Revista Ingeniería Biomédica
ISSN 1909-9762 / Volume 11 / Issue 21 / January-June 2017 / pp. 57-64
EIA University / Envigado, Colombia

Technological Surveillance for the Use of Risk Assessment Criteria used to Manage Biomedical Equipment

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***Abstract*—** This article presents a technological surveillance proposal for risk assessment criteria used to manage biomedical equipment. We present the search equations, along with their respective results and the analysis according to the equation with which the most relevant results were found. The analysis presented corresponds to the dynamics of publications in time, means of publication, related authors, prominent institutions, highlighted countries, document types and thematic areas, in order to identify particular authors, countries, institutions and publishing media leaders on the subject. In the results section, the articles of the main means of publication are analyzed per the pertinence of approaches, according to the regulatory framework, and the patient and medical devices that they offer. From the analysis of results, we obtained conclusive information that enabled us to observe the importance of the generation of norms regulating medical devices during their life cycle, supported by risk management, as well as, the convenience of conducting evidence-based risk analysis.

***Keywords* —** Assessment criteria, biomedical equipment management, risk management.

Vigilancia tecnológica de la utilización de criterios de riesgo para la Gestión de Equipos Biomédicos

***Resumen*—**El presente artículo expone una vigilancia tecnológica realizada para encontrar criterios de evaluación de riesgos usados para gestionar equipos biomédicos. Se presentan las ecuaciones de búsqueda planteadas con sus respectivos resultados y el análisis de acuerdo a la ecuación con la cual se hallaron los resultados de mayor relevancia. El análisis presentado corresponde a la dinámica de publicación en el tiempo, medios de publicación, autores relacionados, instituciones destacadas, países destacados, tipos de documento y áreas temáticas con el fin de identificar particularmente autores, países, instituciones y medios de publicación líderes en el tema. En la sección de resultados se analizan los artículos de los principales medios de publicación debido a la pertinencia de los enfoques según el marco regulatorio, paciente y dispositivos médicos que ofrecen. Con el análisis de resultados se obtuvo información concluyente que permitió observar la importancia de la generación de normativa que regule los dispositivos médicos durante su ciclo de vida apoyada en la gestión del riesgo, así como la conveniencia de realizar análisis de riesgos basado en evidencia.

***Palabras clave*—**Criterio de evaluación del riesgo, gestión de equipos biomédicos, gestión del riesgo.

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DOI: https://doi.org/10.24050/19099762.n21.2017.1174

Vigilância Tecnológica da Utilização de Critérios de Risco para a Gestão de Equipamentos Biomédicos

***Resumo*—**O presente artigo expõe uma vigilância tecnológica realizada para encontrar critérios de avaliação de riscos usados para gerenciar equipamentos biomédicos. Apresentam-se as equações de busca propostas com seus respectivos resultados e a análise de acordo à equação com a qual acharam-se os resultados de maior relevância. A análise apresentada corresponde à dinâmica de publicação no tempo, meios de publicação, autores relacionados, instituições destacadas, países destacados, tipos de documento e áreas temáticas com o fim de identificar particularmente autores, países, instituições e meios de publicação líderes no tema. Na secção de resultados analisam-se os artigos dos principais meios de publicação devido à pertinência dos enfoques segundo o marco regulamentar, paciente e dispositivos médicos que oferecem. Com a análise de resultados obteve-se informação concludente que permitiu observar a importância da geração de regulamento que regule os dispositivos médicos durante seu ciclo de vida apoiada na gestão do risco, bem como a conveniência de realizar análise de riscos baseado em evidência.

***Palavras-chave*—**Critério de avaliação do risco, gestão de equipamentos biomédicos, gestão do risco.

I. Introduction

The aim of this paper is to find risk assessment criteria currently used in the management of biomedical equipment. For this, technological surveillance is the appropriate tool since, by means of data collection, we find the current state of a specific issue, since it is a systematic method [1].

The methodology for technological surveillance introduced in this article consist of of the following steps: (1) planning identifying needs, (2) looking and capture information, (3) analyzing and structuring said information [2], since the results of the study will the the basis for future research. This technological survey aims to contribute to the safety of health technology users by managing risks associated to use and by mitigating the occurrence of adverse events and incidents in the assistance process [3].

This paper also seeks to contribute to the management of biomedical equipment in the optimization of resources during the different stages of the life cycles, since asset management is a modular process in health service providers [4]

II. Methodology

The first step in the technological surveillance method described above is the identification of needs. For this case study, they are the appropriate words for the establishment of the way to input search equations so as to find risk assessment criteria with which sanitation technology is managed. The words used to make the equations of the search are the following:

- Risk management: ISO 31000:2009 international regulation provides the general principles and directives [5].
- Evaluation methods: This is the thesaurus of assessment criteria [6].
- Risk assessment criteria: elements used to evaluate risk.
- Asset management: the general information, principles and terminology found in the ISO 55000: 2014 regulation [7].
- Medical device management: the administration of medical devices
- Equipment is the thesaurus for sanitation equipment [8].
- Medical device management: the administration of medical devices.
- Health technology management: the administration of the technology involved in the administration of health services.

Once the terms for equations are settled, the following step is to search in the Scopus database. The Scopus database is the preferred tool for biomedical studies because of its large content and because it contains a result analyzer. Additionally, the science research is examined by specialists and enables a multidisciplinary view [9].

The equations and their corresponding results are shown in Table 1. In the equations, the search field is carried out by article title, summary and keywords. In addition, publications from the last ten years were searched for, that is starting from 2007.

Table 1. Search equations for technological surveillance

N°	Search equation	Results
1	Risk management and evaluation methods and asset management	223
2	Risk management and evaluation methods and medical device management	263
3	Risk management and evaluation methods and medical equipment management	141
4	Risk management and evaluation methods and health technology management	356
5	Risk assessment criteria and asset management	137
6	Risk assessment criteria and medical device management	108
6*	Risk assessment criteria and “medical device” management *	27*
7	Risk assessment criteria and medical equipment management	53
8	Risk assessment criteria and health technology management	244

Document reviews are carried out from the results obtained from each equation. The equations with the greatest search results are “risk assessment criteria” and “medical device management,” with 27 results. The data found are the following:

A. Publication dynamics in time

In this category, 2014 was the year with the largest amount of written productions on the subjects of risk assessment criteria and medical device management, a total of 9 publications. In contrast, no documents were registered in 2011, followed by 2012, 2013 and 2016 with 3 document publications per year, and 2015, the second largest publication amount, a total of 4. Fig. 1 shows the graph relative to publications per year [10].

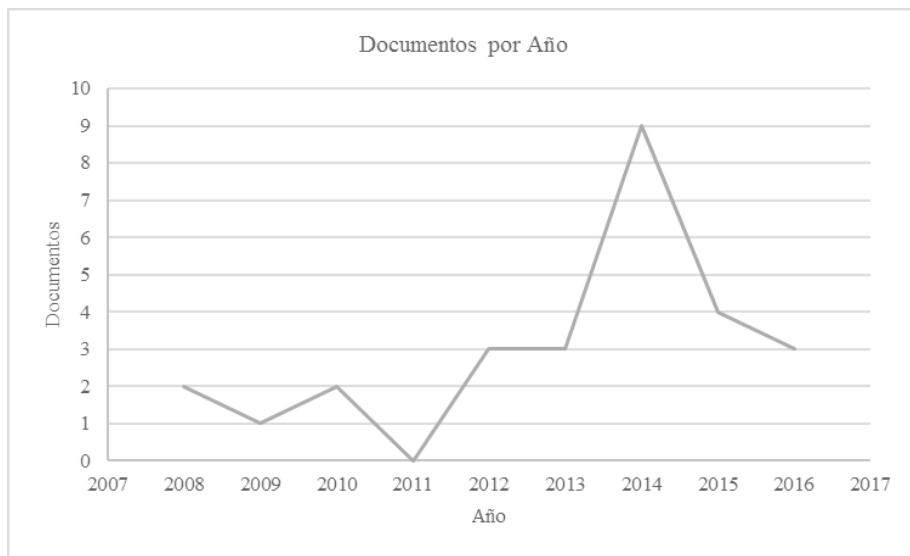

Fig. 1. Documents per year

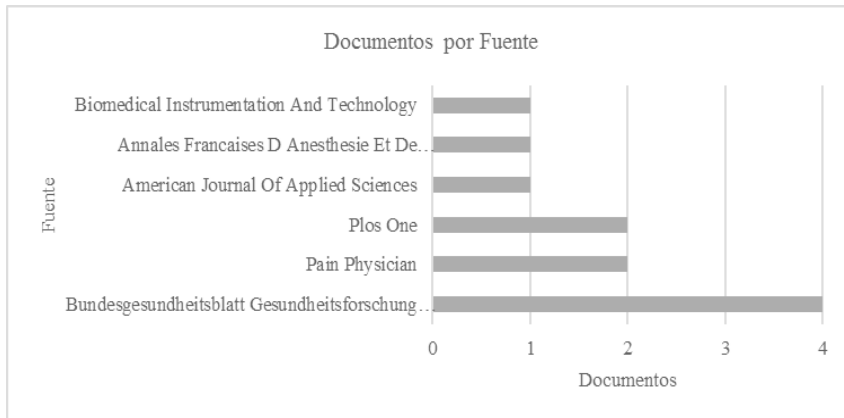

Fig. 2. Documents per source

B. Media Publications

In the analysis by source, between 2007 and 2017, Fig. 2. shows that Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz journal has the most publications with a total of four on medical devices and their corresponding risk assessment. Pain Physician and Plos One journals have 2 publications each [10].

C. Related authors

Fig. 3. shows the amount of publications per author. Ten authors with the greatest amount of publications on risk management and medical devices from 2007 to present day are shown. Among authors who stand out are Benyamin, Boswell, Candido, Cohen and Diwany JanB, each of whom has published 2 articles [10].

D. Leading institutions

This analysis shows the institutions which have been working on topics of risk management in health technology during the last ten years. As in the analysis by author, we can see that each institution has 2 publications, as Fig. 2 shows. The work of the University of Louisville and Rheinisch-Westfalische Technische Hochschule Aachen stands out, as does that of the Millennium Pain Center [10].

E. Leading countries

For the by country analysis, there are 10 with major science publications in the specific search areas. In this category, the quantity of publications in descending order are for the main territories in the United States with 8, Germany with 7, Canada 5 and the United Kingdom with 2. We can see this in Fig. 5 [10].

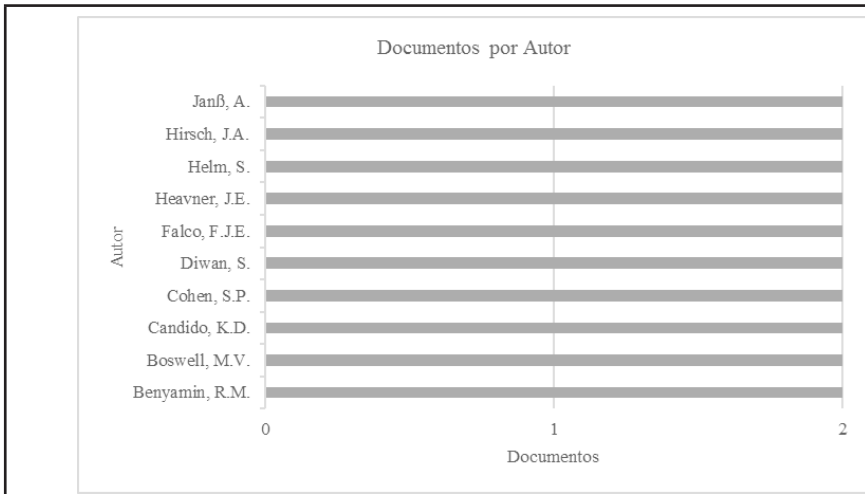

Fig. 3. Documents per Author

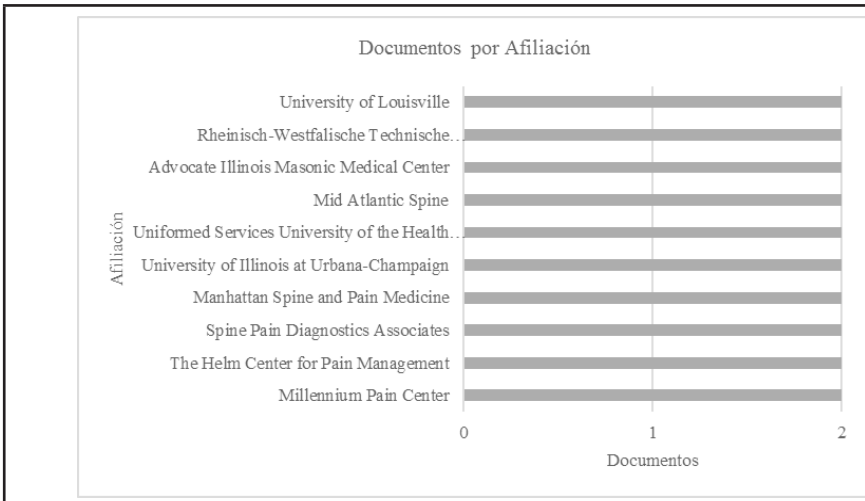

Fig. 4. Documents per Affiliation

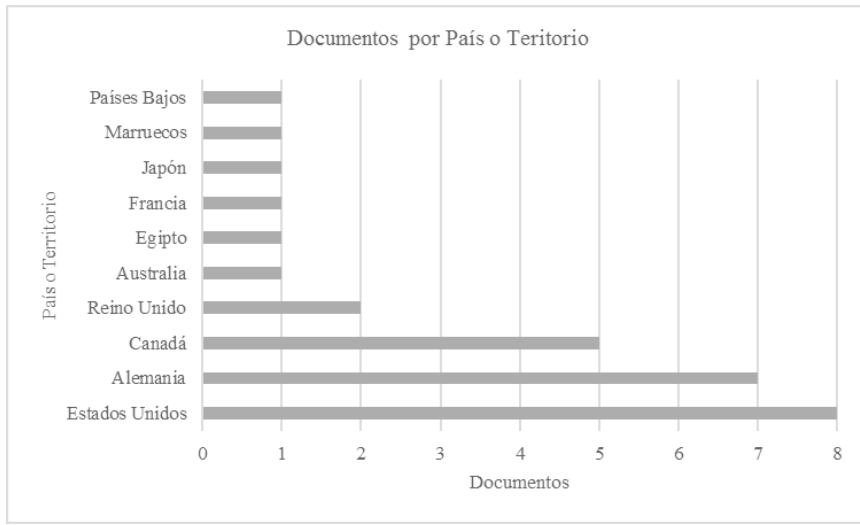

Fig. 5. Documents per country or territory

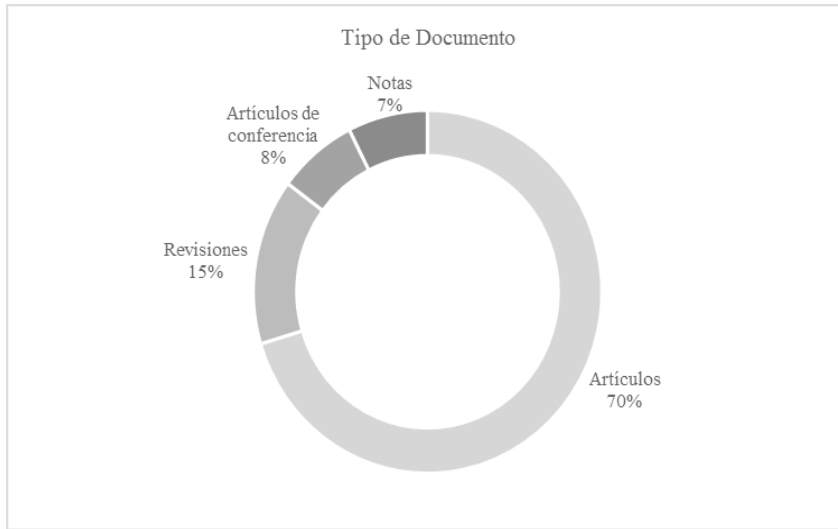

Fig. 6. Document type

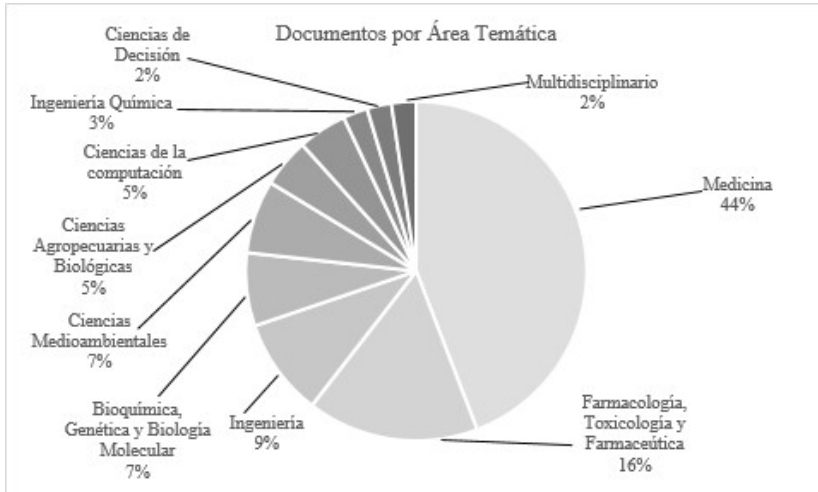

Fig. 7. Documents per thematic area

F. Document types

The types of documents of the 27 analyzed documents is, first, Articles, 70%, followed in second place by Reviews, 15%, then Conference Articles, 8% and finally, Notes, 7. Fig. 6. shows that the preferred media for science publications on the topic of medical device management and risk assessment is the article [10].

G. Thematic areas

The main thematic areas for publications with the search equation are the following: Environmental and Bio-chemical Sciences with 7%, Genetics and Molecular Biology with 7%, Engineering with 9%, Pharmacology, Toxicology and Pharmacy with 16% and, finally, Medicine with 44%, all of which is shown in Fig. 7. The data shows that topics analyzed are mainly those in the health service provider realm [10].

III. Results

Technological surveillance was addressed methodologically from 7 different categories, the results of which will be posed according to the published documents found. Three journals with the greatest amount of publications on the pertinent content will be considered.

A. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz

This journal's publications are shown on Table 2. The first article is introduced within the German regulatory framework for medical devices, taking into account the identification, assessment and mitigation of risks [10].

The second publication refers to the German regulatory framework with regard to essays about medical devices with a risk classification of III and implantable devices, such as from the experience of the "Instituto Federal de Medicamentos y Dispositivos" in requests and user orientation. Likewise, the third article shows German regulations for sanitation manufacturers and products that are high risk [10].

This last article introduces the development of an analytical methodology, as well as, software to make a prospective analysis of human risk in order to aid medical device manufacturers and control risks efficiently in the interaction man-machine[10].

Table 2. Documents published by Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz

N°	Title	Authors	Year
1	Medical devices: Regulatory framework and contribution of the German Federal Institute for Drugs and Medical Devices (BfArM) to the safe application [Dispositivos médicos: Marco reglamentario y contribución del Instituto Federal Alemán de Medicamentos y Dispositivos Médicos (BfArM) para la aplicación segura]	Lauer W., Stößlein, E., Brinker, A., Broich, K.	2014
2	Experiences and recommendations of the GermanFederal Institute for Drugs and Medical Devices (BfArM) concerning clinical investigation of medical devices and the evaluation of serious adverse events (SAE) [Experiencias y recomendaciones del Instituto Federal Alemán de Medicamentos y Dispositivos Médicos (BfArM) sobre la investigación clínica de dispositivos médicos y la evaluación de eventos adversos serios (SAE)]	Renisch B., Lauer, W.,	2014
3	Focus Notified Bodies: New requirements for designation and monitoring [Foco en los organismos notificados: nuevos requisitos para la designación y el seguimiento]	Poos, U., Edelhäuser, R.	2014
4	Usability first: Model-based approach for the use-oriented risk analysis of medical devices [Usabilidad primero: Enfoque basado en modelos para el análisis de riesgo orientado al uso de dispositivos médicos]	Janß, A., Radermacher, K.	2014

NOTE 1: The translation of article titles is not official.

B. Pain Physician

In the Pain Physician journal, we will analyze two documents which disclose, first, a pain management instrument via quality evaluation, as well as Bias risk. The Cochrane review criteria are included. This instrument is superior and offers wide and specific information. The second publication analyzed presents the development of a specific instrument for intervention of pain management. This development is based on Cochrane review criteria and also uses risk assessment and quality criteria [10]. All of the above is shown in Table 3.

Table 3. Documents published by Pain Physician

N°	Title	Authors	Year
1	Assessment of methodologic quality of randomized trials of interventional techniques: Development of an interventional pain management specific instrument [Evaluación de la calidad metodológica de los ensayos aleatorios de técnicas intervencionistas: Desarrollo de un instrumento específico para el manejo del dolor intervencionista]	Manchikanti, L., Hirsch, J.A., Cohen, S.P., (...), Racz, G.B., Raj, Prithvi P.	2014
2	Development of an interventional pain management specific instrument for methodologic quality assessment of nonrandomized studies of interventional techniques [Desarrollo de un instrumento específico para la gestión del dolor intervencionista para la evaluación de la calidad metodológica de estudios no aleatorizados de técnicas intervencionistas]	Manchikanti, L., Hirsch, J.A., Heavner, J.E., (...), Racz, G.B., Prithvi Raj, P.	2014

NOTE 2: The translation of article titles is not official.

C. Plos One

The first file that is reviewed from the Plos One source has a focus on conditions associated with fans and to the monitoring of adverse events in respiratory diseases by the use of invasive mechanical ventilation (Table 4). A management and maintenance analysis is performed on fans using a multivariable analysis of the fans associated risks. The four risk factors found were: absence of intensive participation on ventilated patients, utilization of high driving pressure, edema appearance and increase of body weight. These criteria are key for the development of preventive measures. [10]

In the second instance, a document is analyzed where cardiac implants are introduced, mainly for their associated high risk and their complications linked to mortality (Table 4). The risk factors from the point of view of the device are battery problems and incorrect therapy implementation [10].

Table 4. Documents published by Plos One

N°	Title	Authors	Year
1	Association of patient care with ventilatorassociated conditions in critically ill patients: Risk factor analysis [Asociación de atención al paciente con afecciones asociadas a ventilador en pacientes críticamente enfermos: Análisis de factores de riesgo]	Nakahashi, S., Yamada, T., Ogura, T., (...), Suzuki, K., Imai, H.	2014
2	Recalls of cardiac implants in the last decade: What lessons can we learn? [Recuerdos de implantes cardiacos en la última década: ¿Qué lecciones podemos aprender?]	Zhang, S., Kriza, C., Schaller, S., Kolominsky-Rabas, P.L.	2014

NOTE 3: The translation of article titles is not official.

Next, Table 5 shows the risk criteria found in the articles analyzed according to the approaches found in journals.

Table 5. Risk criteria

Scope	Risk Criteria
Normative/regulations	Probability of occurrence of an event Incident frequency Affected population Level of technology security
Patient	Appropriate method assignment Informed consent Dropout rate Acceptable compliance Duration of pain Previous treatments Duration of follow-up
Medical Devices	Insufficient participation on patient management Higher driving pressure Changes in body weight Edema appearance Battery problems Incorrect therapy

NOTE 4: The translations of risks criteria are non-official.

IV. Discussion

In the technological surveillance methodology, 8 search equations were posed, with keywords for this article and its respective equivalent expressions. Results found that, on occasion, these were not satisfactory, thus the decision to modify to “medical device” in equation

Number 6 so that the exact term could be found in the database and more exact results found.

The publications analyzed by source contained a preferred thematic area of Medicine, although each journal addresses the topic in different ways. The *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*, approaches it from the German regulations for medical devices and risk assessment for sanitation technology.

In *Pain Physician* developed instruments were introduced which were based on review criteria in the Cochrane organization for pain management. Notwithstanding, *Plos One's* focus was on the analysis of specific cases of medical devices and their respective risks associated to use, as well as, to the identification of said risks.

V. Conclusion

The results of technological surveillance are presented based on the documents published in the journals with the greatest amount of publications. Eight total documents from three sources were analyzed. In all of these, we can observe the importance of managing risks in sanitation assistance in order to provide safety to patients during the entire life cycle of the medical devices.

In the publications from the *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* journal, we can see a particular interest in the disclosure of the German regulatory framework for medical devices, especially for those that are classified III, as well as those with high risks. This result is supported by that obtained by country, since Germany is second, after the United States, with the greatest amount of publications.

The assessment of risk criteria based on case studies (or based on evidence) is a source of appropriate knowledge for the study of medical devices particularly. All of the above is evidenced by the analysis of publications in the *Pain Physician* and *Plos One* journals.

Acknowledgment

The authors thank the Program for Technological Surveillance and Competitive Intelligence of the Universidad Pontificia Bolivariana for the contributions and indications for the presentation of information found in the Scopus database.

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