included the terms “ergonomics” or “human factor” was identified.

Training in the use of infusion pumps was a requirement in 22 of the 29 tenders (75.9%). Only in 4 of 63 batches (1.6%) training was considered a criterion for evaluation.
No methodology for evaluation of any of the requirements or criteria related to ease of use, intuitiveness, or usability was identified. Specifically, there was no mention of human factors evaluation-based principles (i.e., observation, heuristic evaluation, or usability testing) in any of the 63 batches.

**Evaluation procurement teams**

In the analysis of the 29 tenders, only in 14 (48.3%) the professional profile of the members that compose the administrative commissions responsible for the evaluation of the tenders were identified. Overall, in 13 (92.9%) a range of 1 to 7 evaluators with technical non-administrative profiles, such as medical doctors, nurses, or engineers, was included. In 8 of them (57.1%) healthcare professionals (nurses or physicians) were included in the commissions. None of the evaluation teams nor the technical teams include safety or human factors experts. In 7 of the tenders (24.1%) a technical report of the assessment of the bidders by the team of experts with identified profiles has been published.

**DISCUSSION**

In this review of tenders of public procurement in Spain for supplying 12,224 volumetric and syringe infusion pumps and consumables for a budget of 30.4M€, we identified the main requirements and criteria for the selection in 63 different batches and specifically analyzed patient safety and human factors related elements. Our data indicate that requirements related to patient safety, such as dose error-reduction systems, alarms, or pump blocking systems are frequently considered as requirements or criteria, independently of the type of infusion pump. In this sense, references to the usability-related terms of the equipment as “ease”, “intuitive” or “usable” were identified in both selection requirements and criteria of the tender documentation in more than half of the cases.

Although concepts related to physical and cognitive ergonomics were present in many of the procurements, no experts in patient safety or human factors were included in the assessment teams of the tenders. With respect to the evaluation of pump usability, no specific methods such as heuristic evaluation or usability testing were identified for any of the procurements.

Since infusion pumps are involved in adverse events, the FDA and other international agencies and associations have launched several initiatives focused on these devices, to improve patient safety, including purchasing procurement strategies. The FDA, in their *Infusion Pump Initiative*, defines several strategies for risk reductions that include formulating and implementing a plan to evaluate infusion pumps prior to purchasing or renting\(^\text{17}\). In England, the Medicines and Healthcare Products Regulatory Agency\(^\text{24}\) emphasized that procurement decision-making should be informed by safety performance and reliability assessments. In Canada, the Western Canada Human Factors Collaborative\(^\text{25}\) demonstrates that when human factors evaluations are incorporated into procurement activities, procurement committees are better informed, so that chosen devices, equipment, and technologies are more usable, effective, and safer for patients and end-users. This guidance provides comprehensive recommendations on how one may integrate human factors evaluations into procurement processes.

Despite the mentioned recommendations, some data suggest that patient safety is not usually considered as one relevant driver of healthcare technology procurement\(^\text{30}\). One investigation of the Healthcare Safety Investigation Branch\(^\text{31}\) found that the procurement of smart pump technology is not primarily driven by the need for smart functionality and was not subjected to a risk assessment or requirements analysis. This agency reinforces that when selecting smart pump devices, it is important to consider how this is likely to impact practice, however, this rarely drives the procurement process.

Currently, public procurement in Europe is an essential vehicle for implementing government policies and meeting national strategic objectives, as well-functioning public procurement markets contribute to improving the competitiveness of quality service strategies\(^\text{32}\). In addition, new strategies are needed to ensure that public procurement addresses the social existing challenges such as environmental protection and sustainable consumption and production\(^\text{33}\) in addition to patient safety\(^\text{35}\). Recent recommendations to improve the safety of infusion pumps reinforce the need to involve large organizational purchasers of these technologies as they can influence infusion device and management system design with manufacturers\(^\text{9}\).

Several reports have been published in relation to human factors evaluation, specifically of infusion pumps, related to the comparison of different equipment\(^\text{34}\), for improving existing designs\(^\text{11}\) or for supporting new design\(^\text{35,36}\). However, human factors evaluation is not a usual practice as a supporting decision tool in medical technology in general\(^\text{30}\). In fact, most medical technology
procurement is driven by engineering standards, and the emphasis is on functional requirements rather than those relating to social or organizational needs\textsuperscript{37}. Few experiences have been reported in the procurement of volumetric and syringe infusion pumps that incorporate human factors in the decision-making process, pointing out that it adds great value\textsuperscript{38–43} and demonstrate that HFE evaluation methods, as heuristics or usability evaluation, are affordable as part of the public procurement pathway of infusion pumps with adequate timing, planning, and multidisciplinary teams.

Implementation is a relevant issue of healthcare technology, specifically for improving infusion pump safety. Procurement processes should consider the implementation resources needed, potential barriers and risks to implementation, and the global impact on the organizations during implementation\textsuperscript{44}. Our data support previous reports that indicate that the potential of the pumps related to their interoperability and dose error-reduction systems is not widely exploited\textsuperscript{45,46}.

This study has some limitations. The database used to retrieve procurement documents may not be comprehensive. Our analysis is focused on data from one country and does not represent all of Europe. Future studies should consider other countries or even other public organizations for greater generalizability.

**CONCLUSIONS**

Deployment of human factors in healthcare organizations implies a global approach, and involvement of different stakeholders, including managers, clinicians, clinical engineers, administrative employees, and human factors experts. Procurement is another opportunity for establishing an adequate implementation strategy, especially when widely used healthcare technology with use-derived hazards such as infusion pumps must be deployed. Public procurement in Europe brings great opportunities for promoting patient safety. Our data indicate that in Spain the involvement of multidisciplinary teams, considering the human factors perspective in the selection and implementation of technology for improving patient safety, at least in the case of infusion pumps, can be improved. This gives healthcare administrators another opportunity to lead organizational change, considering that patients as the center of our organizations.

**Abbreviations**

PLACE: Spanish Public Sector Procurement Database

CPV: Common Procurement Vocabulary

FDA: Food and Drug Administration

**Declarations**

**Ethics approval and consent to participate**

Not applicable

**Consent for publication**

Not applicable

**Availability of data and materials**

Data are available at the Spanish Public Sector Procurement Database (PLACE) (https://contrataciondelestado.es/ ) with the use of Common Procurement Vocabulary (CPV) with the code 33194110 (infusion pumps) in the PLACE database between 2002 and 2022.

**Competing interests**

The authors declare that they have no competing interests

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Authors’ contributions

GP designed the study with LH. LH, BSS and MC took an active part in the data collection and the quality assurance of the data. BSS and RS were mostly responsible for analyzing the data for this manuscript, and GP drafted the manuscript in close collaboration with RR and LH. All authors participated in interpreting the study results, editing the manuscript, and reading and approving the final manuscript.

Corresponding author

Galo Peralta

References


